Mapping of HTA national organisations, programmes and processes in EU and Norway

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Directorate-General for Health and Food Safety

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LIST OF ABBREVIATIONS

AAZ – Agencija za kvalitetu i akreditaciju u zdravstvu i socijalnoj skrbi (Agency for Quality and Accreditation in Health Care and Social Welfare, Croatia)

AEMPS – Agencia Española de Medicamentos y Productos Sanitarios (The Spanish Agency of Medicinal Products and Medical Devices)

AETS-ISCIII - Agencia de Evaluación de Tecnologías Sanitarias - Instituto de Salud Carlos III (The institute of Health Carlos III, Spain)

AETSA - Agencia de Evaluación de Tecnologías Sanitarias de Andalucía (Andalusian Agency for Health Technology Assessment, Spain)

AGENAS - L'Agenzia Nazionale per i Servizi Sanitari Regionali (National Agency for Regional Health Services, Italy)

AIFA - Agenzia Italiana del Farmaco (Italian Medicines Agency)

AOTMiT - Agencja Oceny Technologii Medycznych i Taryfikacji (The Agency for Health Technology Assessment and Tariff System, Poland)

AQuAS - Agència de Qualitat i Avaluació Sanitàries de Catalunya (The Agency for Health Quality and Assessment of Catalonia, Spain)

Avalia-t – A Unidade de Asesoramento Científico-técnico (The Galician Agency for Health Technology Assessment, Spain)

AWTTC – All Wales Therapeutic and Toxicology Centre, UK

CEM - Cellule d'expertise médicale, Inspection générale de la sécurité sociale, Luxembourg

CHIF – Croatian Health Insurance Fund

CIRS – The Centre for Innovation in Regulatory Science

DAP – Diagnostic Assessment Programme (NICE, UK)

DG SANTE - The Directorate General for Health and Food Safety, European Commission

DPA/MFH – Ministry of Health, Directorate for Pharmaceutical Affairs, Malta

EEA – European Economic Area

EHIF – Estonian Health Insurance Fund

EMA – European Medicines Agency

ESNM – Evidence Summaries of New Medicines (NICE, UK)

EU – European Union

EUnetHTA – European network for Health Technology Assessment

FIMEA – Finnish Medicines Agency

FTE – full time equivalent

G-BA - Gemeinsame Bundesausschuss (Federal Joint Committee, Germany)

GÖG – Gesundheit Österreich GmbH/Geschäftsbereich, Austria

HAS – Haute Autorité de Santé (French National Authority for Health)

Hdir – Norwegian Directorate of Health

HIIS – Health Insurance Institute of Slovenia

HIQA – Health Information and Quality Authority, Ireland

HSTs – assessment of Highly Specialised Technologies (NICE, UK)

HTA – Health Technology Assessment

HVB – Hauptverband der Österreichischen Sozialversicherungsträger (Association of Austrian Social Insurance Institutions)

IACS – El Instituto Aragonés de Ciencias de la Salud (The Aragon Health Sciences Institute, Spain)

INAMI-RIZIV (HIHDI) – l'Institut national d'assurance maladie-invalidité - Rijksinstituut voor Ziekte- en Invaliditeitsverzekering (National Institute for Health and Disability Insurance, Belgium)

IQWiG – Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care, Germany)

INFARMED – Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. (National Authority of Medicines and Health Products, Portugal)

IP – Interventional Procedures (NICE, UK)

JA – Joint Action

JAZMP - Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (Agency for Medicinal Products and Medicinal Devices of the Republic of Slovenia)

KCE – Belgian Health Care Knowledge Centre

LBI HTA – Ludwig Boltzmann Institute for Health Technology Assessment

MIB – Medtech Innovation Briefing (NICE, UK)

MoH – Ministry of Health

MoSa – Ministry of Social Affairs, Estonia

MS – Member State (in the European Union)

MTA – multiple technologies assessment

MTEP - Medical Technologies Evaluations Pathway (NICE, UK)

N/A – not applicable

NCPE – National Centre for Pharmacoeconomics, Ireland

NCPHA – National Centre of Public Health and Analyses, Bulgaria

NHS – National Health Service, Latvia

NICE – National Institute for Health and Care Excellence, UK

NIPH – Norwegian Institute of Public Health

NIPN – National Institute of Pharmacy and Nutrition, Hungary

NMA – Norwegian Medicines Agency

OSTEBA - Servicio de Evaluación de Tecnologías Sanitarias (Basque Office for Health Technology Assessment, Spain)

REA – Relative Effectiveness Assessment

RIHTA – Rete Italiana per l'Health Technology Assessment (Italian Network for HTA, Italy)

SBU – Swedish Agency for Health Technology Assessment and Assessment of Social Services, Sweden

SESCS - Servicio de Evaluación y Planificación, Canarias (Evaluation and Planning Unit – Directorate of the Canary Islands Health Service, Spain)

SHTG – Healthcare Improvement Scotland - Scottish Health Technologies Group, UK

SMC – Healthcare Improvement Scotland – Scottish Medicines Consortium, UK

SMCA – State Medicines Control Agency of Lithuania

STA – single technology assessment

SUKL - Státní ústav pro kontrolu léčiv (State Institute of Drug Control, Czech Republic)

TA – Technology Appraisal (NICE, UK)

THL – National Institute for Health and Welfare, Finland

TLV – Dental and Pharmaceutical Benefits Agency, Sweden

UETS – Health Technology Assessment Unit, Madrid, Spain

UK – United Kingdom

VASPVT – State Health Care Accreditation Agency, Lithuania

WP – Work Package

ZIN – National Health Care Institute, Netherlands

EXECUTIVE SUMMARY

Aim of the study

The present study was undertaken at the request of the Directorate General for Health and Food Safety (DG SANTE) of the European Commission with the main objective of mapping the HTA organisations and processes in the EU and the European Economic Area (EEA) countries to contribute to a better understanding of the current HTA organisational framework in the EU and EEA countries. The input of this study will be used, *inter alia*, as input for the Impact Assessment for an EU initiative on HTA[1]. The mapping study was also a practical response to the HTA Network's request expressed in its multiannual work plan 2016-2020[2] to have an overview of the HTA processes and their organisation in the EU MS.

The focus of the study was on organisational and processual /procedural aspects of the HTA process and delivery of HTA results to inform decision-making in the EU Member States and EEA countries at national (country) level.

The mapping study output is a structured collection of information on the elements of the HTA process and organisational characteristics of the HTA bodies in the EU Member States and EEA countries, and includes

- individual EU and EEA Country HTA Profiles and
- a high-level overview of the HTA processes identifying key commonalities and differences in the EU Member States and EEA countries' HTA process organisation.

Background

HTA has a distinct role in determining the added value of a given health technology over and above existing ones. Assessing a technology from clinical and economic perspectives facilitates the EU Member States' decisions on effective health interventions for patients. This also contributes to the sustainability of national health systems. At the same time, HTA provides an incentive for innovation by rewarding technologies with high added value, encouraging industry to address unmet needs of patients.

In this context, a wide variety of different organisations and structures have been set up in the EU Member States, ranging from large HTA bodies to advisory committees and departments in Ministries of Health (MoH). These organisations operate within various national/regional legal and procedural frameworks. [3][4]

A few recent studies addressed and discussed differences and similarities in criteria, methods or outcomes of assessments of drugs[5], or perspectives of HTA bodies regarding medical device assessment[6], or provided a high level overview of the HTA environment [7]. However, literature data providing a comprehensive overview and country-specific, comparable descriptions of the currently existing processual /procedural/organisational aspects of the HTA process and HTA organisation set-up and delivery of HTA results to inform decision-making in the EU Member States and EEA countries on the national (country) level is scarce. The desk research proved that the objectives of the study could not be achieved by only studying the literature and websites of the identified HTA organisations. The Country HTA Profiles were developed based on the data collected via the study questionnaire, the EUnetHTA Joint Action 3 Work

[1] http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_144_health_technology_assessments_en.pdf
[2] https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2016_2020_pgmnetwork_en.pdf
[3] Van Wilder P, et al. Towards a Harmonised EU Assessment of the Added Therapeutic Value of Medicines. Directorate General for Internal Policies, Policy Department A: Economic and Scientific Policy, June 2015
[4] Sorenson C, Ensuring value for money in health care – The role of health technology assessment in the European Union, European Observatory on Health Systems and Policies Observatory Studies Series No. 11, 2008
[5] Kleijnen S, et. al. Relative Effectiveness Assessment of Pharmaceuticals: Similarities and Differences in 29 Jurisdictions. Value in Health 1 5: 954-60 (2012)
[6] Ciani O, et al. Health technology assessment of medical devices: a survey of non-European union agencies. Int J Technol Assess Health Care, 31:3 (2015).
[7] Allen N, et al (CIRS). Development of archetypes for non-ranking classification and comparison of European National Health Technology Assessment systems. Health Policy 113 305–12 (2013)

Package 7[8] data extraction forms, HTA organisations websites, literature review, and discussions and clarifications done via the validation by the HTA Network[9] members. The CIRS Regulatory and Reimbursement Atlas™ (2017) was consulted to gain more information on the relationship between the national regulatory authorities, HTA organisations and pricing and/or reimbursement decision-making bodies in the EU and EEA countries.

Organisation of HTA systems in EU Member States and Norway (EEA)

Twenty-five EU countries and Norway indicated that they have an HTA system informing decision-making at national level. Fifty-six organisations (all public bodies) in 27[10] EU countries and Norway were identified as the HTA bodies having a clearly defined role in the HTA production process to inform decision-making at the national level.

Fifteen EU countries have a singular national body whose main role includes development of HTA recommendations.

Twelve EU countries have a model of the HTA system organisation that includes two or more national HTA bodies whose main role includes development of HTA recommendations. It is worth noting that in the majority of the countries with two or more HTA bodies, only one of the HTA bodies that performs assessment of pharmaceuticals has a *formal remit* to do so *to specifically inform* pricing and/or reimbursement, and in such cases this body also often has a mandate *to make pricing and/or reimbursement decisions*.

Norway has a current model with 3 organisations that share a remit of developing HTA recommendations, while one of the three also has regulatory and pricing and/or reimbursement remit and mandate.

Scope of HTA

Twenty-three EU countries indicated having an HTA system that includes assessment of pharmaceuticals, 20 EU countries indicated having an HTA system that includes assessment of medical devices, and 17 EU countries indicated having an HTA system that includes assessment of other technologies. Norway indicated having an HTA system that includes assessment of all three types of technologies.

Fifteen EU countries indicated using «REA» and 24 EU countries indicated using «REA and economic evaluation» to assess health technologies (Norway applies both scopes to perform HTA). Twelve EU countries indicated performing full HTAs. Individual Country HTA Profiles provide details on the type of technologies that are assessed applying each type of HTA.

Role of HTA in decision-making

HTA is used to inform primarily pricing and reimbursement decisions, with a majority of the EU countries (24) and Norway indicating using HTA to inform reimbursement decisions on pharmaceuticals. With regards to decision-making on medical devices, fewer EU countries (19) apply HTA to inform reimbursement decisions and clear minority (9 EU countries) apply HTA to inform pricing decisions.

The organisation of the HTA process informing reimbursement decisions differs from country to country in terms of number of HTA bodies involved in the HTA process, type of technologies and scope of HTA, however, primarily REA and REA and economic evaluation is applied to inform reimbursement and pricing decisions on pharmaceuticals. In 16 EU countries and Norway HTA is obligatory (i.e., HTA process is formally

[8] http://eunethta.eu/activities/eunethta-joint-action-3-2016-20/work-package-7-national-implementation-and-impact
[9] https://ec.europa.eu/health/technology_assessment/policy/network_en
[10] Cyprus specifically stated that they are in a process of setting up a formal national HTA system including development of appropriate legislation and structure to support the HTA production process, while currently using elements of HTA in informing decision-making on reimbursement. Ministry of Health, HTA Unit was identified in Cyprus as the organisation in charge of setting up an HTA system and coordinating current HTA activities in the country.

established and legally mandated) to inform reimbursement and/or pricing decision-making on pharmaceuticals.

Organisational framework of HTA bodies

The size of the budget of the national HTA bodies was a difficult figure to obtain – it was possible to obtain this information only for half of the national HTA bodies. Most of the national HTA bodies indicated "mostly budget" or "budget only" as forms of financing HTA activities. Service fees were rarely indicated among the methods to finance HTA activities.

The most frequently mentioned competences among the staff of HTA organisations are pharmacist, pharmacologist, health economist, information specialist, medical science professional, epidemiologist, statistician. More than half of the organisations indicated that they commission external experts to perform HTA in addition to having internal HTA staff.

Forty-nine organisations indicated that they have procedures to handle conflict of interest issues when performing HTA.

National HTA processes

Reported numbers, types and scope of HTA of pharmaceuticals indicate prevalence of the STAs and REA and economic evaluation among the EU countries and Norway. More countries indicated using MTAs and full HTA approach when assessing medical devices. Duration of an assessment irrespective of the type of technology, scope or type of HTA does not differ significantly between the countries.

Majority of the EU countries and Norway indicated having an established topic selection process. Analysis of sources for topics suggestion indicated more homogeneity across the countries with regards to HTA of pharmaceuticals. "Company" was the most frequently indicated source for topic suggestion and selection in most of the EU countries with an obligatory HTA process that inform reimbursement and/or pricing decisions on pharmaceuticals. Compared to HTA of pharmaceuticals, clinical groups, hospital providers and regional authorities were more frequently indicated as sources for topic suggestions in HTA of medical devices. With regards to topic selection criteria, the most frequently indicated for HTA of pharmaceuticals were existence of EMA/national authorisation, therapeutic value claims and perceived economic impact on health system. For HTA of medical devices, it was CE-mark presence before the start of an assessment, existence of sufficient evidence to perform HTA, perceived economic impact, professional uncertainty regarding clinical effect, and impact on organisation of care.

For HTA of pharmaceuticals, majority of the EU countries and Norway indicated that company provides information on a technology to undergo HTA, however, many of the same countries also utilise an approach where an HTA body carries out its own HTA and itself identifies the evidence to use (i.e., not using evidence submitted from the company). What approach is used and when is influenced by different circumstances across the countries. For assessment of medical devices, the situation is opposite: majority of the EU countries indicated that it is the HTA body that carries out its own HTA and itself identifies the evidence to use (not using evidence submitted from the company).

With regards to delivery of HTA advice/recommendations, all countries indicated that it is delivered in the national language. A few countries indicated specific document types where English language can be used. Majority of the EU countries and Norway indicated that the status of the advice is either public or public with confidential information removed – in less than one-third of the EU countries the HTA advice/recommendations are indicated as confidential.

Most of the EU countries that have an HTA system for assessment of pharmaceuticals, indicated that they also have a set process for stakeholder engagement for HTA of pharmaceuticals. Norway and slightly more than half of the EU countries that have an HTA system for assessment of medical devices indicated that they also have a set process for stakeholder engagement for HTA of medical devices. Industry, clinical

experts and payers are among the stakeholder groups that get most frequently engaged, while patients and providers get less frequently engaged in either HTA of pharmaceuticals or medical devices.

