

Stakeholder Workshop – 24 March 2021

EU4Health programme 2021-2027

Summary Report

On 24 March DG SANTE organised a stakeholders' workshop on the EU4Health Programme ("the Programme") to inform on the Programme objectives and gather input on priorities and strategic orientations and on the needs to be addressed through the Programme's actions. Through a participatory approach, stakeholders built on the outcome of the 22 January EU4Health Webinar and further explored potential solutions for EU-wide health challenges under the four strands of the Programme.

The event gathered more than 700 participants including representatives of civil society and patients' associations, academics and organisations of healthcare professionals. The workshop was attended by more than 100 organisations and associations (including patient organisations, associations covering various medical professions and specialities, industry associations, international and national federations), regional representatives, platforms, public health organisations, university, national institutes and competent authorities, academia, consultancies, companies, including experts from EU Member States competent authorities active in the EU Health Policy Platform on-line interactive tool.

Plenary session

The plenary session provided details about the EU4Health Programme Regulation and information on the next steps on the implementation of the 2021 annual work programme. The session also provided an overall picture of the Health policy context at EU level that will be supported by the Programme. This included: disease prevention and health promotion and Europe's beating cancer plan; the European health data space; health security, the Health Union Package and the Health Emergency and Response Authority; health systems and the pharmaceutical strategy. In addition, a patient association provided the patient's view on how the EU4Health Programme could be progressive, impactful and patient-oriented.

Breakout sessions

The names and details of the roundtable speakers may be found in the agenda:

https://ec.europa.eu/health/sites/health/files/funding/docs/ev_20210324_ag_en.pdf

The **Disease prevention** breakout session included participants from health authorities; academia; industry; and several associations such as European Association of Urology; IDF Europe; Smoke Free Partnership; European Association for Clinical Pharmacology and Therapeutics; European Ayurveda Association; European Oncology Nursing Society; Alzheimer Europe; ACHIEVE Coalition; European Central Council of Homeopaths; European Alcohol Policy Alliance; European Kidney Health Alliance; European AIDS Treatment Group; Platform for Better Oral Health in Europe; International Association

for Veterinary Homeopathy; Vaccines Europe; European Federation of Allergy and Airways Disease and International Planned Parenthood Federation. The participants identified the following priorities, orientations and needs, and possible solutions:

Health promotion and health information

- Support the Member States in their efforts to improve and sustainably increase health promotion and prevention, namely by
 - Gathering evidence, identifying cost-effective approaches, and supporting their implementation also with the support of EU financial instruments (EU4Health and others).
 - Supporting the transfer and implementation of best/good/innovative practices (e.g. system/population-based approaches; stronger integration of care; non-medical prescriptions);
- Support better and interconnected health information systems and, in particular, data registries;
- Strengthen the capacity of health systems to engage with other actors at all levels (Health in All Policies approach).

Non-communicable diseases – risk factors

- Address the common risk factors for non-communicable diseases by supporting the roll-out of population-based approaches, by addressing commercial determinants and the environment where choices are made, and by enabling citizens to make better-informed lifestyle choices;
- Support exchange and learning in the area of mental health.

Communicable diseases

- Support Member States in working beyond the traditional distinction between communicable and non-communicable diseases (such as HPV, HIV, Hepatitis);
- Improve health literacy, including on sexual health.

Health inequalities and vulnerable groups

- Promote horizontal approach to addressing health inequalities in prevention and care, making sure that this dimension is not forgotten;
- Focus on health since the earliest age, as health problems accumulate over the life course and early action provides the best return on investment;
- Support health literacy and that vulnerable people can access and use digital tools; reach out to at risk groups and children;
- Collect better and comparable data on health inequalities at local, regional and national level.

Cancer

- Support the implementation of national cancer plans;
- Cooperate with international organisations on cancer control;
- Use existing tools and mechanisms to bring about improvements in the quality of care for adolescents and young adult cancer patients.

The **Crisis preparedness** breakout session included participants from health authorities; academia; industry; and medical associations such as: the European Safety Federation; European Cancer Leagues; European Federation of Psychologists' Associations; the Standing Committee of European Doctors; the European University Hospital Alliance; European Patients' Forum; Vaccines Europe; the

Association of the European Self-Care Industry; and Medicines for Europe. The participants identified the following priorities, orientations and needs, and possible solutions:

Surveillance:

- Need to improve monitoring and surveillance by using an evidence-based approach.
- To further strengthen coordination and cooperation through data collection and analysis.
- Need to explore the use of all sources of data available to develop an even more comprehensive surveillance system.
- Cooperation should be inter-sectorial to adequately prepare and respond to current and future cross-border health threats.

