Mid-term Evaluation of the Third Health Programme (2014 – 2020)

Final report

Annex B

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Contents

1. INTRODUCTION

An important part of the evaluation methodology consists of theory-based case studies of eight of the 3HP's thematic priorities. In-depth case studies enabled us to explore the logic behind the thematic priorities of the third Health Programme (3HP), see how actions in the thematic areas are being implemented and delivered and assess their (expected) results and the main factors and processes that have facilitated or hindered their success so far.

As such, the overall purpose of the case studies was to contribute the evidence needed to answer key questions about the relevance of the thematic priority and its expected contribution to HP objectives, in addition to allowing us to draw lessons and recommendations that can be applied more broadly to the current programme and the next funding period. These case studies complement the other data collection tools (for example interviews with a range of stakeholders, surveys, focus groups and desk research), the results of which are provided in Annex A.

The case studies took the form of eight discrete theory-based evaluations (see box below), each concerned with one thematic priority, which set out the logic, or "theory" behind given thematic priorities and placed them in the surrounding context. We then used a review of up to five specific actions per thematic priority to study in detail what is happening in practice. Each case study report is comprised the following sections:

- This **introduction** provides an overview of the sources used and action sample.
- The **policy context** explains how the thematic priority relates to EU health needs and then makes the case for EU action.
- **Theory and practice** present the intervention logic for the thematic priority, then discusses in depth its main parts in terms of both theory and practice.
- **Conclusions** provide insights into higher-level questions relating in particular to relevance, effectiveness and lessons learned.

The 3HP is structured in terms of 23 thematic priorities. In order to examine the appropriateness of this structure and the practical implementation of action under given thematic priorities, we conducted in-depth case studies on eight of them. Since it would not be possible to frame a sample that is representative in any statistical sense, the thematic priorities chosen include a broad range of themes and consider such factors as level of activity to date and scope for assessing initial results. The thematic priorities are presented on the next page, with the eight examined through case studies highlighted in bold print.

Theory based evaluation
An evaluation approach that studies the logic that is inherent to the activity in question**.** This starts by defining the desired ultimate impacts, main intermediate outcomes and outputs, key assumptions that inform the theory of change, and external factors that have the potential to significantly affect the intervention positively or negatively. It then seeks out evidence to test if and how this logic has played out in practice, and thereby understand the contribution the activity has made to the ultimate impacts sought (if any), and how this has come about, as well as key success factors and room for improvements.
Source: Theory-based evaluation, European Commission (DG REGIO), 2011.

Table 1: 3HP specific objectives and thematic priorities

Specific objectives	Thematic priorities (bold priorities subject of detailed case studies)
1) Health promotion	**1.1 Risk factors such as use of tobacco and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity** 1.2 Drugs-related health damage, including information and prevention 1.3 HIV / AIDS, tuberculosis and hepatitis **1.4 Chronic diseases including cancer, age-related diseases and neurodegenerative diseases** 1.5 Tobacco legislation 1.6 Health information and knowledge system
2) Health threats	2.1 Risk assessment additional capacities for scientific expertise **2.2 Capacity building against health threats in Member States, including, where appropriate, cooperation with neighbouring countries** **2.3 Implementation of Union legislation on communicable diseases and other health threats, including those caused by biological, and chemical incidents, environment and climate change** 2.4 Health information and knowledge system
3) Health systems	3.1 HTA 3.2 Innovation and e-health 3.3 Health workforce forecasting and planning **3.4 Setting up a mechanism for pooling expertise at Union level** 3.5 European Innovation Partnership on Active and Healthy Ageing **3.6 Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare** 3.7 Health information and knowledge system including support to the Scientific Committees set up in accordance with Commission Decision 2008/721/EC
4) Access to Healthcare	**4.1 European Reference Networks** 4.2 Rare Diseases 4.3 Patient safety and quality of healthcare 4.4 Measures to prevent Antimicrobial resistance and control healthcare-associated infections **4.5 Implementation of Union legislation in field of tissues and cells, blood, organs** 4.6 Health information and knowledge system

Source: Annex 1, Regulation (EU) 282/2014

For each case study, we examined up to five funded actions[1]. In order to define a suitable sample of actions, we considered the following issues:

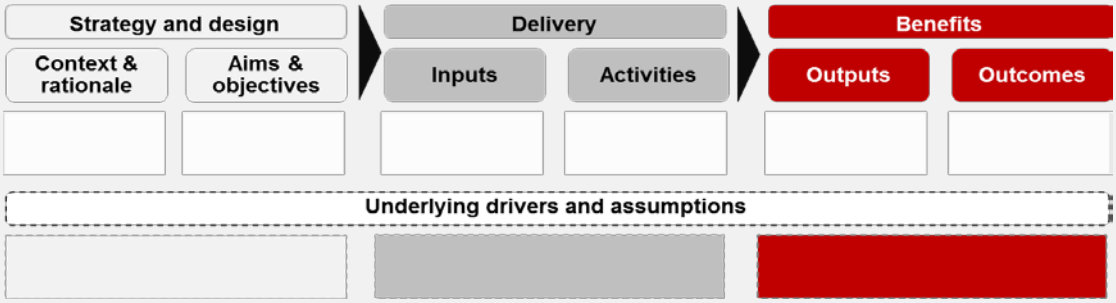
- **Extent of progress**: where possible, we preferred actions from the 2014 AWP, since they are more mature and therefore are more likely to allow for insight into results and lessons learned.
- **Breadth of coverage**: the actions cover a cross-section of funding mechanisms to enable a better understanding of how the different mechanisms respond to and serve identified needs, and display key success factors. The sample also emphasises the three most important funding mechanisms in financial terms, namely joint actions, projects and procurement (i.e. service contracts).
- **Action size**: the sample includes a mix of smaller and larger actions in terms of funding, in order to assess their differing dynamics and scales with regard to the 3HP objectives and thematic priorities.

[1] Note that a selection of five actions per case study was not possible for some thematic priorities due to the limited number of actions that have been funded to date and the need to revise the sample in two cases due to the inclusion of inappropriate actions.

In practical terms the case studies entailed **two main steps**. First, we reconstructed the thematic priority's theory in the form of an intervention logic. The diagram depicts its full causal chain from the desired underlying strategy through delivery and to desired benefits, with a focus on key assumptions that need to hold for the desired changes to occur. The box below presents in more detail how the intervention logic should be read.

Then, to test the theory, we collected and analysed evidence about implementation so far, above all through an examination of five funded actions. The evidence came from several sources, namely contextual literature and programme documentation and about eight interviews per case study with Chafea project officers and representatives of organisations responsible for implementing two of the sampled actions. In addition, the data collection and analysis was supported through on-going consultation with members of the expert panel.

Guide to Intervention logic



Strategy and design

- **Context & rationale**: this consists of the policy framework (TFEU, guiding decisions relating to the overall policy area) and relevant contextual elements that together establish a problem the HP could address.
- **Aims & Objectives**: this box translates the problem into concrete aims and objectives for HP actions under the thematic priority in question.

Delivery

- **Inputs**: these consist mainly of financial resources from the HP and other sources, in addition to the processes for procuring the funding.
- **Activities**: these consist of the types of activities carried out as part of funded actions, with a focus on those we reviewed in depth as part of the case study.

Benefits

- **Outputs**: this level depicts the immediate effects of the funded actions, and includes such aspects as the production of guidelines and reports and sharing of relevant information.
- **Outcomes**: these consist of medium/long-term benefits such as the implementation of good practices and new initiatives by MS and other actors. Few such benefits will be visible at this stage of the HP's implementation. Defining them well will help us test the plausibility & likelihood of future achievements, particularly in relation to the assumptions.

Underlying assumptions and drivers: at each level there are also underlying assumptions and drivers behind envisaged causal relationships. These are outside the HP's immediate control but must hold for action under the thematic priority to have the desired effects. These range from the applicability of given problems to the types of action funded through the HP to interest and enthusiasm among relevant stakeholders. At the benefits level, complementarity with other initiatives is crucial given the relatively small size of HP actions and the multiplicity of influencing factors at play at EU and MS levels

2. SUMMARY OF FINDINGS

The tables below provide a snapshot overview summarising key findings by objective.

Thematic priority	Main contributions to 3HP objectives and Commission priorities (to date and expected) as evidenced in case studies	Remaining challenges / areas for improvement as evidenced in case studies
Objective 1: Promote health, prevent diseases and foster supportive environments for healthy lifestyles taking into account 'health in all policies' principle		
1.1 Support the exchange of evidence-based and good practice for addressing risk factors	• **Collating and sharing evidence for policy making:** MS often lack information on what works well and less well in policy areas relating to risk factors. HP action is helping to collect evidence on e.g. alcohol consumption and alcohol policies in all MS, as well as national policies related to nutrition, physical inactivity, and overweight and obesity related diseases. • **Compiling comparable information**: similarly, comparable data on such issues as alcohol consumption and harm and alcohol policies across Europe can help MS develop better and more coordinated policies. • **Disseminating high—quality evidence**: rigorously researched evidence cannot be effective if the right stakeholders are unaware of it. HP-funded fora are helping to ensure this is the case to support policy-making at national and regional levels. • **Feeding into broader EU policies**: risk factors affect the capability to work, are costly to treat and ultimately impact economic performance. The actions under review were all aligned with such policies and should actively contribute to them, albeit indirectly.	• **Limited inter-DG coordination**: while health risk factors are interlinked with such fields such as agriculture, research and innovation, education and culture as a means to increase impact of relatively small budget which aims to cover a very broad area. • **Inflexibility**: repeated and / or similar actions to some extent crowd out more innovative actors or actions which might involve new approaches to established problems. • **Lack of attention to root causes**: the actions under review showed little focus more on the underlying reasons for health inequalities, which could lead to strategies and approaches to address and reduce inequalities, in particular among vulnerable groups.
1.4 Support cooperation and networking in the Union in relation to preventing and improving the response to chronic diseases	• **Building on previous action to implement best practices**: while some actions have been criticised for petering out, work on e.g. dementia is building cumulatively on previous actions to support the practical uptake of identified best practices. • **Reducing duplication**: supported actions have the potential to contribute to the policy coordination, which reduces the duplication of efforts and leads to a more efficient use of scarce resources. • **Linking to broader initiatives**: actions have shown potential to contribute to wider policy objectives and priorities. For example, results from Alzheimer Europe (an organisation receiving operating grant funding) are feeding into the WHO Global Observatory on Dementia.	• **Overly broad scope**: the thematic priority is so broadly applicable that there is a risk that limited resources can be spread too thinly, making hard to focus and keep momentum on specific diseases. • **Difficulty attracting new players**: while building on successive HP-funded action is in many ways positive, there is a balance to be struck. So far, the actions examined illustrated trouble attracting first-time beneficiaries who could introduce new ways of working and help spread HP funding more widely. • **Suboptimal dissemination**: some actions have not focused sufficiently on communication, making it difficult for results to make a practical difference in addition to undermining the motivation of beneficiaries.

Thematic priority	Main contributions to 3HP objectives and Commission priorities (to date and expected) as evidenced in case studies	Remaining challenges / areas for improvement as evidenced in case studies
Objective 2: Protect Union citizens from serious cross-border health threats		
2.2 Support capacity building against health threats, including where appropriate, cooperation with neighbouring countries	• **Avoiding duplication and improving capabilities:** Supported actions have served to identify gaps in MS' capacities, prioritise actions and implement capacity building activities to fill in those gaps, for example through toolkits and guidelines, stimulation and post command exercises, among others. • **Bringing relevant stakeholders together:** Part of the role of the HP is to bring together relevant stakeholders to give them an opportunity to revise or agree on emergency procedures, as well as enhancing the evidence base for decision-making thereby building capacities.	• **Responding to a constantly evolving situation:** It is worth pointing out that the quest to support capacity building will never be completely satisfied. There is a need for continuous updating of skills to take account emergent issues, new needs, staff and organisational changes happening at national level. • **Suboptimal communication remains a barrier**: the development of communication capacities at MS level (especially in terms of procedures for disseminating messages to the public) remains suboptimal. • **Important areas not yet covered**: increasing industry and MS' understanding of the joint procurement agreement[2], and developing guidelines / protocols / toolkits that support the implementation of coordinated responses.
2.3 Actions required by or contributing to the implementation of union legislation in the field of communicable diseases and other health threats	• **Bringing together competent authorities**: The HP brings together and supports competent authorities to allow them to tackle a challenge which is best dealt with together and which effects all MS in a way that other funding cannot. • **Development of technical expertise**: Through the HP, technical expertise to tackle a specific set of high risk groups (risk group 3 bacteria and risk groups 3 and 4 viruses) has been developed meaning that citizens would be more secure and safer. • **Ability to respond to outbreak**: The action funded is geared towards ensuring on the ground safety, i.e. it included the possibility of switching "mode" from preparation to response mode in the event of an outbreak.	• **Reliance on EU funding**: There are concerns regarding the sustainability of EU funding as it is important to continually maintain expertise. We note that this issue is already high on the agenda with a study on the cost / benefits of a reference laboratory for human pathologies delivered. • **Narrow scope of action to date**: Action so far has been focused on one particular component of protection against health threats of biological origin: the detection of high risk pathogens. Other cross border threats to human health such as those of chemical origin or environmental threats (for instance air pollution) remain significant.

[2] See https://ec.europa.eu/health/preparedness_response/joint_procurement_en

Thematic priority	Main contributions to 3HP objectives and Commission priorities (to date and expected) as evidenced in case studies	Remaining challenges / areas for improvement as evidenced in case studies
Objective 3: Contribute to innovative, efficient and sustainable health systems		
3.4 Provide expertise and share good practices to assist Member States undertaking health system reforms by setting up a mechanism for poling expertise at Union level.	• **A framework for sharing expertise at the EU level:** The expert panel has the potential for promoting innovation in health, and generating economies of scale by connecting expertise in areas of identified importance. • **Improving knowledge base for EC and MS policy makers:** The panel has delivered Opinions in line with the Mandates raised (i.e. in relation to primary care and access to health), and has provided expert advice and input to MS and the EC.	• **Ensure participation and up take of results in MS:** The main challenge is to ensure the active involvement of MS from the beginning (i.e. suggestion of Mandates) to end (uptake / use of Opinions). • **Streamlining the process**: Scope to improve the process for better alignment of priorities. Introducing a lead within DG SANTE (with the responsibility to oversee the selection process) would be one option to ensure the alignment with Commission and MS priorities. • **Suboptimal dissemination**: Although Opinions are disseminated via relevant sector journals; systematising the dissemination process to ensure Opinions are received by MS may encourage both the suggestion of Mandates by MS and the uptake of Opinions.
3.6 Actions required by or contributing to the implementation of Union legislation in the field of medical devices, medicinal products and cross border healthcare.	• **Ensuring effective implementation of existing legislation**: Three of the five actions assessed contribute to the effective implementation of existing EU legislation on medicinal products and medical devices, e.g. by generating up-to-date technical data, developing joint approaches to market surveillance. • **Informing potential legislative developments:** The outputs of the two actions were studies launched to generate information on other areas that are not currently the subject of EU legislation, but in which the EU might consider legislating in the future. • **Linking to broader objectives:** Set in the wider context, this priority aligns with a number of global health recommendations set out in WHO's 'ten leading sources of inefficiency of health systems' and the OECD's recommendations for health system reform. These are reflected in the EC's Investing in Health (2013) and provide a framework for EU action in health to support the achievement of the EU's 2020 Vision for Growth.	• **Better exploit synergies**: Scope to better link the actions funded to ensure their mutual support and coherence (which at a minimum should be the case within - but potentially also across - the fields of legislation covered). • **Sustainability**: There is a question around sustainability, which will depend on funding beyond planned work programmes. MS must buy into the new legislation and ways of working to realise the potential benefits.

Thematic priority	Main contributions to 3HP objectives and Commission priorities (to date and expected) as evidenced in case studies	Remaining challenges / areas for improvement as evidenced in case studies
Objective 4: Facilitate access to better and safer healthcare for Union citizens		
4.1 Support the establishment of a system of European reference networks… on basis of criteria established under Directive 2011/24/EU	• **Access to high quality medical expertise:** actions (e.g. establishment of ERN) support access to high quality medical expertise, also beyond national borders and facilitate the application and results of research and develop tools for the improvement of healthcare quality and patient safety. • **Inequality between and within MS:** ERN contribute to one of the 3HP general objectives namely to decrease inequality, namely by increasing citizens' equitable access to high quality healthcare. • **Actions sequenced to lead to the establishment of ERNs**: the 3HP sets out the goal to establish ERN. The call for applications opened in March 2016 and closed in June.	• **Sustainability**: ERN will need to be anchored in MS in multiple ways, not just financially. For instance MS will need to feel ownership over these networks because their member will be located within their geographic and legal boundaries. • **Balance of representation**: some indication that not all MS will be represented in ERNs (according to the applications received, larger MS are overrepresented). There is a risk that leaving out smaller MS that some of the expected benefits of ERNs such as knowledge transfer via collaboration will not be realised. This illustrates the ongoing difficulties of tackling structural issues.
4.5 Implementation of union legislation in the fields of human tissues and cells, blood, human organs, medical devices, medicinal products and patients' rights in cross-border healthcare	• **Developing harmonised systems**: support for the harmonisation of inspection, authorisation and vigilance systems for blood, tissues and cells, to facilitate and increase in inter-MS collaboration and in confidence in respective inspection and vigilance programmes. • **Common assessment methodology and EU guidelines:** in order to facilitate better and more efficient use of cornea and cells for transplant surgery the EU needs common assessment methodologies and guidelines to reduce patient waiting times and allow for increased self-sufficiency in these tissues. • **Continually building on previous action**: actions funded build directly on previous work showing a sustained focus but also progress in terms of developing methodologies / guidelines in new areas (i.e. novel therapies and products), creating new models for sustainable updating of technical standards, defining procedures in areas where this is lacking (e.g. clinical follow-up).	• **Combat attitudinal barriers:** While the actions are technically strong, there are attitudinal barriers to progress. For instance, more could be done to increase the number of donors (in particular organ donors) by improving communication and awareness to increase support. • **Accessibility of HP to new players**: Many of the actors involved in the actions sampled have been involved in previous actions, while this has a clear benefit in terms of an existing knowledge and experience in dealing with the procedures for EU funding, it does suggest the accessibility of the HP (for "new" players) is not optimal.

3. THEMATIC PRIORITY 1.1 – RISK FACTORS

3.1. Introduction

This case study covers thematic priority 1.1 of the 3HP, on "Risk factors such as use of tobacco and passive smoking, harmful use of alcohol, dietary habits and physical activity". This priority falls under Objective 1 of the 3HP, which is to "Promote health, prevent diseases, and foster supportive environments for healthy lifestyles". A total of 41 actions have been funded under this thematic priority to date (2014 – 2016), amounting to a total of €14.6 M. This funding was spread across all possible funding mechanisms, namely projects, operating grants, joint actions, service contracts, and direct grant agreements. A sample of actions was selected based on consideration of their maturity, breadth of coverage of the mechanisms and a mix of different sized actions (see table below).

Table 2: Actions reviewed for case study on risk factors (thematic priority 1.1)

Funding mechanism	Lead organisation (incl. MS)	Other organisations (incl. MS)	Budget	Start date/duration
Monitoring of the national policies related to alcohol consumption and harm reduction (MOPAC)				
Direct Grant Agreement	World Health Organisation (WHO) – Regional Office for Europe (Denmark)	N/a	Total eligible costs: € 905,307 HP grant: € 500,000 (60% of eligible costs)	01/01/2016 36 months
Joint Action on Nutrition and Physical Activity (JANPA)				
Joint action	European and International Affairs Department (France)	39 partners total[3]	Estimated eligible costs: € 2,034,259 HP grant: € 1,200,000	01/09/2015 27 months
Obesity Training And Information Services for Europe (OBTAINS)				
Operating grant	World Obesity Federation (UK)	N/a	Total eligible costs: € 271,033 HP grant: € 162,619	2014 Specific Grant Agreement duration - 12 months
Smoking prevention in action: the Smoke Free Partnership Coalition (SFP)				
Operating grant	The Smoke Free Partnership (Belgium)	N/a	€ 352,054	2014 Specific Grant Agreement duration - 12 months.
EPHA 2015: Protecting and improving public health and well-being in all policies (EPHA)[4]				
Operating grant	European Public Health Alliance (Belgium)	N/a	Total eligible costs: € 812,462 HP grant: € 487,441	2014 Specific Grant Agreement duration - 12 months.

Note: More information on the sampled action can be found on the Chafea database and in the AWPs available on DG SANTE's website

The methodology for the case studies is provided in detail in the **introduction** to this Annex. But entailed **two main steps**. First, we reconstructed the thematic priority's theory in the form of an intervention logic diagram. Then, to test the theory, we collected and analysed evidence about implementation so far, above all through an

[3] BG; DE; FR = 3 partners each; AT; BE; EL; HR; HU; IE; IT; LU; RO = 2 partners each; CZ; EE; ES; FI; LT; LV; MT; NO; PL; PT; SI; SK = 1 partner each. CY; DK; IS; NL; SE; UK = no partners.

[4] According to the classification of actions, this operating grant was classified as falling under thematic priority 1.1, however we note that the work supported by EPHA spans Objective 1.

examination of five funded actions (as above). The different sources of information are summarised in the table below.

Table 3: Documents consulted and interviews conducted for case study on risk factors (thematic priority 1.1)

Documents consulted	Interview status
• Commission policy documents and other relevant literature (e.g. WHO reports) on public health problems; • Internal working documents for multi-annual planning for the thematic priority; • 2014 Annual Work Plan; • Evaluation Summary Reports for proposals for the sample of actions (2014 call); • Other action documents such as proposals and implementation reports.	• Interviews with three Chafea project officers responsible for four sampled actions[5]; • Interviews with lead implementation partners for two of the sampled actions – World Health Organisation Regional Office for Europe (WHO) and European Public Health Alliance (EPHA);

3.2. Policy context

This section presents the policy context behind the thematic priority and seeks to define the case for EU action in this area. It forms part of the 'theory' behind EU action in this priority area.

3.2.1. Key health needs and priorities

According to the WHO, alcohol consumption, tobacco use and overweight and obesity are among the **major risk factors leading to premature mortality**. Furthermore, the European region has the highest levels of alcohol consumption and tobacco use in the world, and has the second highest overweight and obesity rates.[6]

Alcohol and tobacco use poses a major health risk. Alcohol is one of the main risk factors for disability and for non-communicable diseases as well as a harm to others; while the social and health impacts of tobacco use are well known and well documented. An issue which MS face in trying to implement policies and programmes in the area of alcohol consumption and tobacco use is the complexity of the underlying causes and the need to balance the sometimes fierce opposition from economic operators. Multinational organisations in the alcohol and tobacco industry are very influential actors on the global stage. They have a lot at stake as policy makers seek to manage the health effects of harmful consumption. This translates into opposition when countries attempt to adopt policies in these areas and slows progress.

In the area of **unhealthy dietary habits and physical inactivity**, overweight and obesity rates are increasing, in particular among children and adolescents in the EU. In 2010, around over 30% of children aged 6-9 years old in the EU were overweight or obese, which demonstrates high prevalence despite numerous attempts to tackle it at MS and EU levels.[7] This is closely linked to a problem among adults, particularly in countries such as the UK and Germany where around two thirds of men are either obese or overweight.[8] Overall, the prevalence of overweight and obesity in European countries ranges from 45-67%.[9] Overweight and obesity also comes with high economic costs,

[5] The action not covered in these interviews was EPHA.

[6] WHO (2015). European Health Report.

[7] 677063-JANPA. Evaluation Summary Report.

[8] Eurostat (2015). The EU in the world.

[9] WHO (2015). European Health Report.

placing a large burden on EU finances. Seven percent of EU health budgets are spent each year directly on diseases linked to obesity.

While the individual MS are primarily responsible for dealing with these problems, there are also **discrepancies and cross-border issues that relate to the EU's supporting competence in public health**. For example, the resources devoted to these issues are uneven, varying enormously by MS. Eurostat data indicate the ration between the highest and lowest levels of expenditure per inhabitant in Luxembourg and Romania was 14.3 to 1.[10] As such, public and private EU action can be instrumental in supporting and complementing the MS which lack the resources and capacity to provide the levels of healthcare required on their own.

Furthermore, many of the risk factors which this thematic priority addresses –namely tobacco use, overweight and obesity, and physical inactivity[11]– are linked to **socio-economic status**. This means that less well-off groups in society are more likely to be affected. This has knock-on effects across society and the economy, and has gained increasing attention on the EU agenda. For example, the 2009 Communication on "Solidarity in health: reducing health inequalities in the EU" outlines EU actions and initiatives that support MS in tackling health inequalities between EU citizens.[12] Additionally, the 2011 European Parliament resolution on reducing health inequalities in the EU called on the MS and Commission to implement initiatives in this area.[13] The next section explains in more detail how the EU has acted to address these issues.

3.2.2. Framework for and extent of EU engagement so far

Article 168 of the TFEU outlines the EU's role in improving health and preventing disease; the need for policy coordination amongst MS, and the European Commission's (EC) role in taking any useful action to promote such coordination, including the exchange of best practice, guidelines, monitoring and evaluation.[14] This therefore forms the fundamental basis for EU action to address risk factors for ill health. In the section below, we outline key initiatives at the EU level for the different risk factors in turn: overweight and obesity; physical inactivity; alcohol related harm and lastly tobacco use.

Firstly, the EC's "Strategy for Europe on **Nutrition, Overweight and Obesity-related health issues**"[15], which was adopted in 2007, sets out actions that can be taken at the local, regional, national and European levels to reduce the risks associated with poor nutrition and limited physical exercise[16]. It promotes an integrated EU approach by supporting MS in their efforts to motivate action on healthy nutrition and encouraging physical activity.[17] This strategy attempts to integrate other EC policies in areas such as Agriculture, and Education and Culture, and builds on previous initiatives undertaken

[10] See http://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare_expenditure_statistics#Healthcare_expenditure

[11] The exception is alcohol consumption, which does not appear to be highly correlated with income.

[12] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions (2009). Solidarity in Health: Reducing health inequalities in the EU. See: http://ec.europa.eu/health/ph_determinants/socio_economics/documents/com2009_en.pdf

[13] European Parliament resolution of 8 March 2011 on reducing health inequalities in the EU (2010/2089 (INI)). See: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P7-TA-2011-0081+0+DOC+PDF+V0//EN

[14] Thematic fiche. 1.1. Prevention Measures.

[15] White Paper on A Strategy for Europe on Nutrition, Overweight and Obesity related health issues [COM(2007)279]. See: http://ec.europa.eu/health/archive/ph_determinants/life_style/nutrition/documents/nutrition_wp_en.pdf

[16] See: http://ec.europa.eu/health/nutrition_physical_activity/policy/strategy_en.htm

[17] MAP 2014 - 2017

by the EC, including the EU Platform on Diet, Physical Activity and Health. This platform was set up in 2005 to create a forum for actors at the European level (ranging from the food industry to consumer protection NGOs) who have an interest in engaging in concrete actions designed to tackle current trends in diet and physical activity.[18]

Rates of physical inactivity in the EU remain high. Available data show that the majority of Europeans do not engage in sufficient health-enhancing physical activity, a trend that has not shown much improvement in general terms. Data from individual countries reveal that physical activity rates increased in some Member States, while in others rates remained stable or dropped. Rates of **physical activity in children** also appear to be decreasing, with OECD data showing a decline in average physical activity in both boys and girls across 21 EU countries[19].

EU action to promote physical activity has sought to do essentially three things, boost political commitment, facilitate policy co-ordination and collaboration and provide financial support through transnational networking projects. The Commission's 2007 Strategy for Europe on Nutrition, Overweight and Obesity-related Health Issues called for the launch several initiatives, in particular a **High Level Group on Nutrition and Physical Activity**, to help share information on policies, policy ideas and practices. It also highlighted the role of the **EU Platform for Action on Diet, Physical Activity and Health** which was launched as a forum for cross-sectoral co-operation between different private sector and non-governmental actors at European level. More recently, the High Level Group on Nutrition and Physical Activity adopted an Action Plan on Childhood Obesity 2014-2020 that aims to halt the rise of childhood obesity by 2020. Council Conclusions on Nutrition and Physical Activity were adopted in June 2014, which invited MSs and the Commission to engage in a number of actions.

Alcohol related harm is a major public health concern in the EU. Alcohol is the world's third leading cause of ill health and premature deaths, with the EU accounting for the highest alcohol consumption in the world.[20] The EU strategy to support Member States in reducing alcohol related harm was first introduced in 2006. It sought to provide help to national governments and other stakeholders to coordinate their actions in this area.[21] A WHO representative consulted as part of this case study highlighted that in the EU, alcohol is on the policy agenda in most countries, with more MS adopting national alcohol strategies and plans. Despite advances in EU level strategy and policies, policy changes in MS are slow to take hold. In terms of the specific areas of focus, actions targeting the youth and drink driving have been most prominent, but recently the links between alcohol and cancer are gaining attention.

The WHO Regional Office for Europe has been an important and influential actor in the area of alcohol related harm for the past 20 years. They have been at the forefront of coordinating actions to reduce the harmful use of alcohol and in the past 10 years, such efforts have been increasingly taken up at both the regional and global levels.[22] These developments have "*resulted in important policy documents, including the "Global*

[18] See: http://ec.europa.eu/health/nutrition_physical_activity/platform/index_en.htm

[19] Currie, C. et al. (2008), *Inequalities in Young People's Health*; Currie, C. et al. (2012), *Social Determinants of Health and Well-being among Young People.*

[20] Thematic fiche. 1.1. Prevention Measures.

[21] See: http://ec.europa.eu/health/alcohol/policy/index_en.htm

[22] Contract number 2014 51 02. Annex 1b. Monitoring of national policies related to alcohol consumption and harm reduction.

Strategy to reduce the harmful use of alcohol", the EU alcohol strategy, and the European action plan to reduce the harmful use of alcohol 2012-2020".[23]

The biggest initiative to be implemented on **tobacco use** is the World Health Organisation Framework Convention on Tobacco Control (FCTC). Entering into force in 2005, the treaty signified "*a paradigm shift in developing a regulatory strategy to address addictive substances*", and came at a time when tobacco use was rapidly increasing.[24] Another major milestone for initiatives on tobacco use was the Tobacco Products Directive, which came into force in May 2014 and became applicable in the EU MS in May 2016.[25] The directive outlines rules governing the manufacture, presentation and sale of tobacco and related products, for example the health warning images which can be seen on tobacco products (it is specifically dealt with under thematic priority 1.5).

3.2.3. Fit with the Health Programme

The thematic priority under review in this case study falls under the scope of objective 1 of the 3HP, which is defined in the 3HP Regulation as follows: *"Promote health, prevent diseases and foster supportive environments for healthy lifestyles taking into account the 'health in all policies' principle."*[26] Six thematic priorities are defined with the aim and purpose of feeding into this overarching objective. In the Annex to the Regulation, thematic priority 1.1 is phrased as follows:

*"Cost effective promotion and prevention measures in line, in particular, with the Union strategies on **alcohol and nutrition**, and including actions to support the exchange of evidence-based and best practices for **addressing risk factors such as use of tobacco and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity**, taking into account the public health aspects of the underlying factors, such as those of a social and environmental nature with a focus on Union added value"*

Although the thematic priority is not substantively new for the 3HP the choice of phrasing and introduction of **the words "cost effective" signifies a different emphasis**. These words reflect a broader change in emphasis of the 3HP on the economic factors of implementing health policies. Similarly, where previously reference was made to "health determinants" (such as nutrition and physical activity), the language now refers to "risk factors". A notable change is the absence of reference to "sexual health", which is now dealt with separately under thematic priority 1.3.

Although risk factors are addressed through a distinct thematic priority under objective 1, there is substantial scope for synergies with **other thematic priorities under the objective to promote health within the 3HP** but also risks of overlap, as presented below:

[23] Contract number 2014 51 02. Annex 1b. Monitoring of national policies related to alcohol consumption and harm reduction.

[24] WHO (2003). WHO Framework Convention on Tobacco Control. See: http://apps.who.int/iris/bitstream/10665/42811/1/9241591013.pdf

[25] See: http://ec.europa.eu/health/tobacco/products/index_en.htm

[26] Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC. Annex I.

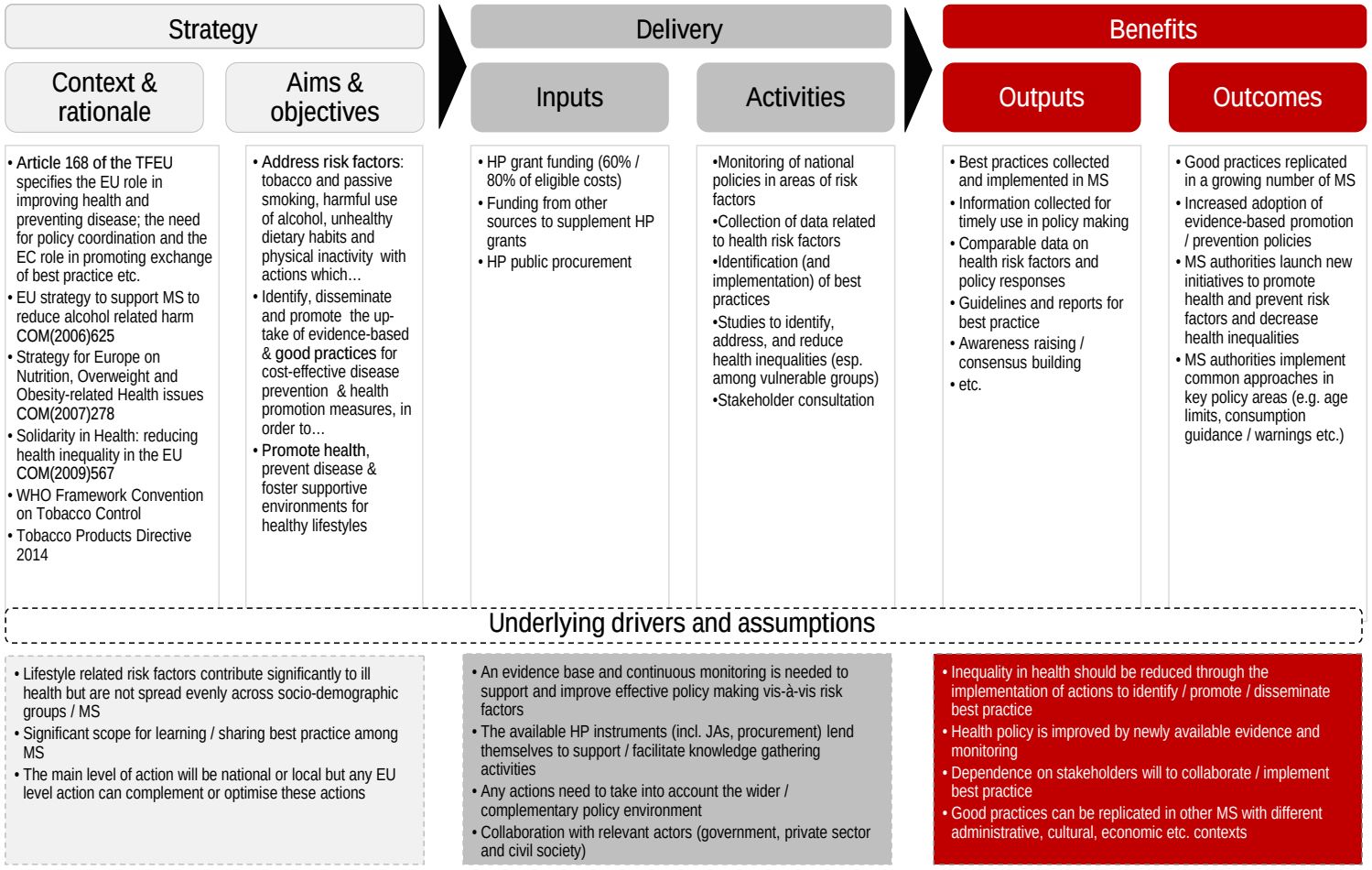
- Some major chronic diseases, such as specific types of cancer, are clearly linked to the risk factors, which naturally therefore connect thematic priority 1.1 with **1.4 on "chronic diseases"**.
- **Thematic priority 1.5** deals with the implementation of legislation in the **field of tobacco products** which is clearly very closely connected to the activities dealing with tobacco use under 1.1.
- There is also a risk of overlap with activities under **thematic priority 1.6** which covers "the development of standardised health information and tools for monitoring health, collection and analysis of health data"[27].

3.3. Theory and practice

This section presents and assesses the **thematic priority's intervention logic.** It starts with a diagram that depicts the theory underpinning the thematic priority. This is followed by sub-section on each of the intervention logic's main parts (strategy; delivery; and benefits). These sub-sections first describe and examine the how HP action under the thematic priority is intended to work in theory. We then analyse what is happening in practice by examining the objectives, activities, outputs, and (early) outcomes of the five actions selected for the case study. This allows us to test the intervention logic's plausibility and determine whether the desired outputs and outcomes of the thematic priority are likely to be achieved through the type of actions that have been funded to date. For a more detailed explanation of the methodology / components, please refer to the **introduction**.

[27] Note that the extent to which these risks are managed in discussed under theory and practice "Delivery" (section 2.3.2)

Figure 1 : Intervention logic for thematic priority 1.1 (risk factors)



Source: created by evaluation team based on case study fieldwork (documentation review and interviews)

3.3.1. Strategy

Rationale for HP action in the thematic priority

The basic premise for HP action in this field follows the discussion from section 2 above: the issues surrounding alcohol consumption, tobacco use, and unhealthy dietary habits and physical inactivity are **widespread**, affecting every MS. While the subsidiarity principal means that the EU has primary responsibility for tackling these risk factors, the EU Treaty specifies the EU's role in health promotion specifically in coordinating action for common challenges. While the **prevalence of risk factors varies** between the MS, so do **initiatives** to tackle these health needs. As a result, the EU is able to facilitate the exchange of best practices between MS (in terms of regulation and marketing in the alcohol and food industry, for instance[28]), unlock the potential of innovation in health, and improve economies of scale in this area.[29]

As mentioned, there is always scope to share information and promote best practices. To give some examples, there is important activity across MS in the fields of nutrition and physical activity, providing the **scope for countries to learn from each other** through the exchange of experiences and best practice at national level. For example, in the field of nutrition the UK has a **School Fruit and Vegetable Scheme** (SFVS), which was piloted in 2001, introduced in parts of the country in 2004, and now covers the entire country. Under the SFVS, all children aged four to six who attend a fully state-funded infant, primary or special school are entitled to receive a free piece of fruit or vegetable each school day. An evaluation carried out in 2006-07 found that participating children's (short term) consumption of fruit and vegetables had increased significantly.[30] Another, more recent evaluation found that this overall improvement had been broadly sustained two years later. In the field of physical activity, a joint health monitor project in the Baltic States and Finland showed that, between 1998 and 2008, Finland registered an increase in the level of leisure-time physical activity[31]. According to the study, this increase is explained by positive economic and social changes, but also by health policy developments, including large reforms of health care systems, that have influenced health behaviours. Regular surveys in England reveal a significant increase in the proportion of those who met government recommendations for the minimum level of physical activity to achieve health benefits, from 27% in 1998 to 36% in 2008[32]. Recommendations follow a tailored approach, responding to different socioeconomic, age and geographic profiles of the target population, incorporating a setting-specific and community-based approach. The focus is on creating active environments, scaling up

[28] For instance, reformulation has cross-border and internal market angles. Since each national food market is supplied by producers from all over the EU, if authorities want to effectively promote the health of citizens via reformulation, they have to do so in coordination. On the other hand, such coordinated approach allows companies to benefit from having a level playing field and from the promotion of food innovation. In terms of marketing: advertising and placement of foods that are high in fat, sugars or salt, or of alcohol, can easily travel across the airwaves or, most importantly, the internet and social media. This means that effective approaches in this domain either require or benefit from coordination at European level.

[29] Thematic fiche. 1.1. Prevention Measures.

[30] National Foundation for Educational Research: The Further Evaluation of the School Fruit and Vegetable Scheme, May 2007

[31] THL, 2011. *Social Determinants of Health Behaviours Finbalt Health Monitor 1998–2008*, p 82. Available from: http://www.thl.fi/thl-client/pdfs/f316c417-cc1d-48e6-a2e2-7389fde28630.

[32] Department of Health: Health Survey for England. Available from: www.dh.gov.uk/en/publicationsandstatistics/publishedsurvey/healthsurveyforengland/healthsurveyresults/index.htm

effective interventions, building a social movement, and engaging professionals with expertise across the fields of education, sports and leisure, and health and social care.[33]

As previously mentioned, stakeholders consulted as part of this case study reported another reason to coordinate action at the EU level is to show a united front in light of **the strength of industries** which stand to lose from action to reduce the harmful consumption of certain goods. In addition, stakeholders felt that while the alcohol and tobacco industries have long been a powerful force in the global market, in recent years the nutrition industry[34] has rapidly grown and now includes many powerful multinational actors. While the growth of the industry has positive aspects, there are risks as well. For example, Chafea representatives pointed to the risk of mixed messages that may come out of the use of nutrition and health claims on foods that do not have a desirable composition, mainly in terms of fat, salt and sugar content. As noted by interviewees, concerns have been raised that placing nutrition or health claims on such foods could encourage greater consumption of these products, and thus give misleading messages about healthy eating. As such, it is believed that the EU is in a stronger position to lead discussions with industries and can ensure that clear messages are transmitted across all MS.

As well as providing a more coherent and stronger voice, and coordinating actions between MS, the EU is also well positioned to **collect data** from MS on policy implementation, alcohol consumption, obesity rates, etc. in order to facilitate comparison between countries on issues such as alcohol consumption and harm, and use this information to inform policy-making.

At the same time, there is an increasing recognition at the WHO and UN level that given that many of these health risk factors transcend national borders, making an **international response** important. Countries are increasingly facing similar problems, and would benefit from a coordinated response to tackle them together. In this framework, the EU and other international organisations are well placed to provide support to national governments and other national stakeholders (including non-governmental and civil-society organisations, researchers and the private sector) in developing adequate policies and actions to fight alcohol consumption, tobacco use, unhealthy dietary habits and physical inactivity. Moreover, while some countries are better equipped to tackle these health issues, others MS lack the adequate resources to address these huge challenges. For example, Malta has the highest obesity rate in the EU[35], but has limited ability to influence some of the dimensions of the problem on its own.

Strategic fit of funded actions

The actions under review show a clear fit with the rationale for action in that they tackle – in different ways - the various risk factors associated with ill health and premature death in the EU: tobacco use, harmful use of alcohol and unhealthy dietary habits / obesity and physical inactivity.

Two of the actions are directly drawn from the AWP of 2014, using negotiated procedures: “Monitoring of the national policies related to alcohol consumption and

[33] United Kingdom of Great Britain and Northern Ireland Physical Activity Factsheet. Available from: http://www.euro.who.int/__data/assets/pdf_file/0010/288127/UNITED-KINGDOM-Physical-Activity-Factsheet.pdf?ua=1

[34] Stakeholders referred to “nutrition industry” as businesses / companies which are working in the area of promoting healthy and nutritious lifestyles and diets.

[35] WHO (2013). *Nutrition, Physical Activity and Obesity: Malta.* See: http://www.euro.who.int/__data/assets/pdf_file/0015/243312/Malta-WHO-Country-Profile.pdf?ua=1

harm reduction (MOPAC)" and the "Joint Action on Nutrition and Physical Activity (JANPA)".

- The direct grant agreement MOPAC aims to reduce alcohol related harm and is therefore clearly in line with the AWP 2014 which calls for the "monitoring of national policies related to alcohol consumption and harm reduction".[36]
- With regards to the joint action JANPA: this is a clear priority area in the 2014 AWP which states the need for an action that facilitates the sharing of good practices between EU MS on national policies related to unbalanced dietary habits and physical inactivity.

The remaining actions in the sample were all operating grants, and these too present an obvious link with the aims and objectives of the thematic priority.

- "Smoking prevention in action: the Smoke Free Partnership Coalition" (SFP) is focused on addressing health risks related to tobacco use and passive smoking through its advocacy strategy to implement and enforce the Framework Convention for Tobacco Control.

- At the same time, the grant for "Obesity Training and Information Services for Europe" (OBTAINS) is designed to address and prevent health risks related to unhealthy dietary habits and physical inactivity.

- While the support for "European Public Health Alliance" (EPHA) is designed to improve health and well-being in all policies, through among others prevention activities. As such, one of the central aims of the EPHA is to support the prevention of non-communicable diseases caused by risk factors and to reduce health inequalities.

One of the main aims and objectives of this thematic priority is to **identify, disseminate** and **promote** the up-take of **evidence based and good practices** in the specified health areas. The core aims and objectives of all actions (most notably the joint action) are all in line with this aim. Part of the overall objectives of actions such as "OBTAINS" is to disseminate evidence for effective treatment methods for obese adults and best practices across the EU region.[37] However, when it comes to the more detailed methodology and plan of how these objectives will be achieved, it is less clear how realistic these aims and objectives are. For example, according to the evaluation of the OBTAINS proposal, there is no dissemination strategy; only a list of activities. The World Obesity Federation (WFO), the beneficiary of this operating grant, would need to present a more detailed dissemination strategy for the different target groups.[38]

This thematic priority also aims to achieve **cost-effective** disease prevention and health promotion measures in order to promote health, prevent disease and foster supportive environments for healthy lifestyles. This is an aspect which is less visible in the aims and objectives of the sample actions.

The direct grant agreement "MOPAC", which demonstrates the potential to achieve this objective by choosing to implement the action through the WHO and making use of existing resources does in its own way represent a cost effective measure (i.e. avoiding duplication). Yet, the specific drive to seek cost effective measures to promote and prevent habits which are detrimental to health were not identified.

[36] Public Health Programme – Work Programme for 2014. Annex I.

[37] Publishable Summary for the action on Obesity Training and Information Services.

[38] 671355-OBTAINS-E Evaluation Summary Report (2014).

3.3.2. Delivery

Planned activities and overall implementation so far

As stated in the 3HP regulation, thematic priority 1.1 consists in a relatively narrowly defined set of activities: i.e. those which **support the exchange of evidence-based and good practice** in the areas of tobacco use and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity.

During the first years of the 3HP, 2014 - 2020, thematic priority 1.1 was allocated around €5 M each year, reaching €14.58 M in total.[39] This makes it the second highest funded thematic priority (after thematic priority 1.4 on chronic diseases). A large portion of the budget allocated to this area to date (€6.4 M) was delivered through annual operating grants to non-governmental organisations whose mission was in line with the reduction of risk factors relating to poor health[40]. For example those covered by the sample of action examined through this case study (OBTAINS, EPHA and SFP). This is larger than the sums allocated through operating grants to any other thematic priority by far. There were also a relatively high share funding through direct grant agreement (nearly €1.7 M) compared to other thematic priorities. This would seem to indicate that the support provided through the HP to tackle risk factors is being strategically channelled to organisations (non-governmental and international) which are well-placed to conduct work in this area.