Norway and majority of the EU countries that perform assessment of pharmaceuticals indicated having a set process for re-assessment, whereas only slightly more than half of the EU countries that perform assessment of medical devices indicated having such a process (Norway indicated as not having a set re-assessment process for medical devices). The timing of performing re-assessment in relation to the initial assessment and criteria for re-assessment vary substantially within and across the countries, both in case of re-assessment of pharmaceuticals and medical devices.

Forty-nine HTA organisations from 25 EU countries[11] and Norway indicated that they use HTA information from other jurisdictions. HTA assessment details, e.g., scoping information, summaries of the evidence, etc, followed by HTA advice and consequent decision-making results were most frequently used types of HTA information from other jurisdictions. Often it was specified that the HTA information from other jurisdictions were used for information purposes and not for direct application in the national HTA production process.

Thirty-eight HTA organisations from 23 EU countries and 3 organisations from Norway indicated that they use EUnetHTA tools in their national HTA processes. Thirty HTA organisations from 19 EU countries and 2 organisations from Norway indicated that they use EUnetHTA joint assessment in their national HTA processes. Several organisations indicated that use of the EUnetHTA joint assessment reports is a part of their national practice of utilising HTA information from other jurisdictions.

Conclusions

The purpose of this mapping study was to survey, examine and document organisational and processual /procedural aspects of the HTA process and delivery of HTA results to inform decision-making in the EU Member States and EEA countries at national (country) level. While the study confirms diversity of HTA processes across EU countries and Norway, it also indicates that there is an opportunity to practically explore appropriate and effective convergence of procedures.

Most HTA bodies in the EU countries and Norway perform REA and REA and economic evaluations; there is a more varied picture with regards to production of full HTAs. There is a prevalence of advisory weight of HTA in relation to the decision-making processes. A large number of HTA organisations indicated use of the EUnetHTA joint assessments. The commonly cited reasons for not using the EUnetHTA joint assessments include timing, topic and scope of assessment not being in line with national HTA process requirements. However, a clear majority of the countries indicated use of the EUnetHTA tools in their national HTA processes.

HTA expertise is present in all EU countries and Norway, however, the staff and financial capacities of the HTA organisations differ across the countries, which makes assistance with building staff capacities to do HTA a helpful undertaking.

Majority of the EU countries (17 countries) and Norway has an HTA system where at least one of the national HTA bodies has pricing and/or reimbursement decision-making functions in addition to the development of HTA recommendations. Thus, further clarification of the boundaries between the HTA process and the decision-making process that the HTA process informs will help identifying appropriate and effective modes and levels of engagement in the European cooperation on HTA in the EU countries and Norway.

Sufficient procedural commonalities can be found in the processes of HTA of pharmaceuticals across the EU countries and Norway in terms of type of HTAs (REA, REA and economic evaluation), processes to define

[11] Cyprus, Greece, Romania were not included due to lack of specific information on the subject.

the scope of the assessment, provision of information for HTA, delivery of HTA advice/recommendation to inform decision-making, stakeholder engagement and re-assessment practices. Further comparative analysis of the specific process steps in HTA of pharmaceuticals, paying focused attention to the pertinent legal framework issues would be helpful in identifying desirable and feasible level of cooperation on HTA of pharmaceuticals.

More diversity and procedural complexity can be observed in the HTA of medical devices. Nevertheless, sharing best practices and assisting with capacity building in this area could bring common benefit.

1. INTRODUCTION

1.1 Background

HTA has a distinct role in determining the added value of a given health technology over and above existing ones. Assessing a technology from clinical and economic perspectives facilitates Member States' decisions on effective health interventions for patients. This also contributes to the sustainability of national health systems. At the same time, HTA provides an incentive for innovation by rewarding technologies with high added value, encouraging industry to address unmet needs of patients.

In this context, a wide variety of different organisations and structures have been set up, ranging from large HTA bodies to advisory committees and departments in Ministries of Health (MoH). These organisations operate within various national/regional legal and procedural frameworks. [12][13]

While a few recent studies addressed and discussed differences and similarities in criteria, methods or outcomes of assessments of drugs[14], or perspectives of HTA bodies regarding medical device assessment[15], or provided a high level overview of the HTA environment [16], literature data providing a comprehensive overview and country-specific, comparable descriptions of the currently existing processual /procedural/organisational aspects of the HTA process and HTA organisation set-up and delivery of HTA results to inform decision-making in the EU Member States and EEA countries on the national (country) level is scarce. Recently Fuchs et al[17] explored structural, procedural, and methodological characteristics of the institutions involved in HTA of medical devices in Europe and commented that structural elements of the organisational set-up of the institutions were rarely included in the publicly available information.

1.2 Aim and scope of the study

The present study[18] was undertaken at the request of the Directorate General for Health and Food Safety (DG SANTE) of the European Commission with the main objective of mapping the HTA organisations and processes in the EU and the EEA countries. The input of this study will be used, *inter alia*, as input for the Impact Assessment for an EU initiative on HTA[19]. The mapping study was also a practical response to the HTA Network's request expressed in its multiannual work plan 2016-2020[20] to have an overview of the HTA processes and their organisation in the EU MS.

The focus of the study was on organisational and processual /procedural aspects of the HTA process and delivery of HTA results to inform decision-making in the EU Member States and EEA countries at national (country) level. Scientific HTA methodology and detailed description of the organisation of the HTA process and HTA bodies at the regional level[21] were out of scope of this study.

The mapping covers

[12] Van Wilder P, et al. Towards a Harmonised EU Assessment of the Added Therapeutic Value of Medicines. Directorate General for Internal Policies, Policy Department A: Economic and Scientific Policy, June 2015

[13] Sorenson C, Ensuring value for money in health care – The role of health technology assessment in the European Union, European Observatory on Health Systems and Policies Observatory Studies Series No. 11, 2008

[14] Kleijnen S, et. al. Relative Effectiveness Assessment of Pharmaceuticals: Similarities and Differences in 29 Jurisdictions. Value in Health 1 5: 954-60 (2012)

[15] Ciani O, et al. Health technology assessment of medical devices: a survey of non-European union agencies. Int J Technol Assess Health Care, 31:3 (2015).

[16] Allen N, et al (CIRS). Development of archetypes for non-ranking classification and comparison of European National Health Technology Assessment systems. Health Policy 113 305–12 (2013)

[17] Fuchs S, et al. Health Technology Assessment of Medical Devices in Europe: processes, practices, and methods. Int J Technol Assess Health Care, 32:4 (2016)

[18] SANTE/2016/B4/020

[19] http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_144_health_technology_assessments_en.pdf

[20] https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2016_2020_pgmnetwork_en.pdf

[21] Inclusion of the regional HTA agencies in Spain in the study was due to their involvement in the Spanish HTA Network that is involved in the national HTA production process in the country.

- The institutions performing HTA in EU and EEA countries, their roles and tasks, technologies assessed, scope of HTA (type of assessments, e.g., REA, REA and economic evaluation, full HTA), organisational frameworks including resources, and use of HTA outputs from other jurisdictions and EUnetHTA.
- The HTA processes, with focus on the main steps of health technology assessments (including re-assessment) of pharmaceuticals and medical devices[22], number of HTAs per year and time needed to complete an HTA, scoping in HTA, provision of information to undergo HTA, types of decision-making on the basis of HTA, stakeholder engagement, use of HTA reports from other jurisdictions as well as use of tools and results of the joint work delivered by EUnetHTA; it provides information on national legal frameworks for HTA in the EU countries and Norway.

The mapping study output is a structured collection of information on the elements of the HTA process and organisational characteristics of the HTA bodies in the EU Member States and EEA countries and includes

- individual EU and EEA Country HTA Profiles and
- a high-level overview of the HTA processes identifying key commonalities and differences in the EU Member States and EEA countries' HTA process organisation.

2. METHODOLOGY

2.1 Key concepts

For the purpose of this study, the following key concepts are defined as follows:

Health technology is the application of scientific knowledge in health care and prevention[23].

Health Technology Assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective, health policies that are patient focused and seek to achieve best value.

Despite its policy goals, HTA must always be firmly rooted in research and the scientific method.[11]

Relative Effectiveness Assessment (REA) is a specific element of health technology assessment (HTA) that focuses on the clinical benefit of the intervention, whereas HTA is broader and can also include other aspects, such as ethical, cost, and cost-effectiveness considerations[14].

Full HTA is an assessment of health technology that also include other aspects in addition to clinical benefit of the intervention, e.g., costs and economic evaluation, ethical analysis, organisational aspects, patients and social aspects, legal aspects[24].

Assessment (phase) is a phase in the process of HTA when clinical (economic, etc) evidence is reviewed and described.[25]

*Appraisal (*phase) is a phase in the process of HTA following the assessment phase when recommendations on the use of health technology are given, it includes value judgement.[25]

[22] Other health technologies were not primary focus of this study, however, were not excluded from the study if the data on the processes of HTA of other technologies was made available.

[23] http://www.eunethta.eu/about-us/faq#t287n73

[24] Kleijnen S, et al. Can a Joint Assessment Provide Relevant Information for National/Local Relative Effectiveness Assessments? An In Depth Comparison of Pazopanib Assessments. Value in Health 18 (2105): 663-672

[25] Drug reimbursement systems: international comparison and policy recommendations. KCE Report 147C (2010)

In the absence of the established/agreed authoritative definitions, the following working definitions of the concepts were used in the study:

HTA production process –development and delivery of HTA information to inform decision-making.

National HTA legal framework – a broad system of rules (including e.g., legal acts or procedural documents) that governs and regulates decision-making regarding HTA process in a country.

National HTA organisation/body is a legal entity having a clearly defined, often formally supported through legislative acts, role in the national HTA production process to inform decision-making on reimbursement, pricing and/or provision of health technologies in the country.

National regulatory body/authority is a national public authority or government agency responsible for control and monitoring of quality, safety and efficacy of health technologies and specifically in relation to pharmaceuticals – being tasked with marketing authorisation of medicines[26] in the country.

2.2 Selection of HTA organisations

A comprehensive approach was adopted to identify national HTA organisations/bodies in the EU and EEA countries. The identification process was based on previous research[27][17] to identify the national HTA organisations. Specifically, for HTA of pharmaceuticals, the CIRS Regulatory and Reimbursement Atlas™ (2017) was consulted when identifying the legal entities involved in the assessment of pharmaceuticals to clarify relationship between the national regulatory authorities, HTA organisations and pricing and/or reimbursement decision-making bodies in the EU and EEA countries. The lists of organisations included in the research of EUnetHTA Joint Action 2 (JA2) on submission templates for pharmaceuticals and medical devices[17] were checked against the membership lists of the HTA Network and EUnetHTA Joint Action 3 (JA3)[28] (as consulted in July 2016).

As agreed with the European Commission, the mapping study was done in cooperation and complementarity with EUnetHTA JA3 Work Package 7 (WP7, National implementation and impact), activity 1[29]. The final list of organisations included in the mapping study was also discussed with the WP7 Lead Partner to allow for effective data collection and extraction to develop and complete a Country HTA Profile.

2.3 Data collection and extraction

To meet the mapping study objectives, and in accordance with the technical specifications laid out for this study by the European Commission, a Country HTA Profile was developed (Appendix 16) and agreed with the European Commission. The elements of the Country HTA Profile were discussed with the EUnetHTA JA3 WP7 Lead Partner to allow for sufficient and appropriate mutual alignment of the Country HTA Profile structure and the WP7 JA3 data extraction form developed by the JA3 WP7 as per the work protocol of WP7 activity 1.

The desk research proved that the objectives of the study could not be achieved by only studying the literature and websites of the identified institutions. The data on the organisational characteristics of an HTA body (section 2 of the Country HTA Profile) was collected via a questionnaire (Appendix 17) that was developed in consultation with EUnetHTA JA3 WP7 Lead Partner (including identification of the relevant contact points in the EUnetHTA JA3). The questionnaire was distributed with the help of the EUnetHTA JA3 Directorate to the dedicated contact persons from the partner organisations involved in the EUnetHTA JA3

[26] http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000109.jsp&mid=WC0b01ac0580028a47

[27] Allen N, et al (CIRS). Development of archetypes for non-ranking classification and comparison of European National Health Technology Assessment systems. Health Policy 113 305–12 (2013)

[28] www.eunethta.eu

[29] http://eunethta.eu/activities/eunethta-joint-action-3-2016-20/work-package-7-national-implementation-and-impact

WP7 activities. The organisations (CEM (Luxembourg), Office of Public Health (Liechtenstein), Medicines Agency (Iceland) identified via the desk research were also approached. The questionnaire responses were reviewed and a consequent follow-up to clarify and/or to collect additional information, where needed, was performed via email and telephone contacts with the responders to the questionnaire. The data on the HTA process (section 3 of the Country HTA Profile) and on the organisations involved in the HTA and decision-making on the availability of health technologies in the national healthcare systems (Section 1 in the Country HTA Profile) were collected in cooperation with the JA3 WP7 via their data extraction exercise. JA3 WP7 Lead Partner assisted with clarification of the information in the data extraction forms, where needed.

The Country HTA Profiles were compiled based on the data collected via the questionnaire, the JA3 WP7 data extraction forms, HTA organisations websites, literature review, and discussions and clarifications done via the validation by the HTA Network[30] members. The CIRS Regulatory and Reimbursement Atlas™ (2017) was consulted to gain more information on the relationship between the national regulatory authorities, HTA organisations and pricing and/or reimbursement decision-making bodies in the EU and EEA countries.

2.4 Validation of Country HTA Profiles

Once the Country HTA Profile was compiled, it went through the review and validation by the HTA Network members from the respective country[31]. Additional information, where missing, was provided by the HTA Network members. Discrepancies were resolved by discussion and clarifications with the HTA Network members, responders to the original questionnaire and by discussion with the JA3 WP7 Lead Partner.

Based on the Country HTA Profiles, analysis of the commonalities and differences of the HTA systems was performed and presented in the Results chapter.

2.5 Limitations of the study

1. While definitions associated with the methodological aspects of conducting HTA are available in the scientific literature and have been fairly agreed on, definitions associated with the HTA process organisation, e.g., HTA body, HTA production process, HTA system, etc are not yet at the stage of being universally agreed. Therefore, for the purpose of this study, a list of working definitions has been included (see above). In addition, lack of an agreed common framework of an HTA process (with defined and commonly understood HTA process steps) coupled with the ambiguity on the boundaries between the *HTA process* and *the decision-making process* that the HTA process informs makes it difficult to draw final conclusions on the commonalities and divergences between the countries' HTA processes. When reviewing the details of the results section of the study report, each Country HTA Profiles must also be individually consulted.
2. Two country profiles (Romania, Greece) have not been validated by the HTA Network members from the respective countries, and all attempts to establish contact to clarify and confirm details in the draft Country HTA Profile were unsuccessful.[32] Where publicly available, information about Romania is included in the main sections of the report and indicated as "non-validated data".
3. No detailed information was possible to obtain to suggest organisation of the HTA system and confirm organisations currently involved in the HTA process in Iceland. Liechtenstein indicated cooperation with the Swiss Medical Board on HTA (out of scope of this study). Thus, this study covers only Norway from the European Economic Area.