Fighting disinformation

- Disinformation is not only linked to vaccine hesitancy but also the health measures to control the spread of coronavirus.
- Health literacy should be a priority in this area. For this reason, any solution would need to be supported by evidence-based data.
- Potential solutions could be focused on building confidence and creating a positive communication environment. This can be done in collaboration with patients associations and civil societies.

Capacity building

- Need to invest on capacity building on crisis relevant products and relevant staff:
 - Any reserve of staff or equipment needs to be able to respond quickly to surges and be adaptable.
 - Flow of knowledge is essential to avoid shortages of crisis relevant products during a future surge: knowledge on their appropriate use, the regulatory requirements (to ensure the products procured complied with them) and knowledge on the real needs to avoid production and supply problems.
 - European blue print with national and European level could give time to allow the time to increase the production of relevant products during a surge, putting a focus on ensuring an adequate distribution.
 - Preparedness activities could include stockpiling at EU level and national level to be deployed when an initial surge occurs. It is especially important to ensure that the reserve staff is able to move freely.
 - Sustainable alternatives need to be further explored.
- Need to invest on capacity building and resilience of the local communities, especially in geographically remote areas to ensure access to health systems including vulnerable people.

Mental health was also mentioned as an essential cross-cutting element.

The **Health System** breakout session included participants from health authorities, academia and several associations such as: European Hospital and Healthcare Federation; BioMed Alliance; Antwerp University Hospital; National confederation of disabled people in Greece; Health Care Without Harm Europe; EURORDIS - Rare Diseases Europe; International Planned Parenthood Federation European Network; European Oncology Nursing Society ; European Society for Paediatric Oncology; European Kidney Health Alliance; International Diabetes Federation in Europe; The European Federation of Allergy and Airways Diseases Patients' Associations; Spanish Patient Platform; European Association of Hospital Pharmacists; European Children's Hospitals Organisation. The participants identified the following priorities, orientations and needs, and possible solutions:

Health Systems

- Switch from hospital-centred towards primary care based and community oriented systems. Starting with integration of social care, public health and primary care, where disease prevention, health promotion, cure-care, rehabilitation and palliative care need major attention.
- Strong health systems require integrated inter-professional care teams, where all involved disciplines and the patient contribute to, with support from integrated IT systems and Artificial Intelligence. Such inter-professional collaboration between primary and specialised care is also required in the field of cancer.
- Consider a healthcare continuity approach and the life-goals of the patient, in order to improve the relevance of the care.
- Build on the potential of digitalisation, which allows to measure health outcomes and collate data for research and policy making.
- Specifically concerning the health workforce, priorities should be given to forecasting and planning, recruitment and retention, and continuing professional development.
- Make the necessary investments in the transition costs of health systems' transformation to effect the above. Synergies with other EU programmes and funds should be considered to reinforce health systems' change.
- To facilitate the exchange of best practices between health systems in the EU, consideration needs to be given to: building common joint infrastructure and datasets; building learning networks and communities; and connecting HTA authorities, regulators, payers and industry together.

European Reference Networks (ERNs)

- Build an infrastructure and to make expertise in rare diseases available for all Member States. ERNs need central funding infrastructure for management, care, research and teaching and therefore there is a need to give a boost to the ERNs.
- Consider a systematic data collection at national level, the creation of disease-specific registries to identify patients and their needs and to effectively address them.
- Strengthen the data sharing in particular in specific areas where the number of patients is especially small and pooling data is essential for the treatment.
- Explore the urgent action related to COVID-19, the so called Long COVID patients, the post-COVID syndromes, affecting both symptomatic and non-symptomatic COVID-19 patients, suffering from neuromuscular, lung, kidney or heart symptoms.

Medicinal Products

- Ensuring patients' involvement along the drug development process, involving all patients, including the vulnerable ones.
- Personalise medicine to ensure the best care to patients considering their personal situation.
- Equity and cross-border access to treatments.
- Enable and facilitate collaboration amongst regulators, HTA, patients, buyers, pharma.
- Define & set criteria for unmet needs in different contexts.

The EU-level coordination on clinical trials can contribute to the development of innovative and safe medicines and this can be done by giving priority to:

- Promoting the involvement of patients (all groups, ages and conditions).
- Promoting new methodologies to perform clinical trials, the use of real world data and re-use of patient data gathered in previous clinical trials and the use of the Health Data Space as an opportunity to foster research.

- Support clinical trials with rare conditions and in general the studies for diseases that do not exist in the adult setting, to ensure that children and young people can have access to better medicines. In this sense, gene and cell therapies present opportunities for treatment (one-time treatment) for many paediatric conditions.
- Equity and cross-border access to clinical trials.
- Platform trials by collaborative groups funded by commercial and non-commercial actors should be envisaged to obtain information on treatment optimisation. Suitable drug candidates can be tested in this environment rather than in isolated insufficient trials.
- Strengthen the EU pharmacovigilance infrastructure-system.