For example, one of the actions funded through a direct grant agreement is the "Monitoring of national policies related to alcohol consumption and harm reduction" (MOPAC), which the WHO started implementing in 2016 for a period of 3 years[41]. The action plans to deliver the **evidence-base** called for, with the EC and WHO cooperating to collect data and develop a shared alcohol information system for the EU and the WHO European Region, something which has been a focus of these direct grant agreements since 2008.[42]

As highlighted elsewhere (under "Fit with the Health Programme") there is a fine balance between the activity under thematic priority 1.1 which seeks to gather information and data for the development of an evidence pool and exchange of good practice specifically in the area of risk factors and the thematic priority 1.6 which is focused on monitoring activities in the area of health promotion more broadly.

As illustrated in the intervention logic, there are certain mechanisms and success factors which must be in place in order to effectively deliver these activities. Firstly, **a strong evidence base can only be achieved with** the capacity and commitment of resources to collect information from across the EU at the EU level. Furthermore, in order for these activities to achieve the desired results, they must also take into account the wider context and policy environment as well as identifying and collaborating with relevant actors from government, private sector and civil society. This collaboration is key to ensuring that there is a sharing of best practices and lesson learning, as well as a coordination of actions.

Lessons learned from specific actions so far

[39] Data provided by DG SANTE and Chafea

[40] There were six operating grants funded in 2014; five in 2015 and 2016 (one of the organisations receiving an operating grant in 2014 ceased operations: "Schools for Health Europe").

[41] The contract for "MOPAC" was signed end 2015 with a foreseen start date in January, 2016.

[42] Contract number 2014 51 02. Annex 1b. Monitoring of national policies related to alcohol consumption and harm reduction.

Although it is difficult to draw lessons from the implementation of actions at this early stage in their implementation, below we suggest some key preliminary lessons which are already apparent.

Strong management was a key success factor which came out of the final 2HP evaluation, and one which again will be crucial for the success of the actions funded under the 3HP. This is most apparent for the joint action examined as part of this case study. In the case of JANPA, one lead partner coordinates 38 other partners, across 28 different cultural and linguistic settings. According to the evaluation of the "JANPA" proposal, their management and allocation of work between the governing bodies is well documented.[43] Since its start, there has been drive, focus and clarity on the way of working together, where all partners know exactly what to do, when to do it, and how, and this Joint Action has been running smoothly and delivering concrete deliverables of very high quality and political relevance.

Implementation of the direct grant agreement "MOPAC" also faced the challenge of coordinating their 28 national focal points (NFPs), ensuring that all NFPs responded to their survey. This was vital for them in order to guarantee that sufficient information data was collected across all MS. The WHO set up network meetings where they discussed any issues and problems with the NFPs, facilitating good, close cooperation with the MS. This strategy of securing buy-in has proven to be successful in the past; according to the WHO representative, the last time they collected the full data set through this survey in 2012, all MS participated.

As one Chafea officer mentioned, **good communication and exchange of information** with beneficiaries is important, particularly for actions which receive funding from other sources (such as EPHA). On-going communication and engagement must be in place between Chafea and DG SANTE. In 2014, an internal evaluation committee was established, comprised of representatives from Chafea, DG SANTE and other DGs. This allowed DG SANTE to be involved in formal negotiations with beneficiaries throughout the implementation of activities.

Findings from the case study suggest that there is good communication between Chafea and DG SANTE. For instance, monthly **coordination meetings** take place between Chafea and DG SANTE, where they share any progress, key information and results, while they are in general contact on a day to day basis. In terms of particular actions, DG SANTE is involved in the quality assurance of JANPA, including meetings with the MS groups to develop ideas for the action. They have a concrete input in organising these meetings before proposals are issued, in order to identify MS priorities.

Beneficiaries seemed to be positive about the relationship and support received from Chafea. The EPHA representative reported that the successful implementation of this action was facilitated by the provision of a **clear structure with deliverables, achievable milestones and deadlines and expected impact**. In particular, requirements on quantification of impact of the action were beneficial for planning purposes. Chafea also provides them with detailed responses and feedback in their evaluations, which helps EPHA track progress. In the view of the EPHA representative, Chafea's flexibility in response to requests for minor changes and the desk officer's availability for answering questions have also been conducive to a smooth implementation of the action.

What is apparent from the interviews with Chafea officers is that in order for an action to be successful, there must be a **strong element of planning and design**. Due to the relatively short time frames for implementing actions under the 3HP,

[43] 677063-JANPA-ESR Evaluation Summary Report (2015).

implementation partners must ensure that they have detailed plans in place in order to be ready to proceed as soon as the contract / proposal is signed. This has proven to be particularly important for the actions which faced delays in their implementation; a common issue which was noted across the sample of actions is that many faced delays when it came to receiving the go-ahead to begin implementation.

A part of this planning, as identified in the final evaluation of 2HP, requires **well-delineated action scope and objectives,** a key condition that needs to be in place for the achievement of desired results. The technical content of an action needs to be developed around SMART objectives which are pragmatic and realistic. However, objectives are harder to measure for certain actions, such as for example, the Smoke Free Partnership Coalition (SFP), an advocacy group which promotes the implementation of the Framework Convention on Tobacco Control (FCTC). As one Chafea officer noted, the impact for this action is likely to come from national authorities, not the SFP directly. This in turn requires an even stronger focus on design, in order to ensure that the programme identifies and reaches key stakeholders including media outlets, which can play a big role in changing public opinion.

According to a Chafea officer, given **the limited time and budget** of many of these actions, there is greater pressure on them to be clearly designed and implemented, in order to focus resources and avoid spreading the available resources too thinly. In view of ambitious objectives, implementation partners need to be fully prepared and ready to kick-off from the moment they sign the agreement. Nevertheless, despite other EU instruments, such as Horizon 2020, having larger budgets and longer time frames, the sampled action demonstrate the HP can focus on implementation and good results.

Lastly, due to the short time frames, actions need to focus on the **sustainability of the results beyond the grant agreement**. For instance, a Chafea officer stated that the WHO is resourced to ensure that this happens, as they already have their platform and NFPs in place. It is perhaps less clear how other actions, particularly operating grants, would manage without EU funding.

3.3.3. Benefits

Expected immediate, medium- and long-term benefits

Over their relatively short time-span, the actions funded under thematic priority 1.1 are expected to deliver a number of key medium- and long-term outputs and outcomes. In order to **increase the adoption of evidence-based promotion / prevention policies**, actions are expected to collect and **compile comparable data and information on health risk factors and policy responses** across the MS. This includes collecting evidence on alcohol consumption and alcohol policies in all MS, as well as comprehensive evidence on national policies related to nutrition, physical inactivity, and overweight and obesity related diseases.[44]

This information is expected to enable beneficiaries to compare the status quo across MS and **identify best practices which can be implemented across countries**. Compiling this data can also feed into the **creation of reports and guidelines for best practice to be shared among relevant stakeholders**.

Identifying, developing and piloting best practice is indeed a major contribution of the programme to public health at EU level. In this context, and in the area of nutrition and physical activity, the joint action JANPA was reported to have been particular important,

[44] Thematic fiche. 1.1. Prevention Measures.

by allowing for the development of concrete deliverables that promote real implementation at MS level.

Another way in which these outputs and outcomes are expected to be achieved is through the funding of MOPAC which, among its expected outcomes, plans to provide a functional and sustainable system to monitor trends in alcohol consumption and harm, as well as alcohol policies across the EU and Europe.[45] By monitoring these trends, it aims to provide a user-friendly online information system to present national and consolidated data, including the indicators on alcohol policies, use and harms. In addition to this, MOPAC plans to produce a report this year that presents data collected through the 2015 survey, executed at country and EU levels, as well as data from the Health for All database[46]. Ultimately, the information gathered as part of this project will enable the assessment of trends in alcohol consumption and harm in order to understand the extent to which the aims and priorities of EU and European strategies are being met. As a result, i*t "will feed into the monitoring of the implementation of the EU alcohol strategy, the European action plan to reduce the harmful use of alcohol 2012-2020, and the EU action plan on youth drinking and on heavy episodic drinking (binge drinking) 2014–2016*".[47] MOPAC has the potential to contribute significantly in terms of providing comprehensive data, reports and identifying trends in the area of alcohol consumption and harm, in order to feed into current EU strategies in this area.

OBTAINS is also expected to play an important role in collating and disseminating rigorous research into obesity-related health issues, as well as promoting the use of best evidence in regional and national policy-making. One of the action's strategic goals is to inform the policies of a range of stakeholders from governments, businesses and NGOs, healthcare providers, healthcare professionals and academia, using the best current evidence.[48] This focus on a large network of stakeholders lends itself to meeting their goal of "*creating a global community of organisations and individuals dedicated to solving the problems of obesity*".[49]

It is also *expected* under this thematic priority that this information will be disseminated to the relevant stakeholders, in a **timely manner that allows it to be used in policy making**. In the longer term, the funded actions are *expected* to have an impact on MS policies and initiatives in this area. It is hoped that by identifying best practices and **raising awareness**, MS authorities will converge their actions and **implement common approaches in key policy areas** such age limits on purchasing alcohol and / or tobacco.

In some instances, these common approaches will be based on best practices which have already been implemented in some MS. However, it is also expected **that new initiatives will emerge** that can ultimately **promote health, prevent health risk factors** related to alcohol consumption, tobacco use, unhealthy diets and physical inactivity, as well as **decrease health inequalities** (one of the general objectives of the 3HP).

EPHA has a more cross-cutting approach in its objectives and planned outcomes with broader, longer-term macro objectives in mind. Its mission is to "*bring together the health community to provide thought leadership and facilitate change; to build public*

[45] Contract number 2014 51 02. Annex 1b. Monitoring of national policies related to alcohol consumption and harm reduction.

[46] See: http://www.euro.who.int/en/data-and-evidence/databases/european-health-for-all-database-hfa-db

[47] Thematic fiche. 1.1. Prevention Measures.

[48] Health Programme (2014) 671355 Signed Proposal OBTAINS-E

[49] Ibid

health capacity to deliver equitable solutions to European public health challenges, to improve health and reduce health inequalities".[50] It plans to achieve this through its wide and diverse network of NGOs, health professionals, academics, other pan-European and international networks and disease specific groups, who together cover a breadth of issues that can enable EPHA to achieve these goals. However, there is little or no mention of income inequalities, which is one of the main underlying reasons for health inequalities. One of the expectations of the funded actions is to undertake **studies to identify, address and reduce health inequalities, in particular among vulnerable groups.** However, the funded actions seem to lack a focus on targeting these vulnerable groups, and refer mostly to general (not tailored) initiatives.

The nature of JANPA, as mentioned, lends itself to supporting and promoting a coordinated approach across MS to improve the situation of childhood overweight and obesity with the involvement of MS health authorities. The joint action is considered to be a good opportunity to strengthen the coordination between MS on actions, in order to halt the rise in overweight and obesity in children and adolescents by 2020.[51] JANPA is part of a much broader action as a step in the implementation of the EU action plan on childhood obesity 2014-2020.[52]

Overall, the medium- and long-term objectives and expected outcomes of the funded actions appear to be fairly well in line with those of the thematic priority, which would be expected given its breadth. However, one area where these goals are not fully in line is the **emergence of new initiatives**. Actions make little or no mention of focusing on developing new, innovative initiatives, as the majority feed into existing EU policies and strategies, such as the FCTC, EU alcohol strategy and EU action plan on childhood obesity 2014-2020. While, the value of consistency and leveraging existing work is important it should not undermine scope for innovation. Additionally, some of the actions make reference to reducing health inequalities in the long run, but few of them have a strategic plan to address the causes of these health inequalities. This is an area where further investment in mainstreaming needs to be promoted.

(Potential) benefits in practice

At this stage of the 3HP's implementation, all the expected benefits are not yet visible. However, taking into account interviews with Chafea officers and implementation partners, we can assess the plausibility and likelihood of these achievements in the future, and if the extent to which there are barriers which might prevent the actions from achieving the desired results and impacts.

According to Chafea officers, JANPA partners are focused on sharing perspectives and investigating what practices are being implemented in the different MS. However, Chafea interviewees also pointed out to the inherent **difficulty in coordinating a joint action which takes into account the various cultural backgrounds and contexts across the EU**. Some of those consulted argued that MS which more recently acceded to the EU are less willing to support and implement policies and initiatives in the area of alcohol. They suggested this could be related to a number of reasons, cultural or economic (e.g. the role that the alcohol industry in these countries plays in their national economies). However, there is not conclusive evidence to support this characterisation and there is in fact data that states the contrary. Additionally, as previously mentioned in this case study, some of the countries where these health risk factors are the most prevalent, such as Romania with alcohol-related harm and Malta with obesity rates, are also countries which lack the capacity and resources to tackle these issues. Despite the

[50] European Public Health Alliance (EPHA). Specific Partnership Agreement 2015 with EPHA - Application.

[51] Health Programme (2014) 677063 Signed Proposal JANPA.

[52] Ibid

aim of EU level action to support coordination of activities to help MS overcome some of these challenges relating to lack of resource, the uptake of the results of actions has to be done at national level. Therefore it is important to take this already in consideration beforehand by including the diverse **administrative, cultural and economic contexts when seeking to spread best practice**.

Achieving these benefits also depends on Member States and **stakeholders' willingness to collaborate / implement best practices**. However, as previously mentioned, many interviewed implementation partners raised the issue of the inherent difficulty of acting in areas such as alcohol, tobacco, physical inactivity and nutrition, where the respective industries are extremely large, influential actors that can pose barriers to implementing initiatives in these fields. **MS will require a lot of support and intervention at the EU level here in order to potentially overcome some of these obstacles**, by having a larger, influential voice and presence in these industries.

For some actions such as SFP, Chafea officers highlighted the **difficulty in assessing their impact** because it is ultimately up to MS to decide whether they wish to implement the initiatives advocated. Similarly, according to WHO, the MOPAC action was challenging in that it required coordination among all 28 national focal points to participate in their survey and provide information. In terms of the extent to which these areas are regulated, actions in the area of tobacco use are more regulated at EU level than initiatives in the fields of nutrition and physical activity. In view of some of those consulted as part of the case study, the lack of a strong EU regulatory framework makes it difficult for MSs to support actions in these areas, and there are some interviewees who would support a stronger regulatory role for the EU in particular in relation to the promotion of nutrition and physical activity actions.

Despite the difficulties highlighted, the actions under analysis appear to be very well **aligned with and complementary to other actions** at the EU level. Actions such as OBTAINS are implemented by a partner which is also involved in Horizon 2020 in the field of obesity, and even though this can potentially result in duplication, the results so far have been positive, with a focus on complementarities. Other actions such as JANPA have taken on board earlier project work and built from it in order to make use of research that is already available. According to Chafea officers, the participation of JANPA's consortium partners in other related actions means that they are well acquainted with the information available and recent research on the topic. MOPAC's new alcohol policy timeline database will be hosted at the Global Health Observatory in order to make use of an existing interface, facilitate access to data and increase linkages with other available data.[53] As such, these actions have a strong potential for complementing existing activities, and while as previously highlighted results to date have been positive, caution must be paid to maintain a coordinated approach and to avoid unnecessary duplication of work.

Implementation partners also face the challenge of **achieving results in a relatively short timeframe**. Chafea officers stated that limited timing and resources highlight the need for actions to be focused and well planned in order to achieve the expected benefits. In view of many implementation partners interviewed by the evaluation, the situation is made more difficult by the **delays in signing the contracts**, which placed more pressure on these actions to deliver results. Additionally, for actions such as JANPA which heavily involve MS ministries and public authorities, Chafea officers consulted stated that decision-making processes are slower than those of independent

[53] Contract number 2014 51 02. Annex 1b. Monitoring of national policies related to alcohol consumption and harm reduction.

organisations, as it needs to be ensured that decisions comply with public authority regulations and other procedures.

3.4. Conclusions

The following conclusions attempt to draw out key points from the evidence collected and analysed, with a focus on the relevance of the thematic priority, its potential to make a difference in practical terms and lessons that can be applied to the HP more broadly.

1. Relevance of the thematic priority, given:

- **Identified needs:** Thematic priority 1.1, which focuses on "Risk factors such as use of tobacco and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity" is consistent with some of the most significant risks to premature death and ill health across the EU. Together, these risk factors pose a considerable burden on healthcare systems.
- **HP objectives:** The HP is an important vehicle for supporting the coordination of action to promote health and activities to identify and share best practices are clearly in line with this aim. There is a logical need to coordinate this and other necessarily related thematic priorities of the HP; for example, chronic diseases (1.4) and action to support the implementation of tobacco products legislation (1.5) and monitoring and collation of health information (1.6) have the potential for overlap.
- **EU objectives more broadly:** An area in which actions fare strongly is in their **complementarity** with wider EU policy objectives and actions. All actions assessed are directly aligned with Commission policies and strategies, with some such as the Smoke Free Partnership (SFP) placing these at the core of their strategy. We note that in the actions reviewed cost-effectiveness is only addressed implicitly (i.e. the assumption being that a coordinated EU approach / sharing best practices is more efficient that actors working alone).

2. Likelihood of actions to make a difference in terms of:

- **Established problems:** There is an inherent difficulty in designing action to promote health in that the EU's role is restricted to coordination, while the primary responsibility to implement activities is at the MS level. There are however certain areas where the EU dimension is clear. In addition, the activities supported can only make a difference to increasing knowledge of ways to address the established problem and improving the evidence base for the most effective solutions.
- **EU added value:** The potential EU added value of actions is high, including the collation of data and information across all MS, identification of best practices and coordination of MS actions as necessary for effective interventions from both a public health and a stakeholder point of view.
- **Wider policy objectives / priorities:** The 3HP has limited capacity in terms of how much can be achieved by an action in just three years, but this highlights the need for actions within the programme to be more coordinated with other actions and initiatives outside of the health realm. Some actions do place a focus on coordinating with DGs dealing with fields such as agriculture, research and innovation, education and culture, but this needs to be systematic.

3. What lessons can be learned in terms of:

- **Strategy:** Given the scale of the challenge, the HP strategy has been to focus on channelling funding to actors already working in the field (for example

through operating grants to established networks, international organisations through direct grant agreements, and competent authorities through joint actions). While this strategy has clear advantages, some of the more innovative actors or actions which might involve new approaches to established problems are not exploited.

- **Delivery:** The evidence from the sample of actions examined through this case study illustrates the commitment of the actors involved at different levels and the importance of ongoing communication for the success implementation of actions. An important lesson learned is that – in view of the ambition of some of the activities – it is crucial to clearly delineate the scope of the work to be completed.
- **Benefits (to the extent available):** The sampled actions have shown that in order for the expected benefits to be fully realised, actions need to be aware of the different administrative, economic, social and cultural contexts across MS (and within each country) and the difficulties this may bring in terms of implementing coordinated actions across all MS. There is a need to focus more on studying the underlying reasons for health inequalities, with a view to providing strategies and approaches to address and reduce inequalities, in particular among vulnerable groups.

4. THEMATIC PRIORITY 1.4 – CHRONIC DISEASES

4.1. Introduction

This case study examines thematic priority 1.4 of the 3HP on "Chronic diseases including cancer, age-related diseases and neurodegenerative diseases"[54]. This priority falls under Objective 1 of the 3HP, which is to "Promote health, prevent diseases, and foster supportive environments for healthy lifestyles taking into account the 'health in all policies' principle"[55]. A total of 18 actions had been funded under this thematic priority to date (2014 -2016), amounting to a total of €17.2 M. This funding was spread across all possible funding mechanisms, namely projects, operating grants[56], joint actions, service contracts, and one direct grant agreement. A sample of actions was selected based on consideration of their maturity, breadth of coverage of the mechanisms and a mix of different sized actions (see table below).

Table 4: Actions reviewed for case study on chronic diseases (thematic priority 1.4)

Funding mechanism	Lead partner (incl. MS)	Other organisations (incl. MS)	Budget	Start date/duration
Joint Action on Dementia 2015-2018 (DEM 2)				
Joint action	Scottish Government (UK)	11 partners in 10 MS[57]	Total eligible costs: HP grant: €2,679,938 € 1,498,710 (60% of eligible costs)	Start date: 01/03/2016 Duration: 36 months
Mental Health – Trimbos Instituut (Mental Health)				
Service contract	Trimbos Instituut (NL)	N/A	HP grant: € 799,777 (60% of eligible costs)	N/A
Participation to Healthy Workplaces And Inclusive Strategies in the Work Sector (PATHWAYS)				
Project	Fondazione IRCCS Istituto Neurologico Carlo Besta (IT)	11 partners in 9 MS[58]	Total eligible costs: €1,615,631 HP grant: € 969,379 (60% of eligible costs)	Start date: 01/05/2015 Duration: 36 months
Alzheimer Europe (2015-2017) (AE 2015-2017)				

[54] As this is the introduction to the case study, and with a view to avoiding unnecessary duplications of the information, we have kept only the title of the thematic priority. The full text is examined in section 2.3.

[55] Annex I to the Regulation (EU) 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020).

[56] These were awarded to two organisations (Alzheimer Europe and European Cancer League) in 2014 and extended in 2015 and 2016.

[57] University Lyon 1 Claude Bernard (FR); National Institute for Health (IT); Medical University of Lublin (PL), Bulgarian Society of Dementia (BG), The Norwegian Directorate of Health (NO); Quality and Assessment Agency of Catalonian Health (ES); Ministry of Health, Welfare and Sport VWS (NL); Norwegian National Advisory Unit on Ageing and Health (NO); National and Kapodistrian University of Athens (EL); Department of Health (UK); and National Mental Health and Antidrug Centre (RO)

[58] Autonomous University of Madrid (ES); Health Park of St John of God (ES); University of Thessaly (EL); Industrial Application Company (AU); Rehabilitation Institute of Slovenian-SOCA University (SI); General University Hospital in Prague (CZ); Jagiellonski University (PL); Oslo and Akershus University College of Applied Sciences (NO); European Association of Service Providers for Persons with Disabilities (BE); Carinthia University of Applied Sciences (AU); and Ludwig-Maximilians University in Munich (DE).

Funding mechanism	Lead partner (incl. MS)	Other organisations (incl. MS)	Budget	Start date / duration
Operating grant	Alzheimer Europe (LUX)	N/A	Total eligible costs: €704,800 HP grant: €422,880 (60% of eligible costs)	Start date (2014 call): 1/1/2015 Duration: 12 months Start date (2015 call): 1/1/2016 Duration: 12 months[59]
Cancer Leagues Collaborating in Cancer Prevention and Control at the EU and National Level (ECL)				
Operating grant	Association Europeenne des ligues contre le cancer ASBL	N/A	Total eligible costs: €525,453 HP grant: €314,972 (60% of eligible costs)	Start date (2014 call): 1/1/2015 Duration: 12 months Start date (2015 call): 1/1/2016 Duration: 12 months[60]

Note: More information on the sampled action can be found on the Chafea database and in the AWPs available on DG SANTE's website

The methodology for the case studies is provided in detail in the **introduction** to this Annex. But entailed **two main steps**. First, we reconstructed the thematic priority's theory in the form of an intervention logic diagram. Then, to test the theory, we collected and analysed evidence about implementation so far, above all through an examination of five funded actions (as above). The different sources of information are summarised in the table below.

Table 5: Documents consulted and interviews conducted on chronic diseases (thematic priority 1.4)

Documents consulted	Interview status
• Commission policy documents and other relevant literature (e.g. WHO reports) on public health problems; • Internal working documents for multi-annual planning for the thematic priority; • 2014 to 2016 Annual Work Plans; • Proposals, evaluation summary reports, websites, and other deliverables of the sampled actions; • Other action documents such as published studies and deliverables.	• Conducted a total of 9 interviews • Interviews with 2 Chafea project officers responsible for all 5 sampled actions; • Interviews with 3 beneficiaries for 3 of the sampled actions – Fondazione IRCCS Istituto Neurologico Carlo Besta; Alzheimer Europe; and European Cancer leagues; and • Interviews with 4 DG SANTE policy officers.

[59] The publication of a call for proposals for a FPA 2015-2017 and for the SGA for financial year 2015 took place in the second quarter of 2014.

[60] The publication of a call for proposals for a FPA 2015-2017 and for the SGA for financial year 2015 took place in the second quarter of 2014.

4.2. Policy context

4.2.1. Key health needs and priorities

Chronic diseases are defined as non-communicable diseases of long duration and slow progression[61]. They include cancer and dementia, and are often related to ageing. They are a **significant and growing problem in Europe**, both in terms of the number of people affected and the costs associated with treatment. Moreover, people with chronic diseases usually experience work-related problems (e.g. unemployment, absenteeism, and reduced productivity), challenging the achievement of important EU objectives such as in the area of **jobs, growth and investment**, which feature highly on the Commission's agenda with the recent New Skills Agenda for Europe that was launched in June 2016.

Europe's ageing population means that chronic diseases are on the rise. According to the WHO, chronic diseases are responsible for 86% of all deaths in the European region, with more than 80% of people aged over 65 affected by them[62]. It is estimated that between now and 2030, chronic diseases will claim the lives of 52 million people in Europe, a figure which the WHO considers as an epidemic[63].

Leading from this, chronic diseases account for the **vast majority of healthcare costs** in the EU (70-80%, or around €700 billion). The rise in chronic diseases means that this figure is expected to increase, with chronic diseases placing an increased burden on health systems, the wider social system across Europe, as well as MS' economies.

Despite the enormous sums spent on chronic diseases, 97% is being used for treatment, **leaving only 3% for prevention**. This highlights the opportunity of investing more in prevention and the potentially huge impact this can have on easing the burden of health, social and economic systems across Europe.

The rise in prevalence of chronic diseases is also creating an **increasing demand for the care of chronically ill patients**. At the same time as meeting this growing demand, healthcare systems and social care structures in EU MS need to ensure that they provide high quality and safe healthcare in an efficient and sustainable manner. The issue of co-morbidity (i.e. the occurrence of multiple diseases) is also creating even greater challenges, highlighting the need for chronic diseases to be **simultaneously** managed for the benefit of patients as well as for the sustainability of healthcare and social protection systems.[64]

While chronic diseases are diverse, **they tend to have common risk factors and health determinants and also present common challenges to health systems**.[65] This provides an opportunity for the development of common approaches and strategies between the MS, as well as the exchange of experiences, which could lead to a more effective use of (limited) resources.

What makes chronic disease more difficult to tackle is the need to incorporate a variety of **systems and stakeholders outside of the health realm and at different levels** (individual, national and EU). EU-level action focusing on comparing different approaches for tackling chronic diseases, effectiveness of prevention strategies, and

[61] Reflection process on chronic diseases: Interim report. Accessed at: http://ec.europa.eu/health/major_chronic_diseases/docs/reflection_process_cd_en.pdf

[62] Thematic fiche 1.4. "Major chronic diseases including cancer and neurodegenerative diseases"

[63] Ibid.

[64] Reflection process on chronic diseases: Interim report. Accessed at: http://ec.europa.eu/health/major_chronic_diseases/docs/reflection_process_cd_en.pdf

[65] Ibid.

needs of stakeholders in different European countries and sectors can lead to the development of 'best practice' guidelines that can potentially serve as basis for the development of EU-level legislation.

There are also **disparities in the way in which chronic diseases are understood, managed and treated**. For instance, interviewees consulted as part of this case study explained there is a common misunderstanding in the international community around the recognition of chronic diseases, with many regarding non-communicable disease as just four major diseases. This overlooks the fact that many people suffer from other chronic diseases such as mental health conditions, musculoskeletal conditions and multiple sclerosis.

4.2.2. Framework for and extent of EU engagement so far

For some time, the EU has been taking action to address the problems outlined above. Table 6 below presents a selection of key initiatives, which goes some way to illustrating the complexity and range of action in this field.

As these actions show, there has been **significant EU engagement in the field of cancer** which has been focused on prevention, early detection and screening. Significant strides have also been made at the EU level to combat diseases such as **Alzheimer and dementia**. Nevertheless, despite these efforts, European strategies have been generally limited to these two fields, and there has not been a European strategy for other chronic diseases such as mental health and diabetes, for example. The rationale for the high level of focus (on cancer, Alzheimer and dementia) was that these provided the greatest scope for EU added-value.

Table 6: EU engagement in the field of chronic diseases[66]

Selected initiatives / engagement by disease	Main features
Mental Health	
European Pact for Mental Health and Well-being (2008)[67]	Recognises the importance and relevance of mental health and well-being for the EU, its MS, stakeholders and citizens, and the need for political action to make mental health a priority.
European Compass for Action on Mental Health and Well-being (2009)[68]	Provides a mechanism to "collect, exchange and analyse information on policy and stakeholder activities in mental health". It aims to disseminate the European Framework for Action on Mental Health and Well-being.
European Framework for Action on Mental Health and Well-being (2016)	Supports MS to share experiences in improving policy effectiveness through innovative approaches in the field of mental health, and provide guidance for the review and development of EU's own policies.
Cancer	

[66] Please note that this is not intended to be a comprehensive list of EU actions but to provide insight into the extent and variety of action undertaken.

[67] Built on international commitments which MS' Ministers of Health made under the WHO Mental Health Declaration for Europe (2005) and other relevant international acts such as the UN Convention on the Right of Persons with Disabilities. The European Pact for Mental Health and Well-being (2008) can be accessed at: http://ec.europa.eu/health/ph_determinants/life_style/mental/docs/pact_en.pdf.

[68] http://ec.europa.eu/health/mental_health/eu_compass/index_en.htm

Selected initiatives / engagement by disease	Main features
European Network of Cancer Registries (1990)[69]	Its objectives include the promotion of collaboration between cancer registries, the definition of data collection standards, training for cancer registry personnel and dissemination of information.
Council Recommendation on cancer screening (2003)[70]	Adopted unanimously by the Health Ministers of the EU. Sets out fundamental principles of best practice in early detection of cancer, and represents a shared commitment by MS to implement cancer screening programmes.
Communication on Action Against Cancer: European Partnership (2009)[71]	Provides framework to MS for identifying and sharing information, capacity and expertise in cancer prevention and control, and by engaging relevant stakeholders across the EU in a collective effort.
Neurodegenerative diseases (e.g. Alzheimer's and dementia)	
French Presidency of the EU (2008)	Marked the start of a range of European actions in this area, by announcing an initiative to engage all MS in setting up a European initiative on Alzheimer's disease.
EU Group of Governmental Experts on Dementia[72] (2013)	DG SANTE has supported the setting up of this group, which meets once or twice a year to identify a number of issues on which they exchange information on good practices and learn from each other.
Luxembourg EU Presidency conclusions (2015)[73]	The Employment, Social Policy, Health and Consumer Affairs (EPSCO) Council of the Luxembourg EU Presidency adopted conclusions on a number of health-related issues, which included conclusions on "Supporting people living with dementia".
European Parliament Written Declaration for EU Action on Dementia (2015)[74]	Calls for the need to adopt a comprehensive strategy for meeting the challenges presented by Alzheimer's disease. Signed by MS.
EU Joint Programme – Neurodegenerative Disease Research (JPND)[75]	Largest global research programme (funded by Horizon 2020) that aims to tackle neurodegenerative diseases.
Cross-cutting initiatives	
Council conclusions (2010) and reflection process on innovative approaches for chronic diseases in public health and healthcare system (2013)[76]	The Council invited MS and EC to initiate a reflection process on chronic diseases aimed at identifying ways to optimise response of and cooperation between MS. This was done in close dialogue with relevant stakeholders and taking into account e-health and the potential contribution of other policy areas (e.g. employment, disability, education and housing).

[69] http://www.europeancancerleagues.org/resources/resources-on-cancer-in-europe/221-european-network-of-cancer-registries-encr.html

[70] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:327:0034:0038:EN:PDF

[71] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52009DC0291

[72] http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=2984

[73] Alzheimer Europe article. "2015 Council adopts Luxembourg EU Presidency conclusions". Accessed at: http://www.alzheimer-europe.org/Policy-in-Practice2/EU-Action-on-Dementia/2015-Council-adopts-Luxembourg-EU-Presidency-conclusions

[74] http://www.alzheimer-europe.org/Policy-in-Practice2/EU-Action-on-Dementia/2015-European-Parliament-Written-Declaration?#fragment2

[75] http://www.neurodegenerationresearch.eu/about/

[76] In conclusions adopted in March 2010, the Council called upon the EC and MS to launch a reflection process on chronic diseases to identify options to optimise the response to the challenges of chronic diseases, including proposed actions in health promotion, prevention and disease management. Three meetings of the Working Party on Public Health at Senior Level (WPPHSL) were held as part of the reflection process, picking up key elements from a consultation process with MS, EU Health Policy Forum and stakeholders representing industry, patient, associations, and other interest groups. See Final Report of the Reflection Process at: https://ec.europa.eu/health/sites/health/files/major_chronic_diseases/docs/reflection_process_cd_final_report_en.pdf

Selected initiatives / engagement by disease	Main features
Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases (2011)[77]	A political statement of commitment, acceptance of the scale of the challenge in relation to non-communicable, outlining core tenets of the approach to tackling the burden.
EU ratification of UN Convention on the Rights of People with Disabilities (2011)[78]	This states that people with disabilities (including people with chronic diseases) should have the right to work and have reasonable accommodations in the work place.[79] Chronic diseases need to be tackled in a way that incorporates a range of systems and stakeholders outside of the health system. This includes employment, an area which Juncker has emphasized as a key pillar for the new European strategy.
European Innovation Partnership on Active and Healthy Ageing (EIP-AHA) (2012)	This initiative (part of Europe 2020 Innovation Union) focuses on actions around "prevention, screening and early diagnosis; care and cure (integrate care); and active ageing and independent living".[80]
Horizon 2020 (2014)	This financial instrument supports research and innovation across a number of societal challenges, including better understanding causes of healthy ageing and disease and improving the ability to prevent, detect and treat disease.[81]
Conclusions of EU Summit on Chronic Diseases (2014)[82]	Presents the key elements of a comprehensive response to chronic diseases, as agreed by participants: strengthening political leadership; targeting key societal challenges such as ageing, equity, and sustainability of health systems; making a more efficient use of resources; strengthening the involvement of citizens, patients and health community in policy-making; and strengthening evidence and information.

4.2.3. Fit with the Health Programme

The thematic priority under review in this case study falls under the scope of objective 1 of the 3HP, which is defined in the Regulation as follows: *"Promote health, prevent diseases and foster supportive environments for healthy lifestyles taking into account the 'health in all policies' principle."*[83] Six thematic priorities are defined with the aim and purpose of feeding into this overarching objective. In the Annex to the Regulation, thematic priority 1.4 is phrased as follows:

> *"Support cooperation and networking in the Union in relation to preventing and improving the response to chronic diseases including cancer, age-related diseases and neurodegenerative diseases, by sharing knowledge, good practices and developing joint activities on prevention, early detection and management (including health literacy and self-management). Follow up work*

[77] http://who.int/nmh/events/un_ncd_summit2011/political_declaration_en.pdf?ua=1

[78] http://europa.eu/rapid/press-release_IP-11-4_en.htm

[79] Despite this being signed and ratified, what is considered as "reasonable accommodation" is not explicitly determined.

[80] Reflection process on chronic diseases: Interim report. Accessed at: http://ec.europa.eu/health/major_chronic_diseases/docs/reflection_process_cd_en.pdf

[81] EU Action on Dementia. Alzheimer Europe. Accessed at: http://www.alzheimer-europe.org/Policy-in-Practice2/EU-Action-on-Dementia

[82] https://ec.europa.eu/health/sites/health/files/major_chronic_diseases/docs/ev_20140403_mi_en.pdf

[83] Annex 1 to the Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020).

on cancer which has already been undertaken, including relevant actions suggested by the European Partnership Action against Cancer".

The specific focus which thematic priority 1.4 places on chronic diseases is a **relatively new development for the EU HP**. When the first Health Programme (1HP) was launched in 2003, chronic diseases were a priority under 'health information', which was one of the three pillars of the 1HP (it was also considered indirectly through the 'health determinants' pillar). At this time, actions aimed at reinforcing the quality of information on chronic diseases, for example through the creation of registries and networks.

In the run up to the 3HP (from 2009 onwards) there was a gradual increase in pressure from different actors to introduce specific EU action for chronic diseases. The establishment of the WHO priority on non-communicable diseases[84] also lent greater weight to the argument that chronic diseases should be specifically addressed through the 3HP. The limited funding available through the HP meant that an umbrella thematic priority for all chronic diseases was considered more feasible than a dedicated thematic priority for specific ones.

In March 2010, the Council called on the Commission and MS to launch a reflection process on chronic diseases which included the active participation of all relevant stakeholders, including patients and people at risk[85]. This led to a stakeholder consultation on chronic diseases in 2012, the results of which fed into the design of this thematic priority. Stakeholders proposed two main areas for EU action in the field of chronic diseases: **prevention and health promotion**, and **chronic disease management** with an emphasis on patient empowerment. Particular focus was also placed on the need for social and technological **innovation**[86].

Now that chronic diseases are addressed through a distinct thematic priority (1.4), there is substantial scope for **synergies with actions funded under other thematic priorities within the 3HP**, for example:

- Some major chronic diseases, such as specific types of cancer, are linked to communicable agents, which therefore connect thematic priority 1.4 with **1.3 on "HIV/AIDS, tuberculosis and hepatitis"**.
- In many cases, cancer is related to life-style health risk factors such as smoking, alcohol consumption and obesity. This links thematic priority 1.4 with **1.1 on "risk factors such as use of tobacco and passive-smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity**".
- Thematic priority 1.4 builds on the actions funded under the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA), which is also the focus of **thematic priority 3.5**[87].
- Thematic priority 1.4 also covers innovative prevention and management of chronic diseases, connecting it to **objective 3** of the 3HP which supports actions that **"contribute to innovative, efficient and sustainable health systems"**.

The multiplicity of related thematic priorities creates some risk of fragmentation, overlap and duplication. Avoiding such pitfalls and maximising potential synergies and

[84] World Health Organisation (2013). "Global action plan for the prevention and control of NCDs 2013-2020". Accessed at: http://www.who.int/nmh/publications/ncd-action-plan/en/

[85] https://ec.europa.eu/health/major_chronic_diseases/reflection_process_en

[86] Reflection process on chronic diseases: Interim report. Accessed at: http://ec.europa.eu/health/major_chronic_diseases/docs/reflection_process_cd_en.pdf..

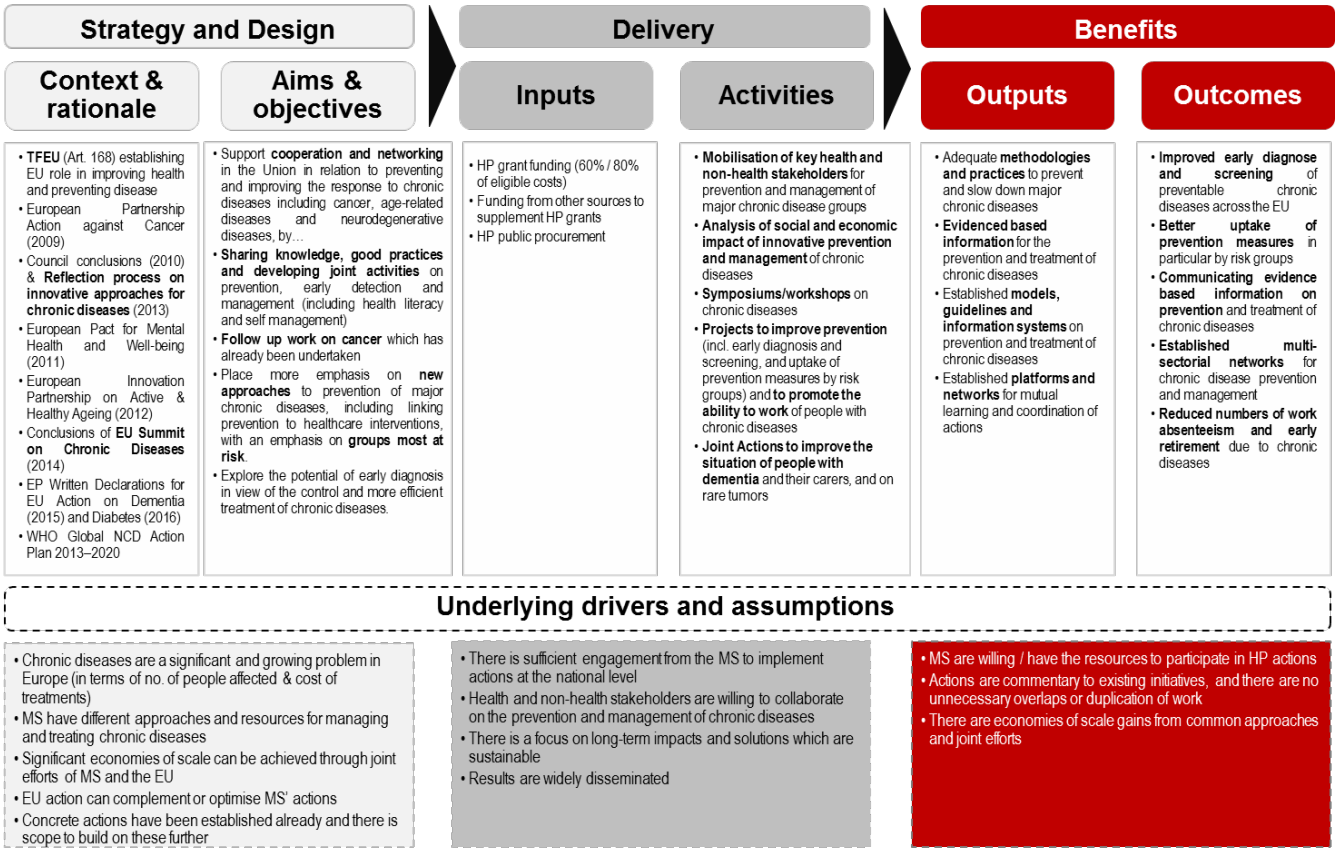
[87] http://ec.europa.eu/health//sites/health/files/programme/docs/factsheet_healthprogramme2014_2020_en.pdf

complementarity within the 3HP calls for open **communication channels and coordination** between SANTE/Chafea officers responsible for setting yearly priorities, drafting calls for proposals and selecting the actions to be supported under the different thematic priorities.

4.3. Theory and practice

This section presents and assesses the **thematic priority's intervention logic.** It starts with a diagram that depicts the theory underpinning the thematic priority. This is followed by sub-section on each of the intervention logic's main parts (strategy; delivery; and benefits). These sub-sections first describe and examine the how HP action under the thematic priority is intended to work in theory. We then analyse what is happening in practice by examining the objectives, activities, outputs, and (early) outcomes of the five actions selected for the case study. This allows us to test the intervention logic's plausibility and determine whether the desired outputs and outcomes of the thematic priority are likely to be achieved through the type of actions that have been funded to date. For a more detailed explanation of the methodology / components, please refer to the **introduction**.

Figure 2 : Intervention logic for thematic priority 1.4 (Chronic diseases)



Source: created by evaluation team based on case study fieldwork (documentation review and interviews)

4.3.1. Strategy

Rationale for HP action in the thematic priority

The section above, "Policy Context", explained that **the main driver for EU action** in this field (which is also depicted in the intervention logic) is the significant impact chronic diseases have on Europe's social and economic situation and the increasing burden these place on MS. Although the competence to prevent and treat chronic diseases is at the national level, the EU can **complement and enhance MS' actions** by helping to avoid duplication of efforts and generating potential savings through economies of scale. These are explored in more detail below.

For example, this is envisaged through the **exchange of best practice, pooling of expertise and resources from across the EU and development of common guidelines and approaches**. The stakeholder consultation carried out in the framework of the reflection process on chronic diseases (2011-2012) [88] echoed this point, reaching a general consensus about the need for increased EU action regarding the identification and dissemination of good practice particularly in **preventing chronic diseases**. Significant international agreement also exists[89] on the importance of prevention and lowering risk factors related to chronic diseases, and the EU has taken a key role in supporting MS in this field, for example, through the implementation of joint actions such as CHRODIS PLUS (EU Joint Action on Chronic Diseases and Promoting Healthy Ageing Across the Life-Cycle) launched in 2014 and funded by the 3HP under thematic priority 1.4[90,91].

Supporting and complementing actions implemented at national level through coordination and joint efforts not only enhances MS initiatives to tackle chronic diseases, but can also lead to **economies of scale**. This is of particular relevance given the significant costs associated with the treatment of chronic diseases. To give a concrete example, in relation to breast cancer screening, the EU plays an important role in **supporting the development of EU guidelines for screening and diagnosis**. It would not be effective or efficient to have 28 different sets of guidelines for detection and screening from each MS. This also allows the EU to compare cancer screening centres across the EU to check that they are acting in the same way and have one single accreditation system for all cancer screening centres across the MS.

Strategic fit of funded actions

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[88] http://ec.europa.eu/health/major_chronic_diseases/docs/reflection_process_cd_en.pdf

[89] For example, the WHO's "Global action plan for the prevention and control of NCDs 2013-2020" (2013) (http://www.who.int/nmh/publications/ncd-action-plan/en/) and the UN's Sustainable Development Goal 3 which includes reducing by one third premature mortality from non-communicable diseases through prevention and treatment (http://www.un.org/sustainabledevelopment/health/)

[90] CHRODIS (2013) is a European collaboration of over 70 partners from 25 EU MS, including national and regional departments of health and research institutions, focused on health promotion and primary prevention, as well as the management of diabetes and multi-morbid chronic conditions. As expressed by interviewees consulted as part of the case study, the added value of type of action, is that research organisations who often have scare resources can benefit from having a platform such as the HP that can provide a network to pool expertise and knowledge from across the EU. This is also important for national governments with a lower capacity or out of date approaches for tackling chronic diseases. http://chrodis.eu/

[91] CHRODIS-PLUS aims to promote the implementation of new or innovative policies and practices in each of the four cornerstones mentioned, in closely monitored implementation experiences that can be validated before scaling them up. For this, a total of 45 associated partners representing 21 European countries will define and agree on a methodology of implementation, acting as advisors and/or supporters for local implementers. New or innovative practices will be based on the collection of policies, strategies and interventions that started in JA-CHRODIS and in its outputs such as the multimorbidity care model or the recommendations for diabetes quality criteria or national plans. Some pilot implementation initiatives and sites have already committed and are described in this project.

This section explores the extent to which the actions funded under the thematic priority correspond in practice to the intervention logic, and if these have realistic aims and objectives. This assessment is based on the examination of **five funded actions** (out of a total of 18 that were funded between 2014 and 2016) that allowed us to test how the strategy described in section 3.1.1 is being put into practice, using a mix of different funding instruments.

The evidence suggests that for the most part, the thematic priority has led to **appropriate and well-designed actions** that are **well-aligned with the aims and objectives of the thematic priority**. The stakeholders consulted agree that this is due to the systematic operationalisation of the thematic priority's aims in the AWPs, which ultimately provide clear indications about the type of actions that are to be funded each year and of the expected results. Beneficiaries' prior experience in delivering actions supported by the HP has also lead to the design and good fit of actions according to evidence collected. Nevertheless, there are also some concerns among the interviewed stakeholders that certain funding instruments (e.g. operating grants) can be too broad and may lead to actions with very general objectives and limited focus. This highlights an opportunity for further refinement of the objectives and content of the actions that are funded under this thematic priority. These findings are explored in more detail below.