[30] https://ec.europa.eu/health/technology_assessment/policy/network_en

[31] Two countries did not respond to the validation request (please see chapter Limitations of the Study). Norway (observer in the HTA Network) was included in the validation exercise and provided response.

[32] Non-validated Country HTA Profiles for Greece and Romania are included in the supporting set of information to this report.

4. Additionally, financial information (budget, staff numbers) and annual count of the differentiated HTA output were provided in a limited number of cases.
5. Finally, the study did not specifically focus on governance aspects of HTA bodies' organisation.

3. RESULTS

3.1 Organisation of HTA systems in EU Member States and Norway (EEA)

The analysis of the data supports the initial assumption of the heterogeneity of the HTA systems in the EU Member States and Norway.

Twenty-five EU Member States and Norway indicated that they have an HTA system informing decision-making at national level.

- Cyprus specifically stated that they are in a process of setting up a formal national HTA system including development of appropriate legislation and structure to support the HTA production process, while currently using elements of HTA in informing decision-making on reimbursement.
- The publicly available data indicates that Romania uses a score-card system based on the assessments produced in other EU countries to inform reimbursement of pharmaceuticals in the country[33]
- Information for Greece gathered through the questionnaire and WP7 data collection exercise (available in a non-validated GREECE HTA Profile) indicates that the formal national HTA system is in the process of being set-up.

Fifty-six organisations in 27[34] EU Member States and Norway were identified as the HTA bodies (Appendix 15) having a clearly defined role in the HTA production process to inform decision-making at the national level.

- In Denmark, Italy, Spain and United Kingdom the organisation of the country's HTA system and how HTA informs decision-making processes in the country reflects the decentralised organisation and governance of the healthcare systems in these countries:
  - In 2010 the HTA production in Denmark was reorganised into a joint regional collaboration between five Danish Regions (the regions are tasked with provision of health services). A coordinating specialist function for assessment of medical devices and other technologies was established and is managed by DEFACTUM, Central Denmark Region in close collaboration with Department of Research and HTA, Odense University Hospital, Region of Southern Denmark.[35]
  - In Spain, the HTA programme is differentiated from reimbursement process but they are closely related. Agency of Medicines and Medical Devices (AEMPS), the 17 regional authorities and the Ministry of Health-DG Pharmacy (HM-DG Pharmacy) are involved in the HTA of pharmaceuticals. Non-pharma assessments can be performed both by individual regional HTA bodies, and in cooperation within the framework of the Spanish HTA Network bringing together regional HTA agencies for HTA cooperation on a national level.
  - In Italy, there are 2 organisations at the national level (AIFA and AGENAS) that have an HTA remit. One is focused on the HTA of pharmaceuticals (AIFA), the other is tasked with HTA of medical devices and is responsible for the coordination of the national Programme of HTA of medical devices (AGENAS).In 2009, Italian Regions and AGENAS agreed to create an Italian Network for HTA (RIHTA – Rete Italiana per l'Health Technology Assessment) – as of June 2015,

[33] Radu C-P, et al. The development of the Romanian HTA scorecard system. Value in Health Regional Issues, 10C (2016) 41-47.

[34] Ministry of Health, HTA Unit was identified in Cyprus as the organisation in charge of setting up an HTA system and coordinating current HTA activities in the country. In Romania National Drug Agency, Ministry of Health, and National Health Insurance Fund are involved in the HTA process (non-validated data).

[35] http://www.regioner.dk/sundhed, www.defactum.net

RIHTA had 16 members (Regions, Autonomous Provinces and Regional Agencies)[36] Formalisation of collaboration between RIHTA members are done on the basis of signed bilateral agreements. MoH of Italy may fund projects to be carried out under AGENAS-RIHTA agreement. Focus of RIHTA's activities are on non-pharmaceutical healthcare technologies.

- In the United Kingdom, there are four distinct HTA bodies (one in England, two in Scotland and one in Wales) that inform decision-making process in each of the countries. For the purposes of this study that looks at the organisation of the HTA system at the country level of an EU Member State, United Kingdom is identified as one country with a national HTA system with one national HTA organisation (NICE) and 3 distinct HTA organisations in devolved administrations of Scotland and Wales.

3.1.1 Models of organising national HTA systems based on the main role of a national HTA body

A variety of different organisational forms and structures have been set up in the EU and EEA countries (Norway). They range from large single HTA bodies with formal singular remit to develop HTA recommendations, to a Working Group within Ministry of Health, to models with two or more organisations performing various functions in the national HTA processes (see Appendix 8).

Fifteen EU countries have a singular national body whose main role includes development of HTA recommendations (Table 1).

Six countries (Bulgaria, Denmark, France, Poland, Slovakia, United Kingdom) indicated having among these HTA bodies, a national HTA body with a singular remit that exclusively focuses on the development of HTA recommendations. Remaining countries with a singular HTA body combine

- regulatory and HTA functions (Finland, Hungary)
- pricing and/or reimbursement (P&/orR) and HTA functions (Latvia, Luxembourg, Malta, Netherlands)
- regulatory, pricing and/or reimbursement and HTA functions (Portugal, Cyprus, Czech Republic).

Twelve EU countries have a model of the HTA system organisation that includes two or more national HTA bodies whose main role includes development of HTA recommendations. It is worth noting that in the majority of these countries, only one of the HTA bodies that performs assessment of pharmaceuticals has a formal remit to do so *to specifically inform* pricing and/or reimbursement, and in such cases this body also often has a mandate *to make pricing and/or reimbursement decisions*. In four countries with two or more national HTA bodies where regulatory, HTA and pricing and/or reimbursement main roles are distributed among different involved organisations, i.e., in Estonia, Lithuania, Romania, Slovenia, it is indicated that the process of HTA of pharmaceuticals is spread over the functions of 3 organisations.

Norway has a current model with 3 organisations that share a remit of developing HTA recommendations, while one of the three also has regulatory and pricing and/or reimbursement remit and mandate.

Table 1. HTA system organisation in EU and Norway

	One national HTA body				Two or more national HTA bodies		
	One national HTA body, having only one main role - HTA recommen-dations	One national HTA body, with regulatory functions	One national HTA body, with P(&/or) R functions	One national HTA body, regulatory +P(&/or) R functions	Two or more national HTA bodies, at least one with regulatory	Two or more national HTA bodies, at least one with P(&/or) R functions	Two or more national HTA bodies, combining regulatory and P(&/or) R functions

[36] http://www.agenas.it/images/agenas/hta/poster/POSTER_RIHTA.pdf

					functions		
Countries	Bulgaria Denmark France Poland Slovakia UK	Finland Hungary	Latvia, Luxembourg Malta Netherlands	Cyprus Czech Republic Portugal	Spain	Austria Belgium Croatia Germany Ireland Sweden	Estonia Italy Lithuania Romania* Slovenia Norway
Total number	6 MS	2 MS	4 MS	3 MS	1 MS	6 MS	5MS + Norway

*Non-validated data

Liechtenstein did not indicate specifically an HTA body with a national HTA remit, however, it pointed out that the Office of Public Health is officially represented in the Swiss Medical Board in its governing body.[37] The Swiss Medical Board has HTA in its formal remit.

With an exception of Lithuania, all 26 EU countries and Norway have at least one HTA body that in addition to their main role of producing HTA recommendations performs at least one of the following other tasks: quality standards development, clinical guidelines development, healthcare promotion, horizon scanning, registries, education, early dialogues and scientific advice (Appendix 9). Clinical guidelines development and education were among the most frequent (14 European countries and Norway) (Table 2).

Table 2. Other tasks performed by national HTA bodies

	Quality standards	Clinical guidelines development	Healthcare promotion	Horizon scanning	Registries	Education	Early Dialogues and Scientific Advice
Countries	Austria Croatia Cyprus Denmark France Germany Ireland Italy Netherlands Slovakia Spain United Kingdom Norway	Austria Belgium Cyprus Estonia France Germany Hungary Ireland Italy Latvia Luxembourg Netherlands Spain United Kingdom Norway	Austria Belgium Bulgaria Denmark Estonia France Italy Poland Portugal Slovenia Spain United Kingdom Norway	Austria Belgium Estonia Italy Netherlands Portugal Slovakia Spain Sweden United Kingdom Norway	Austria Belgium Bulgaria Denmark Estonia Ireland Portugal Slovenia Spain Sweden United Kingdom Norway	Austria Belgium Bulgaria Croatia Denmark Estonia Germany Hungary Ireland Italy Malta Poland Spain United Kingdom Norway	Belgium Estonia Finland France Germany Ireland Netherlands Portugal Slovenia Spain Sweden United Kingdom Norway
Total number	12 MS + Norway	14 MS + Norway	12 MS + Norway	10 MS + Norway	11 MS + Norway	14 MS + Norway	12 MS + Norway

3.1.2 Technologies assessed

Twenty-five EU countries and Norway indicated existence of a national legal framework for HTA:

- Cyprus specifically stated that they are in a process of setting up a formal national HTA system including development of appropriate legislation and structure to support the HTA production process, while currently using elements of HTA in informing decision-making on reimbursement.
- Greece and Romania were excluded due to non-validation of the data available in their respective Country HTA profiles. However, the available data on the development status of an HTA process in these two countries is included in the respective non-validated Country Profiles.

[37] Switzerland HTA system is out of scope of this study.

Please see Table 3 summarising the basis for national HTA legal frameworks in the EU Member States and Norway.

Overall, 23 EU countries and Norway indicated having an HTA system that includes assessment of pharmaceuticals (Appendix 2)[38]:

- Denmark is currently in a process of reorganising its system of HTA of pharmaceuticals[39],
- Cyprus is currently setting up a formalised process for HTA of pharmaceuticals,
- Luxembourg does not have a formalised process for HTA of pharmaceuticals,
- Romania (non-validated data; as per publicly available data[33]) has a process for assessment of pharmaceuticals based on score-card approach.

Twenty EU countries and Norway indicated having an HTA system that includes assessment of medical devices (Appendix 2):

- Cyprus does not have a formalised HTA process for assessment of medical devices,
- Finland is currently in a process of reorganising its system of HTA for medical devices and other technologies,
- Bulgaria, Czech Republic, Malta, Slovenia indicated not having a formalised HTA process for medical devices.

Seventeen EU countries and Norway indicated having an HTA system that includes assessment of other technologies (Appendix 2).

Table 3. National HTA legal frameworks in EU countries and Norway - procedural and/or legal documents as the basis

Country	Pharmaceuticals	Medical Devices
Austria	Legal act(s) and procedural documents	Procedural documents
Belgium	Legal act(s) and procedural documents	Legal act(s) and procedural documents
Bulgaria	Legal act(s) and procedural documents	No formal inclusion of HTA
Croatia	Legal act(s) and procedural documents	Procedural documents
Cyprus	In the process of establishing an HTA system; while currently using elements of HTA in informing decision-making on reimbursement of pharmaceuticals	
Czech Republic	Legal act(s) and procedural documents	No formal inclusion of HTA
Denmark	Currently in a process of reorganising its system of HTA of pharmaceuticals	Procedural documents
Estonia	Legal act(s) and procedural documents	Procedural documents
Finland	Legal act(s) and procedural documents	Currently in a process of reorganising its system of HTA of medical devices
France	Legal act(s) and procedural documents	Legal act(s) and procedural documents
Germany	Legal act(s) and procedural documents	Legal act(s) and procedural documents
Greece*	*Legal act(s) and procedural documents*	*Legal act(s) and procedural documents*
Hungary	Legal act(s) and procedural documents	Legal act(s) and procedural documents
Ireland	Legal act(s) and procedural documents	Legal act(s) and procedural documents
Italy	Legal act(s) and procedural documents	Legal act(s) and procedural documents
Latvia	Legal act(s) and procedural documents	Legal act(s) and procedural documents
Lithuania	Legal act(s) and procedural documents	Procedural documents
Luxembourg	No formal inclusion of HTA	Legal act(s) and procedural documents
Malta	Legal act(s) and procedural documents	No formal inclusion of HTA
Netherlands	Legal act(s) and procedural documents	Legal act(s) and procedural documents
Poland	Legal act(s) and procedural documents	Legal act(s) and procedural documents
Portugal	Legal act(s) and procedural documents	Legal act(s) and procedural documents
Romania*	*Legal act(s) and procedural documents*	*No formal inclusion of HTA*
Slovakia	Legal act(s) and procedural documents	Legal act(s) and procedural documents
Slovenia	Legal act(s) and procedural documents	No formal inclusion of HTA

[38] For specifics on types of pharmaceuticals and/or settings (e.g., inpatient/outpatient) for which HTA is performed, please check individual COUNTRY HTA Profiles.

[39] For details see DENMARK HTA Profile

Spain	Legal act(s) and procedural documents	Legal act(s) and procedural documents
Sweden	Legal act(s) and procedural documents	Legal act(s) and procedural documents
United Kingdom	Legal act(s) and procedural documents	Legal act(s) and procedural documents
Norway	Legal act(s) and procedural documents	Legal act(s) and procedural documents

** - non-validated data*

3.1.3 Scope of HTA – REA, REA and economic evaluation, full HTA

Fifteen EU countries and Norway indicated using «REA» and 24 EU countries and Norway indicated using «REA and economic evaluation» to assess health technologies (Appendix 2).

Individual Country HTA Profiles provide details on the type of technologies that are assessed with application of various HTA scopes. Table 4 provides an overview of the countries' application of three types of HTA based on its scope.[40]

Table 4. Scope of HTA – REA, REA and economic evaluation, full HTA

REA	REA and economic evaluation	Full HTA
Austria, Belgium, Bulgaria, Croatia, Denmark, France, ***Germany***, Ireland, **Lithuania**, Luxembourg, Netherlands, Poland, Portugal, Spain, Sweden, Norway	Austria, Belgium, Bulgaria, Croatia, **Czech Republic**, Denmark, Estonia, **Finland**, France, ***Germany****, **Hungary**, Ireland, Italy, **Latvia**, Luxembourg, **Malta**, Netherlands, Poland, Portugal, **Slovakia,** **Slovenia**, Spain, Sweden, ***United Kingdom**,*** Norway	Austria, Belgium, Croatia, Denmark, Estonia, France, Ireland, Italy, Netherlands, Spain, Sweden, ***United Kingdom (Scotland)*****, Norway
15 MS and Norway	24 MS and Norway	12 MS and Norway

** - G-BA rules of porcedures has an option for including economic evaluation*

*** - It is only SHTG in Scotland that indicates full HTA as the scope of HTA perfomed by the organisation.*

The scope of HTA performed in Lithuania and Germany includes only REA (in Germany, the G-BA Rules of Procedures does have an option for including economic evaluation[41], however, during the past 10 years it was applied only twice in practice).

The scope of HTA performed in Czech Republic, Finland[42], Hungary, Latvia, Malta, Slovakia, Slovenia, United Kingdom (except for Scotland's HTA system for assessment of medical devices) includes only «REA and economic evaluation».[43]

[40] If country appears in more than one column, it means that varying HTA scopes are used for assessments – application of a specific scope depends on eg, which technology is assessed, which national HTA organisation performs the assessment, etc. Please consult individual Country HTA Profiles for details.