In order to reinforce the cooperation with global partners on standards and inspection, there is need to:

- Encourage Member States and provide support to develop guidelines, measures and tools that could be used both at EU level and in national policy making to address structural shortages.
- Increase transparency in supply chain, identify vulnerabilities.
- Create early warning systems on medicine shortages (transparency in stocks too) at both national and European level.

Substances of Human Origin (SoHO)

COVID-19 highlighted the need for:

- More centralised actions, especially when addressing blood shortages or supplies.
- Establishing a centralised EU mechanism for health systems to report shortages and better coordinate EU-wide supplies

To further improve quality and safety standards and to increase the efficiency of public/non-profit blood and transplant services there is a need for:

- Steady update of competences and skills of staff working in such establishments
- Adoption of common, harmonised protocols for authorising and auditing
- Share best practices from professionals/healthcare workers dealing with SoHO (blood, tissues and cells, organs), via sharing information on clinical outcomes through dedicated IT platforms.

Medical devices

- Post market surveillance is a proactive and systematic process to initiate corrective and preventive actions, via gathering, recording and analysing relevant data on the quality, performance and safety of a device.
- Devices registries allow a comprehensive and prospective collection of data and may lead to early detection of safety signals, which assure the long-term safety of devices.
- Priority criteria to establish registers and databanks on specific devices are: new classes of devices, devices for children, high risk devices, artificial intelligence solutions.
- In order to ensure the capacity building of laboratories testing medical devices, priority should be given to high-risk medical devices, diagnostic imaging, cybersecurity, artificial intelligence based solutions, provided that all these priorities fulfil the provisions of the legislations on medical devices and in-vitro devices.
- Integrated information systems are essential for the above.

The **Digital** breakout session included participants from health authorities, academia, industry and several associations and entities such as: MedTech Europe; European Heart Network; Association of European Cancer Leagues; the European Health Telematics Association; European Association of Urology; Plataforma de Organizaciones de Pacientes; European Federation of Allergy and Airways

Diseases Patients' Association; the French Health Data Hub; Standing Committee of European Doctors; Digital Europe; or the Finnish Innovation Fund (Sitra). The participants identified the following priorities, orientations and needs, and possible solutions:

Beyond digital fragmentation and toward an EU-wide access level to health data

- Working towards an easier access to health data by promoting interoperability (both technical and semantic) and common governance of health data ecosystems formed by healthcare providers, universities, research institutions, citizens and entities dealing with secondary uses of health data.
- Moving towards EU-wide connectivity by bringing together national and possibly regional actors to promote the use of health data for healthcare provision and its re-use for research, policy-making and regulatory activities.
- Federating health data ecosystems would also involve the promotion of common agreed standards at EU level while preserving citizens' privacy and respecting frameworks established in each country which provide health data.

Pilot projects and scaling them to a European level

- It is essential to work collaboratively and promote the exchange of knowledge, practices, and developments so as not start from scratch every time.
- To incentivise the development of projects and establishment of and strengthening of the infrastructure at EU-level, European wide regulation (taking into account ethical and data protection aspects) should be available and should provide a legal basis and structure for these projects and their rollout.
- Capacity building would promote the development of these projects. It would include the provision of EU-wide organisational and technical solutions and guidelines.
- The creation of common methodologies and rules for collaboration would enhance the sustainability of these projects.
- Agreed rules of engagement for collaboration with clear and transparent regulatory oversight would increase trust between the various partners.
- Successful projects should be promoted and scaled up to include additional participating member states.

A patient-centric approach for unmet medical needs

- Focusing on digital tools that are useful and visible for citizens' day-to-day life, such as e-prescription and e-vaccination. Common assessment framework for such tools would promote acceptance of health digitalisation.
- Developing a health data ecosystem at a European level in order to have sufficient resources.
- Promoting a user-friendly process and interfaces for digital health systems.
- Reaching, understanding and involving citizens would drive investments in those areas of needs where innovation could really make a difference in peoples and patients' lives.
- Putting patients at the centre of the process on how data is collected, shared, used and processed would increase their ownership and trust in the system and promote their sharing of sensitive data. It would lead to improvement in the quality of the collected health data.

Develop IT skill and literacy in particular among healthcare professionals

- IT in healthcare should not be considered merely as a project but as an essential part of any development process.
- Developing hybrid IT/medical team is critical for the success of any digital health project.

- Strong IT skills and IT literacy skills among healthcare professionals would promote uptake and use of new and available tools. IT awareness of patients would also allow them to fully benefit from such tools.
- IT skilled healthcare professionals could also explain and explain their specific needs around data science, data protection, interoperability, cybersecurity. Taking into account such needs would streamline the integration of digital health into clinical workflows.