The majority of the actions examined through this case study were developed **based on clearly prescribed action in the 2014 AWP**, which meant that expectations and goals were pre-defined by the Commission. This is particularly important given how broad and encompassing the thematic priority is (i.e. supporting cooperation and networking in the Union in relation to preventing and improving the response to chronic diseases). For example:

- **Project grant on Participation to Healthy Workplaces and inclusive Strategies in the Work Sector (PATHWAYS[92])** aims to identify and evaluate strategies for (re)integration to work for people with chronic diseases and mental disorders in Europe[93]. As per the evaluation summary report on the project proposal, the aims and objectives are justified and well presented, and overall very relevant to the actions foreseen in the 2014 AWP related to the promotion of professional integration and employability of people with chronic diseases (priority 2.1.1.3)[94].
- **The operating grant for Cancer Leagues Collaborating in Cancer Prevention and Control at the EU and National Level (ECL)** is designed to increase public awareness surrounding cancer-related risk factors such as obesity; promote cancer prevention; and communicate on the fourth revision of the European Code Against Cancer. This grant addresses one of the actions foreseen in the 2014 AWP, which was to fund "*work supporting the dissemination of the European Cancer Code*"[95]. It also fits properly with one of the general objectives of the thematic priority, which is to continue work on cancer which has already been undertaken[96].

[92] PATHWAYS project website: http://www.path-ways.eu/

[93] Leaflet on PATHWAYS Project – Participation to Healthy Workplaces And inclusive Strategies in the Work Sector (2015).

[94] 663474-PATHWAYS. Evaluation Summary Report.

[95] 664682-ECL OG 2014. Evaluation Summary Report.

[96] The grant beneficiary is also in a strong position to follow up work on actions which were suggested by the previous Joint Action European Partnership Action against Cancer given that it was a work package lead for that joint action, and is currently an associated partner for the 3HP's follow-up Cancer Control Joint Action (CANCON). Therefore, despite the somewhat open wording in the AWP for this operating grant, the ECL's previous involvement in the HP has allowed for aims and objectives to be well aligned with the thematic priority's intervention logic.

In the case of **operating grants**, the 2014 AWP does not specify the scope or focus of non-governmental bodies' actions that are eligible for funding. It only says that operating grants can be awarded to "non-governmental bodies working at the EU level in the fields of chronic diseases, cancer, HIV/AIDS, rare diseases and smoking prevention". As the second example mentioned above shows (ECL), there are nonetheless grants that fit well with the objectives of the thematic priority and have also specific/focused objectives. We suggest that this is in part due to **beneficiaries' previous experience and involvement in the HP which gives them experience in ensuring that their activities fit with the objectives of the HP**. Another example is the NGO Alzheimer's Europe (AE) which also received an operating grant in 2015 to work mainly on the identification and sharing of best practices in the field of Alzheimer's. AE has developed its activities over the years in the framework of operating grants, the first of which was awarded in 2010 and which served to develop its strategic plan for 2011 to 2015.

In terms of the ability of the proposals to address **EU added value** and thereby demonstrate their ability to promote best practice and benchmarking for informed decision-making:

- PATHWAYS includes an assessment of the specific employment needs of people with chronic diseases and mental disorders across the EU. This is unique and has the **potential to deliver strong added value** given that, while such needs would likely be similar across MS, currently there is no established protocol for measuring employment needs in this specific target group[97]. Moreover, as mentioned in the interviews and the project's grant agreement, by providing specific policy recommendations for developing EU-level policies and legislation to improve the employment situation of persons with chronic diseases, the project also supports one of the key priorities of the EU, which is to support jobs, growth and investment.
- The operating grant awarded to AE has also clear potential to deliver EU added value given that the beneficiary is the only European organisation representing people with dementia and their carers, thus creating a unique opportunity to inform decision-making at EU, share experiences and expertise between MS and ensure national-level concerns are reflected in EU decision-making[98]. Its broad network of members enables it to work across all MS, identifying and disseminating best practices in dementia care. It also has the potential to **strengthen networking activities** at EU level through the European Dementia Ethics Network. Moreover, AE intends to turn into a European Dementia Observatory and trusted source of information on national systems and best practices in addressing dementia. This is likely to contribute to health innovation by ensuring that innovative projects and initiatives are better known**.**

Despite the appropriate fit of actions and their potential to deliver EU added value, we note that the broad scope of action under thematic priority 1.4 can also lead to **over-ambitious actions with limited focus on their objectives**. This was for example the case of the proposal for the Joint Action (JA) on Dementia 2015-2018[99] (DEM 2). Overall this action fit well within the thematic priority, but its general and specific objectives were not clearly stated, making it difficult to assess the action's potential impact. After the proposal's evaluation, the beneficiary was able to refine the objectives, increasing their focus and making a more clear reference to the action's potential EU added value (i.e. to support the successful uptake of evidence-based practices on improving the quality of life for people living with dementia and their carers across the EU). The risk

[97] 663474 - PATHWAYS. Evaluation Summary Report.

[98] Health Programme (2014) 671364 Signed Proposal AE 2015-2017

[99] Joint Action (JA) on Dementia 2015-2018

of such over-ambitious actions stemming from the broad scope of thematic priority 1.4 provides a strong case for refining the phrasing of the priority and, through the AWPs, providing clearer indications of what is expected from the actions and/or organisations funded under it[100].

4.3.2. Delivery

Planned activities and overall implementation so far

Based on information provided in the Thematic Fiche for thematic priority 1.4, the intervention logic presents the key activities which this thematic priority is expected to implement. These are also depicted in Table 7 below, alongside the actions that have been selected for funding since 2014. This provides an indication of the extent to which planned activities have been delivered to date.

Table 7: Planned activities under thematic priority 1.4 and implementation to date

Planned activities	Implementation to date
Mobilise key health and non-health stakeholders for prevention and management of major chronic disease groups	Through operating grants such as those awarded to **ECL** and **AE,** the 3HP supports organisations that represent the needs and interests of health and non-health stakeholders and that can inform policy making through the dissemination of best practices, key research and/or policy developments in the field. Health and non-heath stakeholders are also being mobilised through the service contract on **Mental Health** aimed at enhancing the existing EU Compass for Action on Mental Health and Wellbeing by reaching out to stakeholders who are implementing good practices related to mental health from various sectors including health, employments and justice.
Analysis of social and economic impact of innovative prevention and management of chronic diseases	Through the operating grant, **AE** will identify innovative policies, interventions and practices on dementia at national level that will lead to the organisation of a European conference to share best practices and innovative EU projects[101]. Also, the JA **DEM2** is intended to test good practices in addressing dementia in MS with the aim of supporting the successful uptake of evidence-based practices. The action **Innovative Prevention Strategies for type 2 Diabetes in South Asians Living in Europe** [102]is also expected to deliver on this area of activity (but it is not examined as part of this case study).
Symposiums/workshops on chronic diseases	**AE** will present information at conferences organised by third parties, as well as organise its own AE Annual Conference for sharing best practices in a multinational and multi-professional framework. **Mental Health** also includes the organisation of national mental health workshops in each MS, Iceland and Norway to disseminate the findings from the EU Compass for Action on Mental Health and Wellbeing.

[100] Health Programme (2014) 678481 Signed Proposal DEM 2

[101] Health Programme (2014) 671364 Signed Proposal AE 2015-2017

[102] Innovative Prevention Strategies for type 2 Diabetes in South Asians Living in Europe project, http://www.eurodhyan.eu/

Projects to improve prevention (incl. early diagnosis and screening, and uptake of prevention measures by risk groups) and to promote the ability to work of people with chronic diseases	Through activities funded with the operating grant, **ECL** is expected to contribute to increasing public awareness surrounding cancer-related risk factors, promote cancer prevention, and the European Code of Cancer. The JA **DEM2** also includes activities to help MS implement activities to improve early diagnosis and post diagnostic support of dementia. This is also the case of the JA **CHRODIS** which focuses on health promotion and primary prevention, but was not analysed as part of this case study. The project grant for **Tobacco Cessation Guidelines for high risk groups** is also an example of actions aimed at promoting prevention, although this was not examined in this case study either. The project **PATHWAYS** is specifically aimed at developing innovative approaches to promote the professional integration of people with chronic diseases and improve their employability.
Joint Actions to improve the situation of people with dementia and their carers, and on rare tumours	JA **DEM2** focuses on the implementation in MS of coordinated actions to improve the situation of people living with dementia and their carers. A JA on rare tumours started in November 2016.

A total of **18 actions were funded between 2014 and 2016**, nine under the 2014 AWP, three under the 2015 AWP (two being the extension of the two operating grants to AE and ECL awarded in 2014), and six under the AWP 2016 (again, two being the extension of the operating grants to AE and ECL). In addition to the five actions examined in this case study, the remaining actions (five projects, one joint action, and one direct grant agreement, one service contracts) dealt with:

- Determinants of successful implementation of selective prevention of cardio-metabolic diseases across Europe
- Empowering hospitals
- Tobacco cessation guidelines for high risk groups
- Innovative prevention strategies for type 2 Diabetes in South Asians living in Europe
- Support to MS and stakeholders to address the chronic disease challenge
- Joint Action on major chronic diseases (CHRODIS PLUS)
- Grant to WHO contributing to the setup of the WHO Global Dementia Observatory (GDO)[103]
- Presidential conference on Chronic Diseases

In terms of **inputs**, since none of the five actions examined as part of this case study qualified for exceptional utility, the 3HP funding covered 60% of each action's eligible costs. Three were funded based on an open call for proposals (ECL, PATHWAYS and AE), one through public procurement (Mental Health), there was a joint action (DEM 2) which was agreed between DG SANTE and MS health authorities. There was also a conference focused on chronic diseases organised by DG SANTE.

In addition there was two actions, a project ("Migrants health: Best practices in care provision for vulnerable migrants and refugees") and the service contract ("Pilot specific training modules for health professionals, border guards and trainers in migrants and refugees") which dealt with both chronic diseases and HIV/AIDS, TB and hepatitis (i.e. thematic priorities 1.3 and 1.4) and are therefore included[104].

[103] http://www.who.int/mediacentre/news/releases/2015/action-on-dementia/en/

[104] Since these two actions cover both thematic priorities, 50% of each action's budget is included in each thematic priority.

The total allocation of funding to thematic priority 1.4 for the period 2014 - 2016 combined was **€17.2 million**.

In order for these activities to achieve their desired outcomes, there are certain drivers and assumptions which need to function as envisaged. As illustrated in the intervention logic, the funded actions need to ensure that they are **sustainable** and focus on ultimately **delivering long-term impacts and solutions**. This is especially important in the case of promoting innovation in heath (which is one of the expected results of actions funded under thematic priority 1.4[105]), which normally takes time to realise. It is also important to ensure that the **results and findings of actions are widely disseminated** and promoted across all EU MS. Ensuring **sufficient engagement from MS, health and non-health stakeholders** is also an underlying factor which plays a role in the success of the activities funded.

Lessons learned from specific actions so far

Although the funded actions are still being implemented and therefore it is relatively early to examine their results, there are some key lessons which we can draw from stakeholders' experiences of implementation to date.

A first lesson learnt is that **coordination and cooperation with non-health stakeholders** can be quite challenging to achieve. For example, the lead partner of PATHWAYS explained that the project is based on establishing strong collaboration with employment stakeholders; however this implies dealing with a heterogeneous group and a varied range of interests and needs in terms of (re)integrating people with chronic diseases to work. Moreover, legislation in this area is patchy in its coverage of the different chronic diseases and is applied unevenly depending on, for example, a firm's size. There is also some reluctance among policy makers to address this issue given unknown impacts on the labour market. Overcoming these challenges is difficult and takes time. Collaborating with large employment associations such as the International Labour Office (ILO) proved to be very beneficial for the project and for reaching out to the employment stakeholders.

The evidence examined in this case study also reconfirmed the importance of having **clear and specific objectives** for the actions. According to interviewees, **ambitious schedules** can pose a challenge, and can only be managed by coordinators who have extensive experience of managing large-scale projects across Europe. Similarly, having a clear timeline for the year, reasonable aims and budget, and knowing when certain activities need to be delivered, proved to be very advantageous for the beneficiaries consulted. This was particularly important in the case of AE and PATHWAYS, which facilitated a smooth implementation of the activities supported by the HP.

A final observation regarding implementation of the thematic priority to date is the **high level of participation of organisations that have already been beneficiaries or associated partners of other actions** funded under either the current or prior iterations of the HP. While this is advantageous and usually leads to well-designed actions, as well as smooth implementation and reporting processes (given the organisations' familiarity with the EC application and reporting processes, experience in setting and complying with work plans, and understanding of the need to provide evidence on results), it begs the question of whether the HP is sufficiently open and accessible to new players.

[105] As per the Thematic Fiche for priority 1.4, "unlocking the potential of innovation in health" is one of the criteria of EU added value that the outcomes of the actions funded under this thematic priority are expected to fulfil.

For example, in the case of operating grants, even though many of those awarded in 2014 (within this thematic priority and others) were for organisations which had never received such a grant before[106], in many cases, they had been associated partners or main beneficiaries of other financial instruments of the HP. This is the case of ECL, for example, which received an operating grant for the first time in 2014, but that had been an associated partner in two Joint Actions and main beneficiary of a grant to organise conferences, all under the 2HP[107].

According to evidence collected in the interviews, the main **barriers** for the participation of "new" organisations are related to the difficulty in accessing the necessary co-funding and the challenges of managing a consortium where many of the partners have no prior experience working together. In relation to accessing co-funding, this is especially relevant in the case of organisations coming from low GNI countries. In the interviews conducted, it was mentioned that even in cases where they can apply to the exceptional utility criteria, getting the necessary co-funding and equipment to carry out the proposed action is very challenging and therefore feel discouraged and do not apply. About the challenges of managing a consortium, one interviewee mentioned that having a solid consortium and reliable partners is a very important factor when evaluating a proposal. Therefore, having many new partners in a consortium is viewed less favourably by evaluators than when all partners have a track record in working together. Moreover, one beneficiary with experience in applying to HP funding explained that the application (as well as implementation) process normally runs more smoothly when the organisations have been in the field for many years and have well-established tools (e.g. website, newsletter, monitoring/reporting templates etc.) and contacts across the EU.

4.3.3. Benefits

Expected immediate, medium- and long-term benefits

Broadly speaking, the main expected outcome of thematic priority 1.4 is "the creation and maintenance of mechanisms for the **development, identification and exchange of good practices on prevention and treatment of chronic diseases** with a view to their successful implementation"[108].

Given the breadth of the thematic priority, in the Thematic Fiche expected outputs and outcomes (or medium and long-term benefits) are set for specific types of diseases (e.g. action in the area of cancer is expected to lead to sustainable European cancer information systems, as well as the wide use of voluntary accreditation systems for certain forms of cancer). However, for the purpose of this case study, we have examined this information in detail, as well as taken into account evidence collected during the interviews, to identify a set of expected outputs and outcomes that can apply to all chronic diseases. These are presented in the intervention logic and are, namely:

- Adequate methodologies and practices to prevent and slow down major chronic diseases
- Evidence-based information for the prevention and treatment of chronic diseases

[106] For example, for the Smoke Free Partnership (http://www.smokefreepartnership.eu/) and the Association Medicines Du Monde, both under thematic priority 1.1, and the TB Europe Coalition (http://www.tbcoalition.eu/) under thematic priority 1.3.

[107] The two JAs were CANCON (http://www.cancercontrol.eu/) and EPAAC (http://www.epaac.eu/), where it was a work package lead. The conferences organised by ECL were on cancer care (CCC) and were implemented in 2011 (http://ec.europa.eu/chafea/projects/database.html?prjno=20104302)

[108] Thematic fiche 1.4. "Major chronic diseases including cancer and neurodegenerative diseases" provided to the evaluators by DG SANTE.

- Established models, guidelines and information systems on prevention and treatment of chronic diseases
- Established platforms and networks for mutual learning and coordination of actions

Through the mentioned benefits, it is expected that **common approaches and guidelines** are developed and that these help to address common challenges that are faced across MS. This should ultimately result in **economies of scale** through the pooling of resources and avoiding the duplication of work and practices. Additionally, there is the intention that actions funded under the thematic priority serve to **promote new and innovative approaches** in the prevention and management of chronic diseases.

(Potential) benefits in practice

Due to the early stage of implementation of the five actions examined in this case study, it is not possible to determine the extent to which the benefits presented above have been realised. Therefore, we consider mainly *potential* benefits and achievements to date.

Evidence up to this point shows that the sampled actions have made good progress particularly in terms of developing platforms and networks for mutual learning and coordination of actions. For example, the majority of the actions have **developed links and cooperated with other existing actions at the EU, national and international level**. ECL, for example, is an associated partner in the ongoing Cancer Control Joint Action (or "CANCON")[109] and provided research inputs on survivorship and rehabilitation throughout 2016. It also used the CANCON newsletter to promote the European Code Against Cancer, one of the key activities funded by the operating grant. ECL also has a Memorandum of Understanding with the Smoke Free Partnership (which has an operating grant from the 3HP under thematic priority 1.1) to work together and share perspectives. Beyond the HP, ECL is also active in the EU Platform for Action on Diet, Physical Activity and Health[110] and cooperates with the Joint Research Centre's public health unit in its cancer-related activities (e.g. updating the guidelines for breast cancer screening and creating cancer registries). These complementarities will facilitate the dissemination and exploitation of project results and, ultimately, impact on policy-making.

Other examples are AE, which has been asked to contribute to work packages of the JA DEM 2 and the lead beneficiary of PATHWAYS who will participate in the new JA CHRODIS PLUS. The work of AE will also feed into a government expert group on dementia set up by the Commission to promote the exchange of information on national dementia strategies and good practices, and to enhance coordination between MS with regards to their dementia-related activities.[111]. The JA DEM2 is also a continuation of the JA ALCOVE (European Joint Action on Alzheimer Cooperative Valuation in Europe), which built a wealth of evidence and knowledge to support MS in developing their dementia policies and operational capacity. The new JA will now support the uptake of evidence-based practices.

The organisations supported under thematic priority 1.4 have also mentioned cooperation with international organisations such as WHO and ILO, as well as relevant stakeholders at national level. According to all these organisations, the links established

[109] CANCON was funded under the 2HP and will ran until 2017.

[110] http://ec.europa.eu/health/nutrition_physical_activity/platform/index_en.htm

[111] The Group of Governmental Experts on Dementia was created in 2014. For further information, see: https://ec.europa.eu/eip/ageing/news/governmental-experts-dementias-gathered-together-last-week-luxembourg_en

with other interventions and organisations will allow them to ensure an effective dissemination and take up of the results of their activities.

Despite the positive links developed with other interventions which is leading to the development of networks and platforms for mutual learning and coordination of actions, interviewees expressed that there is **scope to further enhance this cooperation** and that more communication and information-sharing between initiatives at EU and national level is necessary to avoid overlaps and duplication, and exploit synergies.

Evidence has shown that all **actions have delivered other important outputs to date**. For example:

- **Mental Health** has contributed to the generation of evidenced-based information for the prevention and treatment of chronic diseases by carrying out surveys with stakeholders and MS aimed at collecting and analysing information on stakeholder and national activities in the field of mental health and well-being, producing a report outlining the key findings[112].
- **PATHWAYS** has also contributed to the same objective by carrying out a survey of patients across the EU to assess the specific employment-related needs of persons with chronic diseases and mental disorders. It has also produced a report comparing the available strategies for professional integration and reintegration of people living with chronic diseases and mental health issues, which should lead to the development of guidelines and models in terms of (re)integrating people with chronic diseases to work.
- Similarly, **Alzheimer Europe** (AE) carried out an inventory and comparison of policies and practices across the EU that foster supportive environments for people living with dementia, set up a multi-disciplinary working group on dementia-related ethical challenges with ethical experts, professional carers and people with dementia, and organised a conference in Slovenia attended by 572 participants from 44 countries[113].
- **ECL** has contributed to the dissemination of adequate methodologies and practices to prevent chronic diseases particularly by communicating the 4th revision of the European Code Against Cancer extensively. This included translating the Code to EU official languages, organising a youth competition to design an infographic for the Code, disseminating the Code through workshops with stakeholders, encouraging ECL's members to disseminate the Code broadly, and incorporating the messages in their work with the EP[114].

Some beneficiaries stated that they have also realised **additional benefits** above and beyond the planned outputs which they consider important in ensuring continuous progress on chronic diseases. For example, involvement in the HP provided beneficiaries with access to the Commission, which they see as a means to build a dialogue with EU institutions and ensure that the issues they work on remain high in the EU agenda.

However, according to evidence collected in interviews, there were also some unexpected **barriers** in terms of realising the expected outputs and outcomes. For example, organisations without experience of EU funding seem to experience "teething problems", taking some time to learn and become adept at dealing with contractual and administrative requirements. This detracts from their ability to deliver concrete results. Other barriers encountered were in relation to working across and conducting research in different national and linguistic contexts. For example, when implementing a survey

[112] EU Compass for Action on Mental Health and Well-being (2016). "Information and data collected on annual activities of Member States and Stakeholders".

[113] Deliverable D5.7 - Commission report (AE 2015-2017), 8 February 2016.

[114] ECL SGA 2016 Proposal.

for patients, the PATHWAYS beneficiary found that in some countries the general public was more difficult to approach, different ethical considerations and technical capabilities had to be considered.

In the long-run, a potential barrier to the realisation of the expected benefits could be the **extent to which the results of the supported actions are used for policy-making**. In the interviews, it was explained that beneficiaries are interested in knowing how results are being used at EU level. This will most likely keep them motivated and engaged as they can see how their work fits into the bigger picture.

4.4. Conclusions

The following conclusions attempt to draw out key points from the evidence collected and analysed, with a focus on the relevance of the thematic priority, its potential to make a difference in practical terms and lessons that can be applied to the HP more broadly.

1. Relevance of the thematic priority, given:

- **Identified needs:** Evidence collected in this case study suggests that joint efforts and coordination of national interventions are needed to strengthen the EU's collective ability to address chronic diseases, particularly in terms of prevention and increasing awareness of risk factors. Pooling resources and sharing experiences and good practices (provided they are later employed) is seen as a means for achieving economies of scale and reducing duplication of work.
- **HP objectives:** The links and synergies that have already been developed between actions funded under thematic priority 1.4 and other thematic priorities of the HP, as well as with actions of prior iterations of the Programme confirm that the thematic priority is relevant and contributes to the HP objectives. There is a need to stay vigilant and identify potential complementarities and scope for coordination between this and other thematic priorities of the HP, for example, risk factors (1.1), HIV/AIDS, tuberculosis and hepatitis[115](1.3), and EIP-AHA (3.5).
- **EU objectives more broadly:** As explained in the case study, there are strong links between actions funded under thematic priority 1.4 and larger EU initiatives such as the Europe 2020 Strategy and Horizon 2020, which are funding a significant amount of research to improve the health and quality of life of older people. There are also links with the New Skills Agenda for Europe, which forms part of Junker's broader EU strategy where employment is a key pillar, as well as with international initiatives supported by the EU such as the Sustainable Development Goals (SDGs), WHO Global Action Plan for the Prevention and Control of Non-Communicable Diseases and the Global Observatory on Dementia.

2. Likelihood of actions to make a difference in terms of:

- **Established problems:** As with thematic priority 1.1, there is an inherent difficulty in designing action to promote health in that the EU's role is restricted to coordination, while the primary responsibility to implement activities is at the MS level. However, support for the uptake of good practices in areas where problems are established supports the realisation of objectives.

[115] These three diseases are considered chronic infectious diseases, which are part of the definition of chronic diseases used by DG SANTE major chronic diseases policy available at http://ec.europa.eu/health/major_chronic_diseases/policy_en

- **EU added value:** As laid out in this case study, ensuring the exchange of best practice between MS, supporting networks for knowledge sharing, and generating economies of scale in dealing with chronic diseases are areas where there is a clear rationale for the EU to act. The evidence shows that the supported actions have the potential to contribute particularly to a process of mutual learning and the coordination of actions at EU level, which reduce the risk for an inefficient use of resources stemming from the duplication of work.
- **Wider policy objectives / priorities:** Actions have shown potential to contribute to wider policy objectives and priorities. For example, results from AE are feeding into the WHO Global Observatory on Dementia and PATHWAYS is playing an active role in creating better (re)integration of people with chronic diseases into the workplace, which is ultimately expected to feed into the New Skills Agenda for Europe.

3. What lessons can be learned in terms of:

- **Strategy:** The coverage of all chronic diseases under one umbrella / thematic priority is a new development of the HP, based on demand from MS and a recognition that the level of resources available to dedicate to individual diseases is limited. However, the risk of a thematic priority with such broad scope is that the focus on certain chronic diseases may be insufficient. Additionally, the limited resources available highlights further the need for targeted action that ensure resources are optimised and not spread too thinly on a broad range of projects. In this sense, it seems appropriate for the EC to allocate reasonable amounts of money to fewer projects, as long as, throughout the years, attention is paid to all (or most) chronic diseases and the actions supported are sustainable.
- **Delivery:** Evidence from the sampled actions suggests that strong working relationships and cooperation between consortium partners is beneficial for the implementation of actions. Although it is not a requirement in the calls for projects and JAs (but it is in the case of a network of not-legally bound organizations when applying for an operating grants), having worked together in the past, as well as having long standing experience and contacts in the field of action, are considered key success factors. Nevertheless, this also raises concerns about the accessibility of the Programme for “new” players and emphasises the key role that Chafea plays in supporting potential beneficiaries during the application process, but also during the grant agreement, implementation and monitoring of actions.
- **Benefits (to the extent available):** The sampled actions have shown that they have the potential to achieve the expected outputs and outcomes, including updated/new evidence on chronic diseases, platforms for knowledge sharing and mutual learning, and guidelines for the (re)integration of people with chronic diseases into the workforce. Moreover, by establishing strong links with health-related networks and stakeholders, beneficiaries are likely to ensure that the results of the supported actions are disseminated and exploited and, ultimately, impact policy-making. There is also a demand for DG SANTE to inform beneficiaries on how results are being used at EU level, which will most likely keep them motivated and engaged as they can see how their work fits into the bigger picture.

5. THEMATIC PRIORITY 2.2 – CAPACITY BUILDING (HEALTH THREATS)

5.1. Introduction

This case study covers thematic priority 2.2 of the 3HP on "Capacity building against health threats in MS including, where appropriate, cooperation with neighbouring countries"[116]. This priority falls under Objective 2 of the 3HP, which is to "Protect citizens from serious cross-border health threats". Between 2014 and 2016, eleven actions have been funded under this thematic priority, all through service contracts, amounting to €7.5 million. A sample of five actions was selected based on consideration of their maturity, breadth of coverage of the mechanisms and a mix of different sized actions (see table below).

Table 8: Actions reviewed for case study on capacity building (thematic priority 2.2)

Funding mechanism	Lead partner (incl. MS)	Other organisations (incl. MS)	Budget	Start date/duration
Preparedness activities relevant to the monitoring, the assessment and the coordination of the response				
Service contract (20146305)	Public Health England (UK)	European CBRNE-centre Swedish Defence Research Agency (SE), Umea University (SE) and Instituto Superiore di Sanita (IT)	HP grant: € **643,559**	Start date: 05/01/2014 Duration: 7 months
Command post exercise on serious cross border threats to health				
Service contract (20147201)	Public Health England (UK)	European CBRNE-centre Swedish Defence Research Agency (SE), Umea University (SE) and Instituto Superiore di Sanita (IT)	HP grant: €**458,989**	Start date: 05/12/2014 Duration: 12 months
Preparedness and response activities in the context of the Ebola epidemic in West Africa				
Service contract (20147203)	Public Health England (UK)	European CBRNE-centre Swedish Defence Research Agency (SE), Umea University (SE) and Instituto Superiore di Sanita (IT)	HP grant: €**499,719**	Start date: 28/04/2015 Duration: 10 months
Study on the cost-benefit analysis of reference laboratories for human pathogens				
Service contract (20147205)	Civic Consulting (DE)	National Institute for Infectious Diseases Lazzaro Spallanzani (INMI, Italy) and Robert Koch-Institut (RKI, Germany)	HP grant: €**199,942**	Start date: 15/12/2014 Duration: 18 months
Study on the Public Health law network supporting the implementation of Decision 1082/2013/EU				
Service contract (20157205)	Public Health England (UK)	European CBRNE-centre Swedish Defence Research Agency (SE), Umea University (SE), Instituto Superiore di Sanita (IT), Sustainable Criminal Justice Solutions (SCJS)	HP grant: €**303,490**	Start date: 01/01/2016 Duration: 10 months

Note: More information on the sampled action can be found on the Chafea database and in the AWPs available on DG SANTE's website

The methodology for the case studies is provided in detail in the **introduction** to this Annex. But entailed **two main steps**. First, we reconstructed the thematic priority's theory in the form of an intervention logic diagram. Then, to test the theory, we collected and analysed evidence about implementation so far, above all through an examination

[116] http://ec.europa.eu/health/programme/docs/factsheet_healthprogramme2014_2020_en.pdf

of five funded actions (as above). The different sources of information are summarised in the table below.

Table 9: Documents consulted and interviews conducted on capacity building (thematic priority 2.2)

Documents consulted	Interview status
• Commission policy documents (including most notably Decision 1082/2013/EU) and other relevant literature (e.g. WHO reports) on health security; • Policy reference documents such as the International Health Regulation 2005 (IHR) and those available in DG SANTE's preparedness and response webpages[117]; • Internal working documents for multi-annual planning for the thematic priority; • 2014 to 2016 Annual Work Programmes; • Proposals, Interim and Final Activity Reports of sampled actions; • Other action documents, such as published studies and deliverables.	• Conducted a total of 5 interviews • Interviews with two Chafea project officers responsible for the sampled actions • Interviews with two DG SANTE policy officers • Interview with the lead partner of action

5.2. Policy context

This section describes how thematic priority 2.2 relates to EU health needs and the case for EU action. It is important to mention that this section is common to case studies on priorities 2.2 and 2.3, given the inter-relations between the issues addressed under them. The linkages (and potential overlaps) between actions funded under the two priorities is further discussed in section 3.1.2.

5.2.1. Key health needs and priorities

Despite major advances in prevention, detection and treatment of **infectious (or communicable) diseases**, they remain a major threat to human health, not least because micro-organisms continue to emerge and mutate, while the flow of people and animals brings them to new environments. EU Member States (MS) periodically face spikes in infection rates which can be considered serious cross-border threats or public health emergencies of international concern[118] (PHEIC).

Two of the more recent examples of such high-threat pathogens are the international outbreaks of Zika and Ebola virus. Both outbreaks required specialised diagnostic and clinical protocols for case management and strong public health responses in Europe and beyond. EU policy has therefore focused on building cooperation and capacity across three dimensions of the threats caused by communicable diseases: preparedness, risk assessment, including **surveillance and early detection and risk management (rapid and coordinated response and risk communication)**.

Besides communicable diseases, the EU recognises the threat of other **biological or chemical agents** and **environmental threats** to human health, for example caused by climate change. As per the Decision 1082/2013/EU (which is discussed in more detail

[117] http://ec.europa.eu/health/preparedness_response/policy_en

[118] For information on health emergencies of international concern see: http://www.who.int/ihr/procedures/pheic/en/

below), these threats may, "*by reason of their scale or severity, endanger the health of citizens in the entire Union*"[119].

MS have varying capacities for detecting, assessing, notifying and responding to public health emergencies. Therefore, supporting capacity building is essential in order to ensure a harmonised and coordinated reaction from MS and reducing the general risk. Promoting interoperability of preparedness systems and ensuring the follow up of international standards, while respecting MS' competence to organise their health systems is key in this respect.

Stemming from this, the basic premise for EU action can be summarised as a recognition of, on the one hand, the **need to improve capacities and ensure** public health preparedness and response across the EU and, on the other hand, fostering of collaboration and interoperability because these **threats do not respect national borders**. As such, it is considered **more appropriate to have a coordinated preparedness and response strategy** which recognises the importance of cooperation in dealing with these emergent and serious-cross border threats.

While EU health action focuses on promoting coordination between EU national governments, the EU does not exist in a vacuum. As the Ebola outbreak which began in West Africa brought into sharp relief, coherent inter-sectoral and effective international collaboration is also vital to protecting EU citizens from serious cross-border health threats. For this reason, the **EU collaborates with international actors on health security issues**. For instance, the EU is a member of the Global Health Security Initiative (GHSI)[120], as well as works closely with the WHO[121]. The WHO leads the implementation of the International Health Regulation (2005) which support global public health security[122].

5.2.2. Framework for and extent of EU engagement so far

The EU has been concerned with protecting its citizens from natural and deliberate biological health threats since the late 1990s, as outlined in the Decision No 2119 (1998)[123] with the setting up of a network for the epidemiological surveillance and control of communicable diseases in the Community. Since then, there has been a series of amendments and new Decisions to reflect evolving circumstances and needs, such as changing disease patterns and emergent (new or increasing) threats, such as migratory movements and climate change[124].

An important political development came in 2002 when the European Council announced a Programme to improve cooperation in the EU for preventing and limiting the consequences of chemical, biological, radiological and nuclear ("CBRN") terrorist threats, which ultimately led to the 2009 Communication of an "EU CBRN action plan"[125].

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[119] Decision 1082 (3) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:293:0001:0015:EN:PDF

[120] As per http://www.ghsi.ca/english/index.asp, this is "an informal, international partnership among like-minded countries to strengthen health preparedness and response globally to threats of biological, chemical, radio-nuclear terrorism (CBRN) and pandemic influenza".

[121] USA, Canada, UK, France, Germany, Italy, Japan and Mexico.

[122] See FAQ on the IHR (2005) http://www.who.int/ihr/about/FAQ2009.pdf?ua=1&ua=1

[123] Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31998D2119

[124] See overview of EU policy in this field here: http://ec.europa.eu/health/communicable_diseases/early_warning/comm_legislation_en.htm

[125] See "EU action plan on chemical, biological, radiological and nuclear security" at: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=URISERV:jl0030&from=EN

The 2002 Programme had three main areas of focus: **1) prevention, 2) detection and 3) preparedness and response**. It also outlined a number of support mechanisms (procedures and tools), and bodies to provide EU level support: namely the **Health Security Committee** (HSC), which had been created in 2001 and has a mandate to address preparedness and response in the event of biological and chemical attacks, to pandemic influenza and management of public health-related crisis[126]. Also, the European Centre for Disease Prevention and Control (known as ECDC) was established in 2004 to "identify, assess and communicate current and emerging threats to human health posed by infectious diseases"[127].

Another important development is the adoption of the **International Health Regulations 2005 (IHR)** which entered into force in 2007[128]. These defined the rights and obligations of States Parties to the WHO, which include all MS, to report public health events, therefore reinforcing countries' coordination of the preparedness for, and response to, a public health emergency of international concern.

The entry into force of the Lisbon Treaty in December 2009 gave the protection of human health new impetus under Article 168 TFEU. This reinforced the EC mandate to support actions to **complement and coordinate national policies** in the fight against the major health threats, particularly in areas as risk assessment, risk management and crisis communication, by promoting research into their causes, transmission and prevention, as well as by health information and education, monitoring, early warning and coordination of response.

This legal acquis, together with the IHR and the EC's experience and lessons learnt from dealing with public health crises in 2009 – 2011 (such as the H1NI flu virus in 2009 and 2010[129], and the spread of Shiga toxin-producing E. coli infection the following year) were cited as providing the **rationale to strengthen the EU's health security framework**[130].

In light of the above considerations and a recognition that the scope of previous legislation dating from 1998 was too limited (for example it did not include all threats from biological, chemical and environmental origin[131]), **Decision 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 extended the framework for crisis management for health threats in the EU**[132].

The Decision covers **preparedness planning, risk assessment, risk management** and **risk communication** aspects of all serious cross-border threats to health caused by communicable diseases, antimicrobial resistance and healthcare-associated infections, other harmful biological agents as well as chemical, environmental events and threats of unknown origin[133]. Since the competence to take public health measures on serious cross-border threats ultimately lies with the MS, the Decision established the HSC to coordinate the exchange of information and consultation among the EU MS **in liaison with the EC** with a view to **enhancing coordination of national responses to serious cross-border threats to health and risk and crisis communication,**

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[126] http://ec.europa.eu/health/preparedness_response/docs/hsc_poster.pdf

[127] http://ecdc.europa.eu/en/aboutus/what-we-do/Pages/Mission.aspx

[128] http://www.who.int/topics/international_health_regulations/en/

[129] See paper on lessons learnt: http://ec.europa.eu/health/preparedness_response/docs/commission_staff_lessonsh1n1_en.pdf

[130] FAQ on Decision 1082/2013/EU: http://europa.eu/rapid/press-release_MEMO-13-645_en.htm

[131] Not least because of the 1995 Sarin attack in the Tokyo subway, the mailing of anthrax spores in the US in 2001, and the Fukishima nuclear power disaster in Japan in 2011.

[132] http://ec.europa.eu/health/preparedness_response/docs/decision_serious_crossborder_threats_22102013_en.pdf

[133] FAQ on Decision 1082

aimed at providing consistent and coordinated information to the public and to healthcare professionals.

5.2.3. Fit with the Health Programme

As with previous iterations of the HP, the 3HP (2014-2020) includes the objective of protecting citizens from serious cross-border health threats (objective 2) and provides the framework for actions leading to the identification, development and implementation of coherent approaches for better preparedness and coordination in health emergencies at Union level (operational objective 2). **Capacity building against health threats in MS including, where appropriate, cooperation with neighbouring countries**, is one of the four thematic priorities under the operational objective (Table 10). Thematic priority 2.2 is then specifically aimed at maximising MS' capacity to tackle serious cross-border health threats, while supporting the EU's broader public health objectives, as expressed in the Treaty[134]. This is a key area of EU action in the sense that protecting citizens from serious cross-border health threats cannot be sufficiently achieved by MS acting on their own.

In the Annex to the Regulation for the 3HP, thematic priority 2.2 is phrased as follows:

> "*Support capacity-building against health threats in Member States, including, where appropriate, cooperation with neighbouring countries: develop preparedness and response planning taking into account, and coordinating with, global initiatives, components of generic and specific preparedness planning, public health response coordination, non-binding approaches on vaccination; address the increasing health threats resulting from global population movements; develop guidelines on protective measures in an emergency situation, guidelines on information and guides to good practice; contribute to the framework for a voluntary mechanism, including the introduction of optimal vaccination coverage to effectively combat the resurgence in infectious diseases and for joint procurement of medical countermeasures; develop coherent communication strategies.*"[135]

Table 10: Operational objective 2 and corresponding thematic priorities under the 3HP

Operational objectives	Thematic priorities
2) Identify and develop coherent approaches and promote their implementation for **better preparedness and coordination in health emergencies.**	2.5 Risk assessment through providing additional capacities for scientific expertise **2.6 Capacity building against health threats in MS, including, where appropriate, cooperation with neighbouring countries** 2.7 Implementation of Union legislation on communicable diseases and other health threats, including those caused by biological, and chemical incidents, environment and climate change 2.8 Health information and knowledge system to contribute to evidence-based decision-making

Source: Annex I to Regulation Third Health Programme

The thematic priorities under operational objective 2 are inter-related, although each focuses on particular aspects of preparedness and response. For example, thematic priorities 2.1 and 2.2 are aimed at building capacity at MS level, whereas 2.3 serves

[134] Article 2 (General objectives) of Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC.

[135] Point 2.3 of Annex I of the 2014 Programme Regulation.

specifically to the implementation of Decision 1082/2013/EU[136]. However, it could be argued that priorities 2.1, 2.2 and 2.4 are indispensable steps for the success of priority 2.3, thereby creating **space for synergies and complementarity** but also a **risk of overlap**. The timing of the Decision 1082/2013/EU meant that it could only be included in the Annex to the Regulation once it had been adopted (i.e. after 2013, on the eve of the 3HP). As such, the possibility for simplification or clarification of these two thematic priorities became apparent at a very late stage.

The precise formulation of thematic priority 2.2 is "new" to the 3HP, given that in previous iterations of the programme there was no objective or priority which referred specifically to capacity building at MS level. As explained below, however, the substance of this thematic priority was already reflected in both HPs and in the EU's Health Strategy, which have dealt with the same issue in different ways.

Under the 2HP, capacity building and cooperation between MS were captured under one of the three specific objectives of the programme ("to improve citizens' health security"). Table 11 below provides an illustration of how diffuse the purpose of action in these fields was in the 2HP and, by contrast, **how focused and consolidated the prioritisation is under the 3HP**.

In effect, under the 2HP these issues were tackled in at least six thematic priorities e.g. developing strategies and mechanisms for preventing, exchanging information on and responding to health threats (1.1.1), improving partnerships, networks, tools and reporting systems for immunisation status and adverse events monitoring (1.1.2), developing risk management capacity and procedures (1.1.3), and others (all underlined in the table below).

This is no longer the case under the 3HP, which deals with capacity building and cooperation between MS, with the EC and other relevant international initiatives in one specific thematic priority, and leaving other (inter-related, but different) issues to be tackled separately (e.g. implementation of legislation and generation of health information and knowledge to support decision-making) (see table below). A recommendation of the evaluation of the 2HP was to "Clarify whether public health capacity building is a HP objective, and if so, carefully consider the potential implications for the setting of Programme priorities and the design of individual actions…"[137]

Table 11: Objective and corresponding priorities under the 2HP

Objective	Priority	Sub priorities
1) Improve citizens' health security	1.1 Protect citizens against health threats	1.1.1. Develop strategies and mechanisms for preventing, exchanging information on and responding to health threats from communicable and non-communicable diseases and health threats from physical, chemical, or biological sources, including deliberate release acts; take action to ensure high-quality diagnostic cooperation between MS' laboratories; support the work of existing laboratories carrying out work with relevance to the Community; work on the setting up of a network of Community reference laboratories 1.1.2. Support the development of prevention, vaccination, and immunisation policies; improve partnerships, networks, tools and reporting systems for immunisation status and adverse events monitoring. 1.1.3. Develop risk management capacity and procedures; improve preparedness and planning for health emergencies, including preparing coordinated EU and international responses to health emergencies; develop risk communication and consultation procedures on counter measures

[136] As with the other three operational objectives (1, 3 and 4), there is a pattern of one thematic priority per operational objective which is dedicated to supporting the implementation of Union legislation in the relevant field.

[137] Ex-post Evaluation of the Second health Programme (2008 – 2013) p11.

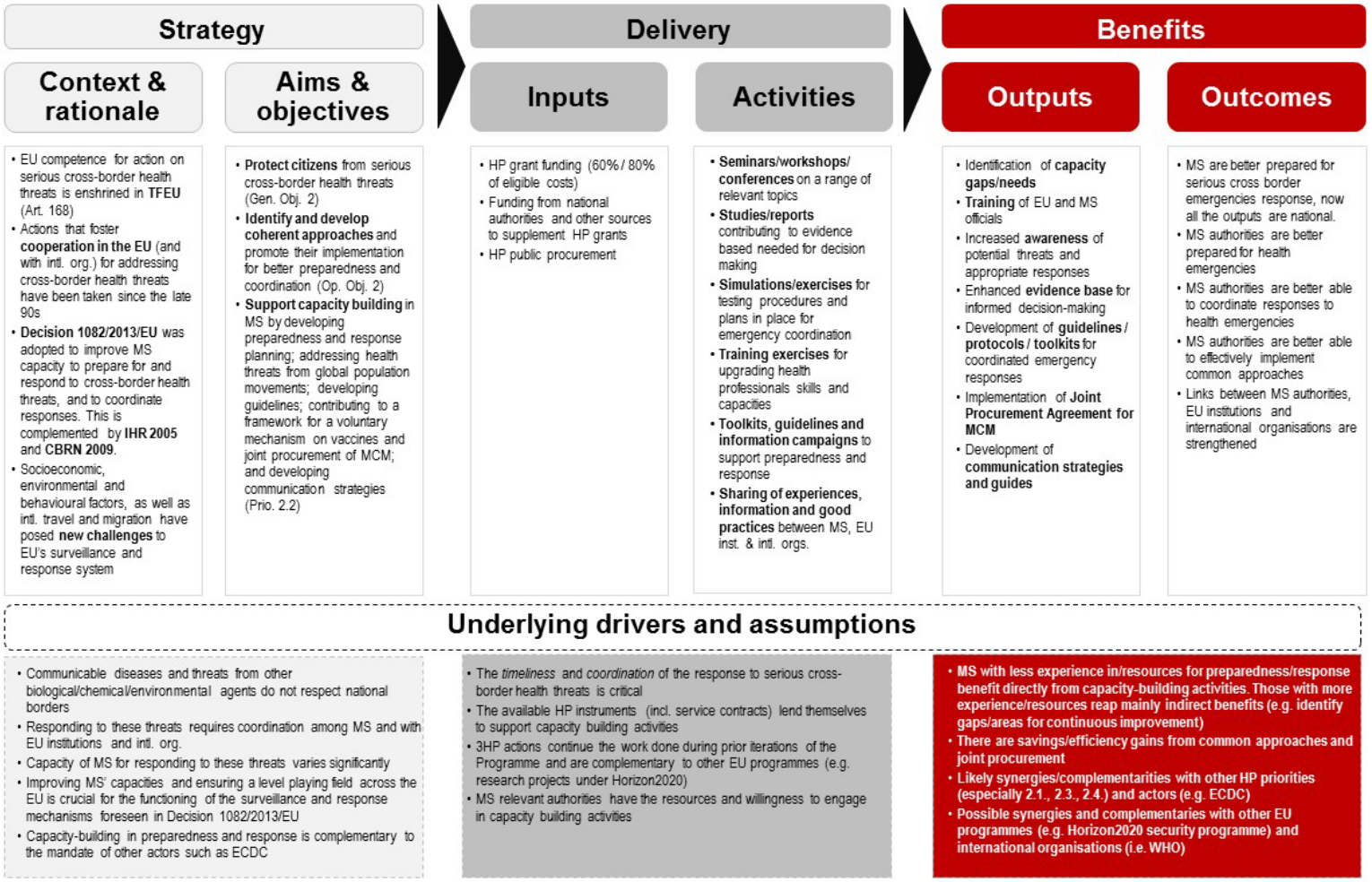
		1.1.4. Promote the cooperation and improvement of existing response capacity and assets, including protective equipment, isolation facilities and mobile laboratories to deploy rapidly in emergencies 1.1.5. Develop strategies and procedures for drawing up, improving surge capacity of, conducting exercises and tests of, evaluating and revising contingency and specific health emergency plans and their inter-operability between MS
	1.2. Improve citizens' safety	1.2.1. Support and enhance scientific advice and risk assessment by promoting the early identification of risks; analyse their potential impact; exchange information on hazards and exposure; foster integrated and harmonised approaches.

Source: Annex I to Regulation Second Health Programme

5.3. Theory and practice

This section presents and assesses the **thematic priority's intervention logic.** It starts with a diagram that depicts the theory underpinning the thematic priority. This is followed by sub-section on each of the intervention logic's main parts (strategy; delivery; and benefits). These sub-sections first describe and examine the how HP action under the thematic priority is intended to work in theory. We then analyse what is happening in practice by examining the objectives, activities, outputs, and (early) outcomes of the five actions selected for the case study. This allows us to test the intervention logic's plausibility and determine whether the desired outputs and outcomes of the thematic priority are likely to be achieved through the type of actions that have been funded to date. For a more detailed explanation of the methodology / components, please refer to the **introduction**.