[41] "The G-BA rules of procedure primarily regulate the methodological requirements for the scientific assessment of the benefit, necessity, and cost-effectiveness of measures as a basis for resolutions. " http://www.english.g-ba.de/legalmandate/rules/ (accessed 2016-10-12)

The full HTA was indicated as not being performed in Bulgaria, Czech Republic, Finland, Germany, Hungary, Latvia, Lithuania, Luxembourg, Malta, Slovakia, Slovenia, UK (except for Scotland's HTA system for assessment of medical devices).

3.2 Role of HTA in decision-making in EU Member States and Norway

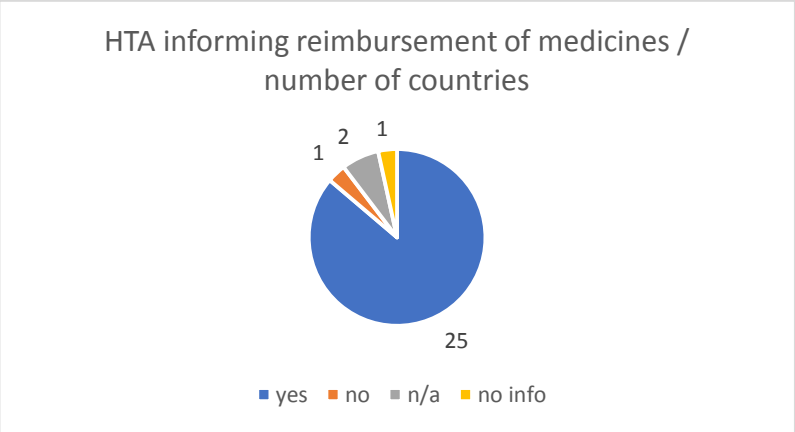
3.2.1 Reimbursement decisions

HTA is used by many Member States to inform decision-making on reimbursement of health technologies, as following:

- 24 EU countries and Norway indicated using HTA to inform reimbursement decisions on **pharmaceuticals** (*N/A* – Luxembourg, Denmark; *No* – Germany; *No info* – Greece);
- 19 EU countries and Norway - on **medical devices** (*N/A* - Bulgaria, Czech Republic, Finland, Malta, Slovenia; *No* - Ireland (but informs investment decisions in national programmes), Cyprus; *No info* – Greece, Romania).
- 12 EU countries (Belgium, Croatia, Denmark, Estonia, France, Germany, Luxembourg, Netherlands, Poland, Portugal, Slovenia, Spain) and Norway indicated that reimbursement decisions on **other technologies** are informed by HTA (*N/A* – Bulgaria, Czech Republic, Finland, Latvia, Lithuania, Malta; *No* – Austria, Ireland, Romania, Sweden; *No info* – Cyprus, Greece, Hungary, Italy, Slovakia, UK)

Diagram 1 illustrates the number of countries and use of HTA to inform reimbursement decisions in the EU Member States and Norway.

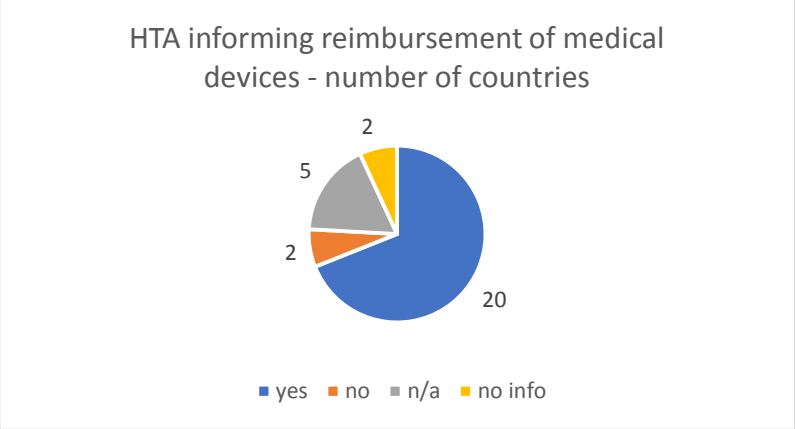
Diagram 1. Use of HTA to inform reimbursement decisions in the EU countries and Norway



N/A – Luxembourg, Denmark;

No – Germany;

No info – Greece



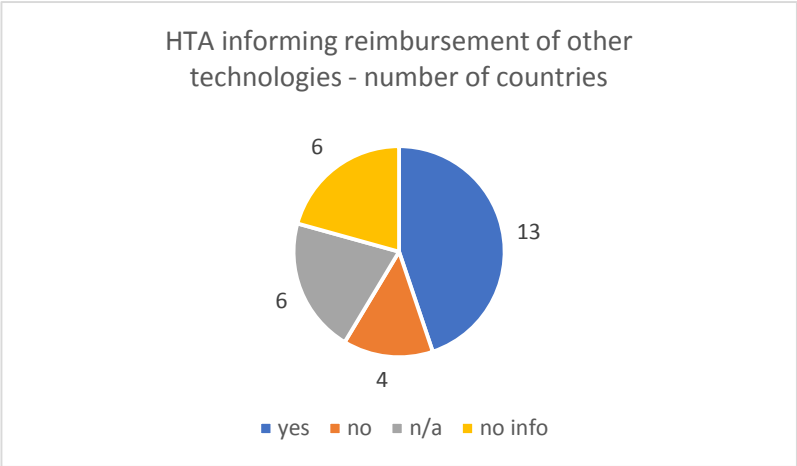
N/A - Bulgaria, Czech Republic, Finland, Malta, Slovenia;

No - Ireland (but informs investment decisions in national programmes), Cyprus;

No info – Greece, Romania

[42] THL performed full HTAs until May 2016. The role of THL in the HTA process in Finland is being clarified.

[43] See individual Country HTA Profile for details on the type of technologies that is assessed using each type of HTA.



N/A - Bulgaria, Czech Republic, Finland, Latvia, Lithuania, Malta

No – Austria, Ireland, Romania, Sweden

No info – Cyprus, Greece, Hungary, Italy, Slovakia, UK

Each country's HTA Profile has to be consulted to obtain details on types of pharmaceuticals (eg, for inpatient/outpatient use), medical devices and/or other technologies that are subject to HTA that informs reimbursement decisions. One needs to keep in mind that different types of HTA with regards to its scope (i.e., REA, REA and economic evaluation, full HTA) might be utilized for different types of technologies.

The organisation of the HTA process informing reimbursement decisions differs substantially from country to country. *To illustrate*:

- Belgium, Croatia, Estonia, France, Netherlands, Poland, Portugal, Spain and Norway indicate using HTA for reimbursement of pharmaceuticals, medical devices and other technologies.
    - France, Netherlands, Poland, Portugal has an HTA system that consists of only one HTA body *that informs* reimbursement decisions – this body also has a mandate *to make* reimbursement decisions.
    - Belgium and Croatia has two HTA bodies with differing HTA mandates with regards to a) informing the reimbursement decision-making process and b) to their role in supporting the production of HTA information to inform decision-making.
        - One HTA body (KCE in Belgium, AAZ in Croatia) does not have a legal mandate to perform HTA specifically to inform reimbursement decisions, however, this organisation's HTA information might be utilised by another HTA body (INAMI-RIZIV in Belgium, CHIF in Croatia) in its HTA production process.

      However, it is the same body in both countries that *informs and makes* reimbursement decisions for pharmaceuticals and medical devices (NIHDI (INAMI-RIZIV) in Belgium and CHIF in Croatia).

    - Estonia and Spain has three or more HTA bodies with differing HTA remits.
        - Spain has a network of regional HTA organisations (the Spanish HTA Network) that together with the Spanish Agency of Medicines and Medical Devices has a specified role and a process to inform reimbursement decision-making at the national level.
        - In Estonia both the responsibility to perform various steps in the HTA process and the decision-making responsibility are shared among three HTA organisations.
- Austria has 3 HTA bodies where one (HVB) has a formal legal mandate to inform reimbursement of pharmaceuticals based on HTA process which has obligatory character. HTA of medical devices in outpatient setting (mainly rapid assessments) may be performed by HVB if thought necessary; that may be done as part of the process when one of the regional sickness funds wants to have a new service item entered into the benefits catalogue (and therefore the assessment may subsequently inform a reimbursement decision), however, HTA is optional and not required by any legislative act. Specific HTAs in these cases could also be contracted to HTA organisations like LBI HTA. In the latter case, the HTA outcomes have an advisory character.

- In Italy both the HTA process and decision-making on reimbursement (and pricing) of pharmaceuticals takes place at AIFA, a governmental body that is also responsible for marketing authorisation of medicines. With regards to reimbursement of medical devices, AGENAS is in charge of the assessment part of the HTA process, while appraisal takes place at the Cabina di Regia, a Steering Committee at the Ministry of Health. MoH is in charge of the decision-making on reimbursement.
- In the United Kingdom, the organisation of the HTA process to inform decision-making on reimbursement reflects the fact that the decision-making is performed at the level of the administrations of the devolved countries – England, Scotland and Wales. While in England there is one HTA body that assesses both pharmaceuticals and medical devices (NICE), in Scotland there are two HTA bodies each charged with the responsibility for one type of technology, ie, pharmaceuticals (SMC) and medical devices (SHTG). In Wales currently HTA is informing decision-making on pharmaceuticals only with AWTCC being in charge of the HTA process. Additionally, NICE together with NHS England takes part in a decision-making on reimbursement of pharmaceuticals.
- In Norway, HTA process is organised through a national system for Managed Introduction of New Health Technologies within the specialist health service (assessment of pharmaceuticals, medical devices and other technologies in inpatient settings) and through the system of preapproved reimbursement of pharmaceuticals (Blåresept; outpatient setting). Inpatient setting is defined as where the Regional Health Authorities have the responsibility for ensuring that specialized health care is provided. NMA is in charge of the HTA process informing reimbursement decisions on pharmaceuticals under the Blåresept system, while HIPH, NMA and Hdir (through the coordinating secretariat) are jointly involved in the HTA process in the Managed Introduction of New Health Technologies within the specialist health service.

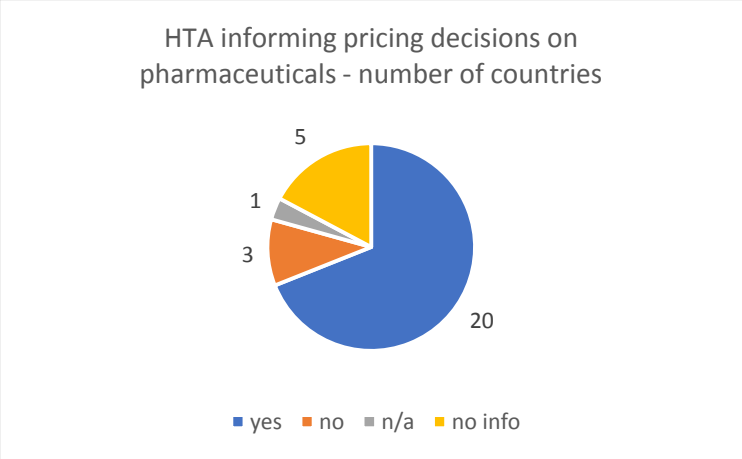
3.2.2 Pricing decisions

HTA is used by many Member States to inform decision on pricing of health technologies, as following:

- 20 EU countries (Austria, Belgium, Bulgaria, Croatia, Czech Republic, Estonia, Finland, France, Germany, Ireland, Italy, Latvia, Malta, Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden) and Norway indicated using HTA to inform pricing decisions on **pharmaceuticals** (Appendix 12).
- 9 EU countries (Belgium, Croatia, Estonia, France, Latvia, Poland, Portugal, Slovakia, Sweden) indicated using HTA to inform pricing decisions for **medical devices**
- 7 EU countries (Belgium, Croatia, Estonia, France, Poland, Portugal, Slovenia) specified using HTA to inform pricing of **other technologies.**

In Norway HTA is indicated as not informing pricing decisions on medical devices and other technologies. Diagram 2 illustrates the number of countries and use of HTA to inform pricing decisions in the EU member states and Norway.

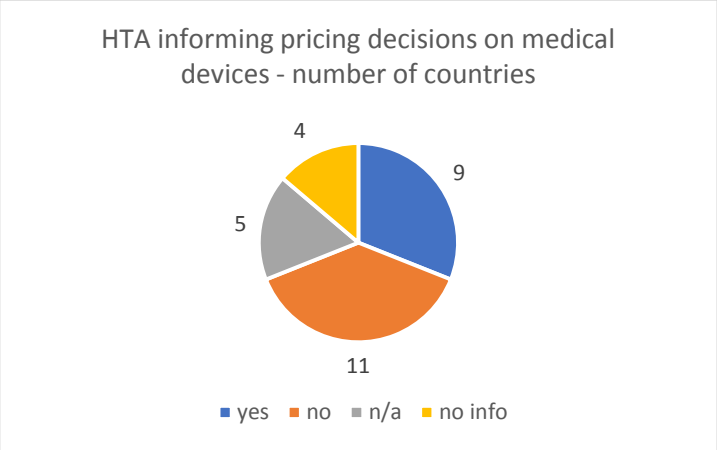
Diagram 2. Use of HTA to inform pricing decisions in the EU countries and Norway



N/A –Luxembourg

No – Lithuania, UK, Norway

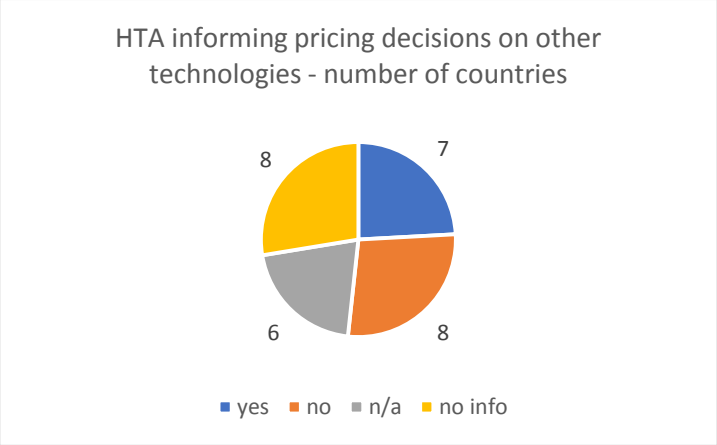
No info – Cyprus, Denmark, Greece, Hungary, Romania



N/A – Bulgaria, Czech Republic, Finland, Malta, Slovenia

No – Austria, Denmark, Germany, Ireland, Italy, Lithuania, Luxembourg, Netherlands, Spain, UK, Norway

No info – Cyprus, Greece, Hungary, Romania



N/A – Bulgaria, Czech Republic, Finland, Latvia, Lithuania, Malta,

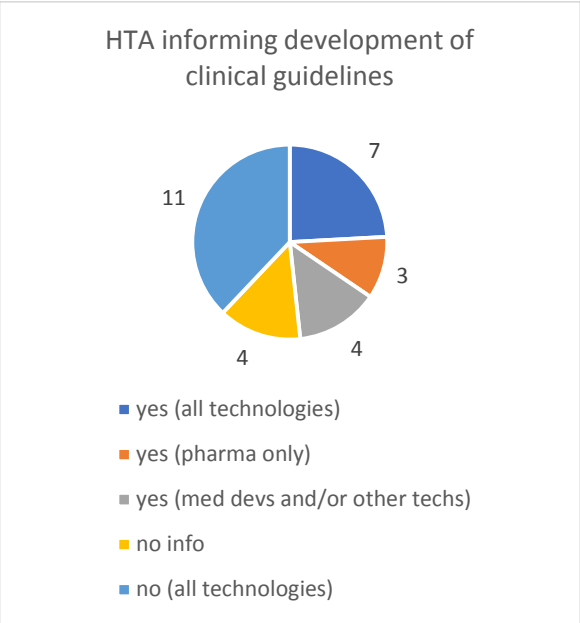
No – Austria, Denmark, Germany, Ireland, Luxembourg, Spain, Sweden, Norway

No info – Cyprus, Greece, Hungary, Italy, Netherlands, Romania, Slovakia, UK

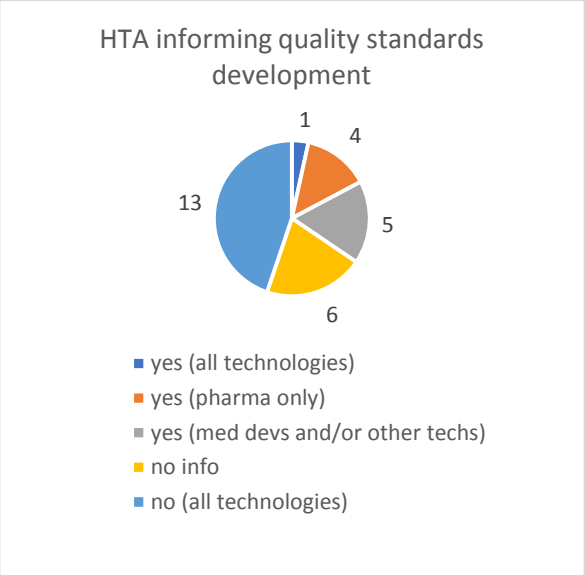
3.2.3 HTA and clinical guidelines, quality standards, capital investment decisions

HTA organisations in all 26 EU countries and Norway also indicated using HTA to inform decisions in some of the following areas: capital investments, clinical guidelines and quality standards development (see Diagram 3).

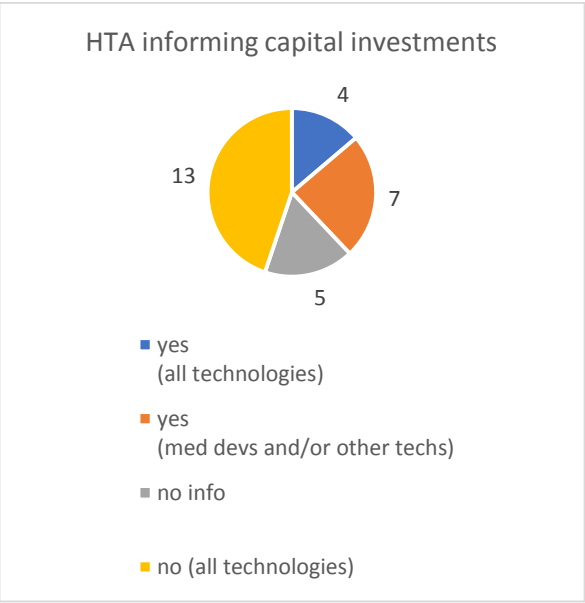
Diagram 3. Use of HTA to inform development of clinical guidelines, quality standards, capital investments in the EU countries and Norway



Thirteen EU countries and Norway indicated that HTA is informing development of the clinical guidelines:
• Croatia, France, Hungary, Ireland, Spain, UK, Norway indicated applicability of HTA without specifying type of technology
• Belgium, Czech Republic, Sweden indicated applicability of HTA only to inform development of clinical guidelines with regards to pharmaceuticals
• Denmark, Estonia, Italy, Luxembourg indicated applicability of HTA to inform development of clinical guidelines for medical devices and/or other technologies



Ten EU countries use HTA to inform quality standards development:
• Austria, Germany, Malta, UK (England) use HTA to inform quality standards development with regards to pharmaceuticals only
• Belgium, Denmark, Estonia, Italy, Luxembourg use HTA to inform quality standards development with regards to medical devices and/or other technologies
• Spain – no specification of types of technologies



Ten EU countries and Norway use HTA for making capital investment decisions:
• Croatia, France, UK, Norway use HTA to inform capital investments with reagrds to any type of medical technology (*Note:* UK specified pharmaceuticals (England) and medical devicesin Scotland)
• Austria, Denmark, Ireland, Italy, Luxembourg, Portugal, Sweden use HTA to inform capital investments with regards to medical devices and/or other technologies

3.2.4 Informative, advisory or obligatory role of HTA?

For the purposes of this study, the HTA weight as **"obligatory"** was defined as associated with the HTA process that is formally established and legally mandated, i.e., an HTA must be performed to inform decision-making, e.g., reimbursement, or pricing, or any other type of decision-making on provision of a specific health technology (pharmaceutical/medical device/other technology) in the country. In other words, HTA has an obligatory character if an HTA must be performed in order for a technology to be considered for, e.g., reimbursement, and this requirement has a legal character through a specific legislative act and/or formal procedural document that introduces such a requirement. The results of an HTA may - but do not necessarily have to - be legally binding for an HTA to be considered "obligatory".

The HTA weight as **"advisory"** was defined as associated with the HTA process that is formally established but not legally mandated, i.e., an HTA can be performed to inform decision-making, e.g., reimbursement, or pricing, or any other type of decision-making on provision of a specific health technology (pharmaceutical/medical device/other technology) in the country, but it is not an obligation. A pharmaceutical/medical device/other technology may - but does not "have to" - undergo HTA in order to be considered for, e.g., reimbursement, as there is no legal requirement of an HTA through a specific legislative act and/or formal procedural document.

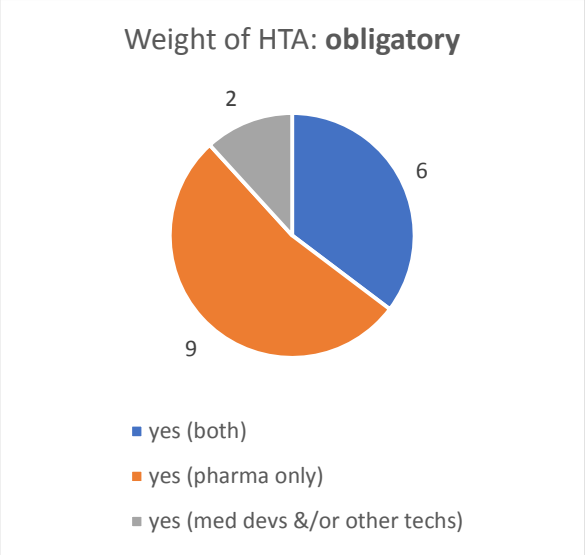
The HTA weight as **"informative"** was defined as associated with the HTA process that is formally established and an HTA is performed for information purposes, to gain more insight on the technology, but there is no legal obligation to perform an HTA.

Appendix 12 presents an overview of the distribution of HTA weight across the EU countries and Norway (further details on the specific circumstances of each country with regards to the weight of HTA can be found in each Country HTA Profile).

Diagram 4 provides a comparative overview of the number of EU countries and Norway that indicated HTA as being obligatory and/or advisory, and specification of the national HTA body (in parenthesis), where relevant, that is in charge of the HTA process with the respective HTA weight.

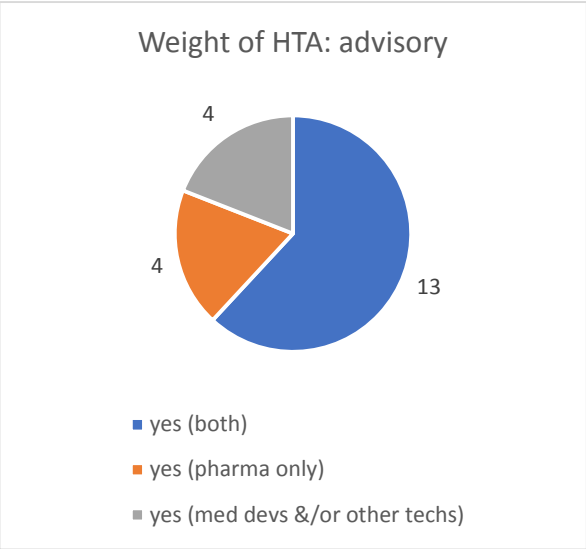
Tables 5 and 6 provide further insight into the status of obligatory HTA in these countries.

Diagram 4. Obligatory and advisory weight of HTA in the EU countries and Norway



Yes (all technologies): Croatia (CHIF), France, Germany (G-BA), Latvia, Poland, Sweden (TLV)
Yes (pharma only): Austria (HVB), Belgium (INAMI-RIZIV), Czech Republic, Finland*, Ireland (NCPE), Italy (AIFA), Lithuania, United Kingdom (NICE, AWTCC), Norway (NMA)
Yes (med dev &/or other technologies): Portugal, Slovenia

* *Outpatient setting*



Yes (all technologies): Belgium (KCE), Estonia, France, Germany (IQWIG), Hungary, Ireland (HIQA), Netherlands, Portugal, Slovakia, Slovenia, Spain, Sweden, Norway
Yes (pharma only): Bulgaria, Finland**, Malta, UK (SMC)
Yes (med dev &/or other technologies): Austria, Denmark (DEFACTUM), Italy (AGENAS), UK (NICE, SHTG)

*** - inpatient setting*

Austria, Belgium, Croatia, Finland, France, Germany, Ireland, Italy, Lithuania, Portugal, Slovenia, Sweden and the UK have indicated more than one kind of HTA influence on decision-making (informative, advisory, obligatory). The weight of the HTA is associated with different type and kind of technology, decision-making or even scope of the HTA performed (REA, REA and economic evaluation, or full HTA).

Table 5 and 6 specify distribution of obligatory (formally established and legally mandated) kind of HTA influence with regards to the type of decision-making, kind of technology in all countries that indicated «obligatory» weight of HTA:

Table 5. Obligatory HTA: Pharmaceuticals

Country	Reimbursment	Pricing	Outpatient setting	No differentiation between outpatient and inpatient
Austria	√	√	√	
Belgium	√	√		√
Croatia	√	√		√
Czech Republic	√	√	√	
France	√	√		√
Finland	√	√	√	
Germany		√		√
Italy	√	√		√
Ireland	√	√		√
Latvia	√	√	√	
Lithuania	√		√	
Poland	√	√		√
Sweden		√		√
UK	√			Comments: specific types of HTAs of medicines in England; HTA of medicines in Wales
Norway	√		√	

Table 6. Obligatory HTA: Medical Devices

Country	Reimbursement	Pricing	Comments
Croatia	√	√	
France	√	√	Depends on the type of medical device and assessment type
Germany	√		
Latvia	√	√	Medical devices only for outpatient use
Poland	√	√	
Portugal	√	√ (maximum price)	Depends on the technology and the assessment type
Sweden		√	Medical device consumables only

Types of medical devices that undergo obligatory HTA differ from country to country though they might inform similar type of decision-making. This mapping study did not collect specific detailed information on type of medical devices undergoing obligatory HTA in each of the studied countries.

3.3 Organisational framework of HTA bodies in the EU MS and Norway

3.3.1 Financing

All 53 HTA organisations from 26 EU Member States and Norway are public bodies (Appendix 3). Irrespective of the model of organisation of the HTA system in the EU countries and Norway (see p.14), majority of the organisations indicated "mostly budget" or "budget only" as forms of financing HTA activities.

Budget and service fees were indicated among the methods to finance HTA activities in 5 MS: Poland, UK (NICE – service fees for scientific advice, SHTG – occasional insignificant consultancy income for advice), Latvia, Czech Republic, Germany (GBA - a fee-for-service is being collected for early dialogues). Spain (AEMPS) and Slovenia (JAZMP) are considering to introduce service fees: AEMPS - fees for specific activities such as HTA-regulatory parallel advice, and JAZMP – implementing a tariff based system from 2017.

Half of the organisations (27 HTA bodies) did not provide information on the size of the budget for their HTA activities. Some of those that provided information, indicated only a percentage of the total organisation's budget dedicated to the HTA activities.

3.3.2 Staffing and commissioning of external experts

The number of staff (full-time equivalents, FTEs) differ greatly between the HTA organisations – from no dedicated to HTA activities staff at all (e.g., HIIS, Slovenia) to 604 total FTEs of permanently employed staff across the whole organisation (NICE, UK). Germany, Cyprus, Greece and Romania did not provide any details on the staff capacities. Unite Kingdom has the highest HTA staff capacity (670,5 FTEs shared among 4 HTA organisations), followed by Sweden (212 FTEs shared between 2 national HTA organisations), France (107 FTEs, 1 HTA organisation), Spain (102 FTEs, 8 HTA organisations connected in the Spanish HTA Network). Other countries have fewer than 100 FTEs per country. Please see Appendix 5 for details.

The most frequently mentioned competences among the staff of HTA organisations are pharmacist, pharmacologist, health economist, information specialist, medical science professional, epidemiologist, statistician.

Thirty-three organisations indicated that they commission external experts to perform HTA. Utilisation of external expertise for HTA via commissioning arrangements does not depend on the size or scope of mandate of the organisations: commissioning of experts is utilised by various size (i.e., in terms of number of permanent staff) HTA organisations, e.g., NICE (604 FTEs), ZIN (54,14 FTEs), AOTMiT (65 FTEs), INFARMED (25 FTEs), CEM (5,5 FTEs).

3.3.3 Conflict of interest procedures

Forty-nine organisations indicated that they have procedures to handle conflict of interest issues when performing HTA. While indicating of not having a specific procedure for handling conflict of interest, LBI-HTA indicated having informal agreements with payers and no industry sponsored projects, no incompatible additional employments, and requirement for transparency on honoraria. No information was provided for CHIF (Croatia), HIIS (Slovenia), SESCS (Spain), and no information on the subject was available for the organisations in Romania.

3.4 National HTA processes in the EU Member States and Norway

The following main characteristics of the national HTA processes were identified for the objectives of this mapping study:

- Type and number of assessments for HTA of pharmaceuticals and medical devices (other health technologies were of interest and were not excluded from the study if the data on the processes of HTA of other technologies was made available) – single technology assessments (STAs), multiple technology assessments (MTAs), initial assessments, re-assessments.
- Topic selection
- HTA Scope definition
- Provision of information for HTA
- Review of the information for HTA
- Delivery of HTA advice/recommendation to inform decision-making
- Stakeholder engagement
- Re-assessments
- Use of HTA output from other jurisdictions

Specific attention was paid to

a) the language requirements for the assessment and HTA advice/recommendation, i.e., if English language could be used
b) status of the HTA advice/recommendation to inform decision-making.