Figure 3 : Intervention logic for thematic priority 2.2 (Capacity building)



Source: created by evaluation team based on case study fieldwork (documentation review and interviews)

5.3.1. Strategy

Rationale for HP action in the thematic priority

As illustrated in the intervention logic, the general objective of EU funding under thematic priority 2.2 is to protect citizens from serious cross-border health threats. This is to be achieved by **identifying and developing coherent approaches and promoting their implementation for better preparedness and coordination** in health emergencies (operational objective 2).

The section above explained the **underlying drivers and assumptions for EU action** in this field (which is also depicted in the intervention logic). Namely, that communicable diseases and threats of other biological, chemical and environmental agents do not respect national borders and cannot be effectively tackled by MS acting on their own. As such, there is a need to build the capacity of MS, to establish a surveillance and response system which recognises the importance of coordination and cooperation, not only between MS but also with relevant EU and international institutions, in dealing with these threats. However, the large disparities between MS in their ability to detect, monitor, report, respond to, and communicate on health threats[138] increase the general risk and challenge the effectiveness of the EU's surveillance and response.

In this context, the purpose of thematic priority 2.2, which is to **support capacity building in MS,** flows logically from the needs identified in terms of ensuring EU citizens' health security. This aim was further operationalised in five specific initiatives which are stated in Annex I of the HP Regulation, namely:

- Developing preparedness and response planning taking into account and coordinating with global initiatives
- Addressing the increasing health threats resulting from global population movements
- Developing guidelines on protective measures in an emergency situation and guides on to good practice
- Contributing to the framework for a voluntary mechanism for introducing optimal vaccination coverage and for joint procurement of medical countermeasures (MCM)
- Developing coherent communication strategies

Stakeholders consulted as part of this case study emphasised it is important that action on these fronts is developed based on an understanding of preparedness capacity in place at MS level, as well as on the identification of gaps. Funding of the 3HP is therefore used to **find ways to bridge the gaps identified** and create opportunities and instruments for sharing best practice.

As specified in the Thematic Fiche developed as part of an internal EC exercise in defining the objectives and activities under this thematic priority, the overall **EU added value** of foreseen actions is to enhance preparedness and response planning, risk assessment and risk management by setting up strategic and technical cooperation on health security at EU level.

[138] For example, according to the Report on the implementation of Decision No 1082/2013/EU published by the European Commission, there is an incomplete implementation of the IHR core capacities across the EU, especially in terms of inter-sectoral cooperation (http://ec.europa.eu/health//sites/health/files/preparedness_response/docs/report_decision_serious_crossborder_threats_22102013_en.pdf)

Strategic fit of funded actions

Based on the examination of five funded actions (out of a total of eleven that were funded between 2014 and 2016), we were able to test how the strategy described above is being put into practice. The documentation reviewed and interviewees consulted **confirm the strategic fit of the actions, but also highlighted some opportunities for further consolidation of the framework for action** (particularly in terms of reducing overlaps between the different thematic priorities under objective 2).

The evidence suggests that the funded actions are strategically aligned to objective 2 of the 3HP, as well as to the specific priorities set by the EC in the Annual Work Programmes (AWP) for years 2014 to 2016. It is worth noting that some of the funded actions consist of various activities that **address more than one AWP priority** e.g. work packages 1 and 2 of the contract on "Preparedness activities relevant to the monitoring, the assessment and the coordination of the response" address priority 3.2.4 of AWP 2014, while work package 3 addresses priority 3.2.1. This may be explained by the fact that health security is a highly specialised area of action and that there are not many organisations that have the expertise needed for delivering capacity building activities on preparedness and response, which ultimately results in the commission of several activities to one consortia (which is the sole provider of services through the framework contract).

The stakeholders consulted also emphasised that these activities have been essential for **mapping capacities in place, identifying gaps and prioritising actions** to address the most urgent needs, which we highlighted as one central element for achieving the objectives of the 3HP in the area of health security (see previous section 3.1.1). We also note the importance that these actions are complementary (and do not duplicate) the work of other actors / agencies operating in this field, especially the ECDC[139] and WHO.

However, it should be mentioned that the actions supported under thematic priority 2.2 address issues similar to those addressed under other thematic priorities, especially thematic priority 2.3[140], indicating **some risk of overlap**. In effect, strengthening MS' capacities to act in response to serious cross-border health threats, which is the focus of priority 2.2, is crucial for the effective implementation of Decision 1082/2013/EU and IHR 2005[141], the explicit aim of thematic priority 2.3. At the same time, it is noted that capacity building can include other elements which are not explicitly required under the Decision, for example cooperation[142], training and workshops. Therefore a consolidation of the two priorities, under a single priority aimed at ensuring the implementation of the Decision or better clarification between the two priorities could be considered.

[139] See details on scope of ECDC here: http://ecdc.europa.eu/en/aboutus/what-we-do/preparedness/Pages/default.aspx

[140] Implementation of Union legislation on communicable diseases and other health threats, including those caused by biological, and chemical incidents, environment and climate change.

[141] IHR core capacities are those required to detect, assess, notify and report events, and respond to public health risks and emergencies of national and international concern, as stipulated in Articles 5 and 13, and Annex 1, of the Regulations.

[142] In some cases (see more detail here:

http://ec.europa.eu/health/preparedness_response/risk_management_en)

5.3.2. Delivery

Planned activities and overall implementation so far

There has been important activity related to health security and protection from cross-border health threats in the EU. From 2014 to date, the 3HP supported **ten actions (all service contracts) under thematic priority 2.2** some of them involving two or three activities such as workshops and studies. In terms of **inputs**, the HP funding allocated between 2014 and 2016 was €7.5 million[143]. As depicted in the intervention logic, the main **activities** under this thematic priority include:

- **Seminars / workshops / conferences / formalised networks[144]** bringing together relevant stakeholders at MS, EU and international level[145] and aimed at enhancing capacities on several areas such as inter-sectoral cooperation, preparedness for and response to serious-cross border health threats including the EVD (emerging viral diseases) epidemic, seasonal influenza vaccination, emergency risk communication procedures, joint procurement of MCM, and climate change.
- **Studies / reports to build the evidence base for policy making** and touching upon a broad range of issues including the identification of existing capacities and available resources at MS, EU and international level to address incidents involving biological, chemical and environmental agents, the assessment of costs and benefits of possible options for establishing an EU system of reference laboratories, and mapping of national public health laws supporting/constraining the implementation of Decision 1082/2013/EU.
- **Simulation / post command exercise** on serious cross border health threats under the chemical and environmental categories aimed at testing procedures and plans in place for emergency coordination and upgrading these. This was targeted at relevant stakeholders such as EU and national public health, chemical and environmental authorities; health experts and professionals; communication specialists; etc.
- **Training, toolkits, guidelines and information campaigns** to support preparedness and response. These activities accounted for a significant share of the overall budget and are clearly a crucial means of addressing new heath security threats, for example, created by the need for well-trained first in-line health professionals dealing with unprecedented levels of migration. Since these were activities launched in 2016 they were not examined in the current case study.[146] Two main actions funded under the 2HP have provided trainings during 2014-2016, the 2012 EQUI HEALTH Direct grant agreement with the International Organisation for Migration (IOM) and the 2013 the MEM-TP[147]

[143] In 2014, €1,802,209 were spent on four actions under thematic priority 2, €1,398,929 in 2015 for funding three actions, and €4,290,000 for an additional four in 2016.

[144] For instance the HP has supported preparatory work (through a workshop and table top exercise) for setting up of a network and multidisciplinary forum of public health law expertise for supporting the implementation of Decision 1082/2013/EU across Europe.

[145] Stakeholders engaged in these activities include MS/EEA authorities or delegates, EC DGs officers, representatives of relevant EU agencies such as ECDC, EFSA, EMA and international organisations e.g. WHO, Red Cross and Medecins Sans Frontieres. Members of the pharmaceutical industry were also engaged in some of the activities e.g. workshop on joint procurement of MCM ("*Preparedness activities relevant to the monitoring, the assessment and the coordination of the response"*), as well as members of networks such as QUANDHIPJA, EMLab, MEDILABSECURE, SHIPSAN ACT and AIRSAN.

[146]EQUI HEALTH Direct grant agreement with the International Organisation for Migration (IOM) http://equi-health.eea.iom.int/

[147] Migrant and ethnic minorities training package (MEM-TP), http://www.mem-tp.org/

contract on training packages for health professionals to improve access and quality of health services for migrants and ethnic minorities, including the Roma.

It is important to highlight that these activities **fit into a broader picture of action to support the implementation of Decision 1082/2013/EU,** for the following reasons:

- As indicated in the intervention logic, there are close complementarities with other thematic priorities, especially 2.3 on implementation of EU legislation (the subject of another case study). One concrete example of this is the study on cost-benefit analysis of reference laboratories for human pathogens which looks at the economic aspects of the most sustainable organisational structure and funding model for an overarching EU laboratory structure for human pathogens, which supports better preparedness by ensuring a sustainable diagnostic capacity and potentially the implementation of the Decision 1082/2013/EC.
- There are also other actions which (in)directly support (different elements of) capacity building and coordination for preparedness and response through the previous iteration of the HP which are (or were) ongoing at the time of the activities described above. For instance, the first command post exercise Quicksilver, "Alerting, Reporting and Surveillance System for Chemical Health Threats", the European Chemical Emergency Network[148] and other EU networks funded under the 2HP that have built preparedness and response capacities at points of entry (airports and ports), like AIRSAN[149] project (2012-2015) and SHIPSAN ACT[150] (2012-2016) joint action.
- Also represented on the intervention logic, there is other work which is not funded by the HP but which is very complementary to support the implementation of the Decision (the work of the ECDC or the DG RTD HORIZON 2020 secure society programme[151] and WHO, for instance).

Lessons learned from specific actions so far

This section looks at the lessons learned from the delivery of actions so far. In the case of the actions under examination in this case study, we have identified the following factors as important for the achievement of the objectives: experience / track record of lead partners; the involvement of relevant actors in activities proposed; opportunities for establishing links and networking with relevant actors and opportunities for practical discussions and review of "real" scenarios/cases.

According to evidence gathered through interviews and desk research, it is possible to say that one key success factor is the **experience of the lead partner** in carrying out capacity building activities and studies. Health security is a highly specialised topic and therefore there is usually a limited number of offers for carrying out actions in this area. For example, in the case of the action providing workshops on the Ebola outbreak and on the study on the establishment of a network of public health law expertise these were procured through a framework contract which only has one consortia. The members of this consortia are from the UK, Sweden and Italy[152]. In the case of the study on cost-benefit analysis of EU reference laboratories for human pathogens, two

[148] ASHT and ECHMNET are now hosted by EMETNET: https://www.gov.uk/government/publications/european-multiple-environmental-threat-network-emetnet

[149] AIRSAN: Coordinated action in the aviation sector to control public health threats: http://www.airsan.eu/

[150] EU SHIPSAN ACT joint action: http://www.shipsan.eu/Training.aspx

[151] http://ec.europa.eu/programmes/horizon2020/en/h2020-section/secure-societies-%E2%80%93-protecting-freedom-and-security-europe-and-its-citizens

[152] Public Health England (UK) European CBRNE-centre Swedish Defence Research Agency (SE), Umea University (SE) and Instituto Superiore di Sanita (IT)

offers were received. The selected proposals came from organisations that had delivered similar actions for the EU institutions. Indeed, the lead partner of the cost-benefit study[153] had performed the evaluation of the EU reference laboratory network (EU-RLs) on animal health in 2011[154], meaning that they had the right background and understanding of the issues at stake, as well as experience in working with the EC.

Identifying capacities in place, highlighting the main gaps and prioritising actions has been a key success factor: All of the actions covered in this study involved the implementation of activities aimed at examining existing capacities and gaps. There is already some evidence indicating that, through these activities, MS authorities/delegates have been able to identify areas for improvement in their own systems and that they will take steps to address them. An example of this was the command post exercise, where some participating countries went further to identify the need to ensure that the knowledge and experience they had gained through the exercise was shared with other colleagues. The results of the exercise also pointed to the need for ongoing training to take account of staff and organisational changes and maintain awareness of Decision 1082/2013/EU and the IHR at national level. The EU has taken action on this respect already by including further training activities in the 2016 Work Programme. Another area of EU action, based on gaps previously identified, was inter-sectoral cooperation, which was addressed via a seminar involving representatives of different sectors at national and EU level and helping them develop collaboration mechanisms and adequate communication channels[155]. The command post exercise also gave the opportunity to test multi-sector arrangements particularly at the EC level, between DGs SANTE, HOME and ECHO.

In addition, cooperation and coordination between relevant stakeholders (at all levels i.e. national, EU, international) is recognised in the 3HP as a key factor for the success of the EU's preparedness and response system. Capacity building activities (workshops, seminars, table top exercises, command post exercises etc.) that provide an opportunity to **identify, meet and establish contact with the most relevant actors**, as well as **discuss and agree on procedures** to follow in the event of an emergency, appear to have a significant contribution to the attainment of objectives under thematic priority 2.2. An example of this is the highly positive evaluation of the post command exercise made by participants, who reported positively of the opportunity given by the exercise of meeting the key actors and increasing their understanding of their different roles and responsibilities in the strategic management of cross-border health threat events[156]. This means that involving the right people from each MS, EU institution and international organisation that have a role in dealing with serious cross border health threats is also important.

Moreover, when examining participants' assessment of the workshops / seminars / command post exercises that were organised within the framework contracts of the supported actions, we see that **the more practical the sessions are, the more interesting and useful the result for participants**. This was evident, for example, in participants' evaluation of the seminar on inter-sectoral cooperation and the workshop on joint procurement of MCM organised under "Preparedness activities relevant to the monitoring, the assessment and the coordination of the response", as well as the workshops on the Ebola outbreak as part of the action on "Preparedness and response activities in the context of the Ebola epidemic in West Africa". The positive comments made by participants emphasised the opportunity of working with different scenarios

[153] Civic Consulting

[154] Evaluation of the EU-RLs in the field of food and feed safety and animal health and live animals (http://www.civic-consulting.de/project_47.html)

[155] Preparedness activities relevant to the monitoring, the assessment and the coordination of the response

[156] Exercise Quicksilver Plus - Command Post Exercise Report, Specific Contract No 20147201

and case studies and examining "real" situations, whereas negative comments related to some of the sessions being too theoretical/detailed and not very interactive[157]. The development of guidelines and recommendations, based on lessons learned and best practice from MS, was also valued.

5.3.3. Benefits

Expected immediate, medium- and long-term benefits

As outlined in the intervention logic (outputs and outcomes), the benefits of the HP funding should ultimately contribute to **citizens being better protected from serious cross border health threats** in the following ways:

- Given the focus on capacity building of this thematic priority, it is expected that the supported actions serve to **identify capacities in place, highlight the main gaps and prioritise actions** to address the most urgent needs;
- Stemming from the identification of gaps, relevant **MS and EU officials will receive appropriate training** that will lead to capacity building in MS, better preparedness and, consequently, an improved management of combating serious cross-border health threats;
- At the same time, through participatory activities (workshops, seminars, post command exercises, etc.) and research / studies, **awareness of potential threats and appropriate responses will increase** among the relevant actors.
- Especially in the case of the studies commissioned under the thematic priority, these will **enhance the evidence base for informed decision-making** and provide helpful guidance for the implementation of actions supporting Decision 1082/2013/EU.
- The production of **guidelines / protocols / toolkits will favour the implementation of coordinated emergency responses.** These will be developed based on the identification of gaps/needs, discussions among actors involved in preparedness and response actions, and lessons learned/best practice from MS, EU institutions and international organisations.
- Drawing from one of the activities proposed under Preparedness and response activities in the context of Ebola (workshop on joint procurement of MCM), which was meant to enhance the relationship between stakeholders, industry and the EC, it is expected that a **Joint Procurement Agreement of MCM will be implemented**.
- **Communication strategies and guides will be developed in order to increase communication capacities** in MS. It is expected this enhances communication both with the general public and with key actors involved in the response (other MS, EEA countries, EU institutions, international organisations).

Through the mentioned mid-term benefits, it is expected that MS authorities are **better prepared** for health emergencies and **better able to coordinate responses**. These will also derive in an effective implementation of common approaches for preparedness and response, as well as in stronger links and enhanced mutual trust between MS authorities, EU institutions and international organisations.

(Potential) benefits in practice

[157] Work Package 1 Final Activity and Evaluation Report, Specific Contract No 20146305 and Final Report of the Conference "Lessons learned for public health from the Ebola outbreak in West Africa – how to improve preparedness and response in the EU for future outbreaks", Specific Contract No 20147203.

The outputs and outcomes outlined above seem to be consistent with the design of the five actions examined and with the results they have delivered. It is worth noting that all actions generally contributed to the delivery of more than one output / outcome. For example, the "Command post exercise" was aimed at building capacity at MS and EU level, but it also served to identify gaps or areas that still needed to be strengthened. Moreover, given its focus on chemical and biological threats, it also served to increase awareness of potential (new) threats and appropriate needed responses. Also, it was an opportunity for testing existing protocols / guidelines/standard operating procedures and communication plans for serious emergency situations.

However, there are still **some areas where further work is needed**, including the development of capacities at MS level to communicate with the public during emergencies/outbreaks, as well as increasing industry and MS stakeholders understanding of the joint procurement agreement. Further work is also needed in terms of establishing guidelines / protocols / toolkits for the implementation of coordinated responses.

Based on the evidence collected, we draw the following insights about how the expected outputs (medium-term benefits) and outcomes (long-term benefits) have been realised so far:

- **MS and EU officials receiving appropriate training**: As evidenced in final activity reports, most participatory activities have been positively assessed by participants. Those who attended the seminars and workshops delivered under the actions reviewed expressed that they were likely to use what they had learnt to strengthen and improve preparedness and response in their home country. In relation to the post command exercise in particular, the feedback showed it enabled MS and EU authorities/delegates to practice their emergency roles and responsibilities, as well as the use of supporting documents and tools. It also increased their knowledge of the response concept, structure and procedures.
- **Increasing awareness of potential threats and appropriate responses**: Decision 1082/2013/EU extended the scope of EU action on health threats by including biological, chemical, environmental and unknown origin threats creating a corresponding need to support capacity building activities in these areas. Based on final activity reports, it is likely that participatory activities and studies delivered have increased awareness of these (new) threats and of the adequacy of the established preparedness and response systems. In particular, the situational analysis and identification of existing capacities and resources in MS, EU and international levels[158] contributed to this by providing an assessment of preparedness for incidents outside of the communicable disease field, which was considered to be well advanced already, in comparison to incidents related to environmental, chemical, other biological agents and those of unknown origin. The workshops on the Ebola epidemic[159] provided an opportunity to reflect on different aspects of this unprecedented complex emergency situation, identifying areas for improvement and needs for capacity building.
- **Enhancing the evidence base for informed decision-making**: According to feedback provided in final activity reports and meeting minutes, the different activities delivered under the supported actions have contributed to enlarging the evidence base needed for policy-making. Participants to a consultation meeting aimed at presenting and discussing the results of the cost-benefit

[158] under Preparedness activities relevant to the monitoring, the assessment and the coordination of the response

[159] Preparedness and response activities in the context of the Ebola epidemic in West Africa

analysis of reference laboratories for human pathogens[160] indicated that they found the report detailed and very useful from both EU and national policy perspectives. There was also broad agreement that it provided a good evidence base for considering a European reference laboratory system for human pathogens. It was also noted that results concerning the coordination options, which were an additional focus of the study, provided helpful guidance for an eventual establishment of such a system. Another example of contribution are the results of the Ebola workshops[161], which were incorporated in a report on the lessons learned from the Ebola crisis that the EU Ebola Coordinator presented to the European Council in December 2015[162]. The recommendations of this report are likely to pave the way for preparedness activities in the coming years both at EU and national levels.

- **Developing guidelines / protocols / toolkits favouring the implementation of coordinated emergency responses**: In order to ensure that MS and EU actors are better able to coordinate responses to serious cross-border health threats, a number of the supported actions included the delivery and testing of guidelines, protocols and tools. In particular, the command post exercise focused on the testing of established procedures, tools and systems for reporting, monitoring and assessing risks and threats to people and the environment following an emergency involving chemicals. In addition, the report on the cost-benefit analysis of reference laboratories for human pathogens, which was made public by recommendation of experts from different networks of EU reference laboratories[163], was considered to be highly beneficial for the EU and national level as it provided a thorough analysis of the potential costs for funding entities such as the EU and MS as well as an outline of the benefits for participating laboratories and society overall.
- **Developing communication strategies and guides to increase MS' communication capacities**: Following Decision 1082/2013/EU, the HSC members are now able to decide on messages to communicate to the public and to the healthcare professionals. As such, activities have included the communication dimension specifically. For instance, the command post exercise included communication specialists from the HSC Committee Communicators' Network; specific health advice was provided to the public through press releases and dedicated websites of professional organisations and social media were used pro-actively to share information and advice with the public. While there was evidence of progress since the last exercise, there is a need to continue developing MS communication capacities, as well as the Communicators' Network to address shortcomings[164]. The contract on "Preparedness and response activities in the context of the Ebola epidemic in West Africa" included

[160] Participants were the lead partner (Civic Consulting), external experts, an ECDC representative and EC officials from various DGs including DEVCO, SANTE, and Chafea (Consultation Meeting Note prepared by Civic Consulting on 21 April 2016).

[161] Preparedness and response activities in the context of the Ebola epidemic in West Africa

[162] https://ec.europa.eu/commission/2014-2019/stylianides/announcements/third-report-christos-stylianides-eu-ebola-coordinator-european-council-16-december-2015_en

[163] The report was published in June 2016: http://ec.europa.eu/health//sites/health/files/preparedness_response/docs/2016_laboratorieshumanpathogens_frep_en.pdf

[164] For instance, two out of the 22 participants did not have dedicated communications staff available and at least four countries out of 16 were not able to issue messages to the public at the appropriate time. In line with this, the exercise's final activity report recommended that MS and EU actors revise their communication arrangements for health emergencies. In particular, they should consider having clear briefing processes for sharing media statements and press releases, pre-prepared key messages, checklists and templates for immediate use.

a communication course for journalists delivered by the European Journalism Centre[165].

- **Implementing a Joint Procurement Agreement of MCM**: This was the focus of one of the workshops of the action on Preparedness[166]. Participants (representatives of MS, EEA countries, industry and the EC) were mostly satisfied with the content and format of the workshop. Having the views of different stakeholders, including the industry's insight, was also appreciated. Although some considered the information provided was "too technical" or "too detailed" or that more information on the topic was needed. Participants were also of the opinion that the EC should continue organising activities around the topic, which indicates that the full implementation of the joint procurement agreement still requires resources from EU, MS and industry.

5.4. Conclusions

The following conclusions attempt to draw out key points from the evidence collected and analysed, with a focus on the relevance of the thematic priority, its potential to make a difference in practical terms and lessons that can be applied to the HP more broadly.

1. Relevance of the thematic priority, given:

   - **Identified needs:** Evidence collected in this study suggests that capacity building activities are needed to strengthen the EU's collective ability to deal with health threats, for example, by strengthening inter-country and inter-sectoral cooperation, as well as improving understanding of the roles and tasks of the sectors and stakeholders.
   - **HP objectives:** Ultimately, these activities contribute to ensuring MS better prepared and able to respond to health threats, implementing EU legislation – Decision 1082/2013/EU - and international regulations (IHR 2005) that seek to ensure an adequate management of serious cross border incidents involving biological, chemical, environmental and unknown origin agents.
   - **EU objectives more broadly:** Awareness raising activities and training exercises targeted at national/EU authorities fit within the EU's broader strategy which recognises the importance of participating in a well-organised global strategy for preparedness and responses by working with the WHO to support the implementation of the IHR.

2. Likelihood of actions to make a difference in terms of:

   - **Established problems:** While the supported actions have served to identify gaps in MS' capacities, prioritise actions and implement capacity building activities to fill in those gaps, there is a need for continuous updating of skills to take account emergent issues, new need, staff and organisational changes happening at national level.
   - **EU added value of the HP:** As laid out in this case study, building capacity in MS and ensuring coordination of response to serious cross-border health threats is one area where there is a clear rationale for the EU to act. The supported actions have contributed to ensuring a harmonised and coordinated reaction from MS and EU institutions, which reduce the general risk for citizens.

[165] the recommendations produced through this course was reported to be one of the most useful aspects of the workshop)

[166] Preparedness activities relevant to the monitoring, the assessment and the coordination of the response

- **Wider policy objectives / priorities:** The ultimate priority is to secure the safety of EU citizens. Taking into account that communicable diseases and threats of other biological, chemical and environmental agents do not respect national borders, actions that have been funded under thematic priority 2.2 have contributed to this broader objective by creating opportunities to bring relevant stakeholders together and revise or agree on emergency procedures, as well as enhancing the evidence base for decision-making thereby building capacities.

3. What lessons can be learned in terms of:

- **Strategy:** While the action supported to date build on the results of and needs identified in previous or current tender contracts and are also mutually supportive, addressing similar issues in different ways (e.g. the post command exercise served to test multi-sector arrangements for responding to an outbreak, which was also one of the main issues to be examined during a workshop delivered under the contract on Preparedness activities for coordinated response) the direct link with the implementation of Decision 1082/2013/EU begs the question whether these two priorities could be combined.
- **Delivery:** The stakeholders consulted emphasised that participatory activities such as workshops, command post exercise, and round tables have helped them identify and involve the relevant stakeholders from across the MS and at EU level, understand their different roles and responsibilities, and develop links that will support coordination and collaboration in case of an outbreak. The more practical these sessions were, the more useful.
- **Benefits**: Based on the evidence collected, actions funded under thematic priority 2.2 appear to be delivering the expected outputs and (early) outcomes. However, there are still some areas where further work is needed: the development of communication capacities at MS level (especially in terms of procedures for disseminating messages to the public), increasing industry and MS' understanding of the joint procurement agreement, and developing guidelines / protocols / toolkits that support the implementation of coordinated responses.

6. THEMATIC PRIORITY 2.3 – IMPLEMENTING EU LEGISLATION (HEALTH THREATS)

6.1. Introduction

This case study examines thematic priority 2.3 of the 3HP on "Implementation of Union legislation on communicable diseases and other health threats, including those caused by biological and chemical incidents, environment and climate change"[167]. This priority falls under Objective 2 of the 3HP, which is to "Protect citizens from serious cross-border health threats". Until the end of 2015, just one action (the joint action investigated as part of this case study) had been funded under this thematic priority, amounting to €5.8 million (HP EC co-funding: €3.5 million).

Table 12: Actions reviewed for case study on implementation of EU legislation on health threats (thematic priority 2.3)

Funding mechanism	Lead organisation (incl. MS)	Other organisations (incl. MS)	Budget	Start date / duration
Efficient response to highly dangerous and emerging pathogens at EU level 2014 (EMERGE)				
Joint action	ROBERT KOCH-INSTITUT, (Germany) and Instituto Nazionale per la Maletti infettive Lazzaro Spallanzani (Italy)	35 organisations, 25 MS involved and 3 collaborating partners[168] 33 Associated Partners and 4 Collaborating Partners from 25 European countries, there are no partner from IE, LV and SK.	Total eligible costs: €5,833,423 HP grant: €3,499,873 (60% of eligible costs)	Start date – June 2015 Duration – 36 months

Note: More information on the sampled action can be found on the Chafea database and in the AWPs available on DG SANTE's website

The methodology for the case studies is provided in detail in the **introduction** to this Annex. But entailed **two main steps**. First, we reconstructed the thematic priority's theory in the form of an intervention logic diagram. Then, to test the theory, we collected and analysed evidence about implementation so far, above all through an examination of five funded actions (as above). The different sources of information are summarised in the table below.

[167] http://ec.europa.eu/health/programme/docs/factsheet_healthprogramme2014_2020_en.pdf

[168] Full list available here: http://www.emerge.rki.eu/Emerge/EN/Content/Partners/Partners_node.html;jsessionid=F8F7F5EC6A6E7162BD083E5FE851F766.2_cid290

Table 13: Documents consulted and interviews conducted for this pilot case study on implementation of EU legislation on health threats (thematic priority 2.3)

Documents consulted	Interview status
• Commission policy documents (including most notably Decision 1082/2013/EU) and other relevant literature from DG SANTE Health security policy pages[169] and other sources (e.g. WHO reports) on health security; • Internal working documents for multi-annual planning for the thematic priority; • 2014 Annual Work Plan; • Evaluation Summary Reports for EMERGE and responses; • Other action documents / deliverables, such as implementation reports, draft Memorandum of Understanding between ECDC and EMERGE.	• Conducted a total of 5 interviews • Interviews with the relevant Chafea project officers responsible for the sampled action • Interview with the lead coordinator of the joint action[170]. • Interviews with 2 DG SANTE policy officers • Interview with the Chief Microbiologist / Head of Section Microbiology Coordination at the ECDC

6.2. Policy context

This section describes how thematic priority 2.3 relates to EU health needs and the case for EU action. It is important to mention that this section is common to case studies on priorities 2.2 and 2.3, given the inter-relations between the issues addressed under them. The linkages (and potential overlaps) between actions funded under the two priorities is further discussed in section 3.1.2.

6.2.1. Key health needs and priorities

Despite major advances in prevention, detection and treatment of **infectious (or communicable) diseases**, they remain a major threat to human health, not least because micro-organisms continue to emerge and mutate, while the flow of people and animals brings them to new environments. EU Member States (MS) periodically face spikes in infection rates which can be considered Public health event of international concern[171] (PHEIC- or a serious cross-border outbreaks. Two of the more recent examples of such high-threat pathogens are the international outbreaks of Zika and Ebola virus. Both outbreaks required specialised diagnostic and clinical protocols for case management and strong public health responses in Europe and beyond. EU policy has therefore focused on building cooperation and capacity across three dimensions of the threats caused by communicable diseases: **surveillance (prevention), rapid detection and rapid response**.

Besides communicable diseases, the EU recognises the threat of other **biological or chemical agents** and **environmental threats** to human health, for example caused by climate change. As per the Decision 1082/2013/EU (which is discussed in more detail below), these threats may, "*by reason of their scale or severity, endanger the health of citizens in the entire Union*."[172]

MS have varying capacities for detecting, assessing, notifying and responding to public health emergencies of international concern. Therefore, supporting capacity building is essential in order to ensure a harmonised and coordinated reaction from MS and reducing the general risk. Promoting interoperability of preparedness systems and

[169] http://ec.europa.eu/health/preparedness_response/policy/index_en.htm

[170] The sampled action is coordinated by two organisations. One did not replay to our request for interview.

[171] Health event of international concern, http://www.who.int/ihr/procedures/pheic/en/

[172] Decision 1082: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:293:0001:0015:EN:PDF

ensuring the follow up of international standards, while respecting MS' competence to organise their health systems is key in this respect.

Stemming from this, the basic premise for EU action can be summarised as a recognition of, on the one hand, the **need to improve capacities and ensure a level playing field** in public health preparedness and response across the EU and on the other hand, the fact that these **threats do not respect national borders**. As such, it is considered **more appropriate to have a coordinated preparedness and response strategy** which recognises the importance of cooperation in dealing with these emergent and serious cross border threats.

While EU health action focuses on promoting coordination between EU national governments, the EU does not exist in a vacuum. As the Ebola outbreak which began in West Africa brought into sharp relief, coherent inter-sectoral and effective international collaboration is also vital to protecting EU citizens from infectious diseases. For this reason, the **EU collaborates with international actors on health security issues**. For instance, the EU is a member of the Global Health Security Initiative (GHSI)[173], as well as working closely with the WHO[174]. The WHO leads the implementation of the International Health Regulation (2005) which support global public health security[175].

6.2.2. Framework for and extent of EU engagement so far

The EU has been concerned with protecting its citizens from natural and deliberate biological health threats since the late 1990s, as outlined in the Decision No 2119 (1998)[176] with the setting up of a network for the epidemiological surveillance and control of communicable diseases in the Community. Since then, there has been a series of amendments and new Decisions to reflect evolving circumstances and needs, such as changing disease patterns and new or increasing threats, such as migratory movements and climate change[177].

An important political development came in 2002 when the European Council announced a Programme to improve cooperation in the EU for preventing and limiting the consequences of chemical, biological, radiological and nuclear ("CBRN") terrorist threats, which ultimately led to the 2009 Communication of an "EU CBRN action plan"[178]. The 2002 Programme had three main areas of focus: **1) prevention, 2) detection and 3) preparedness and response**. It also outlines a number of support mechanisms (procedures and tools), and bodies to provide EU level support: namely the Health Security Committee (which was created in 2001 and has a mandate to address preparedness and response in the event of biological and chemical attacks, to pandemic influenza and management of public health-related crisis[179]).Also the European Centre for Disease Prevention and Control (known as ECDC) which was established in 2004 to

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[173] As per http://www.ghsi.ca/english/index.asp, this is "an informal, international partnership among like-minded countries to strengthen health preparedness and response globally to threats of biological, chemical, radio-nuclear terrorism (CBRN) and pandemic influenza".

[174] (USA, Canada, UK, France, Germany, Italy, Japan and Mexico)

[175] see FAQ on the IHR (2005) http://www.who.int/ihr/about/FAQ2009.pdf?ua=1&ua=1

[176] Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31998D2119

[177] See overview of EU policy in this field here: http://ec.europa.eu/health/communicable_diseases/early_warning/comm_legislation_en.htm

[178] See COM(2009) 273 final Communication From The Commission To The European Parliament And The Council on Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union – an EU CBRN Action Plan " at: http://ec.europa.eu/home-affairs/summary/docs/com_2009_0273_en.pdf

[179] http://ec.europa.eu/health/preparedness_response/risk_management/hsc/members_en.htm

"identify, assess and communicate current and emerging threats to human health posed by infectious diseases"[180]).

Another important development is the adoption of the **International Health Regulations (IHR)** which entered into force in 2007[181]. These defined the rights and obligations of States Parties to the WHO, which include all MS, to report public health events, therefore reinforcing countries' coordination of the preparedness for, and response to, a public health emergency of international concern.

The entry into force of the Lisbon treaty in December 2009 gave the protection of human health new impetus under Article 168 TFEU. This reinforce the EC mandate to support actions to **complement and coordinate national policies** in the fight against the major health threats, in areas as risk assessment, risk management and crisis communication, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

This legal acquis, together with the International Health regulation (2005) and the Commission's experience and lessons learnt from dealing with public health crises in 2009 – 2011 (such as the H1N1 flu virus in 2009 and 2010[182], and the spread of Shiga toxin-producing E. coli infection the following year) were cited as providing the **rationale to strengthen the EU's health security framework[183]**.

In light of the above considerations, the International Health Regulation approach of all threats and a recognition that the scope of previous legislation dating from 1998 was too limited (for example it did not include all threats from biological, chemical and environmental origin[184]), the Commission adopted **Decision 1082/2013/EU which extended the framework for crisis management for health threats in the EU**[185].

The Decision covers **preparedness planning, risk assessment, risk management** and **risk communication** aspects of all serious cross-border threats to health caused by communicable diseases, antimicrobial resistance and healthcare-associated infections, other harmful biological agents as well as chemical and environmental events[186]. Since the **competence to tackle public health measures** on serious cross-border threats ultimately **lies with the MS**, the Decision established the legal basis of the Health Security Committee that coordinates the exchange of information among the EU MS with a view to **enhancing coordination of** response **among themselves in liaison with the Commission**. As example during the Ebola outbreak, the EU MS represented in the HSC have successfully carried out the medical evacuation to the EU of health workers infected or suspected to be infected with the Ebola virus and have put in place in addition, measures to facilitate entry screening of travellers coming to the EU from the Ebola affected countries[187].

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[180] http://ecdc.europa.eu/en/aboutus/what-we-do/Pages/Mission.aspx

[181] http://www.who.int/topics/international_health_regulations/en/

[182] See paper on lessons learnt: http://ec.europa.eu/health/preparedness_response/docs/commission_staff_lessonsh1n1_en.pdf

[183] FAQ on Decision 1082: http://europa.eu/rapid/press-release_MEMO-13-645_en.htm

[184] Not least because of the 1995 Sarin attack in the Tokyo subway, the mailing of anthrax spores in the US in 2001, and the Fukishima nuclear power disaster in Japan in 2011.

[185] http://ec.europa.eu/health/preparedness_response/docs/decision_serious_crossborder_threats_22102013_en.pdf

[186] FAQ on Decision 1082

[187] http://ec.europa.eu/health/preparedness_response/docs/report_decision_serious_crossborder_threats_22102013_en.pdf

6.2.3. Fit with the Health Programme

This thematic priority examined here is one of four thematic priorities directed at efforts to protect citizens from health threats through better preparedness and coordination in health emergencies under operational objective 2.

Table 14: Operational objective 2 and corresponding thematic priorities under the 3HP

Operational objectives	Thematic priorities
3) Identify and develop coherent approaches and promote their implementation for **better preparedness and coordination in health emergencies.**	2.9 Risk assessment through providing additional capacities for scientific expertise 2.10 Capacity building against health threats in MS, including, where appropriate, cooperation with neighbouring countries **2.11 Implementation of Union legislation on communicable diseases and other health threats, including those caused by biological, and chemical incidents, environment and climate change** 2.12 Health information and knowledge system to contribute to evidence-based decision-making

Source: Annex I to Regulation Third Health Programme

Thematic priority 2.3 serves to support the implementation of the **Decision on serious cross-border threats to health**, which entry in force since 6 November 2013, and covers aspects of combating communicable diseases but also other serious cross border health threats (Table 15). Because this legislation was not in place for previous financing periods, the thematic priority which specifically refers to its implementation is technically "new" to the 3HP (which covers the financing period: 2014 – 2020). As explained below, however, the substance of the thematic priority on health security was reflected in previous iterations of the HP which have dealt with the same issues in different ways.

In the annex to the Regulation for the 3HP, the thematic priority is phrased as follows:

"*Actions required by, or contributing to, the **implementation of Union legislation in the fields of communicable diseases and other health threats, including those caused by biological and chemical incidents, environment and climate change**. Such actions may include activities aimed at facilitating the implementation, application, monitoring and review of that legislation*."[188]

The unique purpose of this thematic priority is to support the implementation of the above mentioned legislation[189].

The Decision 1082/2013/EU aims to improved health security in the European Union and the protection of the Union's citizens from communicable diseases, and other biological, chemical and environmental events.

The other three thematic priorities only do this implicitly, thereby creating **space for synergies and complementarity** but also a **risk of overlap**. However, discussions with DG SANTE have clarified that further simplification may in fact be possible. The timing of the Decision 1082/2013/EU meant that it could only be included in the annex

[188] Point 2.3 of Annex I of the 2014 Programme Regulation

[189] As with the other three operational objectives (1, 3 and 4), there is a pattern of one thematic priority per operational objective which is dedicated to supporting the implementation of Union legislation in the relevant field.

to the Regulation once it had been adopted (i.e. after 2013, on the eve of the 3HP). As such, the possibility for simplification in the thematic priorities is only apparent now.

Although the precise formulation of the thematic priority is new to the 3HP, protecting citizens from cross border health threats (or health security) have been integral to previous iterations of the programme and indeed the EU's Health Strategy. Under the Second EU Health Programme (2HP), these issues were captured under one of the three specific objectives of the programme ("to improve citizens' health security"). Looking more closely at the formulation under the 2HP (see Table 19) provides an illustration of how diffuse the purpose of action in this field under the 2HP was, and by contrast (see Table 18), **how focused and consolidated the prioritisation is under the 3HP**. To give a concrete example of this, under the 2HP non-communicable diseases and communicable diseases were combined under "1.1.1"; this is no longer the case under the 3HP which deals with communicable and non-communicable diseases separately.

Table 15: Objective and corresponding priorities under the 2HP

Specific objective	Operational objective	Thematic priorities
2) Improve citizens' health security	1.1 Protect citizens against health threats	1.1.1. Develop strategies and mechanisms for preventing, exchanging information on and responding to health threats from communicable and non-communicable diseases and health threats from physical, chemical, or biological sources, including deliberate release acts; take action to ensure high-quality diagnostic cooperation between MS' laboratories; support the work of existing laboratories carrying out work with relevance to the Community; work on the setting up of a network of Community reference laboratories 1.1.2. Support the development of prevention, vaccination, and immunisation policies; improve partnerships, networks, tools and reporting systems for immunisation status and adverse events monitoring. 1.1.3. Develop risk management capacity and procedures; improve preparedness and planning for health emergencies, including preparing coordinated EU and international responses to health emergencies; develop risk communication and consultation procedures on counter measures 1.1.4. Promote the cooperation and improvement of existing response capacity and assets, including protective equipment, isolation facilities and mobile laboratories to deploy rapidly in emergencies 1.1.5. Develop strategies and procedures for drawing up, improving surge capacity of, conducting exercises and tests of, evaluating and revising contingency and specific health emergency plans and their inter-operability between MS
	1.2. Improve citizens' safety	1.2.1. Support and enhance scientific advice and risk assessment by promoting the early identification of risks; analyse their potential impact; exchange information on hazards and exposure; foster integrated and harmonised approaches. ….

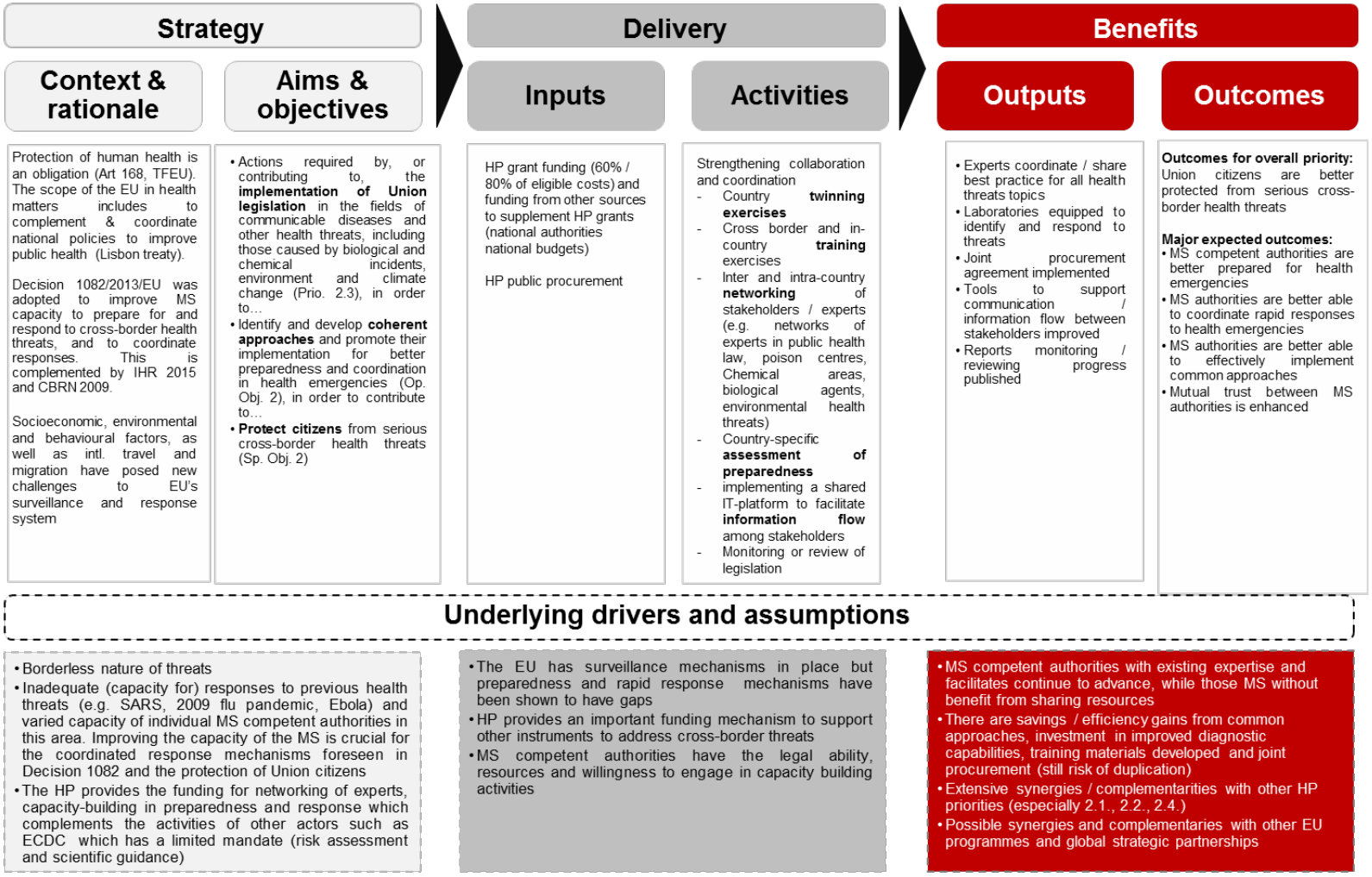
Source: Annex to Regulation Second Health Programme

6.3. Theory and practice

This section presents and assesses the **thematic priority's intervention logic.** It starts with a diagram that depicts the theory underpinning the thematic priority. This is followed by sub-section on each of the intervention logic's main parts (strategy; delivery; and benefits). These sub-sections first describe and examine the how HP action under the thematic priority is intended to work in theory. We then analyse what is happening in practice by examining the objectives, activities, outputs, and (early)

outcomes of the five actions selected for the case study. This allows us to test the intervention logic's plausibility and determine whether the desired outputs and outcomes of the thematic priority are likely to be achieved through the type of actions that have been funded to date. For a more detailed explanation of the methodology / components, please refer to the **introduction**.

Figure 4 : Intervention logic for thematic priority 2.3 (Implementing EU legislation in the field of health threats)



Source: created by evaluation team based on case study fieldwork (documentation review and interviews)

6.3.1. Strategy

Rationale for HP action in the thematic priority

As illustrated in the intervention logic, the specific aim / objective of EU funding under thematic priority 2.3 is that it supports actions **required by or contributing to the implementation of Union legislation** (i.e. Decision 1082/2013/EU).

The section above, "Policy Context", explained **the rationale for EU action** in this field (which is also depicted in the intervention logic). Namely that communicable diseases and health threats caused by chemical or biological agents, or environmental events **do not respect national borders**. At the same time, there are **large disparities** between MS in their ability to identify and respond to these health threats (for example one MS might not have even one laboratory[190] with the bio-security level [191]for diagnosis of high pathogenic agents while another MS has two). Since crises can quickly spread across borders, insufficient preparation / management of outbreaks or other threats in one or more MS can worsen the problems for the EU as a whole. Globalisation and climate change means such crises occur more often, further heightening the need for a common response.