3.4.1 HTA Output - type and number of assessments

The study focused on collecting information on if and how many single and/or multiple technology assessments (STAs, MTAs) are performed per year on each type of technology, i.e., pharmaceuticals and medical devices[44]. In addition, the respondents were asked to indicate type of assessments based on the assessment's scope, i.e., REA only, REA and economic evaluation, and/or full HTA.

Croatia, Latvia, Poland, Slovakia and Slovenia provided data on the number of assessments without division between types of technologies assessed indicating that the HTA process does not differ based on division between pharmaceutical, medical device or other technology types.[45]

It proved difficult to collect specific information on number of assessments and their various types. Most detailed information was provided on the assessment of pharmaceuticals.

Pharmaceuticals

Majority of those countries that provided differentiated data (22 countries including Norway)[46] on the number of assessments of pharmaceuticals apply a single technology assessment approach. Response from the United Kingdom indicated that both STAs and MTAs are used by NICE in England only for Technology Appraisals, while Scotland and Wales indicated that they do not perform MTAs for pharmaceuticals. Respondents from Portugal and Sweden (TLV) specifically indicated that the re-assessments of pharmaceuticals only use MTAs. Table 7 presents an overview of distribution between application of STAs and MTAs for HTA of pharmaceuticals in the EU countries and Norway.

Table 7. Application of STAs and MTAs for HTA of pharmaceuticals in the EU countries and Norway.

STAs	STAs+MTAs	No data or N/A	No division between pharma and medical devices
Austria, Belgium, Bulgaria, Finland,	Czech Republic, France, Malta, Portugal,	Estonia, Denmark, Cyprus, Germany,	Croatia, Latvia, Poland, Slovakia,

[44] Other health technologies were not primary focus of this study, however, were not excluded from the study if the data on the processes of HTA of other technologies was made available.
[45] Information in this section does not include analysis details from these countries. For details, please consult Appendix 10.
[46] No data on pharmaceuticals: Cyprus, Estonia, Germany (STAs/MTAs), Greece, Italy, Romania. Not applicable: Denmark, Luxembourg.

Hungary, Ireland, Lithuania, Netherlands, Spain, *UK (Scotland, Wales),*	Sweden, *UK (England)* Norway	Greece, Italy, Luxembourg, Romania	Slovenia
10 MS	6 MS+ Norway	8 MS	5 MS

The number of **STAs** produced annually varies significantly between the countries that provided the data, with a range between maximum indicated 353 (Austria) assessments to between 10-15 (Finland, Malta) annually. A few further examples: 232 STAs (France), 40-50 STAs (Netherlands), 317 (Portugal), 44 (Spain), 54 (Sweden, TLV process), United Kingdom: 68 (NICE), 101 (SMC), 44 (AWTCC). Most of the numbers provided for the STAs of pharmaceuticals correspond to initial assessments, i.e., not re-assessments[47]. Appendix 10 presents a detailed overview on the number, type and duration of assessments in the EU countries and Norway.

Clear majority of the HTAs of pharmaceuticals are ***REAs with economic evaluation*** – as indicated by 16 MS including Austria, Bulgaria, Czech Republic[48], Estonia, Finland, France, Hungary, Ireland, Italy, Latvia, Netherlands (50% of their HTAs of pharmaceuticals are REAs with economic evaluation, while the rest can be both REA only and Full HTAs), Portugal, Slovenia, Spain, Sweden (TLV process), United Kingdom, and Norway.

Germany and Lithuania indicated that all of their pharmaceutical assessments are ***REAs***; France and Czech Republic indicated that majority of the pharmaceutical assessments are REAs (especially STAs). Netherlands indicated that 50% of their HTAs of pharmaceuticals are REAs.

Sweden indicated that they also perform ***full HTAs*** (SBU process, and some of the TLV assessments). Belgium indicated that they perform only full HTAs on pharmaceuticals (both KCE and INAMI-RIZIV processes).

Comparing the data provided on the time needed to perform an HTA of pharmaceuticals, one can observe significant difference - both between the countries and within the same country depending on the type of assessment performed (STA vs MTA, or special assessment types developed in specific countries, e.g., UK) and on type of settings in which assessed pharmaceutical is intended to be used. Most of the countries provided a range of duration, e.g., in Sweden MTAs of pharmaceuticals can last between 4 and 40 weeks (TLV process). Table 8 presents an information on the time needed to perform an HTA of pharmaceuticals (i.e., from selection/identification of topic for an HTA to delivery of the HTA production process results). One can observe that an HTA with a longer duration of the process is usually undertaken by HTA organisations which do not have any formal mandate/role of directly informing pricing and/or reimbursement decision-making or whose timeframe for assessments is not determined by the Transparency Directive (Council Directive 89/105/EEC)[49].

Table 8. Duration of an HTA of pharmaceuticals in the EU countries and Norway

Type of HTA	<= 90 days	90-220 days	>220 days
STA	Austria (HVB process) Belgium (INAMI process) Bulgaria Czech Republic (rapid	Czech Republic Finland (outpatient) Netherlands** Portugal (inpatient)	Austria (GOG process) Belgium (KCE process) Netherlands** Sweden (SBU process)

[47] Please see Chapter "Re-assessments"

[48] When the amendments/changes to the reimbursement conditions are proposed by MAH/payer/expert groups: if the change leads to broadening of reimbursement conditions, economic evaluation is required, otherwise it is REA only.

[49] https://ec.europa.eu/growth/sectors/healthcare/competitiveness/products-pricing-reimbursement/transparency-directive

	assessments) Finland (inpatient) France (initial assessment) Hungary Ireland Lithuania Malta* Netherlands** Portugal (outpatient)	Spain Sweden (TLV process) UK (specific types of HTAs) Norway	UK (NICE specific types of HTAs)
MTA	Czech Republic (rapid assessments) Sweden (TLV process)	France Sweden (TLV process)	Czech Republic (complex re-assessments) Malta Sweden (SBU process) UK (NICE)

* Up to 3 months

** An interval was given – "between 60 and 365 days"

Medical Devices

Majority of those countries that provided differentiated data (19 countries including Norway) on the number of assessments of medical devices and other technologies combine both single and multiple technology assessment – Table 9:

Table 9. Application of STAs and MTAs for HTA of medical devices in the EU countries and Norway.

STAs	STAs+MTAs	No data or N/A	No division between pharma and medical devices
Belgium, Estonia, Hungary, Lithuania, Netherlands, Spain	Austria, Denmark, France, Italy, Luxembourg, Sweden, United Kingdom, Norway	Bulgaria, Cyprus, Czech Republic, Finland, Germany, Greece, Ireland, Malta, Portugal, Romania	Croatia, Latvia, Poland, Slovakia, Slovenia
6 MS	7 MS + Norway	10 MS	5 MS

The data on medical devices need careful study of details provided by each country as there are specific types of medical devices for each country, e.g., medical aids, invasive vs non-invasive medical devices, "medical devices with pharmaceutical character", etc., that are subject to HTA. Any apparent pattern on what type/scope of HTA is applied to which type of medical devices cannot be established at this point.

Very few organisations provided data on re-assessments of medical devices. In some countries, available statistics do not distinguish between initial and re-assessment, e.g., Belgium statistics on invasive medical devices.

Overall, the number of single technology assessments of medical devices performed annually is much lower than STAs of pharmaceuticals across all EU countries and Norway. The maximum number of STAs of medical devices range from 150 in Belgium (2015 statistics of HTAs of non-invasive medical devices), 90-110 STAs of medical aids in Hungary to 4-6 STAs in Norway.

The annual count of initial MTAs of medical devices is much lower: maximum of 8 initial MTAs per year is reported to be performed in Denmark.

Scotland indicated the highest number of re-assessment MTAs per year – 35.

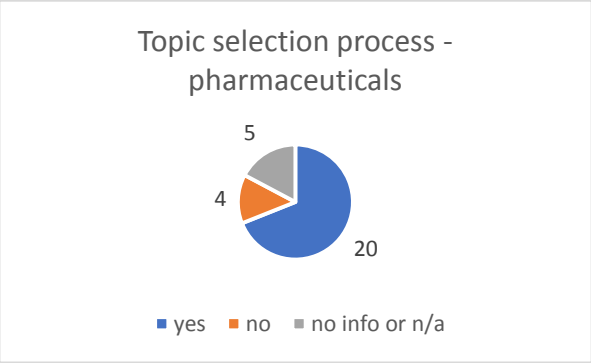
There is a great variety of HTA types in terms of the scope of HTA domains covered when medical devices are assessed by the EU countries' HTA bodies. However, full HTA is used notably more often than when pharmaceuticals are assessed. Full HTA is used in Austria, Belgium, Denmark, Estonia, France, Netherlands, Sweden to assess medical devices. REA and REA and economic evaluation is also used for assessing medical devices.

The time needed to assess medical devices varies significantly even within one country and within the same type of HTA, e.g., STA, and depends on the type of medical devices. For example, Netherlands indicate that STA of medical devices can take between 150 and 365 days; UK indicates that depending on the programme (i.e., Medtech Innovation Briefings (MIBs), Medical Technologies Evaluations Pathway (MTEP), Diagnostic Assessment Programme (DAP), Interventional procedures (IP), the STA can take between 5 and 63 weeks.

3.4.2 Topic selection

Majority of the EU countries and Norway indicated that they have a specific topic selection process both for pharmaceuticals and medical devices - Diagram 5 provides an overview of the number of countries that indicated having a set topic selection process[50]

Diagram 5. Established topic selection process (EU Member States and Norway)

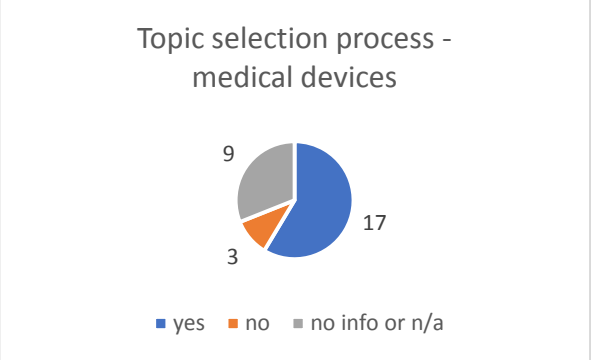


HTA of pharmaceuticals

Countries not having an established topic selection process: Estonia, Germany, Poland, Slovakia;

Countries with no info or n/a:

- Cyprus, Greece, Romania were countries where information is lacking
- in Denmark and Luxembourg HTA of pharmaceuticals is not performed.



HTA of medical devices

Countries indicated not having an established topic selection process: Germany, Poland, Slovakia;

Countries with no info or n/a:

- Cyprus, Greece, Romania were countries where information is lacking;
- in Bulgaria, Czech Republic, Finland, Luxembourg, Malta, Slovenia there is either no formalised process of HTA of medical devices or it undergoes re-organisation

There was insufficient specific data on the process of topic selection for other technologies.

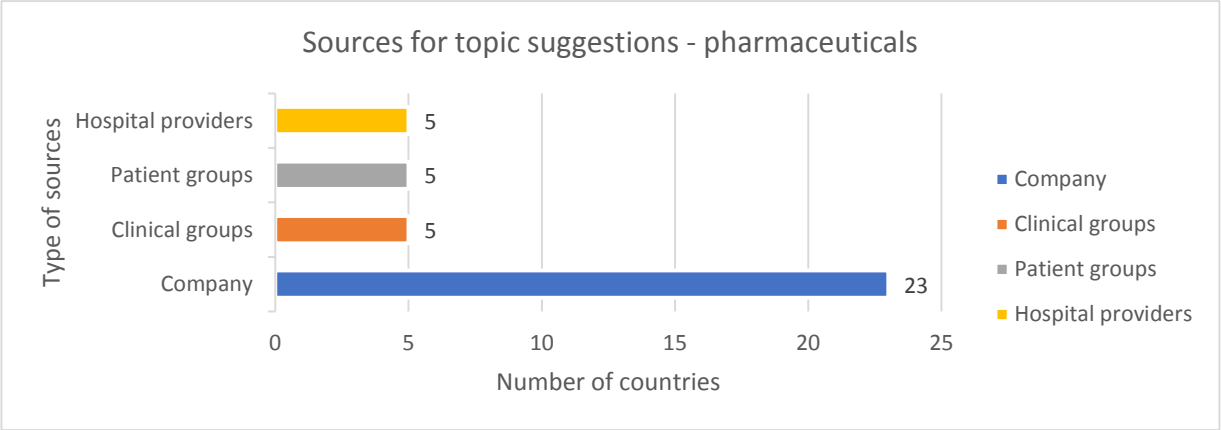
All countries (except for those where detailed information is lacking (Cyprus, Greece, Romania) provided information on the topic selection criteria.

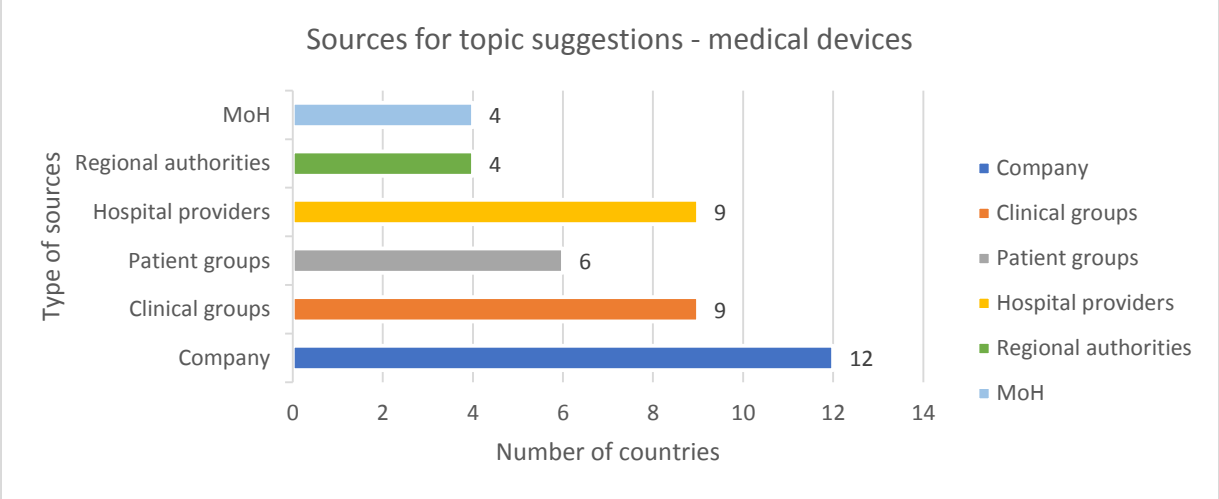
Analysis of sources for topics suggestion (based on available information from 20 countries (including Norway) with the topic selection process and 3 countries with no topic selection process (Estonia, Poland, Slovakia)) indicated more homogeneity across the countries with regards to pharmaceuticals. Diagram 6

[50] Information on the individual topic selection processes is available in each of the individual Country Profiles.

indicates the total number of country responses per category (please note that some countries indicated several sources for topics suggestions).

Diagram 6. Sources for topics suggestions in the EU countries and Norway





Pharmaceuticals

Responses from Austria, Belgium, Ireland, Sweden (i.e., countries that have an HTA system with two or more national HTA bodies, where at least one has pricing and/or reimbursement decision-making functions) indicated that those HTA bodies that do not have a legal mandate to assess pharmaceuticals specifically for pricing and/or reimbursement purposes use various sources – beyond companies - for topic suggestions. These HTA bodies can be involved as needed and/or according to specific agreed arrangements (contractual or otherwise) in the assessment of pharmaceuticals for reimbursement. In addition, they can perform assessment of pharmaceuticals for other than reimbursement decision-making purposes, and in such cases other (than company) topic suggestion sources are utilised.

Some specificities of the topic selection process for HTA of pharmaceuticals include (but not limited to)

- differentiation between inpatient and outpatient settings (Austria, Czech Republic, Finland, Latvia, Netherlands, Norway, Slovakia)
- regional authorities' involvement (Finland (inpatient settings), Spain)
- restrictions on topic selection (not assessed):
  - Slovakia, UK (England), Hungary – generics
  - UK (England), Hungary - vaccines

- Ireland – combination products, specific relation to the price agreement between industry and HSE
- Bulgaria - when a negative health technology assessment for the medicinal product is available by a state institution of the United Kingdom, France or Germany, the HTA procedure is terminated.
- Assessment can start before marketing authorisation – Belgium (INAMI-RIZIV process)

When explicitly indicated by the respondents, the most frequently cited[51] criteria for topic selection were existence of EMA/national authorisation, therapeutic value claims and perceived economic impact on health system.

Medical devices

Several countries specifically highlighted *existence of differences* in the organisation of their topic selection process depending on

- the type of medical devices (Austria, Belgium, Germany, Hungary, Sweden (TLV process), UK),
- outpatient/inpatient use of a device (Austria, Latvia, Norway, Slovakia, Sweden (TLV process),

There are significant differences in the degree of topic selection process organisation and guidance development among countries. For example, UK (England and Scotland) reported an extensive, elaborate list of criteria for topic selection as well as restriction specifications; in addition, both NICE (England) and SHTG (Scotland) produce more than one type of an HTA output when assessing medical devices (please see specifics in UNITED KINGDOM HTA Profile, and other countries' HTA Profiles for details).

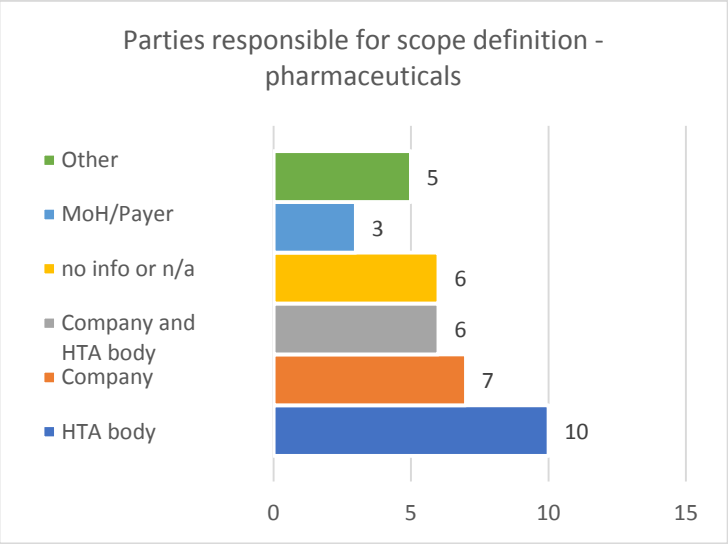
When explicitly indicated by the respondents, the most frequently cited[50] criteria for topic selection were CE-mark presence before the start of an assessment, existence of sufficient evidence to perform HTA, perceived economic impact, professional uncertainty regarding clinical effect, and impact on organisation of care.

3.4.3 Defining scope of a specific assessment

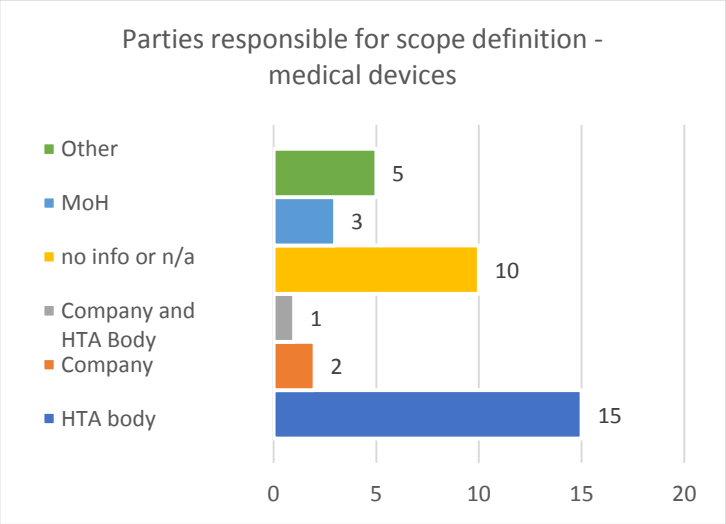
There is visible variability between the countries in indicating who is responsible to define the scope or decision problem of the assessment (ie, identification of the pertinent questions to be answered by an assessment) – both for pharmaceuticals and medical devices. Diagram 7 indicates the total number of country responses per category when assessing pharmaceuticals and medical devices across the EU countries and Norway (please note that some countries indicated several responsible parties). Category "Other" for pharmaceuticals include 3 countries citing "defined by law" (Germany, Hungary, Latvia), 1 country indicating three parties involved in decision-making on a scope of an assessment – company, payer, and an HTA body with the latter making final decision (Czech Republic), and 1 country indicating this country's specific committee – Coordinating Group for Therapeutic Positioning (Spain). Category "Other" for medical devices include 2 countries citing "legally defined" (Hungary, Latvia), 1 country indicating three parties involved in decision-making on scope– company, regional authorities and HTA body with the latter making final decision (Sweden, TLV process), 1 country indicating clinical experts, guideline groups and RHA Ordering Forum (Norway), and one country indicating HTA agency, company and clinical and medical societies being involved in the scope decision-making (UK (Scotland)).

[51] Indicated by four or more countries

Diagram 7. Responsibility for the scope/decision problem of the assessment



Countries indicating "Other": Czech Republic, Germany, Hungary, Latvia, Spain
MoH/Payer: Austria (GÖG process), Bulgaria, Poland
No info or n/a: Austria (HVB process), Denmark, Cyprus, Greece, Luxembourg, Romania
Company and HTA body: Italy, Norway, Portugal, Slovenia, Sweden (TLV process), UK (Wales)
Company: Belgium, Croatia (CHIF process), Estonia, Finland (outpatien setting), France (STA), UK (Scotland)
HTA body: Croatia (AAZ), Finland (inpatient setting), France (MTA), Ireland, Lithuania, Malta, Netherlands, Poland, Sweden (SBU process), UK (NICE in consultation with stakeholders)



Countries indicating "Other": Hungary, Latvia, Sweden (TLV process), Norway, UK (Scotland)
MoH: Austria (GÖG process), Poland, Spain
No info or n/a: Belgium (INAMI-RIZIV), Bulgaria, Czech Republic, Cyprus, Greece, Finland, Malta, Portugal, Romania, Slovenia
Company and HTA body: Croatia (CHIF)
Company: France (STA based on a dossier submission), Slovakia
HTA body: Austria, Belgium (KCE), Croatia (AAZ), Denmark, Estonia, France (MTA, planned assessments), Germany, Ireland, Italy, Lithuania, Luxembourg, Netherlands, Spain, Sweden (SBU process), UK (NICE)

Pharmaceuticals

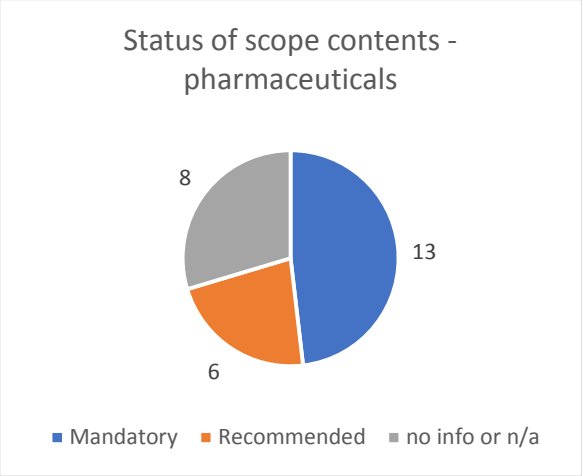
The assignment of responsibility shifts between the indicated agents depending on various factors within the same country.[52] For example, in Austria, Belgium, Croatia and Sweden there is a difference on the responsible agents for scope definition between the national HTA bodies; in Czech Republic and France differences exist depending on the type of assessment (in former - initial assessment or re-assessment, in the latter - STA or MTA). In Finland, the responsible agent for definition of the assessment scope differ for inpatient and outpatient pharmaceuticals. Germany, Hungary and Latvia specifically indicated that the scope definition is set by law. One can observe a general trend that it is often a company or company and

[52] This is valid also for the countries that do not differentiate organisation of the HTA process between assessment of pharmaceuticals and medical devices (Croatia, Latvia, Poland, Slovakia and Slovenia).

an HTA body that define the scope of the assessment of pharmaceuticals to specifically inform reimbursement decisions.

The status of scope contents indicates a prevalence of the mandatory nature (i.e., the scope contents have to be followed). Again, within the same country an HTA assessment scope can be defined both as mandatory and recommended (i.e., suggested to be followed) depending on e.g., the type of assessment, the mandate of the HTA body performing the assessment. Diagram 8 illustrates the total number of country responses per category:

Diagram 8. Status of scope contents – pharmaceuticals



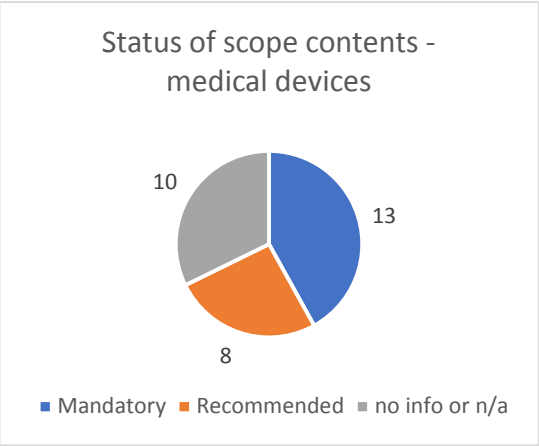
Mandatory: Czech Republic, France, Germany, Hungary, Latvia, Malta, Netherlands, Poland, Portugal, Slovenia, Spain, Sweden (SBU), UK (NICE for TAs and MSTs)
Recommended: Belgium, Bulgaria, Finland (inpatient setting), Ireland, Sweden (TLV), UK (AWTCC)
No info or n/a: Austria, Denmark, Estonia, Italy, Lithuania, Norway, Slovakia, UK (SMC)

Medical devices

Higher number of countries indicated that the HTA body is responsible for the definition of the assessment scope when assessing medical devices. A similar (to assessment of pharmaceuticals) observation can be made about shift of responsibility between the agents within the country depending on various factors, e.g., type of assessments (STA vs MTA), various HTA bodies mandates, type of medical devices. There is also greater variety of agents per se, e.g., in Sweden (TLV process) an HTA body cooperates with the regional authorities to define the scope; in Scotland, it is an HTA agency together with a company and clinical and medical societies' representatives that define the scope in cooperation; in Belgium (RIZIV-INAMI process) there is no scoping for assessment of medical devices.

The status of scope contents indicates a prevalence of the mandatory nature. Again, within the same country an HTA assessment scope can be defined both as mandatory and recommended depending on e.g., the type of assessment, the mandate of the HTA body performing the assessment. Diagram 9 illustrates the total number of responses per category:

Diagram 9. Status of scope contents – medical devices



Manadatory: Austria (GÖG), Estonia, France, Germany (special class of medical devices only), Hungary, Ireland, Latvia, Luxembourg, Netherlands, Norway, Poland, Sweden (SBU), UK (NICE)
Recommended: Austria (LBI-HTA), Belgium, Croatia, Denmark, Italy, Spain, Sweden (TLV), UK (SHTG)
No info or n/a: Bulgaria, Cyprus, Czech Republic, Finland, Greece, Lithuania, Malta, Slovakia, Slovenia, Romania

3.4.4 Provision of information to HTA

Pharmaceuticals

Twenty-three EU countries and Norway indicated that company provides information on a technology to undergo HTA (see Appendix 11). Ten of these countries (Austria, Belgium, Croatia, Estonia, Finland, France, Ireland, Poland, Sweden, UK (England)) also exercise an approach where an HTA body carries out its own HTA and itself identifies the evidence to use (i.e., not using evidence submitted from the company). What approach is used and when is influenced by different circumstances across the countries:

- In Austria, one national HTA body (HVB) performs an HTA using evidence from the company for reimbursement decision-making purposes, while the other 2 national HTA bodies (LBI-HTA and GÖG) utilise the other approach to perform HTAs
- In Belgium, Croatia, Ireland, Sweden, each of the two national HTA bodies use different approaches. In all 4 countries, the approach based on a company submission of evidence is used by the HTA body that has a mandate to perform HTA to inform reimbursement decisions.
- In Finland, each approach is used for a specific (inpatient or outpatient) type of pharmaceutical use
- In France, the specific process depends on the type of HTA (e.g., STA/MTA), and if an assessment is planned or it is based on application from companies to be used for reimbursement decision-making purposes
- In Poland, the specific process is utilised depending on the type of technology and type of the two HTA processes each supported by a different legislative act
- In the United Kingdom (England), the process depends on the types of HTAs to be performed (Technology appraisals (TAs), assessment of highly specialised technologies (HSTs) or Evidence summaries of new medicines (ESNM) – for the first two it is a company that submits evidence to undergo HTA.

Medical devices

Twelve EU countries and Norway indicated that company provides information on a technology to undergo HTA while 17 countries (including Norway) indicated that it is the HTA body that carries out its own HTA and itself identifies the evidence to use (not using evidence submitted from the company), see Appendix 11. Eight countries (Belgium, Croatia, France, Germany, Poland, Portugal, Sweden, United Kingdom (England, Scotland)) indicated that both approaches are used, however, the choice of approach might be influenced by different circumstances across the countries:

- In Belgium, Croatia, Sweden, each of the two national HTA bodies use different approaches. In addition, in Belgium the same HTA body (INAMI-RIZIV) can use evidence submitted by the company

but also utilise HTA information from other jurisdictions to supplement submission from the company (in assessment of invasive and implantable medical devices); in Sweden, the same HTA body (TLV) indicates that the specific process is utilised depending on the type of technology (medical devices or medical device consumables).