In line with this priority action the EC proposed a priority under the Work Programme for 2014[192]: 2.2.2.1. for strengthening of the EU laboratory capacities through the Efficient response to highly dangerous and emerging pathogens at EU level (EMERGE) network. The EMERGE network is expected to offer a framework for rapid identification of pathogens causing serious cross-border threats to health (bacterial and viral), rapid mechanisms for sample sharing in case of an event to be managed under Decision No 1082/2013/EU, confirmation of laboratory diagnoses, quality assurances for detection of highly pathogenic bacteria and viruses of potential bioterrorism risk, training and capacity building in the areas of infection control, biorisk management and quality management, consolidation of biodiverse repository of reference materials; and promotion of interoperability with other relevant EU and international research and public health networks/projects/organizations in the field of emerging infections.

With regards to (national) human pathogen laboratories in particular (which the action examined as part of this case study focuses on), **the highly specialised and costly nature of conducting work in this field** means that the Commission and ECDC and EU MS have recognised that "*enhancing collaboration and sharing"* between MS can *"optimise the use of limited resources and fill existing gaps or significant differences in the quality and timeliness of reference laboratory service provision*"[193], in line with the EC and ECDC Position statement on human pathogens laboratories.

In line with these identified needs, in terms of the **HP specifically**, the Commission and ECDC have previously stated their commitment to use the HP: *"To assure coordination and sustainability of the public health microbiology functions which have been consolidated or developed by the Commission and ECDC over the time and by the currently existing funding mechanism, namely the Health Programme 2008-2013 and the other Union Programmes*"[194]*.* Actors consulted as part of this case study emphasised

[190] these laboratories provide **diagnostics** of human or animal pathogens (i.e. infectious viruses and bacteria that cause diseases in human) **for surveillance and risk assessment of biological health threars**

[191] Laboratory bio-security level: http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

[192]Health Programme Annual Work plan 2014: http://ec.europa.eu/chafea/documents/health/wp2014_en.pdf

[193] As stated in the Position statement of the Commission and ECDC on human pathogen laboratories http://ec.europa.eu/health/communicable_diseases/docs/ref_lab_statement_en.pdf

[194] Ibid

that the EU funding available through the Health Programme is essential to maintain the continuous preparedness of laboratories and build capacity in the EU MS. We also note the importance that Health Programme funding complements (and does not duplicate) the work of other actors / agencies operating in this field, especially the ECDC but also the European Food Safety Authority (EFSA)[195]. The ECDC participates as advisory board member to the EMERGE Joint action and even a Memorandum of understanding is under final development, to ensure the good coordination between the EMERGE and ECDC initiatives in the laboratories domain.

Strategic fit of funded action(s)

In the first three years of the 3HP (2014 – 2016), one action has been funded under thematic priority 2.3: the joint action EMERGE. The evidence reviewed and interviewees consulted as part of this case confirm the strategic fit of the action, but also highlighted some risks.

EMERGE deals with the implementation of Decision 1082/2013/EC in relation to Article 4 specifically: the need for coordination among laboratories testing for high threat pathogens. As explained by the DG SANTE officials consulted as part of this case study, the original need for action in this area in 2011 was the recognition that laboratory capacities to diagnose highly pathogenic agents was required in Europe. To address the first external quality assurance exercise, the ring test project (or proficiency test)[196] was funded and revealed **gaps in laboratory capabilities to correctly identify high threat pathogens**. Compared to other (more common) pathogens, high threat pathogens, such as Ebola, are rare and seldom detected and there is a less even preparedness and technical capability across MS. Yet, their characteristics mean that they are highly contagious (not just among the general population but within the laboratory setting).

Uneven capacity means that while some MS have more than one high-containment laboratory, others have none. This is linked to the huge costs associated with setting up and maintaining these laboratories which is prohibitive for some MS. The highly specialised nature of work in this field thus creates an opportunity for economies of scale through pooling resources. The joint action "EMERGE" seeks to do this by allowing for the **exchange of diagnostic samples** and thereby **boosting overall capacity** in an area critical for protection from health threats. In addition, when MS work together in an established network, they can **gain leverage** in receiving samples from an European repository which may be difficult to obtain for an individual laboratory.

As per the evaluation summary report of the proposal for the joint action put forward by the consortium, and confirmed in discussions with interviewees, there is a strong awareness of the **risk of duplication and the need of collaboration** in this field of work. For instance, the ECDC also support a network dealing with emerging and vector borne diseases (EVD – Labnet[197]), although the specific risk groups and pathogens addressed are not the same and the emphasis is also different. As explained by an interlocutor at the ECDC, while the EMERGE joint action funded through the HP deals with preparedness and response (risk management), the ECDC deals with risk assessment. Nevertheless, to further mitigate the risk of duplication and build an effective collaboration, a memorandum of understanding has been drafted between the EMERGE consortium and ECDC to outline the information flow and roles of the different parties during inter-epidemic and outbreak management mode. In EMERGE, there is also a dedicated work package which aims to establish an exchange of information and

[195] www.efsa.europa.eu

[196] This is an inter-laboratory test that allows for an assessment of the performance of testing laboratories

[197] See: http://ecdc.europa.eu/en/healthtopics/emerging_and_vector-borne_diseases/EVD-LabNet/Pages/EVD-LabNet.aspx

facilitate collaboration between experts and different networks in the field (see work package 4 and further details below).

6.3.2. Delivery

Planned activities and overall implementation so far

As depicted in the intervention logic, the main activities in this thematic priority which are expected to support the implementation of Decision 1082/2013/EU include:

"*mechanisms for coordinated funding, supporting country twinning activities, country-specific assessment of preparedness and networking between countries and joint meetings, and conducting cross-border exercises... facilitating in-country networking of stakeholders, conducting in-country exercises and implementing a shared IT-platform to facilitate information flow among stakeholders."* [198]

More specifically on the topic of networking, the thematic fiche developed as part of an internal Commission exercise in defining the activity under this thematic priority includes a list of expected major outcomes (and activities) and cites the expectation of expert working groups in the field of biological agents, environmental-related health threats, networks in poison centres and public health law (among others) [199].

There has been a high volume of activity related to health security and protection from health threats in the EU[200]. As such, although the 3HP has included just one action under thematic priority 2.3, it is important to highlight that this fits into to a bigger picture of action to support the implementation of the Decision of serious cross border health threats, for the following reasons:

- As indicated in the intervention logic, there are close **synergies / complementarities with other thematic priorities**, especially 2.2 on capacity building (the subject of another case study). One concrete example of this is an action on the cost-benefit study of reference laboratories for human pathogens[201]. This study looks at the cost and benefits as well as the most sustainable organisational structures and funding models for an overarching EU laboratory structure for human pathogens. This highlights there is potentially scope for greater clarity in terms of the differences between thematic priority 2.2 and 2.3.
- There are also other actions which (in)directly support the implementation of Decision 1082/2013/EC **through the previous iteration of the Health Programme** which are (or were) ongoing. For instance, the joint action

[198] Report on the implementation of Decision No 1082/2013/EU of the European Parliament (COM (2015) 617 final) http://ec.europa.eu/health/preparedness_response/docs/report_decision_serious_crossborder_threats_22102013_en.pdf

[199] The fiche is dated 7 March 2013 and, as mentioned, is an internal working document.

[200] Full list here: http://ec.europa.eu/health/preparedness_response/projects/index_en.htm

[201] http://ec.europa.eu/health/preparedness_response/docs/2016_laboratorieshumanpathogens_exe_en.pdf

"SHIPSAN Act"[202] or the predecessor to EMERGE, "QUANDHIP" [203], ECHEMNET[204] and AIRSAN[205].

- Also represented on the intervention logic (and discussed in more detail later), there is other work which is not funded by the HP but which is very complementary to support the implementation of the Decision on cross border health threats (the work of the ECDC or the DG RTD HORIZON 2020 secure society programme[206], for instance)
- Finally, looking ahead, the **plans for the second half of the 3HP** include a joint action on preparedness and action at points of entry (air, maritime and ground crossing), as well as: a series of regional workshops on serious cross border health threats, on the core capacities under IHR and another series of workshops of best practices on entry/exit screening.

Lessons learned from specific action(s) so far

While EMERGE is the only action under this thematic priority funded through the 3HP so far, it is the fifth largest joint action in the 3HP to date with a grant of €3.5 million (total budget of €5.8 million), involving competent authorities in 25 MS and wide-ranging work. Holding it up to the activities funded through EMERGE to those listed in the intervention logic shows that, partly due to its size, many elements are covered. For example:

- Cross border and in-country **training** exercises on diagnostics and biorisk management
- Inter and intra-country **networking** of stakeholders / experts laboratory response establishing and strengthening the cooperation between networks
- Country-specific **assessment of preparedness through Quality Assurance** for laboratory diagnostics by External Quality Assurance Exercises and improving capabilities for **rapid laboratory diagnosis** of new or emerging pathogens (e.g. sample sharing)

EMERGE also provides an important innovation: the **possibility to switch work modes in the event of an outbreak** from the inter-epidemic mode (IEM) to outbreak response mode (ORM). This switch can be triggered by the Health Security Committee (HSC), thereby providing a direct link with risk management. Each work package has these two work modes. As explained by interviewees, this structure was the result of previous lesson learning: another Joint Action funded through the 2HP (QUANDHIP) required this flexibility to support laboratories needing to respond to concurrent outbreaks, such as the Ebola 2014 outbreak.

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[202] http://www.shipsan.eu/

[203] This joint action itself brought together two networks of highly pathogenic agents led by the same organisations which coordinated QUANDHIP and now EMERGE ("Establishment of Quality Assurances for Detection of Highly Pathogenic Bacteria of Potential Bioterrorism Risk – EQADeBa[203] coordinated by the Robert Koch-Institut (RKI) from 2008 -2011, and European Network of Level 4 Laboratories – EuronetP4[203], coordinated by L.Spallanzani National Institute for Infectious Diseases (INMI), Italy from 2005-2008)[203]. In turn, these networks were set up on the basis on results from previous research. Another spin-off of the network EuronetP4 is the HORIZON 2020-funded ERINHA and ERINHA2 project which "aims at building a pan-European research infrastructure to reinforce the European coordination and capacities for the study and the surveillance of highly pathogenic micro-organisms"

[204] ASHT and ECHMNET are now hosted by EMETNET: https://www.gov.uk/government/publications/european-multiple-environmental-threat-network-emetnet

[205] Coordinated action in the aviation sector to control public health threats, http://www.airsan.eu/

[206] http://ec.europa.eu/programmes/horizon2020/en/h2020-section/secure-societies-%E2%80%93-protecting-freedom-and-security-europe-and-its-citizens

The Joint Action was officially launched in June 2015, but since the duration of the joint action is 36 months (3 years), the findings to date are limited to the first year of activities. Nevertheless, interviewees provided insight into the building of laboratories technical capabilities. For instance, specific training has been delivered and a first series of external quality assurance exercises (EQAE) have also been delivered which provide evidence that **technical capabilities have been improved through HP funding** thereby improving laboratory preparedness.

Yet, as you would expect at this stage, **important elements of the design have not been tested.** Most notably, the innovation of including the possibility to switch from IEM to ORM has not been activated (as it has not been required). While this is a commendable innovation, an amendment to the contract would be required to re-allocate resources. Similarly, in the event of an outbreak, the interoperability between the work of EMERGE and other EU networks, and collaboration with the ECDC will be tested. More specifically, while EMERGE would be responsible for gathering information on the characterisation of the agent, defining the diagnostic procedures and providing training of laboratory technicians to perform the diagnosis, ECDC and its laboratory networks would be responsible for performing a rapid risk assessment, both structures will provide support to the Health security committee and the EC for the coordination of the outbreak response. The importance of a good flow of information would be crucial to an effective response.

6.3.3. Benefits

Expected immediate, medium- and long-term benefits

As outlined in the intervention logic, the benefits of EU Health Programme funding in this area should ultimately be contributing to **citizens being better protected from serious cross border health threats**, through the following medium- and long-term benefits:

- Given the high laboratory (infrastructure and maintenance) costs and highly infectious nature of these pathogens, there is an expected EU added-value in experts **coordinating and sharing best practice** for all health threat topics (especially being mindful of the risk of duplication of efforts and the need to pool expertise and knowledge);
- Ensuring laboratories are technically equipped **to effectively identify and respond to threats**, for example improved (and accurate) diagnostics of emerging pathogens, will ultimately support the rapid containment of pathogens and protect citizens from health threats;
- As experts, competent authorities and agencies collaborate to manage their responses to health threats and avoid duplication of efforts, there is an expectation that the **communication / information flow** between stakeholders should and will be improved, for example through common sharing of information during the Health Security Committee meetings, using the European expertise to identify the most adequate health measures or increased networking and collaboration which builds trust and awareness of the work undertaken, bilateral agreements between countries to ensure referral of suspected cases and confirmatory diagnosis;
- Continuously **monitoring and reporting progress** is an important aspect of ensuring the most appropriate and effective responses to health threats, as well as identifying gaps and areas where further or continued investment is required to ensure EU citizens are protected from serious health threats.

If well designed, actions in this field should fill gaps and complement activities supported by national governments, EU agencies and international actors.

(Potential) benefits in practice

The outputs and outcomes outlined above and expected by stakeholders seem to be consistent with the design and delivery of EMERGE to date. However, on the one hand EMERGE is only a small piece of the puzzle in terms of protecting citizens from health threats, and on the other hand it is also too early to assess progress on the desired outcomes. Based on the evidence collected, we draw the following insights about experiences so far and how they contribute to protecting citizens from cross border health threats.

In terms of **coordinating and sharing best practice** for all health threats topics: this is supported through a dedicated work package on networking of networks. More specifically, a **benefit of the joint action funding mechanism** (as opposed to other grants) is the benefit that it has a negotiation process that secures the buy-in of competent authorities from across the EU (through the official nomination process) and, due to the co-funding requirement, leverages an overall higher level of funding compared to other funding mechanisms (i.e. 40% from co-funding). Nonetheless, some stakeholders felt that such collaboration would benefit from longer-term funding sources. These would help alleviate the uncertainty around repeated proposals and avoid some of the repetition associated with consecutive applications for joint actions under the HP. This could become a reality when there is a political support to the establishment of the European reference laboratories for human pathogens[207].

With regards to the expectation that **laboratories are technically equipped to identify and respond to threats**: the evidence to date indicates that the technical capabilities of laboratories have been improved through exchange of reference materials, training and external quality assurance exercises activities supported. MS which are already more advanced will continue to maintain and improve their capacity to respond to health threats (for instance by testing new technologies and developing quality assurance protocols) but at the same time, those MS which are not as well equipped benefit from sharing resources and expertise. This helps develop a higher level of expertise overall.

However, two important preliminary observations related to the **delivery partners**. On the one hand, while the involvement of experienced institutes is vital for the quality and usefulness of the work performed through the joint action, some stakeholders pointed out that not all MS were benefiting equally from it. On the other hand, it is clear that the joint action has managed to reach most of the EU highly pathogenic laboratories partners, in particular the most European network of highly pathogenic bacteria and the European network of BSL4 laboratories. These include public health laboratories and animal health laboratories, in addition to the types of institutions that typically work with the ECDC, based on the European network of Microbiology focal points[208] . This highlights the potential of joint actions to unite diverse stakeholders in pursuit of a common interest.

6.4. Conclusions

The following conclusions attempt to draw out key points from the evidence collected and analysed, with a focus on the relevance of the thematic priority, its potential to make a difference in practical terms and lessons that can be applied to the HP more broadly.

[207] Study on cost -benefit analysis of reference laboratories for human pathogens ,http://ec.europa.eu/health/preparedness_response/docs/2016_laboratorieshumanpathogens_frep_en.pdf

[208] http://ecdc.europa.eu/EN/HEALTHTOPICS/MICROBIOLOGY/national-microbiology-focal-points/Pages/national_microbiological_focal_points.aspx

1. Relevance of the thematic priority, given:

- **Identified needs**: Recent pandemics, most notably the Ebola crisis, but also findings of the ring tests illustrate that despite advances in dealing with communicable diseases, there remains a need for better laboratory preparedness in order to effectively respond and contain serious health threats. In an increasingly inter-connected world, changing disease patterns and effects of climate change, infectious diseases represent a continued serious health threat requiring highly specialised technical capabilities for surveillance and diagnostics, case management, but also, crucially a coordinated response.
- **The HP's objectives**: The distinct need for EU level action is recognised in the fact that the EU has consistently placed the protection of citizens from serious cross-border health threats at the top of its agenda and the legislative framework (including the 2009 Lisbon Treaty and the 2013 Decision on cross border health threats) provide the mandate for EU action.
- **EU objectives more broadly**: Implementing EU legislation on communicable diseases and other health threats has a direct fit within the wider policy agenda. The EU is signed up to the Chemical, biological, radiological and nuclear defence Action Plan, which aims to prevent, detect and ensure preparedness and response to cross border health threats. The EU has also been working with the WHO to support the International Health regulation (2005) implementation and with the G7 within the Global Health Security Initiative, in order to create an effective and well-organised global strategy for preparedness and responses to all potential health threats.[209]

2. Likelihood of actions to make a difference in terms of:

- **Established problems**: EMERGE is designed to fill some of the gaps in technical expertise by building the capacity of competent authorities to correctly identify and deal with emerging highly dangerous pathogens, as well as able to respond to an outbreak in a resource-efficient way.
- **The EU added value of the HP**: The HP, through actions like EMERGE, has the ability to bring together competent authorities to tackle a common challenge in a way that other funding does not. For example, the procedure for funding a joint action allows for co-funding which increases the overall funding level and ensures buy-in from all national policy - decision makers. In terms of the work itself, the coordination of efforts across the EU prevents the duplication of work, thereby creating economies of scale and optimising financial resources in an area which is extremely costly to build expertise, thereby improving efficiency and building mechanisms for collaboration which are more effective.
- **Wider policy objectives / priorities**: The EU's priority in this field is ultimately to secure the safety of its citizens. While EMERGE is clearly very much in line with this goal, it is the only action that has been funded so far and it is focused on a specific set of risk groups (risk group 3 bacteria and risk groups 3 and 4 viruses).

3. What lessons can be learned in terms of:

- **Strategy**: The design of EMERGE clearly builds on the previous joint action "QUANDHIP". This and other actions, to some extent, support the implementation of Decision 1082/2013/EC. Indeed, there are close synergies / complementarities with other thematic priorities and EU initiatives, but these also

[209] See for more information at http://ec.europa.eu/health/preparedness_response/cbrn_threats/ghsi/index_en.htm

pose the risk of duplicating work. The fact that there is a strong awareness of this risk and efforts have been made in the design of EMERGE to reduce / remove this aspect is a positive finding. Lastly, there are concerns regarding the sustainability of funding. But once again there is awareness of this, and the 3HP has funded a cost benefit study looking specifically at sustainable funding models for such reference laboratories for human pathogens going forwards (this action will be looked at in more detail in another case study).

- **Delivery**: Despite the limited implementation to date for EMERGE, interviewees expressed that some evidence has been generated to show that technical capabilities have been improved through HP funding[210]. However, at this stage of implementation the innovative aspects of this action have not been tested as no major outbreak in the area of interest of the Joint Action has occurred. It is recognised that this will be a significant undertaking, requiring some administrative effort. Nevertheless, there is significant scope for lesson learning if this is implemented.
- **Benefits (to the extent available)**: Based on the evidence collected, the expected output and outcomes of this thematic priority appear consistent with the design and delivery of EMERGE to date. It should be noted that this joint action provides the function of detection of high risk pathogens, an essential component of protection against health threats from biological origin under Decision 1082/2013.

[210] For example through the implementation of first external quality assurance exercise, which show a rate of correct positive results varying from 69 – 86%, respectively for life and inactivated samples. Another important early result is the design of the method for prioritization of High Consequence Viruses to Improve European Laboratory Preparedness for cross-border health threats, developed for the selection of the emergent pathogens for the EQA, working group on improving diagnostic and training programme.

7. THEMATIC PRIORITY 3.4 – POOLING UNION EXPERTISE

7.1. Introduction

This case study covers thematic priority 3.4 of the 3HP on "Setting up a Mechanism for Pooling Expertise at a Union". This priority falls under Objective 3 of the 3HP, which is to "Contribute to innovative, efficient and sustainable health systems". Between 2014 and 2016, €0.9 million has been allocated to the fund an Expert Panel on Health (EXPH) is the only specific action that has been funded under this priority to date. It has been running since 2013 and is the focus of this case study.

Table 16: Actions reviewed for case study on pooling union expertise (thematic priority 3.4)

Funding mechanism	Lead organisation incl. MS)	Other organisations (incl. MS)	Budget	Start date/duration
Tenders / Framework contracts	DG SANTE	EXPH members	Total eligible costs from Annual Work Plans: 2014: €300,000 2015: €320,000 2016: €320,000[211]	June 2012, to last for duration of Third Health Programme

Note: More information on the sampled action can be found on the Chafea database and in the AWPs available on DG SANTE's website; at the time of writing, the panel has sat for its first term and has now disbanded; a second round of recruitment is currently underway. As such, this case study should be taken to refer to activities of the first term only.

The methodology for the case studies is provided in detail in the **introduction** to this Annex. But entailed **two main steps**. First, we reconstructed the thematic priority's theory in the form of an intervention logic diagram. Then, to test the theory, we collected and analysed evidence about implementation so far, above all through an examination of five funded actions (as above). The different sources of information are summarised in the table below.

[211] The actual spend has been lower in the years for which complete data is available. Actual spend has been closer to €235,000 in 2014, and €231,000 in 2015.

Table 17: Documents consulted and interviews conducted for this case study on pooling union expertise (thematic priority 3.4)

Documents consulted	Interview status[212]
• Commission Decision of 05.07.2012 on setting up a multisectoral and independent expert panel to provide advice on effective ways of investing in health, Official Journal of the European Union, (06.07.2012) • Commission Decision of 30.8.2015 amending Decision 2012/C198/06 on setting up a multisectoral and independent expert panel to provide advice on effective ways of investing in health, European Commission (30.09.2015) • Call for expressions of interest in membership in the multisectoral and independent panel to provide advice on effective ways of investing in health, European Commission (11/09/2012) • Note to Commissioner Dalli: SANCO mechanism to provide advice to MS on Health Systems, European Commission Health and Consumers Directorate-General (04/05/2011) • Decision on the members of the Expert Panel on effective ways of investing in health, European Commission Health and Consumers Directorate-General (21/05/2013) • EC Fiches on Health: Expert Panel on Health (20.02.2013) • Council conclusions on the economic crisis and healthcare (20.06.2014) • Council's conclusions: Towards modern, responsive and sustainable health systems (06.06.2011) • 3HP Annual Work Plans 2014, 2015, 2016 • 2HP Annual Work Plan 2013 • EC (2007) White paper: Together for Health: a strategic approach for the EU 2008–2013, EC DG R&I (2014) • Population ageing in Europe: facts, implications and policies (2014) • EC (2013) Investing in Health, a Commission Staff Working Document • Other relevant programme documentation, such as advice notes	• Interviews with 5 consultees: • 4 DG SANTE policy officers • 1 previous panel member

7.2. Policy context

7.2.1. Key health needs and priorities

Calls for an EXPH pre-dated the 3HP by some time. Its existence is rooted in Article 168(2) of the Treaty on the Functioning of the European Union[213]. This article states that, despite Member States (MS) coordinating their own health policies and

[212] Eight potential consultees were approached, with five agreeing to participate. Attempts were made to identify relevant MS individuals to speak with, but consultees were unable to suggest any suitable participants. As a result, some caution has been exercised in the interpretation of consultees' opinions and the authors would equally encourage readers to take note of this. Nonetheless, it is felt that a good degree of insight has been garnered from these discussions and that, when understood in conjunction with the documentary review, useful learnings have emerged.

[213] http://www.cvce.eu/content/publication/2010/5/3/e49fd232-e12a-4a45-924e-1b35b3631f94/publishable_en.pdf

programmes, the European Commission (EC) may also use initiatives to promote this coordination where deemed suitable, in order to support the sharing of best practice. Sharing of expertise is something that MS have been committed to since the concept featured in the Council's conclusions on common values and principles in EU health systems, as adopted in June 2006.

Specific calls for an expert panel include the Council's conclusions *Towards modern, responsive and sustainable health systems* (2011)[214] which outlined a body which could enable reflection on health issues by 'facilitating the access to informal and independent multisectoral expert advice'. This document marked the end of the Hungarian Presidency of the Council of the EU and reflects the political legacy of this period, which included an emphasis on encouraging MS and the EC to jointly reflect on health policy. One consultee framed this legacy within the wider picture of both the economic crisis, discussed below, and the growing demand from MS, the European Parliament and the Council for greater attention to be paid to pan-European healthcare issues[215]. There has therefore been demand for an expert panel building over a number of years, which has more recently been adopted and furthered by the EC.

Meanwhile, at the time of the EXPH's conception, the global financial crisis heightened concern within the EU around the sustainability of the health systems and policies in place in MS. This was a particular concern given the fact that public health expenditure had fallen in many MS since 2009, despite the EU's firm commitment to continued investment in health promotion and disease prevention. As emphasised in the Council conclusions on the economic crisis and healthcare[216], health systems provide crucial safety nets for citizens and the strengthening of their efficiency and sustainability is vital to addressing future challenges. A major part of this challenge, at the time of the 3HP's inception, was how to address issues such as population ageing, the rise of chronic diseases and multi-morbidity, rapid technology diffusion, shortages and uneven distribution of health professionals, rising citizen expectations and increasing costs of healthcare, against a backdrop of economic crises, declining budgets and global financial uncertainty.

Moreover, as mentioned by consultees, the concept of an expert panel became particularly compelling at this time in part due to the ongoing reflection process regarding health systems within the EC. An interest in creating a "soft doctrine" in health policy was a key goal for the EC, with a focus on synthesising best practice and experiences across MS. Following the Joint Report on Health Systems (December 2010)[217], there was also pressure from the European Parliament for the EC to begin playing a more prominent role in the ongoing debates regarding best practice in health and its financing; given its inherent expertise in the field, much of the onus of this driver fell to DG SANCO (now SANTE). With this goal in mind, consultees said that the concept of an expert advisory panel, which could provide some much-needed and high quality advice, became a key priority for the EC.

Furthermore, financial crises and budgetary constraints have major impacts on economic indicators such as income and unemployment; these in turn are social determinants of health[218]. Moreover, large spending cuts in the supply of healthcare can affect access to care and can subsequently have long-term health and economic

[214] http://ec.europa.eu/health/systems_performance_assessment/docs/com2014_215_final_en.pdf

[215] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF

[216] https://www.idf.org/sites/default/files/EPSCO%20economic%20crisis%20healthcare.pdf

[217] http://ec.europa.eu/economy_finance/publications/occasional_paper/2010/pdf/ocp74_en.pdf

[218] The social determinants of health are the conditions in which a person is born, grows up, lives during adult life and works. The World Health Organization's Member States adopted the Rio Political Declaration at the World Conference on Social Determinants of Health in October 2011, calling upon them to act in five areas and acknowledging the importance of health equity and social determinants of health

consequences, frequently putting the most vulnerable groups in society at particular risk. Concern that "universal coverage" in all MS was not being achieved was a powerful contextual factor[219].

7.2.2. Framework for and extent of EU engagement so far

Priority 3.4 promotes supporting dynamic health systems and new technologies; it also aligns with a number of recommendations set out in World Health Organisation's (WHO) 'ten leading sources of inefficiency of health systems' and the Organisation for Economic Co-operation's (OECD) recommendations for health system reform. These are reflected in the EC's Investing in Health (2013) and provide a framework for EU action in health to support the achievement of the EU's Europe 2020 Strategy for Growth.

The OECD recommendations most relevant to Priority 3.4 are: helping MS improve the efficiency of health systems, encouraging more cost-effective provision; and reducing inequalities in health between countries.

Furthermore, Priority 3.4 indirectly supports the third core strategic objective (Generate and Disseminate Health Information and Knowledge) expressed in the EC's White Paper 'Together for Health' (2007), which complements national health policies in line with Article 168 of TEU.

Moreover, this priority builds on the EU Second Health Programme's (2HP) key objective of generating and disseminating health information and knowledge by providing analysis and technical support to policy makers. The funding of the EXPH commenced in 2013, the final year of 2HP, thereby providing the foundations for its further development and implementation in the 3HP from 2014 onwards.

7.2.3. Fit with the Health Programme

The thematic priority under review in this case study falls under the scope of objective 3 of the HP, which is defined in the 3HP Regulation as follows: "*Contribute to innovative, efficient and sustainable health systems"*[220]*.*

Under this objective, there are seven thematic priorities which are feed into the overarching objective. The focus of Priority 3.4 in particular is on *"Setting up a mechanism for pooling expertise at Union level".* This thematic priority did not exist in the 2HP, but activity was incorporated in the final year of the 2HP to fund the initial set-up and work of the Panel. Priority 3.4 in its current form builds on similar, pre-existing priority areas from the 2HP as outlined in Table 4. There is just one key activity associated with this thematic priority: the setting up of the EXPH, managed by the EC and made up of independent healthcare policy experts. As noted above, work on the delivery of this activity pre-dates the 3HP and began with a Decision[221] in mid-2012 which set up 'a multisectoral and independent expert panel to provide advice on effective ways of investing in health'.

As already outlined, the EU has, for some time, been interested in pooling scientific knowledge and expertise for use by both the EC and MS. The 2HP (2008-2013) included,

[219] For a summary of some of the projects on health inequalities supported by the Commission's public health programme, see http://ec.europa.eu/health/archive/ph_determinants/socio_economics/documents/project_list_en.pdf

[220] http://eur-lex.europa.eu/legal-content/EN/TXT/;jsessionid=5Qj3TvyCyBqbhfLZzzBttjDGh3gyXkQWYrjhrt36mChMJJlp02XX!2060916514?uri=uriserv:OJ.L_.2014.086.01.0001.01.ENG

[221] Commission Decision of 05.07.2012 on setting up a multisectoral and independent expert panel to provide advice on effective ways of investing in health, Official Journal of the European Union (06.07.2012)

as one of its three overarching objectives, the aim to "Generate and disseminate health information and knowledge". Encompassed within this were a focus on exchanging best practice between MS, further developing and sustaining health monitoring systems, establishing regular reports on health status in the EU and providing analysis and technical assistance to support the development of health policies and legislation. In many ways, the EXPH bridges the gap between the third objective of 2HP and the third objective of 3HP, given that the decision to set up the panel was first announced in mid-2012, it was incorporated into the 2013 Annual Work Plan for 2HP (under 3.2.2),[222] and was later included in the design of the 3HP.

Consultees made reference to the EC' interest in using expert advice to create better informed and expertly ratified health policy recommendations; in particular, the DG's emphasis was on better advising MS's policy makers about how to protect their healthcare systems from adverse economic conditions and the challenges inherent in designing healthcare policy for the twenty-first century. Consultees also considered that, at a pan-European level, the key political priorities were concerned with integrating ideas such as person-centeredness and preventing inequity in access to healthcare. One consultee also alluded to the EC's interest in promoting the EU's activities more generally and creating a more favourable view of the Union. As such, the EXPH fits not only with the rest of the 3HP, but also with wider EU promotional priorities. Tables 3 and 4 below show how this priority fits within the overarching operational objective from the 3HP, and with related priorities from the previous Health Programme.

Table 18: Operational objective 3 and corresponding thematic priorities under the 3HP

Operational objectives	Thematic priorities
3) Contribute to innovative, efficient and sustainable health systems	3.1 Health Technology Assessment 3.2 Innovation and e-health 3.3 Health workforce forecasting and planning **3.4 Setting up a mechanism for pooling expertise at Union level** 3.5 European Innovation Partnership on Active and Health Ageing 3.6 Implementation of Union legislation in the field of medical devices, medicinal products and cross-border healthcare 3.7 Health information and knowledge system including support to the Scientific Committees set up in accordance with Commission Decision 2008/721/EC

Source: [Summary of] Annex I to Regulation of the Third Health Programme

Table 19: Objective and corresponding priorities under the 2HP

Objective	Thematic priorities
3) Generate and disseminate health information and knowledge, exchanging knowledge and best practice on health issues	3.1. Exchange knowledge and best practice. 3.1.1. Exchange knowledge and best practice on health issues within the scope of the Programme. 3.1.2. Support cooperation to enhance the application of best practice within MS, including, where appropriate, supporting European reference networks.
	3.2. Collect, analyse and disseminate health information. 3.2.1. Develop further a sustainable health monitoring system with mechanisms for collection of comparable data and information, with appropriate indicators; ensure appropriate coordination of and follow-up to Community initiatives regarding registries on cancer, based, inter alia, on the data collected when implementing the Council Recommendation of 2 December 2003 on cancer screening (1); collect data on health status and policies; develop, with the Community Statistical Programme, the statistical element of this system.

[222] http://ec.europa.eu/health/programme/docs/wp2013_en.pdf

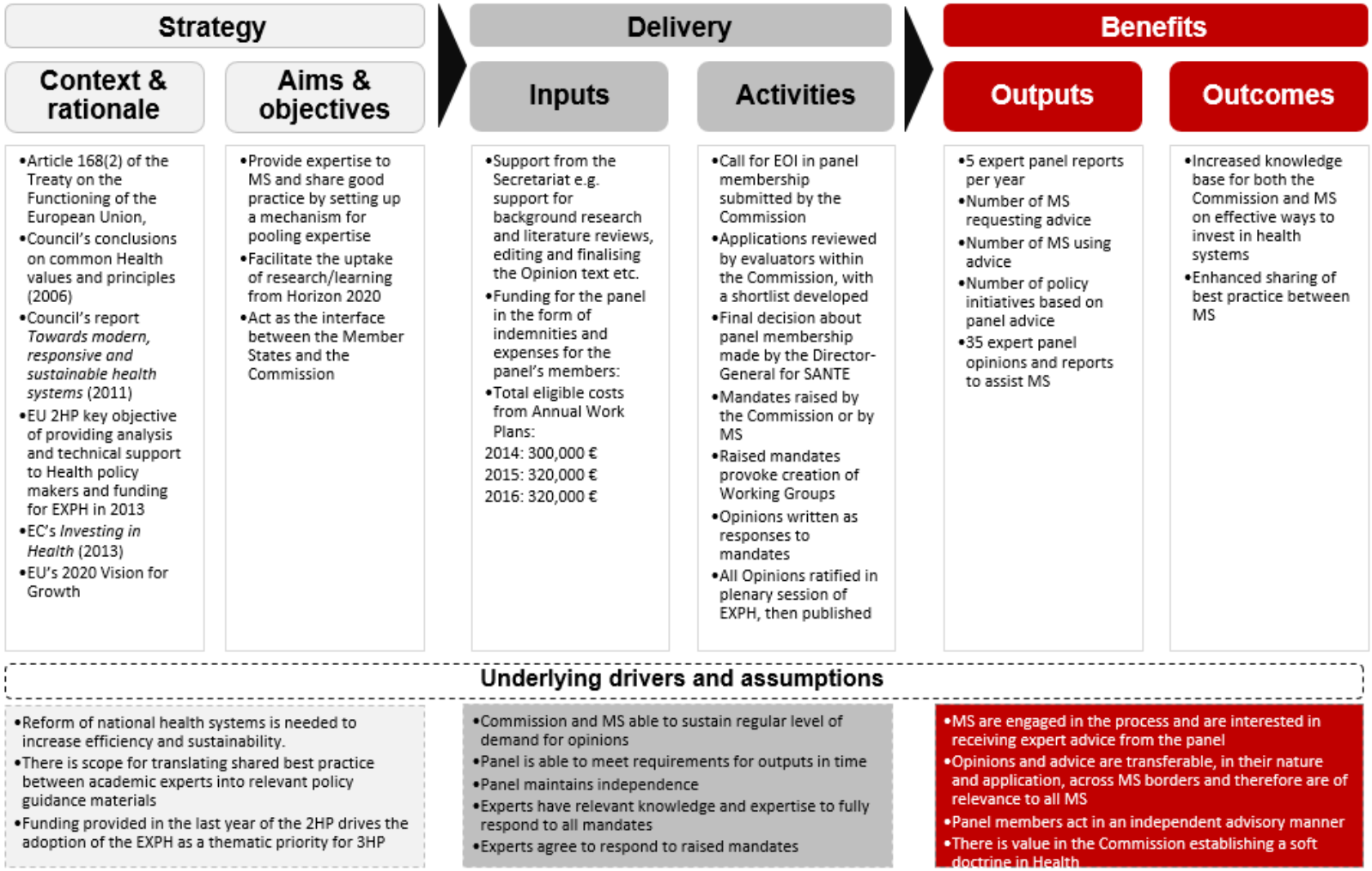
		3.2.2. Develop mechanisms for analysis and dissemination, including Community health reports, the Health Portal and conferences; provide information to citizens, stakeholders and policy makers, develop consultation mechanisms and participatory processes; establish regular reports on health status in the European Union based on all data and indicators and including a qualitative and quantitative analysis. 3.2.3. Provide analysis and technical assistance in support of the development or implementation of policies or legislation related to the scope of the Programme.

.....Source: Annex to Decision No 1350/2007/EC establishing the Second Health Programme

7.3. Theory and practice

This section presents and assesses the **thematic priority's intervention logic.** It starts with a diagram that depicts the theory underpinning the thematic priority. This is followed by sub-section on each of the intervention logic's main parts (strategy; delivery; and benefits). These sub-sections first describe and examine the how HP action under the thematic priority is intended to work in theory. We then analyse what is happening in practice by examining the objectives, activities, outputs, and (early) outcomes of the five actions selected for the case study. This allows us to test the intervention logic's plausibility and determine whether the desired outputs and outcomes of the thematic priority are likely to be achieved through the type of actions that have been funded to date. For a more detailed explanation of the methodology / components, please refer to the **introduction**.

Figure 5 : Intervention logic for thematic priority 3.4 (Pooling EU expertise)



Source: created by evaluation team based on case study fieldwork (documentation review and interviews)

7.3.1. Strategy

Rationale for HP action in the thematic priority

As previously mentioned, dual threats of economic instability and increasing pressures on European health systems from various factors such as population ageing, co-morbidity and the rise of chronic diseases explain the rationale for HP action in the thematic priority. Moreover, DG SANTE recognised that multiple bodies and institutions had called for an expert panel on health to disseminate high quality advice concerning these issues. As such, its incorporation to the Health Programme was seen by consultees to be a sensible fit. Given that this priority developed from the panel's inclusion in 2HP and the funding of the panel has been the only action to date, the priority and the action can be considered to be one-and-the-same at this stage.

The EC's unique position within Europe means it is well placed to facilitate the sharing of information and good practices. Moreover, the EC is able to exploit economies of scale by helping to bring new health innovations to market and ensure public safety in healthcare across all MS. DG SANTE has prior experience in managing panels designed to provide specialised scientific advice to the EC, although the focus of these has not historically been on the sustainability of European health systems. These included the Scientific Committee on Consumer Safety, and the Scientific Committee on Health, Environmental and Emerging Risks. As a result of this previous experience, the DG developed and disseminated learning which helped to provide the foundation of the EXPH.

Moreover, the DG's prior experience of managing scientific panels is coupled with its ability and capacity to select and appoint an independent set of experts, and thereby avoid some of the potential conflicts of interest which could have arisen were MS to have chosen panel members themselves. Consultees commented on the thorough and intensive administrative and evaluative task of selecting the panel's members, with each application being evaluated by two different officials. This assessment task was supported by the breadth of healthcare knowledge and expertise of colleagues in DG SANTE and other DGs where appropriate.

In terms of choosing an EC-maintained panel as opposed to ad hoc advice and input from consultancies, consultees commented that internally maintaining the panel is a significantly cheaper option. This particular management design also means that the EC is able to access expert opinion quickly, offering efficiencies in terms of both time and spend. Moreover, consultees commented on the quality of the experts who were attracted to apply for the EXPH. It appears that the rigorous application procedure and high profile of the panel were enablers, with consultees commenting that these factors helped to ensure that high quality and well-informed Opinions could be written. Each of these elements ensures that the panel aligns with the Objective-level priorities of creating innovative, efficient and sustainable systems.

Strategic fit of the funded action

From a review of relevant documentation and consultations with both DG SANTE staff and a previous member of the expert panel, the evidence suggests that the EXPH has strategically aligned with the priority in the expected manner, as outlined in the programme's logic model and the internal fiche on the Expert Panel on Health, developed by DG SANTE in 2013. The actions described in each of the AWPs were loosely defined, with funding essentially provided to finance the indemnities and expenses of the expert panel, alongside any requisite scientific and technical assistance from the EC in data mining, scoping and editing Opinions. The non-prescriptive nature of the priority's scope is likely to offer benefits, in that there is a wide-ranging remit for both MS and the EC to decide and amend the priority's focus as the panel matures.

However, by setting such loosely defined expectations for outcomes and impacts, DG SANTE has had difficulties in identifying behavioural or policy change resulting from the Opinions and the panel more widely. This is largely a problem of attribution: establishing a counterfactual scenario (i.e. what would have happened in the absence of the EXPH or a particular Opinion issued by it) is very challenging. This was noted by consultees, with some highlighting the challenges of providing evidence of outcomes in such a limited timeframe of funding. However, seemingly the main issue is that the underpinning logic for the priority does not sufficiently consider how to measure impact and account for the expenditure of funding. There was a sense amongst the consultees that evaluative measurement was being undertaken in a largely ad hoc, anecdotal manner. Whilst it is necessary to take care not to extrapolate too greatly the impressions of the five interviewees for this case study, so too is it important to be cautious in interpreting the anecdotal feedback which the EC has received regarding the EXPH. Caution needs to be exercised in both regards, in order to avoid overstatement, misattribution or confirmation bias.

7.3.2. Delivery

Planned activities and overall implementation so far

As mentioned, just one activity - the EXPH - was funded under thematic priority 3.4, and it received funding in each of the years from 2014 to 2016. In a sense, therefore, the priority and the panel are one and the same. The total allocation of funding to the priority over the course of the three years was 940,000 €[223]. This was roughly evenly split across each of the three years, with 300,000 € funded in year one, and 320,000 € each in years two and three, though it should be noted that actual spend seems to have been roughly 20-30% lower than the intended amounts.

The EXPH panel runs for three years at a time, after which expressions of interest for membership are opened and a new panel is selected. The first session sat from mid-2013[224] (with the inaugural plenary meeting taking place in Brussels on 11-12 July 2013) until its final plenary meeting on 3 May 2016. At the time of writing, the application and selection process remains ongoing for the election of a second panel; it was originally expected that this would be concluded in October 2016, but there has been some delays.

Panel members were selected, for the first term, on the basis of their expressed interest, via an application form[225], which was submitted to, processed and evaluated by the EC. In total, 425 applications were received for the first term, of which 420 met the necessary criteria[226]. Each application was reviewed by two evaluators who were either DG SANTE staff or had relevant health knowledge and sat within another DG. The Decision[227], which outlines the remit of the panel, allows for up to 17 panel members. However, the Director General at the time of the selection of the first panel made the decision that only 12 members would be instated. The ambition is that the membership of the panel provides breadth of scientific expertise, depth of knowledge, recognised

[223] Note that this only covers the funding paid as a part of the 3HP

[224] The funding originally came from the 2HP[224], whereby an indicative amount of 500,000 € was set aside for 2013. See http://ec.europa.eu/health/programme/docs/wp2013_en.pdf

[225] Call for expressions of interest in membership in the multisectoral and independent panel to provide advice on effective ways of investing in health, European Commission (11/09/2012)

[226] The necessary criteria for membership were that the candidate had a university degree in a relevant scientific area, at least 10 years' professional experience and a good knowledge of the English language.

[227] Commission Decision of 05.07.2012 on setting up a multisectoral and independent expert panel to provide advice on effective ways of investing in health, Official Journal of the European Union, (06.07.2012)

international standing and fair representation across key criteria such as MS, gender and ethnicity.

The main elements of the panel's delivery are the issuing of Mandates (which are always delivered via the EC but which can come from any DG or from MS) and the responses to those Mandates, which take the form of Opinions written by the panel. Experience from the first panel session shows that Mandates were largely based on questions which had been asked or put forward within the EC; typically, these came from DG SANTE, but also from DG ECFIN and the EC (it is understood that one Mandate was put forward by a MS, via the EC and is therefore listed as being from the EC as a whole)[228]. The Mandate itself is a document, up to around three pages in length, which explains the issue and question at hand to the panel. It outlines what the EC would like to understand, the expected output from the panel and the timeframe for submission. Consultees mentioned that the Mandate process was more complex than the written documentation alone might suggest. In fact, there was a period of discussion and development between the EXPH and DG SANTE for each Mandate, ahead of its adoption by the panel. This allowed for clarification questions and changes to the scope of the Mandate as needed. Panel members were ultimately allowed to decide whether or not they would adopt a particular Mandate, but in practice this decision process was not dogmatic as there was the inbuilt capacity and expectation than the Mandate itself was a document designed to be negotiated. As such, none were entirely 'rejected' by the panel.

Once engaged in creating an Opinion in response to an agreed Mandate, a working group was established for the purpose. This would typically consist of both panel members and also additional expert input as necessary[229]. Consultees reflected on the input of DG SANTE, which had dedicated personnel to support the scoping review and data mining phases of the process of drafting Opinions. The panel members then debated the relevant issues, analysed the available documentation and data, and provided a written response to the Mandate. Once refined and completed, the Opinions were debated in a plenary session and it was imperative that each was ratified by all members of the panel before being published.

From discussions with consultees, three broad 'types' of Opinions seemed to emerge. This is based on consultees' reflections on the ten Opinions which were commissioned in the first session and the pattern is far from prescriptive, but can be seen as a useful loose framework for understanding the purposes and potential uses of the work published by the panel. The three broad categories are:

- **'Best practice' Opinions:** these provide a 'road-map' with specific advice related to the implementation of a particular policy approach or design, and summarise best practice. An example of such an Opinion was that entitled *"Best practices and potential pitfalls in public health sector commissioning from private providers*", which allowed MS to fully understand the considerations and ramifications involved.
- **'High policy' Opinions**: these are essentially designed to be used by the EC. They flag up which factors should be considered in a particular policy area, identify the main indicators which can be measured and monitored and, fundamentally, can act as a set of expert reference documents for the EC which can help them towards their aim of creating various doctrines in health. An

[228]Six of the ten Opinions written in the first session of the panel were requested by DG SANTE; three of the Opinions were requested by DG ECFIN; one of the Opinions was requested by the Commission.

[229]Additional expert input typically came from either the pool of experts who had applied to be considered for the panel but had been unsuccessful, or from the professional contacts of the panel members, whose expertise was well-aligned with the topic at hand

example of this type of Opinion was entitled *"Access to health services in the European Union".*

- **'State of play' Opinions:** one consultee referred to these as being 'intellectual' documents, which describe the "state of play" of a particular policy idea/approach, draw out the pros and cons which have been established thus far, and are intended to inform both MS and the EC. They draw together the relevant literature and conversations with health policy teams in various countries, thereby helping to prevent duplicated efforts to summarise policies across the EU. An example of one such Opinion was entitled "*Health and Economic Analysis for an Evaluation of the Public-Private Partnerships in Health Care Delivery across Europe".*

These are far from distinct categories and the intention is that a wide range of actors and institutions can make good use of the shared learnings and best practice summaries in each Opinion; the above is simply designed to try and develop an understanding of how the impact of the panel might best be assessed and to categorise the focus of their outputs.

Once written, Opinions have been published on the EXPH's website and disseminated via conferences and other fora, such as the European Forum for Primary Care, and in journals including The Lancet Oncology, Primary Health Care Research & Development, The European Journal of Health Economics and others[230].

Lessons learned from specific action(s) so far

Arguably, the clearest lesson emerging from the first session of the panel is the **need for a firmer sense of how to measure the impact** which this priority is having. There is currently little infrastructure or thinking in place to capture how successfully the action is meeting the anticipated outcomes of *i) increasing the knowledge base for the EC and MS*, and *ii) encouraging the sharing of best practice between MS*. Whilst it is possible to identify the activity's physical outputs - the ten published Opinions - it is challenging to determine how widely these have been read or, indeed, used in influencing policy decisions and direction.

Moreover, there is a **lack of firm understanding around how Opinions have been used by MS**. One consultee mentioned that the Opinion relating to Primary Care[231] has been debated in the European Forum for Primary Care, and has been used by the Belgian and Estonian Governments in guiding their thinking on their respective Primary Care systems. However, evidence is again anecdotal, building largely on conversations between individuals in fora debates and conferences, and would benefit from additional, formalised support in the form of a feedback system for requesters and recipients (MS and the EC). It is understood, from consultees, that some work is being undertaken in order to gather feedback from those individuals who raised particular Mandates, but we were unable to access examples of this when requested. There was consensus amongst consultees that the second session of the EXPH will need to address the issue of measuring and accounting for impact more concretely, but this was coupled by an emphasis on the as-yet short lifetime of the panel and the expectation that this kind of activity can take upwards of a decade to create concrete and evidenced change.

Aside from this learning, it is useful to **reflect on the role of the EC in the requesting and delivering of Mandates and Opinions.** A key criteria of the panel is that it is

[230] Publications: Primary Health Care Research & Development, The European Journal of Health Economics, The Lancet Oncology, Health Policy, the European Journal of Public Health, European Journal of General Practice, European Journal of Health Law and International Journal for Equity in Health

[231] http://ec.europa.eu/health/expert_panel/sites/expertpanel/files/004_definitionprimarycare_en.pdf

independent and therefore provides innovative and highly-informed insight into a range of health policy issues. However, the role of the EC is fundamental in the delivery of the activity; as highlighted by consultees, all Mandate requests must be submitted via DG SANTE, which holds the ultimate say on whether or not a question is put to the panel, with even some DG SANTE staff somewhat unsure of the criteria by which one Mandate is selected above another. Alongside this, the EC both selects the panel members and has a fundamental role to play in publishing and disseminating the outputs. Consultees mentioned that, whilst MS were permitted to suggest Mandates, just one of those requested in the first session came from MS. This seems to diverge somewhat from the original intention that MS would play an active role in requesting mandates.

Moreover, one MS did make a specific, geographically and political-limited request in a pre-electoral context, but this was ultimately not answered by the panel due to the complexities inherent in spending panel time in addressing the questions of a single state. As mentioned, this single request went against the grain, as few MS were engaged in requesting mandates. One reason for this could be the fact that all Opinions produced by the panel are published publicly. As a result, one consultee suggested that MS might be wary of requesting Opinions which might reflect badly on their policy or governance. There are clearly **challenges in creating outputs which are practically useful for MS as guidance or 'checklist' documents, which are applicable to the wide-ranging contexts of the MS and which do not alienate states**. Moving forwards, it may be useful for DG SANTE to consider whether impact might be more easily achieved and evidenced if MS had a more considerable role to play in defining the EXPH's agenda.

In terms of the EXPH's functioning, consultees commented on the **ease with which Opinions were typically ratified**, suggesting that there was a high degree of cohesive group thinking. One interviewee did suggest that this could be seen to indicate limited aspiration in the Mandates being requested (meaning that Mandates did not cover particularly controversial topics), but that nevertheless it was most useful for both the EC and MS to receive Opinions that offered a viable and accepted, rather than a radical, perspective. It could be suggested that a larger panel membership, for example if the next session is enlarged to include more members, may encourage a greater degree of group dynamics which could result in more diverse and innovative thinking. However, there may be a risk that more diverse thinking may stall the formation of Opinions. In terms of innovation in healthcare recommendations, consultees agreed that panel members were keen to develop new ideas and ways of working, but there was no specific mention of how this might tie into technological innovations and advances.

Moreover, consultees commented on the occasional **delays between the panel's agreement to consider a Mandate and delivery of a finalised and ratified Opinion** from the panel. Some consultees mentioned that sometimes the Opinion would be delivered too late to be used for its original purpose, such as advising on a particular piece of policy. It was recognised that this occasionally occurred because public consultations formed a part of several Opinion-writing processes and this procedure is inherently lengthy. It is therefore important for the panel to consider the relative benefits of a quicker turnaround and a more thorough approach in each instance.

Whilst DG SANTE did have a significant role to play in managing the panel, and consultees said that there was a positive and productive relationship between the panel and EC. One consultee who sat on the panel mentioned that **increased capacity for administrative and drafting support** would have made the most efficient use of experts' time. Rather than being involved in the redrafting of Opinion-text, experts should primarily be engaged in debating and analysing the health policy issues. For this to be possible, it was felt that the DG would benefit from additional capacity, in the form of a staff member with an academic background and the requisite skills to finalise the outputs.

Finally, one consultee expressed the hope that the second session of the panel would include **a more diverse and representative panel**, with a particular focus on ensuring adequate representation in terms of both geography and gender. In particular, a better reflection of Eastern European interests by electing more experts from this region was suggested as useful, to enable the panel to incorporate the best possible range of viewpoints and expertise.

7.3.3. Benefits

Expected immediate, medium- and long-term benefits

It was commonly recognised by consultees that it would likely take upwards of a decade to truly witness the impact of the panel's activity. This is anticipated to require continuity of funding and sustainability of planning, given the fact that promotional, awareness-raising activity is time-consuming and reliant on the regular publishing of Opinions in order to keep stakeholders and beneficiaries engaged. To this end, one consultee commented that the time-lag between terms could be damaging from a promotional perspective; the current 'downtime' in which the second round of panel members is being recruited risks damaging the engagement in activity - by both MS and the EC - which was enjoyed towards the end of the first term.

Despite this, the potential of the panel was spoken of highly by all consultees, both in the medium- and longer-term. For the former, the programme has the potential to influence MS policy decisions. It offers the potential to disseminate cohesive and expertly-ratified guidance regarding specific elements of health policy and potentially in the longer-term, help to harmonise policies across MS, leading to an increase in the overall quality in the policy area. The crucial (and challenging) element here, as already mentioned, is in identifying the role that the panel has played and distinguishing this from the complex picture of policy design and the multiple and varied inputs from a range of fora, journals and expert advice.

Although all consultees believed that the Opinions were valuable and that they were being used as anticipated, evidence was anecdotal. Within the EC, interviewees commented that the Opinions provide a good set of reference documents for staff and policy teams to draw on in the design of policy and advice for MS. Some consultees also discussed the value of having expertly-ratified guidance and analysis to draw on and thereby give 'weight' to the EC's guidance documents. However, as mentioned previously, consultees had difficulty in identifying specific examples of this usage in practice.

In the longer-term, and from the EC's perspective, the ambition of creating a "soft doctrine" in health policy seems to be a major driver behind the creation of the panel. By utilising expert advice, the EC hopes to raise the profile, reputation and credibility of the EU in developing such a doctrine and in providing evidence-based health policy guidance. Consultees shared a belief that setting out a common EU-level approach would be beneficial in raising the standards and outcomes of healthcare in all MS, offering potential to consolidate commonly-held policy beliefs, such as of the importance of person-centred healthcare, as well as providing a centralised and thoroughly-researched hub as an interim outcome, in the form of the EC.

Finally, one consultee identified wider potential benefits emerging from the panel, with the panel reflecting a positive image of the EU as a whole, both within the continent and further afield.

(Potential) benefits in practice

It is still very early days in terms of evidencing outcomes and benefits in practice for the EXPH. However, there is some early evidence, largely anecdotal in source, which points to some of the benefits of the expert panel.

In particular, one consultee made reference to the example of the Opinion relating to primary care[232] which appears to have been debated and used extensively since its publication. This has included usage by the Belgian government in its healthcare reforms, the European Forum for Primary Care and the Estonian government in particular.

Another oft-cited Opinion in consultations was that relating to Access to Health[233], a key priority area for the EC in ensuring the reduction of health inequality in Europe. One consultee referred to the significant and lasting impact of this Opinion on the way the EC is considering health inequality, as well as in the EC's usage and recommendation of health indicators. Moreover, one consultee referred to the important role that this Opinion is playing in the ongoing design of the European Pillar of Social Rights[234]. This Opinion would specifically support the category calling for "Adequate and sustainable social protection" which will include access to health and social protection in the form of high quality healthcare.

One consultee also referred to the impact which the EXPH is having in supporting symmetry in thinking and research between the EU and the WHO. Having cohesion between key international bodies was considered to be key to ensuring the effectiveness and uptake of recommendations.

However, it is clear that understanding the impact of the EXPH on developing an increased knowledge base for MS on effective ways to invest in health systems, which is a key outcome measure of the priority, is very challenging. One consultee reflected on the fact that this is at least in part because MS have not requested mandates to the degree originally anticipated at the priority's outset. More and ongoing work to engage MS over the remaining years of the project would likely contribute to a greater sense of MS ownership of the process and an understanding that expert advice is designed to advise MS as much as it is to be used by the EC.

7.4. Conclusions

The following conclusions attempt to draw out key points from the evidence collected and analysed, with a focus on the relevance of the thematic priority, its potential to make a difference in practical terms and lessons that can be applied to the HP more broadly.

1. Relevance of the thematic priority, given:

   - **Identified needs:** The need for the EXPH was originally identified several years before the panel was initiated. There remains inefficiency and inequality in health care systems across the EU, and the EC has a key role to play in coordinating expert knowledge and the sharing of good practice in order to improve health outcomes. MS do not necessarily have the resources (human or financial) to undertake the panel's work on their own, and the EXPH offers economies of scale by generating Opinions that can be used by any MS. The thematic priority addresses the resourcing issue head-on by creating an expert panel which brings

[232] http://ec.europa.eu/health/expert_panel/sites/expertpanel/files/004_definitionprimarycare_en.pdf

[233] http://ec.europa.eu/health/expert_panel/sites/expertpanel/files/015_access_healthservices_en.pdf

[234] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1457706909489&uri=COM:2016:127:FIN

together knowledge and expertise, designed to inform both MS and EU policy development and decision making. However, the current prioritisation process for selecting Mandates for review, and the urgency underpinning the EXPH's Opinion forming, remains unclear. Introducing a DG SANTE lead to oversee the EXPH and Mandate selection process may assist with this, and may also help to ensure explicit alignment with other EC and international priorities.

- **The HP's objectives:** The EXPH sits under priority 3.4 and is relevant to and addresses the third operational objective of facilitating the voluntary take-up of public health intervention and prevention strategies. There is no mandate requiring MS or indeed the EC to act on panel Opinions. It also appears to indirectly support the 3HP objective of contributing to innovative, efficient and sustainable health systems, although the evidence regarding the uptake and impact of Opinions remains limited and largely anecdotal. Opinions are disseminated via relevant sector journals; however, systemising the dissemination process, seeking to ensure Opinions are received by MS, may help to encourage the suggestion of Mandates and uptake of Opinions.
- **EU objectives more broadly:** The formation of the EXPH is expected to contribute to wider EU objectives such as decreasing inequality between and within MS, by providing information and sharing good practice in a manner accessible to all MS.

2. Likelihood of actions to make a difference in terms of:

- **Established problems:** In its design and output so far, the expert panel and its Opinions are expected to inform and support the decision making by the EC and MS, to varying degrees. However, due to the lack of MS influence to date regarding the focus of the Mandates, it remains challenging to identify the impact of the action on any existing problems within MS health systems, or indeed the likelihood of it doing so moving forward. There is limited evidence as to how Opinions have been used by MS to date. There is a risk that, if MS do not engage more actively in proposing Mandates, the EXPH will continue to function as more of an advisory panel for the EC.
- **The EU added value of the HP:** As laid out in the rationale for acting at the level of the HP and thus at European level, the EXPH is one area where there is a clear rationale for the EU to act in a coordinating capacity. As such, this action offers economies of scale in the coordination and dissemination of expert Opinions and good practice, reducing the need for duplication or effort at MS level. It can offer different insights obtained from experts drawn from across MS. However, the absence of an accountable officer within DG SANTE to oversee and lead the panel's work, and ensure its alignment with other priorities at a system level, may limit the extent to which its full potential added value has been realised to date.
- **Wider policy objectives / priorities:** The first session of the panel has been implemented to provide benefits at different levels: to inform EC decision making; to inform MS decision making; and to inform decision making at both EU and MS levels. The potential for promoting innovation in health, and generating economies of scale by connecting expertise, is large. The EU has a clear role to play in coordinating action at the European level and helping to create relationships and share knowledge between experts who normally do not work together.

  In a time of population ageing and economic recovery, managing and reducing costs in the formation of guidance and knowledge is in the interest of all MS. It is expected that through the work of the panel efficiency can be gained by creating economies of scale. However, it remains unclear the extent to which the

focus to date on EC decision making has been helpful in informing MS decision making, and we recommend systematically following up with those requesting Mandates, to assess the extent to which they are used to inform decision making, at both EC and MS level.

3. What lessons can be learned in terms of:

- **Strategy**: It remains unclear how the panel will inform decision making at MS level, and consequently how it is currently helping to achieve the objectives of the priority. It is worth considering whether increased MS involvement in Mandate setting may help to better align the focus of the panel with the needs of MS health systems.
- **Delivery**: The sustainability of this panel will depend on funding existing beyond the next years. But the panel will also need to be anchored in both the EU and MS in multiple ways, not just financially. For instance, MS will need to feel ownership over the panel and its focus, to ensure it achieves maximum impact. The first session of the panel has delivered Opinions as planned, findings have been published, and recruitment to the second panel is underway.
- **Benefits (to the extent available)**: The panel has delivered Opinions in line with the Mandates raised, and has provided expert advice and input to MS and the EC. In this respect, it is achieving the expected benefit of sharing good practice and improving the existing knowledge base. However, it remains unclear the extent to which MS have accessed and acted upon the Opinions, and the benefits emerging at the present time are extremely difficult to evidence.

8. THEMATIC PRIORITY 3.6 – IMPLEMENTING EU LEGISLATION (MEDICAL DEVICES, MEDICINAL PRODUCTS AND CROSS-BORDER HEALTHCARE)

8.1. Introduction

This case study examines thematic priority 3.6 of the 3HP on "Implementation of Union legislation in the field of medical devices, medicinal products and cross-border health care". This priority falls under Objective 3 of the 3HP, which is to "Contribute to innovative, efficient and sustainable health systems". A total of 78 actions have been funded under this thematic priority, amounting to €12 million (2014 – 2016)[235]. A sample of actions was selected based on consideration of their maturity, breadth of coverage of the mechanisms and a mix of different sized actions (see table below).

Table 20: Actions reviewed for case study on Implementing EU legislation (medical devices, medicinal products and cross-border healthcare) (thematic priority 3.6)

Funding mechanism	Lead organisation (incl. MS)	Other organisations (incl. MS)	Budget	Start date/duration
European Pharmacopoeia				
Direct Grant Agreement	Council of Europe	N/A	Total eligible costs –€3,003,114.97 3HP grant: €1,100,000 (36.6% of total eligible costs)	2015 activity 01/01/2015 12 months
Statistical data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)				
Project	National Health Insurance Fund Administration (OEP), Hungary –lead contractor	Austrian Public Health Institute (GÖG), State Institute for Drug Control (SÚKL) in the Czech Republic, Dental and Pharmaceutical Benefits Agency (TLV) in Sweden, Pharmeca a. s. in the Czech Republic	Estimated eligible costs –€731,999.84 3HP grant: €299,999.70 (41% of total eligible costs)	2014-2017 activity Start date: 01 June 2015 36 months
Study on the regulation of advanced therapies				
Service Contract	Consortium led by Ecorys	Consortium members: University Utrecht, National Institute for Health and Welfare in Helsinki (Finland) and Universita Cattolica del Sacro Cuore in Milan (Italy)	Contract value: €161,500	2014 Start date: 23 April 2015 10 months
Study on off label use of medicinal products in the European Union				
Service Contract	Consortium led by Stichting Nederlands Instituut voor Onderzoek van de Gezondheidszorg (NIVEL) in the Netherlands	Consortium members: National Institute for Public Health and the Environment (RIVM) in the Netherlands, European Public Health Alliance (EPHA) in Belgium	Contract value: €226,500	2014 Start date: April 2015 14 months Study still ongoing – to be finalised by February 2017
Market surveillance of medical devices (JAMS)				
Joint Action	Coordinator: Medicines and Healthcare Products Regulatory Agency (MHPRA) UK	The Joint Action is delivered by ten National Competent Authorities representing more than 50% of the EU-	Total eligible costs: €1,415,814 3HP grant: €849,487 (60% of eligible costs)	2016 Contract start date: 17 October 2016 36 months

[235] 14 of these actions were managed by Chafea, while the other 64 were managed by DG SANTE.

Funding mechanism	Lead organisation (incl. MS)	Other organisations (incl. MS)	Budget	Start date/duration
		population, with MHPRA acting as the Coordinator. The participating agencies are based in: Ireland, Netherlands, Austria, Cyprus, France, Italy, Portugal, Sweden and Spain.		

Note: More information on the sampled action can be found on the Chafea database and in the AWPs available on DG SANTE's website

The methodology for the case studies is provided in detail in the **introduction** to this Annex. But entailed **two main steps**. First, we reconstructed the thematic priority's theory in the form of an intervention logic diagram. Then, to test the theory, we collected and analysed evidence about implementation so far, above all through an examination of five funded actions (as above). The different sources of information are summarised in the table below.

Table 21: Documents consulted and interviews conducted for case study 3.6 on Implementing EU legislation (medical devices, medicinal products and cross-border healthcare) (thematic priority 3.6)

Documents consulted	Interview status
• 3HP Annual Work Plans 2014, 2015, 2016 • Documentation for each of the actions, including grant agreements and annexes, award decisions for grants, signed contracts, technical descriptions, tender specifications and signed off proposals, intermediate and final outputs (e.g. interim reports, final reports) • Evaluation Summary Reports for proposals for the sampled actions • EU legislation in the field of medical devices, medicinal products and cross-border health care, specifically: Directive 2001/83/EC (Article 111, Article 19, Article 118a, Annex I); Regulation 726/2004; Regulation (EC) No 470/2009 (Article 28) • EC (2007) White paper: Together for Health: a strategic approach for the EU 2008–2013; EC DG R&I (2014) Population ageing in Europe: facts, implications and policies; EC (2013) Investing in Health, a Commission Staff Working Document	• Conducted a total of 11 interview. • Interviews with five DG SANTE policy officers responsible for the sampled actions. • Interview with a DG GROW policy officer responsible for action 3.6.5 • Interviews with two Chafea project officers responsible for the sampled actions • Interviews with three implementation partner (beneficiary) representatives

8.2. Policy context

8.2.1. Key health needs and priorities

EU Member States (MS) will face profound health challenges over the next two decades. A 'perfect storm' of rising demand, higher morbidity rates and fiscal constraints is placing increasing strain on national health systems. These challenges are specified in the EU's health strategy, expressed in the EC's White Paper 'Together for Health' (2007)[236]. They include rising demand due to **an ageing population with more complex health needs, and the growth of preventable illnesses** due to

[236] Source: European Commission (2007) White paper 'Together for Health: a strategic approach for the EU 2008–2013' COM (2007) 630 final

intensifying lifestyle risk factors. Another challenge relates to the **substantial health inequalities** that exist in Europe, with data from Eurostat[237] showing that health outcomes are highly diverse across MS and dependent on geography as well as socio-economic status.

Large discrepancies in public health expenditure exist between MS, as well as variance in the quality of care. Moreover, public finances for healthcare have been tightening as a result of the 2008 financial downturn[238] as MS implement austerity measures. Greater needs and tighter finances mean there is a pressing need to ensure innovative, efficient and cost effective treatments (including medicinal products and medical devices) can be brought to the market, and to ensure that cross-border healthcare operates as effectively and efficiently as possible.

Opportunities for improving health are also highlighted in the White Paper. These include innovation (for instance ICT advancements, the development of advanced therapies and innovation in biotechnology), which have transformed healthcare in recent years and are expected to continue to improve services and outcomes in future.

Europe's health systems need to innovate, maximise value for money and improve sustainability so that they can provide safe, quality healthcare for all EU citizens. At EU level, there is recognition of the need for reform; in 'Investing in Health, a Commission Staff Working Document'[239], the EC stated that "*ensuring efficiency and making the provision of health services more cost-effective and efficient is crucial if countries are to ensure universal access to and equity in health services and their adequate and sustainable financing*". But it also warned that "*sudden significant reductions in healthcare budgets risk creating new inefficiencies, undermining access to and the quality of care, damaging health outcomes and ultimately jeopardising the sustainability of the health system even more by increasing costs"*[240].

EU support of health system reform is enshrined in Objective 3 of the 3HP, for EU action to: *Identify and develop tools and mechanisms at Union level to address shortages of resources, both human and financial, and facilitate the voluntary up-take of innovation in public health intervention and prevention strategies.* Although responsibility for healthcare regulation largely lies with each Member State, the EU plays a key role in harmonising the markets for medicinal products and medical devices, which should help national health systems better control costs and introduce innovations. Cross-border healthcare is another area where EU legislation is key to ensuring effective, equitable and efficient access and care.

8.2.2. Framework for and extent of EU engagement so far

The EU is well placed to address the issues outlined above, and has for some time been taking action to do so. As regards *legislative* action, the key parts of the current EU legal

[237] http://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare_statistics

238 As part of policy responses to the economic crisis between 2007 and 2011, 10 Member States reduced their healthcare budgets: Bulgaria, Estonia, Hungary, Ireland, Italy, Greece, Latvia, Romania, Portugal and Spain. Between 2009 and 2012 health spending in real terms decreased by 0.6% annually across all Member States due to austerity cuts. Source: European Commission (2013) Investing in Health, a Commission Staff Working Document, Social Investment Package:

http://ec.europa.eu/health/strategy/docs/swd_investing_in_health.pdf

239 Source: European Commission (2013) Investing in Health, a Commission Staff Working Document, Social Investment Package http://ec.europa.eu/health/strategy/docs/swd_investing_in_health.pdf

240 Source: European Commission (2013) Investing in Health, a Commission Staff Working Document, Social Investment Package http://ec.europa.eu/health/strategy/docs/swd_investing_in_health.pdf

framework for medical devices, medicinal products and cross-border healthcare were adopted in 1993, 2001 and 2011 respectively, and have been subject to a number of revisions, updates and additions since then.

The legal basis for the EU to adopt legislation to ensure high standards of quality and safety for medicinal products and devices for medical use stems from TEU Article 168 paragraph 4[241]; it is one of only a few health-related areas where the EU has a legislative responsibility:

Article 168 paragraph 4. By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, […] shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

In the context of priority 3.6, several pieces of EU legislation are relevant. These have the potential to contribute to enabling, fostering or facilitating the use of innovative, cost-effective treatments or procedures to support innovative, efficient and sustainable health systems across the EU.

Medicinal products

The EC's role is to ensure pricing transparency whilst also ensuring the highest quality of medicinal products through EU legislation. The legal basis for medicinal products in the Single Market is **Directive 2001/83/EC**[242], specifically the community code relating to medicinal products for human use. Medicinal products must satisfy strict authorisation procedures to prove they meet quality, safety and efficacy standards[243]. The Directive details mandatory packaging information, with strict controls for advertising. All medicines placed on the EU market must have prior authorisation from a national authority or the EC, and a mutual recognition procedure exists to enable medicines authorised in one EU country to be sold in another. To receive authorisation, detailed therapeutic information must be provided about the product, including possible side effects. The EC has also issued guidelines for the manufacture and distribution of medicinal products.

[241] European Union, Treaty of Lisbon Amending the Treaty on European Union and the Treaty Establishing the European Community, 13 December 2007, 2007/C 306/01

[242] Council Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, Official Journal L – 311, 28/11/2001, p. 67 – 128. As amended by: 2002/98/EC 27 January 2003, Council Directive 2004/24/EC 31 March 2004, Council Directive 2004/27/EC 31 March 2004, Council Directive 2011/62/EU 8 June 2011.

[243] Specifically, Article 111b which provides for public health protection by ensuring that Member States' regulatory frameworks are sufficient for guaranteeing the safety of medicinal products. Article 118a outlines the conditions for penalties of non-compliance (including the manufacturing, distribution, brokering, import and export of falsified medicinal products).

The EU supports the European Pharmacopoeia, established by the Council of Europe[244] to harmonise national laws on the manufacture, circulation and distribution of medicinal products in the EU. The Pharmacopoeia aims to harmonise specifications for medicinal products and to speed up the listing of specifications for newly emerging medicinal products.

The Pharmacopoeia contributes to the implementation of EU legislation on medicines, to the development of monographs (technical specifications on standards for medicinal products) and analytical testing methods. Interviewees report that the monographs are crucial for the assurance of high quality of medicinal products in the EU, to protect public health and animal welfare, whilst underpinning the competitiveness of EU companies.

The European Directorate for the Quality of Medicines and Healthcare (EDQM), a division of the Council of Europe, ensures the secretariat for the European Pharmacopoeia. The EDQM coordinates the network of national control laboratories that verify the composition of medicinal products, as required by the EU legislation, and develops common terminology for medicines. The pharmaceutical legislation makes a direct reference to the European Pharmacopoeia and the national control laboratories.

Regulation (EC) No 726/2004[245] provides for a centralised authorisation procedure for medicinal products carried out by the Commission, based on the scientific assessment made by EMA. **Transparency Directive 89/105/EC** aims to ensure the transparency of measures established by EU countries to control the pricing and reimbursement of medicinal products. It defines a series of procedural requirements designed to verify that national pricing and reimbursement decisions do not create obstacles to the pharmaceutical trade within the EU's Internal Market.[246] The Directive lies at the interface between EU responsibilities for the Internal Market and national competences in the area of Public Health in accordance with **Article 168(7) of the Treaty on the Functioning of the EU**. The Transparency Directive provisions do not affect MS policies on the setting of prices, except as far as necessary to achieve transparency.

Concerns regarding off label use of medicinal products were discussed in the European Parliament in 2013 (reference A7-0320/2013 /P7 TA(2013)0435 - 22/10/2013)) enabling the EC to take action to explore the issue further. This emerged due to concerns regarding patient safety. The EMA was called upon to draw up list of off label medicines being used in spite of alternatives, with a view to developing guidelines regarding off label medicinal product use based on evidence of need.

The Regulation on advanced therapies (Regulation (EC) No 1394/2007) was adopted in 2007 and effective from 30 December 2008 onwards. It provides a dedicated framework for medicinal products based on gene therapy, somatic cell therapy and tissue engineering.

[244] Council Decision 94/358/EC of 16 June 1994.

[245] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

[246] DG GROW Transparency Directive overview https://ec.europa.eu/growth/sectors/healthcare/competitiveness/products-pricing-reimbursement/transparency-directive_en

Medical devices

The core legal framework for medical devices[247] in the Single Market comprises three directives. **Directive 93/42/EEC[248]** on medical devices generally, **Directive 90/385/EEC[249]** on Active Implantable Medical Devices (AIMD)[250]; and **Directive 98/79/EC[251]** on In Vitro Diagnostic Medical Devices (IVDMA)[252]. These directives aim to ensure universally high safety standards for the design and manufacture of medical devices, the smooth operation of the single market, and the efficacy of medical devices used in the EU. Medical devices must comply with strict health and safety requirements set out in the legislation and are given a certificate enabling the device to be used throughout the EU.

Cross-border healthcare

Directive 2011/24/EU[253] on cross-border healthcare is intended to support patient access to healthcare in another EU country and promote cooperation between Member State health systems. New national contact points for cross-border healthcare were established to facilitate access by providing patients with reliable information on healthcare quality, patient safety and reimbursement advice. This is intended to help patients make informed choices before going abroad to access healthcare.

8.2.3. Fit with the Health Programme

The inclusion of a priority with a legislative focus is not unique to Objective 3; the other three 3HP Objectives also contain thematic priorities that aim to support the implementation of EU legislation designed to optimise both the free movement of goods and public health protection. The implementation of legislation can vary across EU MS due to differences in resourcing, such as disparities in fiscal funding and human resources/expertise, and divergence in practice. Priority 3.6 was introduced to ensure the effective implementation, monitoring and review of EU legislation despite the differences.

Priority 3.6 was also defined to support the development of EU legislation in emerging areas, to understand what (if any) new legislation, or amendments to existing legislation, are required.

Set in the wider context, this priority aligns with a number of recommendations set out in WHO's 'ten leading sources of inefficiency of health systems' and the OECD's

[247] Medical devices include: appliances, including the necessary software, to diagnose, prevent, monitor, treat or alleviate disease or injury, to diagnose, monitor, treat, alleviate or compensate an injury or handicap, to investigate, replace or modify the human body or a physiological process, as a contraceptive. Active medical devices: medical device relying on electrical energy or power source other than that directly generated by the human body or gravity.

[248] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

[249] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.

[250] Active implantable medical devices (AIMD): active medical device intended to be totally or partially introduced, surgically or medically, into the human body.

[251] Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

[252] In vitro diagnostic medical devices (IVDMA): medical devices, such as reagents, calibrators, control material test tubes, to perform a diagnostic test, like checking blood for signs of infections or urine for the presence of glucose, using material from the human body.

[253] Council Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

recommendations for health system reform. These are reflected in the EC's Investing in Health (2013) and provide a framework for EU action in health to support the achievement of the EU's 2020 Vision for Growth. The recommendations most relevant to priority 3.6 are: helping MS improve the efficiency of health systems; encouraging more cost-effective provision; promoting the use of cheaper generic medicines; pharmaceuticals pricing transparency and improving the assessment of the effectiveness and cost-effectiveness of medicines in general; reducing inequalities in health between countries; and improving cost-efficiency through innovation such as new technologies.

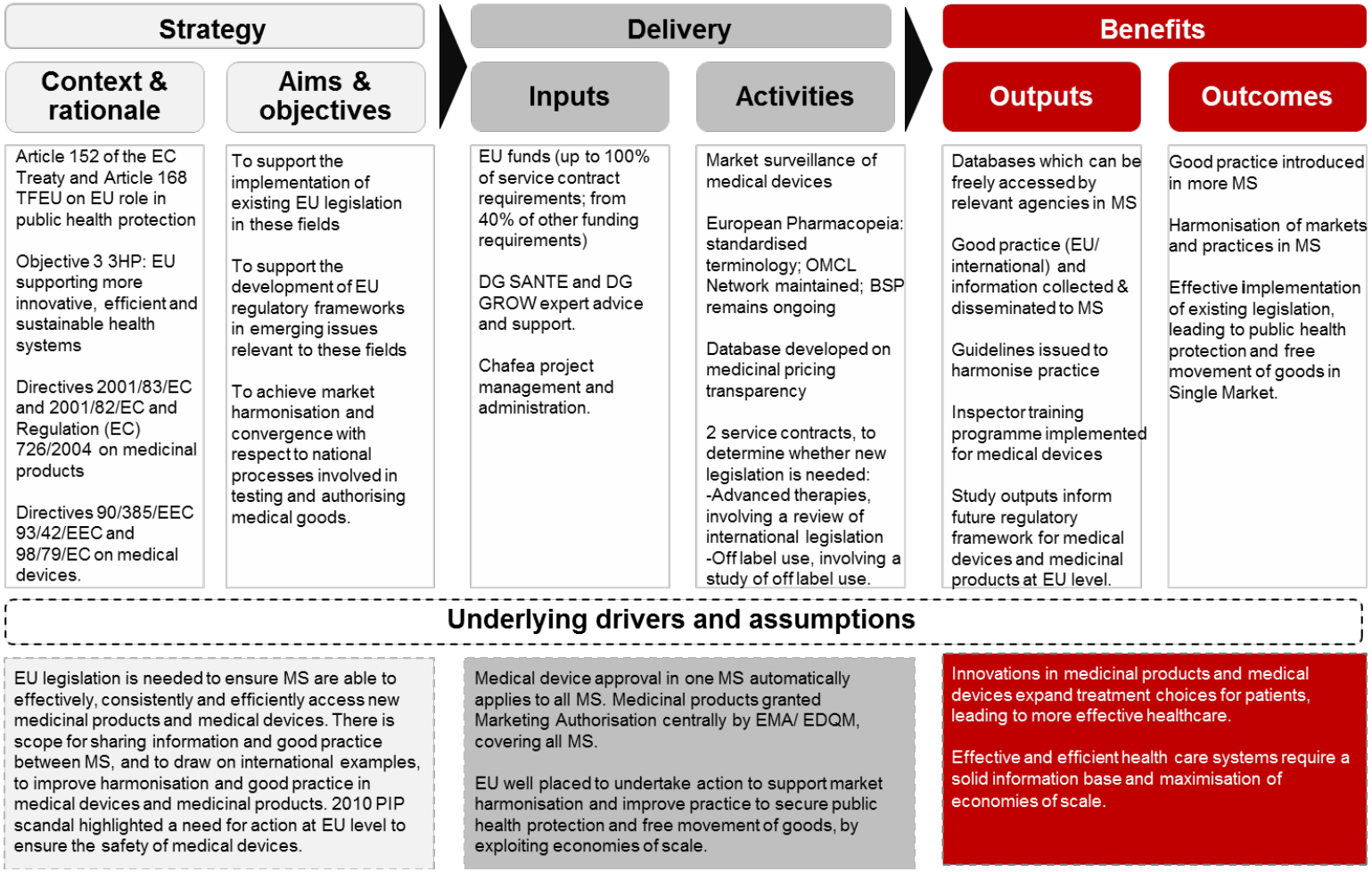
Priority 3.6 directly supports one of the three core strategic Objectives expressed in the EC's White Paper 'Together for Health' (2007), which complements national health policies in line with Article 168 of TEU. Priority 3.6 promotes supporting dynamic health systems and new technologies[254].

8.3. Theory and practice

This section presents and assesses the **thematic priority's intervention logic.** It starts with a diagram that depicts the theory underpinning the thematic priority. This is followed by sub-section on each of the intervention logic's main parts (strategy; delivery; and benefits). These sub-sections first describe and examine the how HP action under the thematic priority is intended to work in theory. We then analyse what is happening in practice by examining the objectives, activities, outputs, and (early) outcomes of the five actions selected for the case study. This allows us to test the intervention logic's plausibility and determine whether the desired outputs and outcomes of the thematic priority are likely to be achieved through the type of actions that have been funded to date. For a more detailed explanation of the methodology / components, please refer to the **introduction**.

[254] The other two Objectives are: fostering good health in an ageing Europe; protecting citizens from health threats

Figure 6 : Intervention logic for thematic priority 3.6 (Implementing EU legislation in field of medical devices, medicinal products and cross-border healthcare)



Source: created by evaluation team based on case study fieldwork (documentation review and interviews)

8.3.1. Strategy

Rationale for HP action in the thematic priority

The rationale for 3HP action under priority 3.6 is considered in this section. None of the sample of actions focuses on the relatively recently introduced cross-border health care legislation. Within the case study scope it was not possible to assess legislation implementation at Member State level.

Widespread reform is required to increase the efficiency and sustainability of national health systems, to enable them to cope with the challenges outlined above. The effective implementation of EU legislation is relevant here, as the legislative framework for medicinal products and medical devices encourages harmonisation of these markets in terms of quality, safety and efficacy. This offers the potential to increase efficiency, by exploiting economies of scale from working at an EU level. Improved cost-effectiveness for national health systems (arising, for example, from a centralised marketing authorisation process for drug licensing), is expected to enhance health system sustainability.

Stakeholders agreed that there is **room for better cooperation across MS** in the field of medical devices and medicinal products; problems in one Member State are likely to occur in others.

The legislation governing the development and marketing of medicinal products and medical devices applies at EU level, and therefore, according to EC officials, action to improve how these markets operate must be at the EU level. Despite a high level of legislative harmonisation, it would appear that the implementation of certain aspects of legislation is sub-optimal. For instance, stakeholders report that transparency of pricing information between MS, a requirement of Directive 89/105/EEC[255], needs to be improved. This is increasingly important in light of rising pharmaceutical prices and the financial pressures on health systems.

Now we look in more detail at medicinal products, medical devices and cross-border healthcare in turn.

Medicinal products (legal basis: Directives 2001/83/EC, Regulation 726/2004, Regulation 1394/2007)

The EU legal framework for medicinal products for human use is intended to ensure a high level of public health protection and to promote the functioning of the internal market, with measures to encourage innovation. The placing on the market of medicinal products is subject to the granting of a marketing authorisation by the competent authorities or the EC, and a large body of EU legislation has developed around this principle. To facilitate the interpretation of the legislation and its uniform application, various regulatory and scientific guidelines have been adopted.

The EMA delivers scientific opinions for products authorised by the EC, commonly known as the centralised marketing authorisation procedure for medicinal products. This procedure is compulsory for some groups of medicinal products. For products not eligible for the centralised procedure, the pharmaceutical

[255] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems

companies can apply for marketing authorisation in any Member State, using the **mutual recognition procedure** for recognition in some or all MS.

Actions at the EU level to ensure the effective implementation of the quality aspects of legislation are a core priority and applicable for all medicinal products independent of the marketing authorisation procedures. The European Pharmacopoeia exists to provide recognised common quality standards for medicinal products and their components, supporting implementation of the legislation on medicinal products for a number of years. Action to develop and update the Pharmacopeia is essential; without it new types of medicines would not receive the European Pharmacopoeia badge of quality, and the placing on the market of new medicinal products in all MS would be compromised.

Actions to develop the regulatory framework of new and emerging areas of medicinal products are also important under this priority. The field of **advanced therapies**, controlled by Regulation (EC) No 1394/2007[256], is a logical area for EU action, since the technology and potential users are similar in different MS. In this field the priority at present is to **evaluate whether the regulatory framework is fit for purpose in light of the fast-changing nature of this emerging industry**. Only the EU can act; individual MS cannot enact change.

The link between **medicinal product pricing** and legislation focuses on the need for transparency in pricing and reimbursement. It is intended to avoid obstacles being created at Member State level to the pharmaceutical trade within the EU's Internal Market. The EURIPID action aligns well with the aims of priority 3.6: greater cooperation between MS and sharing standardised information about pricing will provide national authorities with better information about pharmaceutical costs, to improve decision making. This type of activity is best delivered at the EU level and will help MS to achieve better value for money from their health budgets.

Some MS have taken legislative measures to try to tackle the **off label use** of medicinal products, with no overview at EU level. Developing a full understanding within the 3HP is intended to inform decision making regarding any legislative developments at EU level.

Medical devices (legal basis: Directives 90/385/EEC 93/42/EEC & 98/79/EC)

The requirements for marketing medical devices in the EU vary according to risk; manufacturers can declare that *low risk* devices meet the requirements, whereas *higher risk* devices require the involvement of an independent notified body designated by a Member State during design and manufacture. MS are obliged to manage the approval of devices and enforcement of EU legislation at the national level**. A medical device that receives marketing authorisation in one Member State receives a CE marking allowing the product to be marketed in all other EU countries.** Therefore, it is in the interests of all MS to ensure that approval and market surveillance activities guarantee the quality and safety of medical devices.

The PIP scandal in 2010, which exposed the illegal manufacture of non-medical grade silicone gel breast implants, highlighted problems with enforcement and market surveillance. According to an interviewee, inequalities in the resourcing of health systems mean that some MS (particularly new joiners to the EU) struggle to address the challenges on their own, and can benefit from support to implement EU legislation. In response to the PIP scandal (and faulty hip replacements), the EC proposed action to strengthen the safety, efficacy and market surveillance of medical devices. They have

[256] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

established two Joint Actions involving a large number of MS in developing joint solutions, to potentially harmonise and improve the market surveillance of medical devices.

Cross-border healthcare (legal basis: Directive 2011/24/EU)

Directive 2011/24/EU[257] on Patients' Rights in Cross-Border Healthcare, which obliges MS to ensure transparency around quality and safety standards, was introduced as a result of European Court of Justice rulings on patients' rights to travel abroad for operations. Historically, cross-border healthcare has been limited in the EU, and is mainly taken up by EU citizens who fall ill while on holiday or studying abroad. There are barriers to accessing planned healthcare in another Member State[258]. The legislation establishes basic principles and it is for MS to interpret and implement the principles in national legislation. The legislation clarifies issues such as the responsibility for the quality and safety of healthcare being provided to EU citizens; responsibilities for continuity of care; access rights to medical records; prohibition of exploitative prices for other EU citizens; and rights to restrict healthcare for EU citizens travelling from abroad for care when necessary to protect domestic provision of healthcare. Given the complex and politically sensitive nature of facilitating what the media term 'health tourism', it is perhaps not surprising that little progress has been made in implementing the legislation. Action to investigate the issues facing health systems in facilitating cross-border healthcare will be best achieved at EU level.

Strategic fit of funded action(s)

The aim of priority 3.6 is **the implementation of EU legislation in the field of medical devices, medicinal products and cross-border health care**. Based on the five funded actions under review we are able to explore how far the theory outlined above is being put into practice. The actions appear so far to align well with the underpinning rationale; they tackle the key challenges and need for action, albeit in different ways and to varying degrees. There are five actions sampled under this priority:

- Action 3.6.1: European Pharmacopeia: This Direct Grant Agreement follows a long established cooperation between the EU and Council of Europe to support the European Directorate for the Quality of Medicines (EDQM), responsible for the secretariat of the Pharmacopeia. Medicinal products are continuously being developed, with a corresponding need to ensure quality. The 3HP funding covers 41% of the total costs of the EDQM, allocated on an annual basis. The remaining funding is provided by the Council of Europe. Grant funding is intended to ensure:
    - Harmonisation of quality standards vested in the EU pharmaceutical legislation
    - Facilitation of the placing on the market of medicines in all the MS
    - Availability of medicines for the whole European population.
- Action 3.6.2 'Statistical Data and Guidance Document for medicinal product pricing and for the use of ERP (EURIPID)' is funded on a Project basis. This action involves voluntary and non-profit cooperation between European countries to

[257] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare

[258] Source: World Health Organization (2014) Cross-border health care in Europe, Policy summary 14, Katharine Footman, Cécile Knai, Rita Baeten, Ketevan Glonti, Martin McKee. World Health Organization 2014 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies)

develop a database on official prices of publicly reimbursed medicinal products that are published by national authorities. This aligns with the Transparency Directive 89\105\EC. Without this round of EU funding, stakeholders report that improvements to the database and the development of guidance would not be possible. Most MS are involved in EURIPID (with the exception of Germany, Malta, Luxemburg and Romania). The work builds on previous HP funding to develop the EURIPID database.

- Action 3.6.5: Market Surveillance of Medical Devices. This Joint Action is delivered by ten National Competent Authorities representing more than 50% of the EU-population. This aims to harmonise approaches to the surveillance of medical devices across the EU, with greater sharing of information and intelligence.

The other two actions in the sample are Service Contracts, and are slightly different in their nature and underpinning theory for action. Rather than seek to contribute to (more) effective implementation of legislation, they aim to explore the case for revision or extension of EU legislation in specific areas:

- Action 3.6.3: Study on the regulation of Advanced Therapies: This Service Contract is designed to compile comprehensive information about the advanced therapies (biomedical based treatments) already available to patients and in development phase in the US, Canada, Japan and South Korea, as well as the relevant regulatory frameworks in these jurisdictions. The outcome of this study will feed into a reflection process on the EU legislation on advanced therapies, with a view to ensuring that the EU legislation is adequately adapted to the needs of this emerging sector.
- Action 3.6.4: Study on Off Label Use of Medicinal Products in the EU: This Service Contract is intended to gather information and provide for a factual analysis. The intentional use of authorised medicinal products outside the terms of its marketing authorisation and therefore not in accordance with the Summary Product Characteristics (e.g. doses, indications, age groups) is unregulated by the EU legislation on medicinal products. Such use, commonly called “off-label use”, remains in most MS the responsibility of prescribing physicians. The EC is fielding a growing number of queries from stakeholders and the European Parliament related to off-label use. The study intends to cover the public health aspects related to the off-label use of medicinal products, and in particular the balance of risks and benefits for patients, and the regulatory framework for the off-label use of medicines. The conclusions will be considered by the EC and discussed with MS as to whether there is need for coordination at the EU level and, if so, the nature and scope of such coordination.

Actions fall into two categories. The first category is intended to **support the implementation of existing EU legislation**, where Member State implementation is sub-optimal or inconsistent. The second category, into which the two Service Contract actions fall, is designed to capture information with a view to exploring the need for, and **potentially informing, EU legislative development**.

One of the main aims of Objective 3 is to **address shortages of resources, both human and financial**. Some of the actions appear more closely aligned to this aim than others. For example, action 3.6.2 is designed to pool pricing information regarding medicinal products. This action can be seen as indirectly addressing shortages in resources, by offering the potential for MS to secure cost effective prices for medicinal products. In addition, action 3.6.5 is designed to achieve efficiencies and harmonise practices with regards to the market surveillance of medical devices, which aligns with the aim of addressing shortages in both human and financial resources at Member State level.

Chafea, DG SANTE and DG GROW officials found the **explanations of EU added value** in the action proposals to be clear and well targeted. All actions were perceived to be adding value to the existing knowledge and activity base at EU level, with EU wide action seen to be the most appropriate approach.

8.3.2. Delivery

Planned activities and overall implementation so far

Under this thematic priority, 14 actions were funded and managed by Chafea between 2014 and 2016. In addition to the five actions examined in this case study, there was, for example a Direct Grant for the European Pharmacopoeia (EDQM) for its 2016 Activity Programme, and Service Contracts that dealt with:

- Health-related constraints to raising Retirement Ages in the EU
- A probabilistic Markov Model of age-related disability rates for selected disease causes and related impacts on public payer cash benefit expenditure
- Study on enhanced cross-country coordination in the area of pharmaceutical product pricing.

Funding to thematic priority 3.6 for 2014 – 2016 for actions managed by Chafea totals nearly €6 million. The total allocation for actions managed by DG SANTE for 2014 - 2016 totals €6 million, giving a combined total of €12 million funding for priority 3.6 for 2014 - 2016 actions.

As illustrated in the intervention logic, there a number of key activities which this thematic priority is expected to implement. These are depicted in the table below.

Actions should deliver activities which contribute to the specific objective of innovative, efficient and sustainable health systems. Specifically, under priority 3.6, the 3HP intended to fund actions that help to support the *implementation of EU legislation in the field of medical devices, medicinal products and cross-border health care*. Therefore, funded actions should cover activities aimed at ensuring the implementation, application, monitoring and review of such legislation.

Table 22: Main expected activities under thematic priority 3.6 and implementation so far

Main expected activities	Implementation so far
Action to implement the European Pharmacopeia: The activities fall under 3 headlines: a) Biological Standardisation Programme Development of Reference Standards for all groups of biological medicines. Replacement of expired or "out of stock" Biological Reference Standards for the quality control of biological medicines. Studies in relation to the 3Rs (Reduce, Refine and Replace) concept to animal testing in routine controls of biological medicines, in line with the EU legislation regarding the protection of animals used for experimental and other scientific purposes. b) Official Medicines Control Laboratories (OMCL) Network Coordination of a specific OMCL network capable to detect falsified medicines. Development and maintenance of databases for exchange of information, data and results within the Network. Quality Management Systems for OMCLs. Annual meeting and thematic meetings. c) Terminology Development of Standard Terms and a database. Participation in the development of the Identifier for Medicinal Products (IDMP).	BSP: Activity underway as planned The EQDM has published guidelines, standard terms, methods and reference standards. Work has progressed to reduce animal testing for certain medicinal products. OMCL Network: Activity underway on market surveillance programmes as planned. Terminology project: Action underway, a database of standard terms has been developed, with over 25 language translations provided. Terms are continuously updated and revised. Cooperation is in place to support the use of consistent terms internationally.
Study: Pricing of medical products across MS (EURIPID)	Action underway to gather evidence regarding the pricing of medicinal products across MS. Implementation has progressed as planned. The work originally commenced in 2010, with the 3HP funding expansion of the platform and guidelines for ERP. Building the website is the next activity planned.
Study: Off label use of medicinal products	Study underway to collect information and provide for an analysis of the collected information. Implementation has progressed and is expected to be finalised by February 2017.
Study: Advanced Therapies: learning from international legislation	The study into the use of advanced therapies is completed; a report of the findings has been produced.
Joint Action to develop training and share good practice for inspectors undertaking Medical Device Market Surveillance	The action is progressing as planned. Some MS have been core funded partners involved in implementation; others have played a less active role in implementation. The joint action is also developing E-learning for clinical processes and data.

There are certain mechanisms and success factors that must be in place to effectively meet the overarching priorities. Firstly, a strong evidence base must be established, coupled with ongoing monitoring, to underpin effective policy making.

All actions except the (completed) study into advanced therapies have required effective communication channels across MS, to share information, intelligence and good practice.

In order for the activities to achieve the desired results in an effective and efficient way, they must also take into account the wider context and policy environment, especially given the need for the 3HP to complement the actions of MS, other nations, and organisations developing medicinal products and medical devices. By understanding the surrounding context, the implementation partners will be in a better position to collaborate with others; this will be key to ensuring that the actions form a cohesive programme that addresses the thematic priority.

Lessons learned from specific actions so far

With the exception of the study into advanced therapies, actions are still being implemented, and results are therefore limited. However, there are some key lessons that we can draw from stakeholders' experiences to date. We consider action-specific learning first, followed by more generic learning points.

Action 3.6.1: Undertaking annual reviews of priority and focus for the BSP is seen as a critical success factor, ensuring continued relevance. The strong foundation of past work between the EC and EDQM is seen as critical, with a framework for activities and a good understanding of expected outcomes.

In regards to the OMCL, there are certain restrictions placed on Member State laboratories, which has made delivery more complicated than anticipated. Under the terminology work stream, a key challenge has emerged in terms of getting terminology and definitions agreed by all MS. Further challenges have emerged regarding the need to apply for annual funding, despite the deliverables taking longer than one year to realise. This has resulted in milestones being developed and additional monitoring being undertaken without obvious alignment to deliverables. It is difficult for EQDM to provide evidence that the whole action will run effectively and deliver its intended outcomes, if delivery and benefits realisation fall outside of the funding timeframe.

Whilst some good progress has been made in terms of reducing experiments involving animals, this has proved challenging; the EQDM has a European focus, but pharmaceutical companies operate on a global scale, and "for industry it is a problem if the rest of the world still requires animal experiments" (Stakeholder consultee). The EQDM has engaged in discussions with the WHO and governments and laboratories, particularly in Japan and the US, to try to ensure consistency.

Action 3.6.2: The project provides the platform for sharing pricing information to support national level decision-making. However, stakeholders report that other activities undermine its aim, such as parallel trade (confidential agreements between national authorities and pharmaceutical companies). Whilst the platform for sharing pricing information is reportedly easy to use, users need to be able to speak English to interpret the information, despite the common pharmaceutical phrasing. Stakeholders anticipate challenges in developing the guidance for the ERP, in terms of achieving consensus on the content, terminology and how guidelines are formulated, due to conflicting interests between MS.

Action 3.6.3: The study benefitted from detailed terms of reference, ensuring focus on key areas of importance. However, stakeholders highlighted the rapidly evolving field of gene therapy, sitting at the interface between medicinal product legislation and genetically modified organism legislation. This can result in competent authorities not always being fully informed about governing legislation.

Action 3.6.4: The study remains ongoing. Access to specialist lawyers and physicians to provide advice and analysis was not easy to secure.

In response to the two Service Contracts, few tenders were received, with each invitation to tender only resulting in one response being received. Submissions were fully evaluated and quality assured, and would not have been accepted if not deemed to meet the stated requirements, but this lack of competition in responses was disappointing for Chafea officers.

Action 3.6.5: Having access to the necessary secretarial support is a key enabler for the multi-partner Joint Action. The secretariat is hosted by the Health Research Authority, with full-time support. There are 'premium partners'; with Irish and Dutch partners having the main responsibilities for taking work forward. This highlights the importance of resourcing at strategic and operational levels, and clarity of responsibilities when implementing actions across different MS.

Getting a representative but manageable consortium together has proved to be a challenge when seeking to involve so many MS. There is an inherent conflict between seeking to limit the number of potential partners whilst maximising Member State involvement. Offering varying roles to MS, depending on their appetite to engage and resource base, is seen as a key enabler. Under 3.6.5, wider partners are able to engage, some benefitting from financial support and others not receiving support but playing a less active role in implementation.

An issue for the partners is that there is a lot of administrative work required in the Joint Action. It is perceived that some MS may have chosen to be non-financial partners partly due of the paper-work burden associated with securing funding. Linked to this, the Joint Action has only just launched (October 2016), following a protracted grant agreement sign off process.

DG SANTE interviewees highlighted the importance of ensuring that Member State leads are aware of the actions and how to access outputs. Coordinating networks are in place to disseminate insights from action 3.6.5 across MS. Joint Action requires as many MS to be involved as possible (depending on applicability of the topic to each Member State), and the objectives need to be SMART and translated into quality deliverables that will have the desired impact. It is seen as vital under this priority that the EC informs target groups that the EU is funding this Joint Action.

In terms of more general learning emerging, the move towards more Direct Grant funded projects and Joint Actions is seen as a critical enabler for this 3HP in this field. This enables the most relevant organisations to be actively involved. Projects and Service Contracts are typically more exploratory in nature, testing out new ideas that may or may not prove effective or require EU legislation. Actions 3.6.2, 3.6.3 and 3.6.4 are more speculative and exploratory, focusing on peripheral areas of the legislation and possible future developments, and so lend themselves to Project or Service Contract arrangements (i.e. studies delivered by a single contractor). The actions in the sample illustrate how the action types and funding instruments of the 3HP can be used to tackle different information needs.

However, some general challenges emerging relate to a lack of staff resources to engage in the actions, compounded by the financial crisis. Delivering the actions requires initial human resource investment, despite the longer-term aim to realise human and financial resource efficiencies. Sustaining engagement for the duration of the funding period has not always proved possible. There have been challenges in fully engaging smaller MS alongside larger, better-resourced nations. However, this has been mitigated by the design of actions to ensure that it is not necessary for all potential beneficiary MS to engage equally in implementing each action.

In addition, **some policy leads highlighted Brexit and its potential implications** as a key risk moving forward, with the continuing uncertainty presenting a 'dark cloud

on the horizon' overshadowing delivery and progress. However, others reported 'business as usual' to date.

Despite the challenges outlined above, Chafea, DG SANTE and DG GROW officers highlighted that with clear objectives and a good description of technical aspects, few unexpected problems are arising, and the challenges are typical of any cross-border programme involving action over several years.

8.3.3. Benefits

Expected immediate, medium- and long-term benefits

Actions under this priority are expected to deliver a series of outcomes, although the exact benefits expected vary across different actions, as might be expected given their different activities and focus.

Medium term and interim outcomes

The medium term outcomes can be categorised as:

1. Ensuring correct and/or effective implementation and application of existing legislation, by individual MS and across the EU as a whole

2. Ensuring that the EU legislative framework remains fit for purpose, is informed by high quality information and reflects the needs and priorities of MS and the EC as a whole.

In order to realise these intermediate term outcomes, a range of short to medium term benefits and interim outcomes must be realised. These can be summarised as:

1. Accurate and up to date scientific/technical knowledge, information and tools, to support effective application and interpretation of existing legislation

2. Information and knowledge of practical implementation of the legislation, including the identification and dissemination of good practice across MS

3. Information and evidence on relevant current and likely future developments and trends, to inform potential future legislative development.

Longer-term outcomes

Ultimately, the expected outcome is a regulatory environment that facilitates the adoption of innovative, cost-effective, sustainable solutions across all EU MS. By contributing to such a regulatory environment, the actions are intended to lead to improved public health protection across all MS, and more efficient and effective health systems. When longer term expected outcomes are considered, these can be summarised as:

- Harmonisation of quality standards in the EU medicinal product and medical device legislation
- Safe, regulated access to medicinal products, medical devices and advanced therapies
- Reduced administrative burden and effective and efficient use of human and financial resources in the implementation of EU legislation in the field of medical devices and medicinal products

- Promotion of innovation by streamlining processes across the whole of the EU
- Reduction of animal testing for medicinal products
- More effective and efficient access to the market for innovative medicinal products and advanced therapies, and earlier availability of effective treatments
- Understanding of legislative frameworks in place both within MS and in other parts of the world, to inform potential future EU legislative decision making.

(Potential) benefits in practice

At this stage of implementation, few of these benefits are evident. Stakeholders are optimistic about the potential of the actions to realise the anticipated benefits, but recognise that it remains 'early days' in implementation. Below we assess the plausibility and likelihood of these achievements in the future, and if any barriers are likely to prevent the actions from achieving the desired results and impacts.

The EU added value is clearly defined in documentation underpinning the sample of actions. Stakeholders from Chafea, DG SANTE and DG GROW are confident that actions undertaken at EU level under this thematic priority are adding value. The specific added value relates to best practice exchange between MS in what has previously been a disparate area of focus, with lack of consistency and harmonisation of approach across the EU; and the formation of collaborative networks for knowledge sharing and mutual learning, for the benefit of all MS.

In addition, action under priority 3.6 offers potential to address issues related to the EU internal market for medicinal products and medical devices, offering the potential for benchmarking to facilitate informed decision making, both at EU level and by MS. This offers the potential for improved efficiency and effectiveness of Member State health systems, whilst generating economies of scale through adopting EU-wide approaches to the generation and distribution of information and guidance.

However, despite these identified expected benefits, about which programme stakeholders consulted were broadly in agreement, some of the impacts will be difficult to measure. The action milestones are seen to be important indicators to measure success, with a perception from DG SANTE that it is very clear at interim report stage whether or not a particular action is progressing as expected. However, the potential *impact* will emerge much later and will be difficult to measure.

Action 3.6.1: This action involves the ongoing development of the European Pharmacopeia, which does not sit neatly within a fixed timeframe. This is an ongoing requirement, reflecting the continuous evolution and development of new medicinal and pharmaceutical products. The action is expected to lead to high quality medicines in particular biologicals and reduced animal testing. Some progress has already occurred, with non-animal based testing being implemented for specific medicinal products.

Action 3.6.2: This action is expected to increase transparency of prices paid for medicinal products.

Action 3.6.3: The study has been completed and published online, disseminated through the EMA. Stakeholders report that the findings reveal that the EU legislative framework is comparable to the other four jurisdictions researched. There is international recognition that the field of advanced therapies is complex and requires exploration on a case-by-case basis. The findings are reported to have already informed the decision not to review the advanced therapy medicinal products (ATMP) legislation, but to focus instead on implementation of existing legislation, to create more favourable conditions as far as possible for the introduction of advanced therapies across the EU. An action

plan is being devised for AMTPs, building on the possibilities offered by the current regulatory framework.

Action 3.6.4: The study is in the process of being finalised. This has been delayed (Work Programme 2). The study is not currently expected to generate recommendations for EU action; instead, it is expected to provide factual analysis and options appraisal.

3.6.5: This action is expected to lead to more effective joint working across MS. To evidence this outcome, the action coordinator plans to send a satisfaction survey to competent authorities towards the end of the project. Activity also involves liaison and engagement with Iceland and Liechtenstein, and agreements are in place with Turkey and Switzerland to involve them in elements of activity. The guidance will be available for all participating countries and MS. Correspondingly, the benefits are expected to be felt more widely than the 28 EU MS.

8.4. Conclusions

The following conclusions attempt to draw out key points from the evidence collected and analysed, with a focus on the relevance of the thematic priority, its potential to make a difference in practical terms and lessons that can be applied to the HP more broadly.

1. Relevance of the thematic priority, given:

- **Identified needs:** As it currently stands, there is not equitable and efficient access within all MS to effective medicinal products and medical devices, including advanced therapies. MS pay varying amounts for medicinal products, vary in their use of off label drugs, whilst there have been failings in the monitoring of medical devices. The priority addresses these issues by developing knowledge regarding practices both inside and outside of the EU, and supporting the implementation of good practice and legislation.
- **The HP's Objectives:** The thematic priority addresses the aims of Objective 3, to '*Identify and develop tools and mechanisms at Union level to address shortages of resources, both human and financial, and facilitate the voluntary up-take of innovation in public health intervention and prevention strategies*.' However, the actions vary in terms of the extent to which they focus on '*voluntary uptake'*: whilst the actions focused on medicinal pricing, off label use and advanced therapies are based on voluntary participation by the EU and/or MS, the actions focused on European Pharmacopeia and Market Surveillance of Medical Devices require compliance and engagement by all EU MS. Despite this disparity, the actions do appear to align well with the wider aims of this Objective.
- **EU objectives more broadly:** The actions are expected to contribute to EU Objectives such as decreasing inequality between and within MS by increasing citizens' equitable access to effective and innovative medicinal products and medical devices. The actions should provide new insights, with a view to informing potential legislative developments, and/or to focus on effective implementation of existing legislation. Citizens should receive equitable access to innovative, effective, safe medicinal products and medical devices regardless of location.

2. Likelihood of actions to make a difference in terms of:

- **Established problems:** In their design and output so far, the actions should address identified knowledge gaps and identified problems. The outputs of the

two exploratory studies will define more clearly the pricing disparities and off label use of medicinal products across MS, and good practice in legislation from elsewhere regarding advanced therapies. Whilst these actions are exploratory, the action focused on market surveillance of medical devices is focused on addressing an identified problem arising from the PIP scandal. This, and the action focused on ongoing implementation of the European Pharmacopeia, are addressing issues which require intervention at EU level.

- **The EU added value of the HP:** There is a clear rationale for the EU to act in a coordinating and/or knowledge generation capacity, given that this priority addresses fields where the EU has legislative powers. This provides significant EU added value because, with the exception of the European Pharmacopeia, this domain has had limited cooperation between MS previously. Beneficiaries have the potential to coordinate joint efforts and exchange best practices across MS; there is already strong Member State engagement and buy in to the actions. This priority is also expected to unlock the potential of innovation, for example in the fields of advanced therapies and medical devices.
- **Wider policy objectives / priorities**: There is some coherence between the actions and larger EU initiatives such as the Europe 2020 Strategy. There is significant potential for collaboration and promoting innovation in health by generating and connecting expertise. The EU has a clear role to play in coordinating action at the European level and helping to create relationships and trust between MS, whilst also providing clarity to medicinal product and medical device developers in the terms of the underpinning legislative framework. The work offers potential to meet transparency requirements, and to provide access that is more equitable across all MS.

3. What lessons can be learned in terms of:

- **Strategy**: It is important for the priority and individual actions to be logically linked and mutually supportive, at least within (but potentially across) the fields of legislation covered (medicinal products, medical devices and cross-border healthcare). Currently the linkages between actions are not clear, with no coherent ‘thread’ running through.
- **Delivery**: Implementation largely remains ongoing. However, key lessons have begun to emerge. The liaison between DG SANTE and Chafea is credited with leading to effective communication and strategic input to inform delivery. When sustainability is considered, it will depend on funding beyond planned work programmes. MS must buy into the new legislation and ways of working to realise the potential benefits.
- **Benefits (to the extent available):** As it stands, the goals of the actions are likely to be reached, despite some delays in implementation. The actions analysed are designed to better understand and/or address key health needs in this field, harmonising approaches across disparate MS. The EU added value is clearly articulated by key programme stakeholders, who see the potential EU impacts as high. The actions address issues which have proved difficult for many MS to tackle in isolation, particularly those with smaller populations and particularly stretched resources. Benefits have been clearly identified at the interim and longer term level, although it is not clear how achievement of the benefits will be evidenced and attributed back to the 3HP.

9. THEMATIC PRIORITY 4.1 – EUROPEAN REFERENCE NETWORKS

9.1. Introduction

This case study examines thematic priority 4.1 of the 3HP, on supporting "the establishment of European Reference Networks" (hereafter ERN). This priority falls under Objective 4 of the 3HP, which is to "Facilitate access to better and safer healthcare for Union citizens". Until the end of 2016, 36 actions have been funded under this objective amounting to total committed funding of €12.6 million. A sample of actions was selected based on consideration of their maturity, breadth of coverage of the mechanisms and a mix of different sized actions (see table below)[259].

Table 23: Actions reviewed for case study on European Reference Networks (thematic priority 4.1)

Funding mechanism	Lead organisation (incl. MS)	Other organisations (incl. MS)	Budget (EUR)	Start date / duration
Promoting implementation of recommendations on policy, information and data for rare diseases 2014				
Joint action	Institut national de la Santé et de la Recherche Médicale, France	33 associated partners[260]	Total budget – €8,344,080 HP grant: (60 % of eligible costs): €4,379,979	Start date – 01/06/2015 Duration – 36 months
Development of a manual and toolbox for the assessment of European reference networks				
Service contract	EURORDIS -Rare Diseases Europe (consortium lead), France	Accreditation Europe ASBL – Belgium (member) & European Hospital and Healthcare Federation (HOPE) – Belgium (member)	HP grant: €488,006	Start date – 21/12/2014 Duration – 15-16 months
Study on services to be provided by European reference networks				
Service contract	Pricewaterhouse Coopers (PwC) Portugal	N/A	HP grant: €172,660	Start date – 09/2015 End date – 31/10/2016 Duration – 14 months

Note: More information on the sampled action can be found on the Chafea database and in the AWPs available on DG SANTE's website

The methodology for the case studies is provided in detail in the **introduction** to this Annex. But entailed **two main steps**. First, we reconstructed the thematic priority's theory in the form of an intervention logic diagram. Then, to test the theory, we collected and analysed evidence about implementation so far, above all through an examination of five funded actions (as above). The different sources of information are summarised in the table below.

[259] Note that a selection of five actions per case study was not possible due to the inclusion of inappropriate actions in the original sample.

[260] IT; FR = 3 partners each; UK; DE; BE; NO; HU = 2 partners each; AT; BG, CZ; EE; ES; FI; HR; IE; LT; LV; NL; PL; PT; SE; SI; SK; RO = 1 partner each. CY; DK; IS = no partners.

Table 24: Documents consulted and interviews conducted for this case study on European Reference Networks (thematic priority 4.1)

Documents consulted	Stakeholders interviewed
• Desk review of project documentation including deliverables for both Service contracts and RD-Action Joint Action • Review of RD-Action website and publically available information • Review of summary evaluation reports of the proposals completed by evaluators • Thematic fiche	• A total of six interviews were conducted • Two DG SANTE policy officers • One Chafea project officer (responsible) for all actions • Lead implementation partners for each action

9.2. Policy context

9.2.1. Key health needs and priorities

One of Europe's health needs is to provide **access to high quality healthcare for all Union citizens**, where inequalities persist both within and between MS. Such inequalities are particularly true for patients suffering from **rare diseases (RDs),** which are defined as affecting fewer than 5 people in 10,000.[261] RDs affect large numbers of people (estimated at 27-36million in the EU) despite the low incidence of individual diseases, with most sufferers afflicted by the rarest of diseases.[262] It is estimated that between 6-8% of the EU's population will at some point in their lives suffer from an RD.

Despite the size of the problem, the health care systems of individual MS face numerous challenges in dealing with RDs effectively and efficiently on their own. Given how infrequently national healthcare practitioners in a MS encounter RD, there is a general lack of knowledge and expertise required to diagnose and treat RD patients. Due to the rare nature of their conditions, RD patients are at high risk of receiving poor quality healthcare: at the national level, patients often remain undiagnosed or misdiagnosed for long periods of time. Furthermore, even when a patient has been successfully diagnosed, their condition is often life-threatening and their treatment resource intensive, with national healthcare systems unable to provide this care.

Given the total number of RDs (estimated at 5,000 - 6,000 diseases described), issues with equitable access to high quality health care for RD patients are faced by all MS but more so by smaller EU MS, as they all struggle with a lack of expertise and scattered patients.

The EU has committed itself to provide all EU citizens with equitable access to high quality health care. In this regard, patients suffering from RD face particular vulnerabilities that stem from their condition and their equitable access to health care must be also considered a priority. It has also been stressed that common values and principles in EU health such as universality, access to good quality care, equity and solidarity are of paramount importance for patients with RD.[263]

On the MS level, RDs have a low prevalence and medical practitioners normally have limited experience and expertise with diagnosing and treating RD. Medical advancement

[261] http://ec.europa.eu/health/rare_diseases/policy/index_en.htm

[262] Occurring in one in 100,000 people or less. Council recommendation of 8 June 2009 on an action in the field of rare diseases.

[263] Ibid.

in the field of RD depend on funding for research, but given the small number of patients at the national level this cannot be justified nor is it clinically viable. The expertise required for diagnosis and treatment is therefore is often missing and MS have not been able to effectively address this issue. Examined at the EU level, however, the total number of RD and total number of patients suffering from RD becomes highly significant. The EU has recognised that RD pose a threat to the health of EU citizens[264].

9.2.2. Framework for and extent of EU engagement so far

Article 168 of the TFEU outlines the EU's role in improving health and preventing disease; the need for policy coordination amongst MS, and the European Commission's (EC) role in taking any useful action to promote such coordination. This forms the fundamental basis for EU action to address the issues mentioned above.

The Commissioner's objective in the field of rare diseases is to improve the chances for patients to get appropriate and timely diagnosis, information and care. To implement this key objective the EU has the following initiatives in place: Commission Communication (2008) on Rare diseases: Europe's challenges creating an integrated approach for the EU action in the field of rare diseases; Council Recommendation (2009) on a European action in the field of rare diseases recommending actions at national level; Commission Decision setting up the Commission expert group on rare diseases.

The Commission white paper, ***Together for Health: a strategic approach for the EU 2008-2013[265]*,** developed on the EU's strategy identifying RD as a priority for EU action. Importantly, **Directive 2011/24/EU[266] on the application of patients' rights in cross-border healthcare** provides the foundation mandate for the Commission to support MS in the creation of European Reference Networks (ERN) between healthcare providers (HCP) and centres of expertise. This Directive created the legal framework under which such networks will operate. Furthermore, the Commission's Delegated Decision 2014/286/EU[267] set out the criteria and conditions that ERNs and HCP wishing to join an ERN would have to fulfil, and implementing Decision 2014/287/EU[268] went further to set out the criteria for establishing and evaluating ERNs and their Members.

RD is an area in which the EC has been particularly active and supportive. **Rare diseases was one of the priorities of the EU's 6th Framework Programme for Research and Development and was also included in the 7th Framework Programme**. RD was also a topic addressed in the previous Health Programme. The EUCERD Joint Action (EJA) in the Second Health Programme (2HP) was established to support the EU Committee of Experts on Rare Diseases (EUCERD), the group responsible for overseeing implementation of EU priorities and actions related to RD.[269] This built on the previous Joint Action in the First Health Programme, which supported the Rare Disease Task Force (RDTF), the precursor to the EUCERD. Similarly to RD-Action, the Joint Action supported in the 3HP under priority 4.1, EJA aimed to enhance the visibility

[264] Ibid.

[265] Published 23 October 2007.

[266] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

[267] Commission Delegated Decision of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil.

[268] Commission Implementing Decision of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks.

[269] The EUCERD is mandated to assist the EC in formulating and implementing the Community's activities in the field of rare diseases, to foster exchange between MS and stakeholder as regards relevant experience, policies and practices.

and recognition of RD, to contribute to the development and dissemination of knowledge on RD and to contribute to improvements in access to quality services and care.

Although there has been engagement by the EU in the field of RD, the field itself is broad and the problems posed by patients are many. On the MS level these problems have not been solved, as MS lack both the capacity and the critical mass to act. **Existing action on the EU level in the field of ERN and Rare Diseases has made progress but there are still pressing issues which remain.**

9.2.3. Fit with the Health Programme

The EU has acknowledged support for **ERNs as the appropriate constellation to address RD.** As mentioned above in section 2.1, centres of expertise already exist in Europe, however they are not connected to each other and are not organised along thematic lines. Successive iterations of the HP have sought to link up such centres in order to offer patients in all MS the best care, to pool resources and ensure that knowledge is disseminated across borders.

In the 2HP, ERNs were included under Objective 3: to generate and disseminate health information and health knowledge. This objective had two goals: first, to exchange knowledge and best practice on health issues to support the coordination of ERNs and MS' public health policies and, second, to collect, analyse and disseminate health information focusing on health monitoring systems with appropriate indicators and ways of disseminating information to citizens.[270]

As mentioned above in section 2.2, "RD-ACTION" which was funded under in the 2HP sought to enhance the visibility and recognition of RD, contribute to the development and dissemination of knowledge on RD[271] and to contribute to improvements in access to quality services and care. Its work covered multiple points:

- promoting the implementation of plans and strategies for RD at national level;
- working to standardise the RD nomenclature at international level;
- mapping the provision of specialised social services and promote the integration of RD into mainstream social policies and services;
- mapping national initiatives to address the quality of care in the field of RD across the continuum of care;
- and integrating various RD initiatives across thematic areas and across MS.

Following from the work of the RD-ACTION and according to interviews, the establishment of the thematic priority in the 3HP followed a logical next step in the timeline of previous HP work in the areas of RD and ERNs. **The Cross Border Health Directive (Directive 2011/24/EU) specifically called for the creation of ERNs and thematic priority 4.1 represents bringing ERNs to life.** Including ERNs as a thematic priority under Objective 4 represents consolidation: taking a step forward in the timeline of action in the field of RD.

Under priority 4.1, the creation and operation of ERNs as networks of expertise in the domain of rare and complex diseases will help unlock the potential contained within already existing centres of expertise and lead to greater access for RD patients to high quality healthcare.

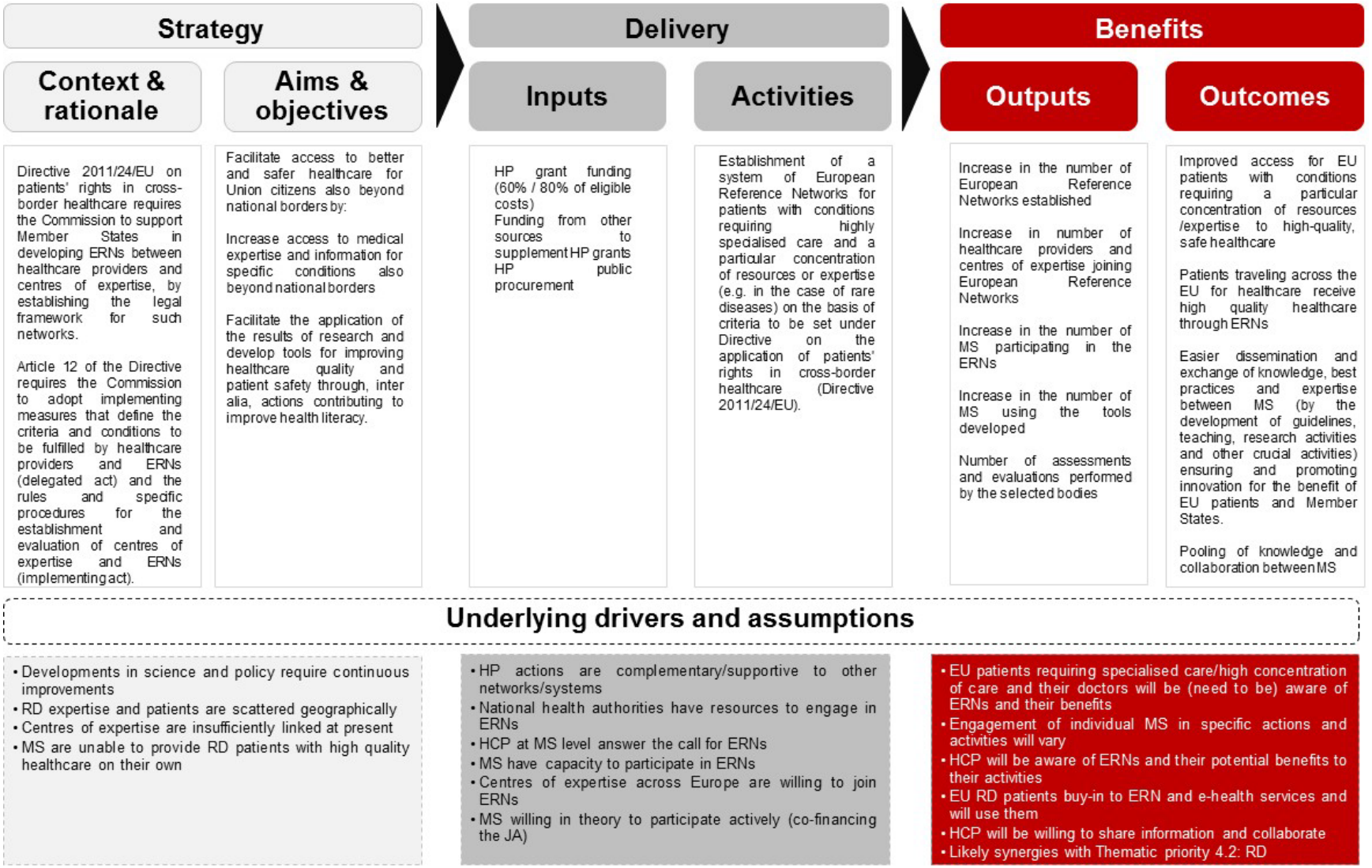
[270] Such as a Health Portal, conferences and regular reports on health status in the EU.

[271] From specialised research, through to the support of the healthcare professionals and the empowerment of patients.

9.3. Theory and practice

This section presents and assesses the **thematic priority's intervention logic.** It starts with a diagram that depicts the theory underpinning the thematic priority. This is followed by sub-section on each of the intervention logic's main parts (strategy; delivery; and benefits). These sub-sections first describe and examine the how HP action under the thematic priority is intended to work in theory. We then analyse what is happening in practice by examining the objectives, activities, outputs, and (early) outcomes of the five actions selected for the case study. This allows us to test the intervention logic's plausibility and determine whether the desired outputs and outcomes of the thematic priority are likely to be achieved through the type of actions that have been funded to date. For a more detailed explanation of the methodology / components, please refer to the **introduction**.

Figure 7 : Intervention logic for thematic priority 4.1 (European Reference Networks)



Source: created by evaluation team based on case study fieldwork (documentation review and interviews)

9.3.1. Strategy

Rationale for HP action in the thematic priority

The thematic priority covering ERNs is one of the more focused and specific thematic priorities of the EU's 3HP. This section examines the strategy of the thematic priority as it is defined in the 3HP. The rationale for EU-level action in this field along with its aims and objectives will also be examined and then compared to its implementation in practice in the next section.

The overall aim of Objective 4 is to facilitate access to better and safer healthcare for Union citizens, also beyond national borders. This should be achieved by:

- increasing access to medical expertise and information for specific conditions; &
- facilitating the application of the results of research and develop tools for improving healthcare quality and patient safety through actions contributing to improve health literacy.

With the aims of this objective in mind, the main rationale for creating ERNs is to improve the access of RD patients to high quality healthcare by pooling knowledge from multiple experts and centres of expertise in Europe.[272] **In its design, the development of ERNs is strongly related to equity in patient care**, which informs the overall work of the HP in general.

There is a clear rationale for addressing RD in the HP, as access to high quality healthcare for RD patients is a health issue affecting all RD patients across Europe which can best be addressed at the EU level. Indeed, MS vary greatly in their capacity to provide RD patients with the necessary healthcare they require. ERNs are expected to address such issues and be centres of expertise in RD where the latest developments in science can be disseminated and shared quickly among partners from all across the EU, as well as developed further. ERNs should increase patients' access to medical expertise and information. In the RD field especially, it is essential to remain up to date on key developments in science and policy.

EU level competences and acting to coordinate and support MS' activities has excellent potential to improve patients' conditions, to develop expertise and promote innovation in RD. **The nature of the problem and the high potential gains of coordinated EU action demonstrate a clear rationale to act on the EU level.**

Significant progress has been made by previous actions including a long history of action in the field of RD on the EU level and more recently with ERNs. Nevertheless, additional work remains to be done. Centres of expertise already exist in many MS with many recognised for their ability to perform a particularly complex procedure or treatment. However, such centres are spread across a large geographic area and vary in the expertise they offer. If MS pool their knowledge and resources (including experts) in RD as well as their patients, they would be better able to offer RD patients state-of-the-art care and achieve economies of scale. In addition, by bringing together knowledge, resources and patients from multiple countries across the EU, this could lead to innovation in developing new diagnostic tools and treatments for RD.

To conclude this section on theory, the overall rationale for creating ERNs is sound. The argument is strong for pooling knowledge and resources to achieve economies of scale

[272] Although ERNs are not thought of only for RD, in practice it is expected that most of their function will be in this area.

and efficiency gains for the greater benefit of patients. In theory, creating ERNs has strong potential to increase patients' equitable access to high quality healthcare.

Strategic fit of funded action(s)

Agreement among MS on Article 12 of the 2011 Cross Border Healthcare Directive (CBHD),[273] which described in detail the role that ERNs would be expected to play, illustrates that ERN's added-value is recognised by MS. This is especially noteworthy, as some of the other aspects of the Directive (e.g. how ERNs relate to RD and e-health more generally) were harder to reach agreement on.

Based on three funded actions examined as part of this case study, we were able to test how the strategy described above is being put into practice, using multiple funding instruments. The evidence suggests that the thematic priority led to appropriate and well-designed actions.

In their design, the three actions are closely linked logically and to the overarching priority of ERNs. There is coherence between their aims and their design attempts to contribute to the creation, implementation and operation of ERNs. The sequencing of the three actions is sound, in theory. The **Joint Action RD-Action**, for example, builds on the work of the previous Joint Action in the 2HP. It supports the adoption of a codification and knowledge management system for rare diseases, which will be necessary for ERNs to diagnose patients and share knowledge and expertise across the EU.

The **Study on the Manual and Toolbox for Assessing ERNs** will develop an assessment manual that will serve as an evaluation framework for ERNs. It is designed to coincide chronologically with applications received to the call for ERN status.[274] The study will develop a practical tool that will be used for the identification and assessment of the networks and HCP applying to become ERNs with the outputs of this study designed to be used to assess applicant ERNs in the fall of 2016.

The only cause for some concern is the timeline of the **Study on Services to be provided by ERNs** (which will support the implementation and functioning of the networks by identifying the possible sets of services that Network Members will provide alone as well as together in a network).[275] Although highly logical in its design and fit with the expected activities of ERNs, the outcomes of the study will be used as a theoretic model to be tested only after the approval of the Networks.

On the whole, the design of the three actions reviewed for this case study very fit closely the rationale, aims and objectives of the priority. At this stage, ERNs do not yet exist, but it is clear to see how the actions that were examined for this case study should contribute to the creation and future work of ERNs.

9.3.2. Delivery

Planned activities and overall implementation so far

[273] DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients' rights in cross-border healthcare

[274] The call for interest to establish ERNs took place in March, 2016. The call for grants for ERN closed on July 22 2016. http://ec.europa.eu/health/ern/implementation/call/index_en.htm

[275] The Study will seek to conceptualize in concrete terms the services that ERNs will be expected to provide, aiming to catalogue and develop a typology and establish what are the characteristics and costs of services that can be provided by the ERNs and their Members.

The financial inputs of the HP are designed to lead to a series of actions that will contribute to establish European Reference Networks (ERN). In theory, the activities of these three actions should support this goal by clarifying and informing the functioning of ERNs with their outputs.

Following the creation of the legal framework for ERNs by Directive 2011/24/EU, the framework for evaluation and approval assessment bodies was created, as were MS boards for ERNs. RD stakeholders were reportedly very active in these discussions and experts issued their opinions on several issues (e.g. the grouping of RDs in ERNs and patient involvement).[276] This formed the legal basis for taking further steps to establish ERNs which thematic priority 4.1 is taking further to implement.

The table below shows the main expected activities undertaken in priority 4.1 from the 2014 call and their implementation thus far.

Table 25: Main expected activities under thematic priority 3.6 and implementation so far

Main expected activities	Implementation so far
Study: "Development of a manual and toolbox for the assessment of ERNs"	Study completed with final deliverable due in end 2015 / early 2016. Outputs have been used to inform call for interest to establish ERN and to evaluate these applications.
Study: "Services to be provided by ERNs"	In progress, final deliverable due November 2016. Useful for the future testing but unclear to what extents outputs were available in time to inform
Joint action for Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases: RD-Action	In progress across all six work packages. Work in progress until June 2018.
Call for interest to establish ERN	Call occurred in March 2016; applications are currently under assessment and successful ERNs to be announced in March 2017

Under priority 4.1 ERNs, the deliverables of the two studies commissioned will serve to inform both the scope of ERNs' practical day-to-day work and be used to assess candidate ERNs applying for ERN status.[277] The possible catalogue of services, and its costing model, that the bulk of ERNs will deliver, were the subject of the "Study on services to be provided by ERNs". Given that ERNs do not yet exist, it is highly relevant to design a study that practically clarifies ERNs' scope and the range of their activities. **Looking at the timeline, however, it is not entirely clear how the deliverables produced by this study will be used to inform the functioning of ERNs**. The call for applications for interest to establish ERNs took place in March 2016, whereas the study is due to be completed in October 2016. It is possible that deliverables of this study informed the call for applications, however, because the study was only designed to last a year, it seems the sequencing of the actions did not leave sufficient time to use the knowledge generated by this study for the call for ERNs.

RD-Action, the Joint Action under Promoting Implementation of Recommendations on Policy, Information and Data for Rare Diseases, is delivering progress on supporting ERNs' future work within its six work packages. The work packages build on the work of the previous Joint Action by contributing progress to implementing EC recommendations on policy and information as they pertain to the RD field. The main activities involve:

[276] Patient organisations have reportedly held a strong voice in these developments and have been actively involved in the both the current and previous JA, as well as the Expert Group on RD.

[277] The criteria on which these ERN are based have been set out under the Cross-border Healthcare Directive (Directive 2011/24/EU) and the Commission delegated decision (2014/286/EU) which specified the criteria and conditions that European Reference Networks and healthcare providers must fulfil in order to join these Networks.

- disseminating RD related information as well as seeking to improve the flow of information between national and European levels;
- creating a sustainability plan for cataloguing the activities of the JA to ensure that its outputs and knowledge are properly archived;
- improving and evolving the Orphanet database on RD into a sustainable European model which all MS could use;
- steering, maintaining and promoting the adoption of Orphacodes across MS[278]

At this early stage, the activities mentioned above show a coherent fit and are supporting what ERNs will do in their operations.

The study, "Development of a manual and toolbox for the assessment of ERNs", is designed to develop a manual for assessing future applications for the status of recognised ERNs. The lead partner in the consortia is a patients' rights organisation with a long history of working with the EC in the RD community. This study is close to completion and its outputs should be ready in time to be used to review and evaluate the applications answering the call for ERNs.

Lessons learned from specific action(s) so far

Analysing work undertaken in the two studies examined under thematic priority 4.1 can tell us about the progress made so far in reaching the goal of establishing ERNs, making them operational and any lessons learned so far.

At this point, the main lessons learned were that some **additional flexibility would be necessary for designing (and then carrying out) studies, such as the two undertaken under 4.1**. Since ERNs are not yet operational, procedures and rules of operation can only be surmised; they are still very theoretical and there is no history on which to base decisions. Considering also that compatibility with MS healthcare systems is crucial to the successful operation of ERNs, tailoring a European approach requires thorough engagement with MS in the development phase. Engaging with MS was found to be essential for completing both of the studies reviewed here. Although they were designed to be carried out in a more linear way, the large number of unknowns required extensive consultation at times with MS and flexibility in order for them to be able to deliver their contractual outputs. It was suggested that a learning component be included so that future adjustments can be made when ERNs inevitably deal with a more complicated reality in their early years of operation.

Following interviews with the beneficiaries of the three actions and a thorough desk review, one observation that can be made is that given the specific objective of the thematic priority, which is the creation of ERNs, the individual actions needed to be very **strongly supportive of this objective in their activities.** ERNs are an untried concept, which means clarity in the purpose of specific actions is necessary, however enough flexibility has to be built-in to enable learning and adaptation as they begin to operate.

Our review found **strong links exist between the objectives of the three individual actions and the objective of the thematic sub-priority.** The study that was commissioned to create the manual and toolbox to assess ERNs was very specifically described in the Terms of Reference so that the objectives of the study were clear. The end goal of the study was to use the outputs of the work to assess and evaluate applicant ERNs. This study has been completed and the resulting work is

[278] Based on the Recommendation of the Commission's Expert Group on Rare Diseases on ways to improve codification for RD in health information systems. It should enable countries to implement coding RD in a standardised and inter operable way in their national health systems.

currently being used to assess the ERNs that have answered the call for applications earlier this year. Feedback received on the quality of the assessment framework that was developed has been very positive. Although the study design needed to be somewhat adapted to the realities of designing such an assessment framework, more engagement with stakeholders (i.e. MS) meant that the results would ensure that a European assessment framework would tie into national assessment structures. The content of the operational level has been designed to tie into and build on some of the same themes as on the national level. The process of designing this framework had to be conducted as a continuous engagement process.

In sum, the three actions reviewed have been strongly linked to each other and to the goal of the thematic priority. As such, **there is strong complementarity between the actions and coherence with previous EU work in the field of RD.** However there is some concern that it is not always possible to sequence optimally, as demonstrated in one of the examined actions.

9.3.3. Benefits

Expected immediate, medium- and long-term benefits

HP funding leading to the creating of ERNs are expected to deliver a number of benefits over the medium and long-term. In the medium to longer term, **the creation and implementation of ERNs should provide EU citizens with greater access to high quality health care and information**. In terms of quality of life and greater access to high quality healthcare, ERNs should help RD patients, who often suffer from no diagnosis or even misdiagnosis to, first, be accurately diagnosed and, second, to then receive appropriate treatment from their health care providers. Patients suffering from rare or low prevalence complex diseases will be provided with high quality and highly specialised healthcare.

By pooling expertise and knowledge, **ERNs will maximise the speed and scale with which innovations in medical science and health technologies in the field of RD are developed and put into use**. Patients suffering from RD tend to be too few nationally to justify significant spending on research but by first diagnosing and then cataloguing patients, RD will become visible in national statistics and in turn justify allocating funding to research.

Also, economies of scale can be achieved by connecting existing reference networks found in individual MS, and **greater efficiency and coordination can be achieved by sharing resources and expertise across the EU**. The chief beneficiaries of these Networks will be patients and healthcare systems suffering from (or treating) rare and complex diseases. Because ERNs do not exist at present, it will not be possible to make judgements at this point.

As MS cooperate within ERNs to provide healthcare services, a **more long-term aim is that differences in the quality and outcomes of the healthcare found in individual MS will be reduced**. As knowledge and expertise will be shared between MS of varying geographic and economic size, it is expected that, over time, a more equitable, uniform level of high quality healthcare will emerge in all EU MS. This outcome is very far into the future and cannot be assessed in a meaningful way at this stage.

(Potential) benefits in practice

The outcomes and impacts outlined above and expected by stakeholders seem very plausible given the progress already made on the actions under review here. At this stage it is too early to measure any real changes on any of the outcome variables. However, based on early evidence and our data collection (desk review and interviews

with stakeholders) we can draw some insights about experiences with the actions undertaken so far and how they will impact on the development of ERNs.

- *Increase in the number of ERN established*: Examining the evidence viewed under this case study, it is very likely that **there will be an increase in the number of ERNs established**. At this stage, ERNs do not yet exist and are still being evaluated following the call for applications in March this year. However, this evaluation process is close to completion and the successful applicant ERNs will be named in March 2017. According to the interviewees consulted, the quality of the applications for ERN status were very high. Because of the number and high quality of applications received – 24 applications-, and the amount of funding available, estimates are that most of them will be eligible for funding.
- *Increased cooperation between centres of expertise:* According to interviewees who have seen the applications received for ERN status, there is strong evidence that **silos are being broken down** and parties who have historically never worked together have come together within an ERN. Parties who have previously 'lived' in competing domains and have typically competed for funding are now collaborating and the applications received showed a high level of maturity in this regard. What this indicates is that **pooling of expertise** and making previous competitors into colleagues **has excellent potential to build trust, encourage sharing and thereby unlock knowledge to support innovation**. Breaking the isolation of expertise and silos and creating dialogue between experts who would otherwise be unconnected or unaware of each other provides patients with better chances in their health outcomes. Sharing good and best practices should lead to better life expectancy for patients. In this regard, strong applications for ERN status have laid a solid foundation for implementation next year.
- *Increase in number of healthcare providers and centres of expertise joining ERN:* **Healthcare providers and centres of expertise are present as core members** in the applications received. Following the first call for interest to establish a European Reference Network (ERN) and the call for grants for ERN, which closed on July 22 2016, the Commission has received 24 applications; involving a total of 370 hospitals and nearly 1000 highly specialized units. . A more thorough analysis of the breakdown of types of centres and healthcare providers will be possible following the announcement of successful ERNs.
- *Increase in the number of MS participating in the ERNs:* **There was some concern that not all MS will be represented in ERNs but** according to the preliminary data, 26 MS (25 EU plus Norway) are participating in the Networks applications. Interviews have indicated that there is some amount of overrepresentation in ERNs by some of the bigger MS. Smaller MS tend to be underrepresented and could be at risk of missing out on some of the benefits in knowledge sharing and innovation which are expected to result from collaboration within ERNs.

On the other hand, given that ERNs do not yet exist, there are a number of challenges that ERNs will face in the future where a solution has not been specified.

- Managing *expectations:* At present there is great enthusiasm and expectation placed on the future work of ERNs. These **high expectations will need to be managed so that disappointments and discouragement can be avoided**. As with all new projects, programmes or initiatives, there will be a phase of working out processes, internal relationships, and rules of operation. All of these will take time to establish, to learn from and to consolidate.
- *Coordination:* The situation with the creation of ERNs is very dynamic. Many elements are not yet established. **It is not clear for many parties how ERNs will be linked to national healthcare providers.** ERNs are not intended to be

supranational entities and their members (and patients) will be on the national level. Coordination between the European and national levels will need to be clarified.

- *Anchoring ERNs in national health systems:* One final challenge that multiple stakeholders mentioned was that **anchoring or integrating ERNs in national health systems might prove a future challenge.** Successful ERNs will be eligible for funding for five years, after which there is no secured funding stream. The sustainability of ERNs will largely depend on how they will be connected to the national level and financed. MS will need to feel a connection to the ERNs that their national organisations belong to. Funding possibilities will exist in Horizon 2020, which is well positioned for ERNs and a multiple funding model will be the most likely option with support coming from MS, grant funding through the EC, and the pharmaceutical industry. Nevertheless, a feeling of ownership and responsibility towards ERNs will be crucial to securing sustainable funding beyond the 3HP.

9.4. Conclusions

The following conclusions attempt to draw out key points from the evidence collected and analysed, with a focus on the relevance of the thematic priority, its potential to make a difference in practical terms and lessons that can be applied to the HP more broadly.

1. Relevance of the thematic priority, given:

- **Identified needs:** As it currently stands, a significant portion of Union citizens (sufferers of RD and low-prevalence diseases) lack equitable access to high quality health care. Many have not yet been diagnosed while others cannot access the resources needed to obtain a diagnosis, without which it is not possible to start treatment. The thematic priority of ERNs addresses this issue head on by creating ERNs which bring together knowledge and existing centres of expertise.
- **The HP's objectives:** The thematic priority of ERNs under 4.1 is relevant and addresses both aims of objective four. Conceptually, ERNs have been designed to be multi-functional: their work should increase access to high quality medical expertise, also beyond national borders and facilitate the application and results of research and develop tools for the improvement of healthcare quality and patient safety.
- **EU objectives more broadly:** In their design, the general aim of creating ERNs will contribute to EU objectives such as decreasing inequality between and within MS by increasing citizens' equitable access to high quality healthcare through ERNs. The actions under priority 4.1 should contribute progress to solving issues of equality in the EU. Patients should receive the same level of care regardless of where they are located. Patients suffering from RDs are especially vulnerable and geographically scattered. Even in more prosperous MS there is often a lack of sufficient knowledge/expertise on their rare condition.

2. Likelihood of actions to make a difference in terms of:

- **Established problems:** In their design and output so far, the actions being undertaken as part of this priority should inform and support the functioning of ERNs. The outputs of the two studies will define more clearly what it is that ERNs will provide in terms of services and how their procedures and operations will be regulated. The Study on the Manual and Toolbox for Assessing ERNs has developed an assessment manual that serves as an evaluation framework for ERNs. It was used in time to evaluate the applications for the status of ERN. The

Study on Services to be provided by ERNs aimed to clarify the operations of ERNs by developing a catalogue of services that ERNs would provide, an operational model of an ERN including how their activities will be structured and a costing model of the services. Although the outcome of the report will serve as basis for testing the theoretic services and costing model with the real functioning of the Networks in the future, the only concern has been if the outputs of this last study would be ready in time to inform the ERN call for proposals.

- **The EU added value of the HP:** As laid out in the rationale for acting at the level of the HP and thus at European level, the domain of RD is one where there is a clear rationale for the EU to act in a coordinating capacity. As such, this role provides significant EU added-value because this domain has had limited cooperation between MS thus far.
- **Wider policy objectives / priorities:** The potential for unlocking collaboration and promoting innovation in health by connecting expertise is large. The EU has a clear role to play in coordinating action at the European level and helping to create relationships and trust between actors who normally do not work together. The creation of ERNs is also symbolically important because it demonstrates solidarity with all MS, big or small, rich or poor.

  In a time of population ageing and economic recovery, managing and reducing costs in the public health sector is in the interest of every MS. It is expected that through the work of ERNs misuse or overuse of resources can be avoided and efficiency gained by creating economies of scale.

3. What lessons can be learned in terms of:

- **Strategy**: In terms of design, it is important for the thematic priority and its **individual actions to be logically linked and supportive of each other**. It should be absolutely clear how the individual actions will inform and support the overall objectives of the sub-priority. In this case, the three actions reviewed showed close linkages and have fully supported the creation of ERNs.
- **Delivery**: For both studies examined as part of this thematic priority, **flexibility** in terms of the requirements of the study was necessary for their successful completion. Both required consultation with MS and the processes followed had to be more consultative than planned earlier. Additionally, the **sustainability** of this priority will depend on funding existing beyond the next years. But ERNs will also need to be anchored in MS in multiple ways, not just financially. For instance, MS will need to feel ownership over these networks because their member will be located within their geographic and legal boundaries.
- **Benefits (to the extent available):** As it stands, the overall goal of creating ERNs is likely to be reached. The call for applications opened in March of this year (2016) and closed in June. The applications were reportedly of high quality and funding exists for about half of these ERNs over the five year period from 2017-2021. There is also evidence that ERNs will be of high quality based on the applications received. There is therefore good potential for ERNs' work to break down silos between healthcare practitioners who have historically never worked together and have actually often competed with one another.

  On the other hand, there is some indication that not all MS will be represented in ERNs. According to the applications received, larger MS are overrepresented. This risks leaving out smaller MS from some of the expected benefits of ERNs such as knowledge transfer via collaboration.

10.

11. THEMATIC PRIORITY 4.5 – IMPLEMENTING EU LEGISLATION (SUBSTANCES OF HUMAN ORIGIN)

11.1. Introduction

This case study examines thematic priority 4.5 of the 3HP on "Implementation of Union legislation in the fields of tissues and cells, blood, and organs"[279]. This priority falls under Objective 4 of the 3HP, which is to "Facilitate access to better and safer healthcare for Union citizens". A total of 11 actions have been funded under this thematic priority to date (2014 – 2016), amounting to a total budget of €7.2 million. This funding was spread across a mix of funding mechanisms, namely projects, an operating grant to one organisation for three consecutive years[280], joint actions, service contracts and one direct grant agreement. A sample of actions was selected based on consideration of their maturity, breadth of coverage of the mechanisms and a mix of different sized actions (see table below) [281].

Table 26: Actions reviewed for case study on Implementation of Union legislation in the fields of tissues and cells, blood, organs (thematic priority 4.5)

Funding mechanism	Lead organisation (incl. MS)	Other organisations (incl. MS)	Budget	Start date/duration
Vigilance and inspection for the safety of transfusion, assisted reproduction and transplantation (VISTART)				
Joint action	ISTITUTO SUPERIORE DI SANITA, Italy	17 organisations (including lead) from 14 countries (13 EU MS)	Total eligible costs: €2,972,112 HP grant: €2 328 664 (80% of eligible costs)	Start: October 10, 2015 36 months
Good Practices for demonstrating safety and quality through recipient follow-up (EURO GTP II)				
Project	Banc de Sang I Teixits, Spain	14 associated partners from 11 MS	Total eligible costs: €1,296,988 HP grant: €1,037,580 (80% of eligible costs)	Start: April 1 2016 36 months
European Cornea and Cell Transplantation Registry (ECCTR)				
Project	European Society of Cataract and Refractive Surgeons Limited, United Kingdom	7 organisations from 4 MS (UK, Italy, Sweden, The Netherlands)	Total eligible costs: €707,617 HP grant: €424,567 (60% of eligible costs)	Start: May 1, 2016 36 months
Study on the uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015) in the EU MS (FACTOR)				
Service contract	NIVEL- Netherlands institute for health services research, the Netherlands	n/a	HP grant: €199,030	Start: January, 2016 16 months

Note: More information on the sampled action can be found on the Chafea database and in the AWPs available on DG SANTE's website

The methodology for the case studies is provided in detail in the **introduction** to this Annex. But entailed **two main steps**. First, we reconstructed the thematic priority's theory in the form of an intervention logic diagram. Then, to test the theory, we collected

[279] http://ec.europa.eu/health/programme/docs/factsheet_healthprogramme2014_2020_en.pdf

[280] under one framework partnership agreement, awarded to one organisation for three consecutive years

[281] Note that a selection of five actions per case study was not possible due to the inclusion of inappropriate actions in the original sample.

and analysed evidence about implementation so far, above all through an examination of five funded actions (as above). The different sources of information are summarised in the table below.

Table 27: Documents consulted and interviews conducted for case study on Implementation of Union legislation in the fields of tissues and cells, blood, organs (thematic priority 4.5)

Documents consulted	Interview status
• 2014 -2016 Annual Work Plans (AWP) • EC Directives, strategies and follow up legislation in the fields of SoHO, and specifically blood, organs, tissue and cells (references included throughout report) • Evaluation Summary Reports and documentation for actions examined (VISTART, Euro- GTP II, ECCTR and FACTOR)	• Conducted a total of 9 interviews • Interviews with 2 Chafea project officers responsible for the 4 sampled actions; • Interviews with 4 beneficiaries, one for each action in sample • Interviews with 3 DG SANTE policy officers

11.2. Policy context

11.2.1. Key health needs and priorities

The use of medical therapies involving Substances of Human Origin (SoHO), including human blood, organs, tissue and cells is a well-established practice in Europe and worldwide. As research in the field of SoHO continuously evolves and procedures improve, new developments are being implemented constantly. SoHO materials are essential for hospitals and health service providers to treat patients but also for the advancement of medical research. Improvements in the field of medicine have led to donation and transplantation of organs, tissues and cells becoming ever more routine.

Given their nature, SoHO are **valuable resources but they cannot be manufactured** - their availability depends on human donors. As such, SoHO represents a scarce resource (especially in the case of organs), where demand exceeds supply. Although national initiatives have been in place to increase and effectively manage supplies, there are **natural limits to what can be achieved in individual EU MS**.

In recent years **donation rates have risen** due to national and European initiatives[282], while better use is being made of a limited supply. Consequently an increase of 4.000 transplants was recorded in the EU-28 from 2010 to 2015 (+14%). However, scarcity and associated problems (e.g. organ trafficking) persist in Europe and worldwide. Indeed, scarcity means that there is a Europe-wide need to increase availability of SoHO (particularly organs) for donation. MS with smaller populations also face natural barriers to increasing donation numbers.

European legislation in the fields of blood, organs, tissue and cells, and healthcare has addressed part of this problem by encouraging greater coordination and exchange of SoHO between MS, and passing legislation to allow for patients to receive healthcare in another EU MS[283]. As such, these initiatives have resulted in greater exchange of SoHO across Europe in recent years.

Nevertheless, national differences in procedures, regulations, and vigilance procedures present substantial barriers to increasing supply of SoHO and ensuring their effective use and allocation throughout the EU. Safety and quality standards and traceability

[282] Such as the Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States (COM (2008) 819/3), an initiative which worked to set the national agenda in many MS on organ donation.

[283] Commission Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.

requirements are essential for eliminating the health risks associated with SoHO, but these still vary between MS. It needs to be noted that part of these different standards are required to deal with different risks between EU MS, e.g., Malaria or West Nile Virus, which is only prevalent in Southern (warmer) EU MS. In addition, practical differences in how SoHO are collected, stored, handled and employed lead to difficulties in exchanging and making use of them from one country to another. Equivalent levels of safety and quality would help reduce these barriers and thereby facilitate MS exchange between MS and mutual confidence in each other's traceability and surveillance procedures.

Greater harmonisation and exchange of SoHO would in turn help reduce health inequalities faced within and across EU MS. **There is therefore a need in Europe to increase the safe supply and availability of SoHO to patients** by achieving a degree of harmony in the application of good practices, quality standards and accreditation systems for SoHO, while allowing MS to apply additional requirements to deal with local risks.

11.2.2. Framework for and extent of EU engagement so far

The EU has been engaged in the field of SoHO for some time to help find solutions to the problems outlined above. Article 168 of the TFEU outlines the EU's role in improving health and preventing disease, the need for policy coordination among MS and the European Commission's role in taking any useful action to promote such coordination, including the exchange of best practice, guidelines, monitoring and evaluation. This forms the fundamental basis for EU action in the field of SoHO.

In practical terms, the EU has implemented legislation and guidelines related to SoHO (on blood, organs, tissue and cells) and sought to support the efforts of MS. The EC has also taken related measures aiming **to increase both the availability of SoHO and access to transplant and transfusion therapies** for EU citizens.

EU legislation and guidelines aim to ensure that there are comparable levels of health protection across the EU. Legislation at the EU level in the field of SoHO seeks to secure a minimum level of safety and quality for SoHO substances by setting down:

- requirements for health professionals and organisations on how to select and test donors and handle substances.
- requirements for national competent authorities (CA) to oversee all actors and activities in the chain from donation to transplantation/transfusion/human application
- requirements on the European Commission to coordinate and support the implementation of these requirements, e.g., by developing common standards and IT-tools for vigilance and traceability.

In addition EU supported work aims to help structure and organise the donation of blood, organs, tissue and cells, and consolidate available information to identify where gaps exist; and, address scarcity in the field of organs.

There have been numerous Directives which cover **blood and plasma**. More specifically, there have been Directives on standards for quality and safety for the collection, testing, processing, storage and distribution of human blood and blood

components[284], technical requirements for blood and blood components[285], traceability requirements and notification of serious adverse reactions and events[286], and standards and specifications relating to a quality system for blood establishments[287]. These, and more, are presented in a dedicated webpage on DG SANTE's website[288].

Regarding **tissues and cells** for transplantation and for assisted reproduction technology, Directives have also focused on developing standards, verifying these standards have been applied, setting technical requirements for tests, and so on, in order to provide quality and safety assurance. The implementation of legislation that regulates SoHO activities had a major impact in the way these activities were organised in the EU: before 2004 the majority of the MS did not have any regulations or standards for developing activities with tissues and cells. The publication of Commission Directive 2004/23/EC[289], and the following EC Directives 2006/17/EC[290], 2006/86/EC[291], and more recently 2015/565[292] and 2015/566[293] have changed the way these activities are performed at EU level. Overall a reduced number of more consolidated tissue banks (around 3000[294]) are active following stricter requirements.

Recognising the problem of **organ scarcity,** the European Commission has an overarching *Action Plan on Organ Donation and Transplantation (2009-2015)* (Action Plan)[295] in parallel to the legal framework laid down in Directive 2010/53/EU[296] on standards of quality and safety of human organs intended for transplantation. The Action Plan aimed to increase the availability of organs, enhance the efficiency and accessibility of transplant systems and to improve overall quality and safety (where Directive 2010/53/EU focuses exclusively on safety and quality). Key priority actions and specific actions contained within the Action Plan were developed with and amongst MS with the goal of it being supported by EU funded projects under the Health Programme or other instruments (e.g. research funding) or by expert working groups organised by the Commission. However, MS were ultimately responsible for implementation of the Action Plan.

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[284] Directive 2002/98/EC of European parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (O.J. L33,8.2.2003)

[285] Commission Directive 2004/33/EC of 22 March 2004 (note, Directive 2014/110/EU amends Directive 2004/33/EC as regards temporary deferral criteria for donors of allogeneic blood donations)

[286] Commission Directive 2005/61/EC of 30 September

[287] Commission Directive 2005/62/EC also of 30 September (note, Directive (EU) 2016/1214 of 25 July 2016 amends Directive 2005/62/EC as regards quality system standards and specifications for blood establishments)

[288] These are all compiled on DG SANTE's website

[289] Commission Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

[290] Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.

[291] Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC (as above)

[292] Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells.

[293] Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells.

[294] Compendium of EU authorized tissue establishments can be found online

[295] Communication from the Commission of 8 December 2008 - Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States COM (2008) 819.

[296] Commission Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.

The Commission estimated that over a ten year period (2003 -2013) it had funded around 50 activities in the framework of EU health programmes, research framework programmes and other European funding schemes. A selection of these are illustrated in a comprehensive report entitled "Transplantation and Transfusion: Projects and Actions for saving and improving the quality of life of citizens by facilitating transplantation and blood transfusion in the European Union"[297].

11.2.3. Fit with the Health Programme

This thematic priority examined here is one of six thematic priorities under operational objective 4 (as presented in the table below), which all aim to increase **Union citizens' access to medical expertise and information, and facilitate the application of research results to improve healthcare and patient safety**.

In the annex to the Regulation for the 3HP, thematic priority 4.5 is phrased as follows:

> *"Actions required by, or contributing to, the implementation of Union legislation in the fields of human tissues and cells, blood, human organs, medical devices, medicinal products, and patients' rights in cross-border healthcare, while fully respecting the competences and ethical choices of MS in those fields.*
>
> *Such action may include activities aimed at facilitating the implementation, application, monitoring and review of that legislation."*

Table 28: Operational objective 4 and corresponding thematic priorities under the 3HP

Operational objectives	Thematic priorities
Increase access to medical expertise and information for specific conditions also beyond national borders, facilitate the application of the results of research and develop tools for the improvement of healthcare quality and patient safety	European Reference Networks Rare Diseases Patient safety and quality of healthcare Measures to prevent Antimicrobial resistance and control healthcare-associated infections Implementation of Union legislation in field of tissues and cells, blood, organs, medical devices, medicinal products, and patients' rights in cross-border healthcare Health information and knowledge system to contribute to evidence-based decision making

Source: Annex I to Regulation Third Health Programme

Thematic priority 4.5 serves to support the implementation of a number of key pieces of EU legislation in the field of SoHO through practical actions that involve the MS directly within the HP. As explained further below, the focus of thematic priority 4.5 was reflected in previous iterations of the HP which have dealt with the same issues in similar ways, while taking into account scientific developments and gradually broadening in scope. Interviewees explained that thematically the actions funded in this area under the 3HP were similar to the 2HP but had evolved to reflect progress and other developments in recent years. In this vein, actions funded through the 2HP are in any cases being taken forward through the 3HP. For example, EURO-GTP II builds on the work of EURO-GTP and the FACTOR study follows up on the ACTOR study. The ACTOR study was basis for the mid-term evaluation of the set-up of organ donation and transplantation in the EU MS, uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015), focusing on the period 2009-2012.

The scope of actions now includes legal safety and quality and availability in national health systems. Indeed, actions funded under thematic priority 4.5 in the 3HP represent

[297] http://ec.europa.eu/health//sites/health/files/blood_tissues_organs/docs/transplantation_pub_en.pdf

the progress and evolution of activity in the field of SoHO over the past 10-15 years and build on previous work supported through the HP. For instance interviewees explained that a certain level of development has been reached by some MS in these fields (e.g. tissues and cells is a new area and evolving quickly, whereas blood and organs generally have more established systems in place across the EU). There is now knowledge that has been accumulated and can be shared; actions funded under the thematic priority aim to, among other things, encourage the diffusion of knowledge and expertise[298].

One important development is that the current HP features a **joint action which includes the fields of blood and tissues and cells together** for the first time. Comparatively, in terms of choice of funding mechanism, the 2HP had focused on joint actions in the area of organs. Interviewees consulted as part of this study report that there is now more emphasis on achieving a balance across all three sectors. Indeed, one of the biggest changes from the 2HP to the 3HP is the funding of more horizontal actions covering more than one field (e.g. organs and tissue and cells for instance, or blood and tissues and cells), allowing for cross-sector learnings and exchange of expertise. Actions in previous HP under the theme of SoHO were more fragmented along individual specific thematic lines (i.e. either on organs, blood, or tissues and cells). Another change from the 2HP to the 3HP in the area of SoHO is the funding of larger actions (reportedly due to administrative considerations[299]).

In terms of overlap with other thematic priorities, we note the reference to implementation of legislation in the field of "medical devices and medicinal products" is also mentioned under thematic priority 3.6.

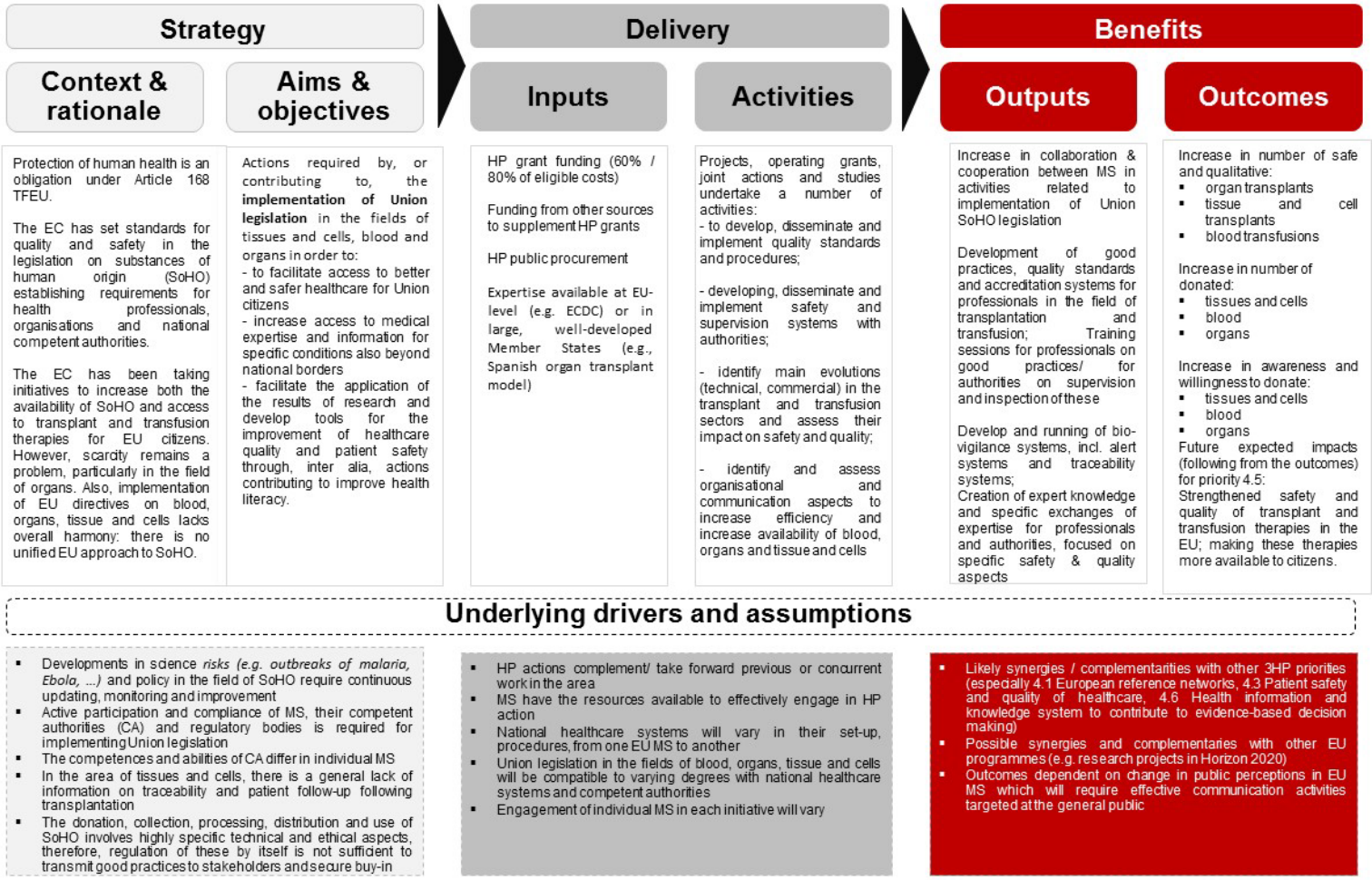
11.3. Theory and practice

This section presents and assesses the **thematic priority's intervention logic.** It starts with a diagram that depicts the theory underpinning the thematic priority. This is followed by sub-section on each of the intervention logic's main parts (strategy; delivery; and benefits). These sub-sections first describe and examine the how HP action under the thematic priority is intended to work in theory. We then analyse what is happening in practice by examining the objectives, activities, outputs, and (early) outcomes of the five actions selected for the case study. This allows us to test the intervention logic's plausibility and determine whether the desired outputs and outcomes of the thematic priority are likely to be achieved through the type of actions that have been funded to date. For a more detailed explanation of the methodology / components, please refer to the **introduction**.

[298] Current HP action in the field of SoHO in terms of implementing legislation in the areas of blood, organs, tissue and cells continues under the same legislative framework as the previous iteration of the HP. Previous action is often being continued and takes forward the progress achieved by 2HP actions (for example, EURO-GTP II builds on the work of EURO-GTP and the FACTOR study follows up on the ACTOR study. The ACTOR study focused on the set-up of organ donation and transplantation in the EU Member States, uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015))

[299] These being reportedly easier to manage and monitor at DG SANTE and Chafea.

Figure 8: Intervention logic for thematic priority 4.5 (Implementing EU legislation - Substance of Human Origin)



Source: created by evaluation team based on case study fieldwork (documentation review and interviews)

11.3.1. Strategy

Rationale for HP action in the thematic priority

The section above, "Policy Context", explained the **rationale for EU action** in the field of SoHO. Namely, the EU recognises **the need for improved quality and safety standards to address health inequalities which exist both within and between EU MS in the field of SoHO.** As explained in detail, EU legislation in the area of SoHO has sought to achieve a minimum level of safety and quality by setting down requirements that health professionals, organisations and CA in the field have to adhere to.

However, since responsibility for vigilance and inspections, and for the organisation of the health systems themselves, remains with the MS, differences and inconsistencies between MS remain. Put differently, legislation can provide the legal framework for minimum safety and quality, but this alone cannot eliminate the existence of varying practices and standards being applied. These differences can create risks and barriers for the exchange of SoHO across borders. As such, the rationale for **targeted activities in the field of SoHO to support the legislative approach** to increase the degree of uniformity across the EU in terms of safety and quality standards across MS which the HP is in a position to fund.

Given the highly specialised and rapidly evolving technological aspects, regulation alone is not sufficient to tap into specialised agencies within the MS to gain and share critical knowledge more widely, to secure stakeholder buy-in and transmit good practice. One of the key advantages of supporting actions at the EU level in the field of SoHO **is to share, build on and exchange existing knowledge and best practice and to connect to overarching centres of expertise at EU level** (e.g. the ECDC[300], EMA[301]).

The aim of HP action is summarised in the intervention logic, which presents the specific "aim or objective" of EU HP funding under thematic priority 4.5: to support activities which are **required by or contribute to implementing Union legislation in the fields of tissues and cells, blood and organs[302]**.

Strategic fit of funded actions

In the first years of the 3HP (2014 – 2016), there have been 11 actions funded under thematic priority 4.5 (with a budget of 7.2 €million). Based on a review of four funded actions (one joint action, two projects and a service contract) we were able to test how the strategy described above is being put into practice under a variety of circumstances. Overall, based on a review of available project documentation and interviews, there is strong evidence that the actions fit well with thematic priority 4.5. Indeed, each action supports activities which help MS to implement what has been set out in Union legislation for how to better regulate that respective field (i.e. blood, tissues and cells

[300] The European Centre for Disease Prevention and Control (ECDC) is an EU agency that aims to strengthen Europe's defences against infectious diseases. See http://ecdc.europa.eu/en/Pages/home.aspx

[301] The European Medicines Agency (EMA) is a decentralised EU agency responsible for the scientific evaluation, supervision and safety monitoring of medicines developed by pharmaceutical companies for use in the EU. See http://www.ema.europa.eu/

[302] Including what is specified in the following: Commission Directives 2004/23/EC, 2006/17/EC, 2006/86/EC, 2015/565, 2015/566, the Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States COM (2008) 819, and Commission Directive 2010/45/EU, among others (see also, section 2.2 for more detail)

or organs) and each of the actions presents a logical link between their expected outputs and outcomes to those of the thematic priority as specified in the intervention logic.

The actions examined involve a number of activities which are specified in the proposals[303]. These support the four broader aims of thematic priority 4.5 as follows[304]:

- to develop, disseminate and implement **quality standards and procedures in the field of SoHO**;
- to develop, disseminate and **implement safety and supervision systems in the field of SoHO**;
- to identify **main evolutions** (technical, commercial) **in the transplant and transfusion sectors and assess their impact on safety and quality**;
- to increase both the **efficiency and availability of SoHO 'products'** (i.e. blood and blood components, tissues and cells and organs) by identifying and assessing organisational and communication aspects.

Our review found that the **aims of the actions were both realistic and fit well with those of the thematic priority**. These in turn directly support EU legislation in the field of SoHO, contributing to objective four ("To facilitate access to better and safer healthcare for Union citizens") by increasing both the availability and safe supply of SoHO for all EU patients.

An example of how an action examined in the sample fits the thematic priority is the joint action *VISTART*[305]. This joint action supports EU MS to **develop and strengthen their capacity for monitoring and control** in the field of blood, and tissue and cell transplantation. As such, this action responds to the EC's legal mandate in this area of health as it aims to promote and facilitate harmonisation of inspection, authorisation and vigilance systems for blood, tissues and cells, and thereby to increase inter-MS collaboration and confidence in respective inspection and vigilance programmes. Enhancing **confidence is expected to lead to increased trust** and therefore to greater exchange of products, which in turn should increase availability.

Another example of how an action fits to the rationale and aims of the thematic priority is the European Cornea and Cell Transplantation Network (ECCTR) project. At present there is no harmonisation of information across the European Union on the numbers or origins of the cornea tissues that are available for transplant, or on the optimum procedure for transplant and the visual outcome and quality of life of cornea transplant patients. The project is working to link three existing cornea registries and to recruit additional centres of excellence and eye banks to contribute data on the availability of cornea tissue, methods of transplantation, and visual outcomes of surgery. The project aims to collect and aggregate information to build a common assessment methodology to allow academics, health professionals and authorities to **assess and verify safety, quality and efficacy of (new) transplantation therapies and/or other types of clinical applications** of human tissues and cells. The data from the completed project is expected to be used to develop European guidelines for cornea and cell transplant surgery that will allow for better and more efficient utilisation of cornea tissue and ensure European self-sufficiency in these tissues and reduce patient waiting lists.

Overall, the actions under review fit with the rationale, aims and objectives defined in the intervention logic. Such action in the field of SoHO should therefore also contribute

[303] Sometimes these are amended prior to implementation based on feedback from independent evaluators.

[304] These activities are described in the thematic priority fiche for thematic priority 4.5, which is a Commission internal working document.

[305] Vigilance and inspection for the safety of transfusion assisted reproduction and transplantation. https://vistart-ja.eu/home

to the overarching goal of objective four of the health programme: to increase access to safe and high quality healthcare for Union citizens.

11.3.2. Delivery

Planned activities and overall implementation so far

As previously mentioned, out of eleven actions funded under priority 4.5 to date (December 2016), the study here reviewed four actions: the joint action VISTART; the ECCTR project; the EURO-GTP II project, and the FACTOR study.

The sample chosen for this case study provided a **good representation of the types of actions** that were funded under priority 4.5 in the 3HP for the period under review. Although it is still early in the implementation of these actions, discussions with beneficiaries, Chafea and DG SANTE indicate that they are off to a good start: key kick-off meetings have taken place, as have initial project and coordination meetings, and early deliverables (e.g. inception reports) have been received and formally accepted. These are all multi-year actions (except for the FACTOR study which lasts 14 months), and progress across all work packages has begun.

The paragraphs below summarise the key planned activities for the actions and where possible information regarding their implementation so far.

EURO-GTP II (Project) - *Good Practices for demonstrating safety and quality through recipient follow-up*

- The project kicked off in April 2016. It aims to set up the good practices applied to tissues and cells preparation processes and patient follow-up procedures.
- The work is organised across various work packages. Four are related to management, dissemination, evaluation and coordination. The other four thematic packages focus on developing good practices for recipient follow-up (generally) and developing good practices more specifically in the areas of tissues, hematopoietic stem cells, Assisted Reproductive Technologies and tissues and cells, respectively.[306]
- EURO-GTP II will develop practical tools which will assist tissue establishments and organisations responsible for human application, in the implementation of technical requirements defined for the assessment and verification of the quality, safety and efficacy of therapies with human tissues and cells.
- These tools will be developed in accordance with regulatory principles, legislation and good practices, and will be made available to CA, which will also facilitate evaluation and the authorisation procedures.

ECCTR (Project) - *European Cornea and Cell Transplantation Registry*

- The ECCTR project began in May 2016 and runs for three years.
- The aim of the project is to build a common assessment methodology and to establish an EU web-based registry and network for academics, health professionals and authorities to assess and verify the safety, quality and efficacy of (new) human tissue transplantations and in ophthalmic surgery.

[306] These work packages are called: “Generic good practices for demonstrating safety and quality through recipient follow-up”, “Good practices for demonstrating safety and quality through recipient follow-up in tissue”, “Good practices for demonstrating safety and quality through recipient follow-up: hematopoietic stem cells”, “Good practices for demonstrating safety and quality through recipient follow-up in ART”, and the “development of a tissue and cell database and interactive assessment tool”.

- The project is also engaged in awareness-raising activities because there is growing understanding that surgeons need to be convinced that it is important to collect relevant data in the first place. Therefore communication training for doctors will also take place.
- Although the project is in an early stage, interviews with DG SANTE and Chafea confirm that the clear focus is translated into a sound work plan. For example, there was a strategic decision not to include advanced therapy medicinal products within the EU-funded project as this would jeopardise the overall quality of the project.

FACTOR (Procurement) - *Study on the uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015) in EU MS*

- The "FACTOR" study began in January 2016 and will last for 16 months
- The study aims to provide information on the current set-up of organ donation and transplantation in the EU MS and on the level of implementation of the 10 priority actions of the Action Plan on Organ Donation and Transplantation[307] (hereafter the Action Plan) over its entire period (2009-2015).
- It will map what results have so far been achieved, both at MS and European level, taking into account results of the mid-term review (ACTOR[308]) conducted in 2012-13. The study will also consider recent and ongoing developments in the field of transplantation and assess if there is a need for a follow-up to the Action Plan at EU level.

VISTART (Joint Action) - *Vigilance and inspection for the safety of transfusion, assisted reproduction and transplantation*

- The VISTART joint action, began its work in October 2015 and will be funded for three years.
- This JA seeks to promote and facilitate the harmonisation of inspection, authorisation and vigilance systems for blood and tissues and cells and to increase inter-MS collaboration and confidence in each other's inspection and vigilance programmes.
- Thirteen MS and Norway are associated partners and many others are also collaborating in this initiative, which is the first action to bring together the worlds of blood transfusion and tissues and cells.
- The action will lead to proposals for improvements to the annual vigilance reporting exercises and also seeks to build strong collaboration with the WHO's Notify Library[309] (which is a global collection of analysed adverse occurrences that are associated with the donation or use of substances of human origin).

Lessons learned from specific actions so far

This sections examines to what extent the implementation of the actions reviewed for this case study under thematic priority 4.5 have been successful and what lessons can be learned from early implementation. Key success factors were identified in the final evaluation of the 2HP and included: strong management, a well-delineated action scope

[307] Communication from the Commission of 8 December 2008 - Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between Member States [COM (2008) 819– Not published in the Official Journal]

[308] Study on the set-up of organ donation and transplantation in the EU Member States, uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015) (ACTOR) funded under the 2HP as a study (service contract).

[309] http://www.notifylibrary.org/

and objectives, constructive engagement from DG SANTE and Chafea, credible plans for performance management, monitoring and evaluation, and finally, effective communication and dissemination of results. Analysing evidence from the sample of actions against these success factors we can draw some early remarks on how likely it is that the actions will be successful.

- In terms of the **process for engagement** with Chafea and DG SANTE, all parties interviewed reported communication, monitoring and feedback were proceeding successfully. There was, however, some feedback regarding the new online application process at Chafea. As you would expect putting a new system in place has led to some teething problems for beneficiaries as they grapple with new systems.
- On the point of **strong management**, beneficiaries reported being aware of the importance of having a lead partner who could provide this and therefore emphasised this point when drafting their proposals. Prior experience with working on EU-funded actions or even on the precursor actions (e.g. the EURO GTP which is followed up with EURO GTP II project or the ACTOR study, which has been followed up with FACTOR) provided an advantage in terms of putting in place the necessary safeguards to ensure strong management, but also making this a concrete, convincing element in the proposals. For instance, because of prior experience partners were prepared for the challenges associated with working in large teams, and could present which elements would be put in place to deal with these challenges in the proposal, such as regular coordination meetings.
- **Plans for dissemination and promotion of results** were well defined for each of the actions reviewed and interviewees confirmed their importance. As such, dissemination and communication was a key point in proposals and beneficiaries generally envisaged using a myriad of channels and tools (such as online, printed brochures, conferences and presentations) for disseminating and communicating findings and results.
- The **involvement of relevant stakeholders and end users** was mentioned as the key for successful outcomes. Interviewees explained that their definition of success involved recognition by professionals in the field of the value and utility of the tools under development (e.g. ECCTR or in EURO-GTP II). To this aim they reported developing content in close contact with end users, tissue bankers and officers from CA.
- On the point of **coherence and coordination in the actions**, multiple interviewees confirmed that partners (e.g. from the joint action VISTART and the two projects ECCTR and EURO-GTP II) follow each other's developments, even attending some of the other group's coordination meetings to ensure that their work does not overlap and that they can cooperate where possible. Interviewees explained that the three actions represent key SoHO areas where work needs to be done. As such, the two projects and the JA are working toward the same objective, which is to improve safety, quality and vigilance and promote the development of good practices in the field of SoHO. Chafea and DG SANTE confirmed that coordination has been good and effective. The organisation by SANTE of regular expert group meetings with National Competent Authorities, where progress of all actions is regularly foreseen and where wider contextual discussions take place, have been key success factors in coordinating work in different actions. One beneficiary did comment that from a contractor's point of view (for undertaking studies) a vast amount of knowledge already exists at DG SANTE which could and should be made greater use of in the studies they commission.
- **Regarding organ donation in particular, the battle to change attitudes and encourage support** from across different groups is far from over. On the

one hand, public awareness and willingness to donate organs is sensitive to scandals (some of which recently in the EU) or health scares which can decrease willingness of potential donors. On the other hand, the importance of organ donation as a means to improve quality of life and save public funds is not as well communicated as it could be, according to interviewees.

11.3.3. Benefits

Expected immediate, medium- and long-term benefits

Overall, HP action in implementing SoHO legislation under thematic priority 4.5 is expected to deliver a number of benefits in the form of outputs in the medium-term as well as longer-term benefits in the form of outcomes.

As illustrated in the intervention logic diagram, the foreseen **medium-term outputs** of the activities within thematic priority 4.5 include:

- an increase in collaboration and cooperation between MS in specific activities that contribute to the implementation of Union legislation in the field of SoHO;
- the development of good practices, quality standards and accreditation systems for professionals in the field of transplantation and transfusion;
- training sessions for professionals on good practices and for authorities on supervision/ inspection of these practices;
- the development and running of bio-vigilance systems, including alert systems and traceability systems;
- expert knowledge on new developments in SoHO;
- specific exchanges of expertise for professionals as well as for authorities, focused on specific safety and quality aspects e.g., import of tissues.

These outputs and outcomes are contained in key deliverables for the actions reviewed and, as such, constitute integral parts of them and indeed provide the rationale behind their designing. Therefore the outputs listed above are key components contained in the work plans of the actions themselves. From a design and strategic point of view, as long as the actions follow the proposals and inception reports that have already been delivered and accepted, it seems likely that the expected outputs will be achieved.

In the **longer term**, the outputs mentioned above are expected to lead to a number of **outcomes.** These include increases in:

- the number of safe and qualitative organ transplants, tissue and cell transplants and blood transfusions;
- the number of donated tissues and cells, blood, and organs;
- the awareness and willingness to donate tissues and cells, blood and organs.

The connection between the outputs mentioned above and the longer term outcomes is more evident for some than others. For instance, it is foreseeable that increased cooperation and collaboration between MS in the SoHO field via HP action (an output) should increase contact and trust between relevant stakeholders (e.g. CA, universities, centres of expertise, tissue and cell establishments) and encourage better coordination in the use of SoHO materials across Europe, thereby resulting in an increase in the number of safe and qualitative transplants/transfusions. It is also logically coherent that by developing good practices and agreeing on comparable standards across Europe (the output), this will increase trust between CA in MS in each other's procedures and approaches in the handling and vigilance of SoHO. It is logical that enhanced trust

should increase the speed with which exchange of SoHO can take place and therefore result in an increase in the number of safe and high quality transplants. Even so, it is worth highlighting that these activities do not operate in a vacuum and there is a need for all the surrounding supporting healthcare structures to support activities by, for instance, facilitating the adoption of guidelines and new procedures.

It is less clear though how the outputs of the thematic priority connect to the last two outcomes, *an increase in the number of donated tissues and cells, blood and organs* and *greater awareness and willingness to donate tissues and cells, blood and organs*. These outcomes will largely depend on a change in public attitudes in EU MS and that will require effective communication activities targeted at the general public[310]. As it stands, actions under thematic priority 4.5 largely involve specialised bodies and entities. While communication and dissemination activities are integral to all the actions and is a point on which they are evaluated, awareness raising among the public **is not a main focus of any of the actions reviewed**. And yet, the lack of focus may be a significant barrier to the achievement of the objectives. Ensuring that mechanisms are envisaged to improve awareness on the importance of donating blood, tissues and cells and organs and this should be addressed going forwards.

(Potential) benefits in practice

The early evidence from the actions indicates that the **expected benefits of the thematic priority as a whole are likely in practice** and some outputs are already clearly visible (e.g. enhanced cooperation and collaboration between CA in EU MS). At the same time, it is difficult to know whether all expected long-term outcomes will be achieved, even if the actions are implemented well, due to the influence of other factors. As the actions develop over time, early evidence indicates that if they follow the planned course of action they should be able to achieve their outputs and outcomes.

Evidence from the four actions reviewed under thematic priority 4.5, illustrates the tendency for direct continuity with the work undertaken under the previous HP, which shows a sustained focus of action and work which addresses an identified need.

- The project EURO-GTP II, for instance, builds on the work of EURO-GTP, which was funded in the 2HP, by taking the results of the previous project to the next level and filling in the remaining gaps. The work under EURO-GTP II expands thematically the work of EURO-GTP by beginning the systematic evaluation of the efficacy of tissues and cells and promoting good practices for the implementation of novel therapies and products. The project also intends to establish a sustainable model for the updating of technical standards and implementation of accreditation systems that promote good practices in all MS. In addition, the definition of clinical follow ups and evaluation of efficacy has never been sufficiently developed so Euro-GTP II along with the joint action VISTART will begin this process, which will take some time to implement in the EU.
- Also, the beneficiary of EURO-GTP II is the incumbent of EURO-GTP, which is seen positively, as confirmed by interviews. This continuity with previous HP work in the field is also demonstrated by ECCTR, VISTART and the FACTOR study. More specifically, in the case of FACTOR: the *Study on the uptake and impact of the EU Action Plan on Organ Donation and Transplantation (2009-2015) in the EU MS* is the final study reviewing and mapping how the EU MS adopted and incorporated the key points contained in the Action Plan on Organ Donation in

[310] The evaluation team were advised that a new pilot project is focused on building public awareness for the work of the organ transplant sector

their national healthcare systems. The first study, ACTOR[311], a midterm review, examined how MS were initially going about incorporating the key points of the Directive on Organs (Directive 2010/53/EU) and the Action Plan on Organ Donation. In 2016 FACTOR looks back and examines the entire period with a focus on identifying where, if any, gaps remain. The same institution that completed ACTOR, NIVEL in the Netherlands, is carrying out FACTOR.

There is also an opportunity to incorporate possible synergies / complementarities with other HP priorities. In the case of actions under priority 4.5, there are possible synergies and complementarities with thematic priorities 4.1 (European Reference Networks), 4.3 (Patient safety and quality of healthcare), and 4.6 (Health information and knowledge system to contribute to evidence-based decision-making) or possible complementarities with other EU programmes (e.g. Research projects in Horizon 2020).

The actions have realistic objectives and aims and clear plans for achieving their outputs and outcomes. Based on a review of the documentation made available by Chafea, publicly available information on the projects, the proposals and key deliverables submitted to date (but not necessarily public) there is strong evidence that the actions reviewed have a strong design (in particular EURO-GTP II and ECCTR), have realistic objectives and timeframes and are being carried out by competent bodies with the required set of skills.

11.4. Conclusions

The following conclusions draw out key points from the evidence collected and analysed, with a focus on the relevance of the thematic priority, its potential to make a difference in practical terms and lessons that can be applied to the HP more broadly. These are presented in terms of answers to three research questions.

1. Relevance of the thematic priority, given:

- **Identified needs**: The basic premise for action in this field is that despite increases in donation rates in recent years, there continues to be greater demand for (safe) SoHO than supply of (safe) SoHO. There is thus a continuing need to increase the availability of SoHO (particularly organ) donations. This is facilitated by ensuring safety standards and best practices are followed across MS. In turn, this facilitates an increase in the availability of safe SoHO.
- **The HP's objectives**: While regulatory aspects can provide the legal approach, the particular need for supportive activities (projects, joint actions, studies) which are best funded at the EU level is covered by thematic priority 4.5. This thematic priority supports activities that are required by or contribute to implementing Union legislation in the fields of tissues and cells, blood and organs to facilitate the safe supply of SoHO, to ensure updates to policy in the field of SoHO and coordination of action, guidelines and procedures between MS.
- **EU objectives more broadly**: Better coordination, collaboration and harmonisation between MS in their procedures and approach to regulating SoHO is key to improving the quality of life of European citizens.

2. Likelihood of actions to make a difference in terms of:

[311] Study on the set-up of organ donation and transplantation in the EU Member States, uptake and impact of the EU Action Plan on Organ Donation and Transplantation

- **Established problems**: One of the strengths identified in the sample of actions assessed is that they build on previous work in the field and thereby set out to (continue to) address established problems. For instance, the study known as "FACTOR" builds on a previous study "ACTOR" to identify gaps in the implementation of the Action Plan on Organ Donation. One established problem where there has been less focus relates to changing public attitudes towards donation, which would benefit from more communication and awareness building actions.
- **The EU added value of the HP**: The SoHO sector is a fast evolving, complex sector and has an EU dimension (through the exchange of SoHO across borders). The added value of EU action is sharing of best practice, guidelines and tool kits which can be applied throughout the EU, thereby not only creating economies of scale, but raising standards and increasing trust.
- **Wider policy objectives / priorities**: the actions supported indeed support the ultimate goal to increase the safe exchange of SoHO which ultimately ensures the safety of patients and access to healthcare. However, more could be done to increase the number of donors (in particular organ donors), for example by improving the communication and awareness around organ donation to increase support.

3. What lessons can be learned in terms of:

- **Strategy**: From the sample of actions assessed, the activities show a strong fit with the overall strategy to increase the number of safe and quality transplants and to increase the number of donations. However (as mentioned above), the current strategy appears to have one major gap: a lack of awareness raising activities to support the above goals and begin to change public attitudes.
- **Delivery**: Regarding the delivery of actions in the sample, despite being in their early stages, there is evidence that they are being delivered successfully. Among the reasons for this are the level of experience of the partners involved in delivering the actions and the coordination / collaboration between actions which has contributed to coherence.
- **Benefits (to the extent available)**: the benefits of the actions have yet to be realised, however, as mentioned above, a clear benefit is that the actions funded take further previous work by developing methodologies / guidelines in new areas (i.e. novel therapies and products), creating new models for sustainable updating of technical standards, defining procedures in areas where this is lacking (e.g. clinical follow-up). This means that they are addressing an identified need and should lead to concrete progress.

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