- In Germany, Poland specific process is utilised depending on the type of technology and type of the HTA processes each supported by a different legislative act
- In France, the specific process depends on the type of HTA (e.g., STA/MTA), and if an assessment is planned or it is based on application from companies to be used for reimbursement decision-making purposes
- In Portugal, the HTA process of assessment of medical devices is still being established, but both pathways of the provision of the information to undergo HTA have been indicated as possible
- In the United Kingdom (England, Scotland), the process depends on the types of HTA products to be delivered (different HTA programmes).

3.4.5 Review of information for HTA

The information for HTA is reviewed during the assessment and appraisal phases of an HTA.

All EU countries (except for the United Kingdom (England) that indicated commissioning of the reviews to other organisations for certain NICE HTA products, and for Cyprus, Greece and Romania where detailed information on the subject is not available) and Norway perform the review themselves. Table 10 summarises information on the presence of the stop-the-clock mechanism and status of the review of information for HTA in the EU countries and Norway.

Table 10. Review of information for HTA

Technologies	Stop-the-clock mechanism	Status of the review of information for HTA		
		Public	Confidential	Public with confidential information removed
Pharmaceuticals	Belgium (KCE), Bulgaria, Croatia (CHIF), Czech Republic, Estonia, Finland (outpatient), Norway (Blå recept), Poland, Portugal, Slovakia, Slovenia, Sweden (TLV), UK (Wales; England – specific HTA products)	Belgium (KCE), Croatia (AAZ), Latvia, Lithuania, Netherlands, Slovakia, Slovenia (HIIS), Spain, Sweden (SBU)	Austria (HVB), Croatia (CHIF), Hungary, Ireland, Italy, Malta, Slovenia (JAZMP)	Belgium (INAMI-RIZIV), Bulgaria, Czech Republic, Estonia, Finland, France, Norway, Poland, Portugal, Sweden (TLV), UK
Number of MS	12 MS + Norway	9 MS	7 MS	9 MS + Norway
Medical Devices	Belgium (KCE), Croatia, France, Hungary, Ireland, Latvia, Luxembourg, Netherlands, Poland, Portugal, Slovakia, Sweden (TLV, assessment of medical device consumables),	Austria (LBI-HTA – inpatient setting; GÖG), Croatia (AAZ), Denmark, Estonia, Italy, Latvia, Lithuania, Netherlands, Slovakia, Spain, Sweden (SBU; TLV – assessment of methods for using	Croatia (CHIF), Hungary, Luxembourg	France, Ireland, Norway, Poland, Portugal, Sweden (TLV, assessment of medical device consumables), UK

	UK (England – specific HTA products)	medical devices).		
Number of MS	13MS	11MS	3 MS	6 MS + Norway

Bulgaria specifically indicated that a summary of HTA (assessment of pharmaceuticals) can be made publicly available with the consent of the company. In Germany the process of review, delivery of the HTA advice, and consequent decision-making based on the HTA advice in case of assessment of pharmaceuticals may be organised with involvement of two HTA bodies, IQWIG and GBA, with the latter also being a decision-maker[53]. This process includes oral and written hearing, and public access to information changes from one step to the other in the process. Due to this process complexity, Germany was not included in the table above[54]. Thus, for the details on the process of review of the information for HTA and delivery of the HTA advice/recommendation please consult the GERMANY HTA Profile.

NICE (UK, England) indicated that other (than the HTA body) organisations are involved in the review of information for HTA for certain HTA products during assessment of both pharmaceuticals and medical devices.

3.4.6 Delivery of HTA advice/recommendation to inform decision-making

The set of HTA documentation that is provided to the decision-makers can include several types of documents and can vary across the countries. However, an HTA report as a form of documentation was indicated by all 23 EU countries[55] that perform HTA of pharmaceuticals. Nineteen EU countries[56] (that perform HTA of medical devices) and Norway provide HTA report among the set of documents that are delivered to decision-makers.

With regards to HTA of pharmaceuticals:

- Belgium (INAMI-RIZIV process), Czech Republic, Estonia, Finland, Poland, UK (England and Wales) specifically indicated inclusion of experts' opinions in the documents set
- Belgium (INAMI-RIZIV), Czech Republic specifically indicated that remarks of the company on the HTA advice are also included in the documents set.
- Latvia, Malta, Hungary, Sweden (SBU process) indicated inclusion of a summary of the HTA report in the documents set.

With regards to HTA of medical devices:

- Norway, Poland, UK specifically indicated inclusion of experts' opinions in the documents set.
- Denmark, Ireland, Latvia, Lithuania, Norway, Sweden (SBU process) indicated inclusion of a summary of the HTA report in the documents set.

With regards to the language of advice, all countries indicated that the national language is used. In addition to the national language of the advice, only the following countries indicated that the English language is allowed/used in the following cases:

- Austria (HVB process on pharmaceuticals): company submission dossier
- Belgium (KCE process, both technologies): summary of an HTA report
- Estonia (medical devices): summary of an HTA report

[53] http://www.english.g-ba.de/legalmandate/procedures/ ; http://www.english.g-ba.de/benefitassessment/information/; https://www.iqwig.de/en/methods/results.3016.html (accessed March 17, 2017)

[54] Please also see section Limitations of the Study.

[55] Norway did not specify what type of documents are delivered

[56] Germany did not specify what type of documents are delivered

- Italy (medical devices): HTA advice in both Italian and English
- Latvia (both technologies): clinical trial documents
- Lithuania (medical devices): HTA advice in English (summary in Lithuanian)
- Malta (pharmaceuticals): HTA advice in English
- Norway (pharmaceuticals): HTA advice can be in Norwegian or English
- Slovenia (pharmaceuticals): HTA advice in Slovenian and English

In several countries, the status of an HTA advice can differ between public, confidential, or public with confidential information removed – this depends on what HTA organisation issues an advice (as legal mandates of the HTA organisation in the same country differ), on what type of technology the HTA advice is issued on, or on the type of an HTA product.

Table 11 presents

- an overview of the countries where it was specifically indicated that a company submission file is included in a document set,
- a distribution of various types of the HTA advice status across the countries.

Table 11. Overview of the countries requesting company submission files and status of the HTA advice

Technologies	Company submission file	Status of the HTA advice		
		Public	Confidential	Public with confidential information removed
Pharma-ceuticals	Austria (HVB), Czech Republic, Estonia, Finland (outpatient), France, Hungary, Ireland, Italy, Latvia, Poland, Slovakia, Slovenia, United Kingdom	Belgium (KCE), Croatia (AAZ), Latvia, Lithuania, Netherlands, Slovakia, Slovenia (HIIS), Spain, Sweden (SBU)	Austria (HVB), Croatia(CHIF), Hungary, Ireland, Italy, Malta, Slovenia (JAZMP)	Belgium (INAMI-RIZIV), Bulgaria, Czech Republic, Estonia, Finland, France, Norway, Poland, Portugal, Sweden (TLV), UK
	13 MS	9 MS	7 MS	10 MS + Norway
Medical Devices	Belgium (INAMI-RIZIV), France, Hungary, Latvia, Poland, Slovakia, UK	Austria (LBI-HTA – inpatient setting), Belgium (KCE) Croatia (AAZ), Denmark, Estonia, Germany (HTA of methods using high-risk medical devices), Ireland, Italy, Latvia, Lithuania, Netherlands, Slovakia, Spain (REAs), Sweden (SBU; TLV – assessment of methods for using medical devices).	Croatia (CHIF), Germany (assessment of medical devices with pharma-ceutical character), Hungary, Luxembourg	France, Norway, Poland, Portugal, Spain (horizon scanning reports), Sweden (TLV, assessment of medical device consumables), UK
	7MS	14 MS	4 MS	6 MS + Norway

3.4.7 Stakeholder engagement

Out of 23 EU countries that have an HTA system for assessment of pharmaceuticals, 20 countries indicated that they also have a set process for stakeholder engagement for HTA of pharmaceuticals (Croatia indicated as not having a fully established process, Hungary and Slovakia indicated that they do not have such a process).

Out of 20 EU countries that have an HTA system for assessment of medical devices, 13 countries and Norway indicated that they have a set process for stakeholder engagement for HTA of medical devices[57]. Croatia and Estonia indicated as not having a fully established process. Hungary, Luxembourg, Portugal, Slovakia, Slovenia, Lithuania indicated not having such a process. Please consult Appendix 13 for the details on the countries and organisation of the stakeholder engagement process.

Table 12 provides information on the patient engagement in the EU MS and Norway. One can observe that it is mostly those countries with a longer tradition of HTA (ie, countries where HTA activities have been established for a longer period of time) that have indicated existence of a process for patient involvement. Further looking into the stages of the HTA process in which patients get engaged in these countries, a visible difference is observed: in the HTA of pharmaceuticals nine countries (highlighted in green) indicate involving patients at the step of advice and decision-making, while in the HTA of medical devices and other technologies they are more often involved in the step of review of the produced assessment (6 and 5 countries respectively (highlighted in blue)).

Table 12. Patient engagement in the EU MS and Norway.

HTA of pharmaceuticals	HTA of medical devices	HTA of other technologies
Estonia	Denmark	Denmark
France	France	France
Ireland	Germany	Germany
Italy	Ireland	Ireland
Lithuania	Italy	Poland
Malta	Netherlands	Spain
Netherlands	Poland	Sweden
Poland	Spain	UK
Spain	Sweden	
Sweden	UK	
UK	Norway	
11 MS	11 MS + Norway	8 MS

Each Country HTA Profile includes further details on the stages of the HTA process at which each stakeholder group is involved and their modes of involvement. The stages of the process included horizon scanning, topic selection, scoping, production of assessment, review of the assessment, advice or decision making.

Pharmaceuticals

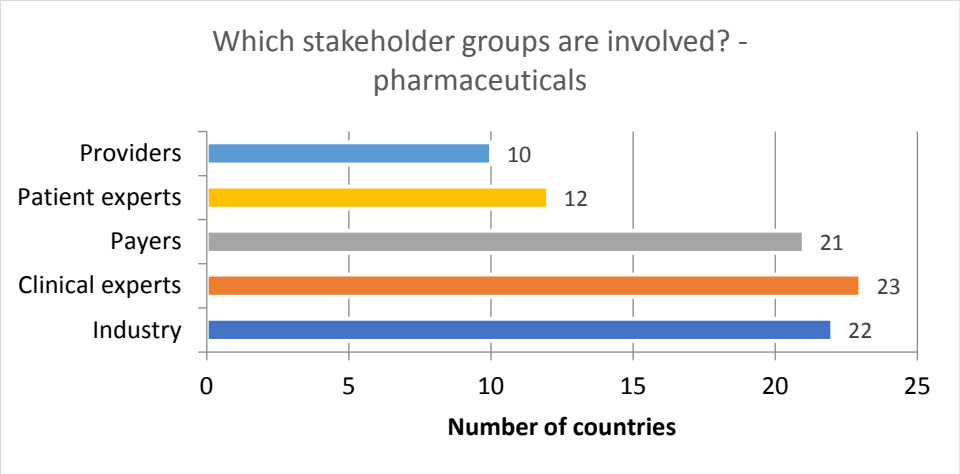
Involvement of various stakeholder groups was specified by all countries with HTA of pharmaceuticals irrespective of the existence or lack of a set process for stakeholder engagement – Diagram 10 presents number of countries where a specific stakeholder group was indicated as involved in the HTA process. The following specificities about the data in the diagram need to be considered:

- Croatia provided information only on the AAZ process

[57] Germany specified that a set process currently exists only for the HTA process of assessment of methods for using high risk medical devices.

- Slovakia did not indicate industry stakeholder group among those involved in the HTA process.
- Patient experts' involvement was indicated in Belgium for the KCE process only. In the UK patients are involved in the development of all types of HTA products in Scotland, Wales, and England (except for ESNMs in the latter).
- Providers involvement was indicated in Finland for assessment of pharmaceuticals only in inpatient settings, in Slovenia only for the HIIS process, in Sweden only for SBU process
- Payers engagement was indicated in Sweden only for the TLV process, in the UK only for the HTA processes in England and Scotland.

Diagram 10. Stakeholder groups involvement in HTA of pharmaceuticals in the EU countries and Norway

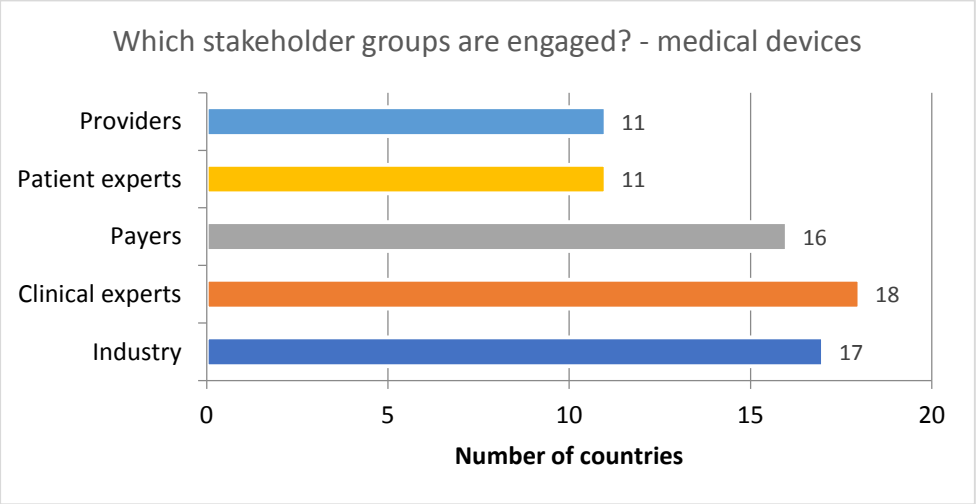


Medical devices

Involvement of various stakeholder groups was specified by all countries with HTA of medical devices (except for Germany and Lithuania) irrespective of the existence or lack of a set process for stakeholder engagement. Diagram 11 presents number of countries where a specific stakeholder group was indicated as involved in the HTA process. The following specificities about the data in the graph need to be considered:

- Austria (LBI-HTA) is in the piloting phase of patient involvement in the HTA process
- In Sweden, payers were indicated as being involved only in the TLV process of assessment of medical devices, whereas providers were indicated as being involved in the SBU process of assessment of medical devices
- In the UK, payers were indicated as being involved in the SHTG (Scotland) process of assessment of medical devices.

Diagram 11. Stakeholder groups involvement in HTA of medical devices in the EU countries and Norway



3.4.8 Re-assessments

Majority of the EU countries that perform assessment of pharmaceuticals (17 countries, 74%) and Norway indicated having a set process for re-assessment.

Only slightly more than half the EU countries that perform assessment of medical devices (12 countries, 60%) indicated having such a process.

Table 13 and 14 present the distribution of the responses per EU countries and Norway (Norway indicated of not having a set re-assessment process for medical devices). The following specificities about the data in the tables need to be considered:

- Belgium: INAMI-RIZIV has a re-assessment process for both pharmaceuticals and medical devices (with an exception for HTA of the non-invasive medical devices); KCE indicated not having a set process for re-assessment
- Finland: a set re-assessment process is applied in cases of HTA of pharmaceuticals for outpatient use; no such process in case of HTA of pharmaceuticals for inpatient use.
- Germany has a set process for both pharmaceuticals and medical devices; however, such process is applicable only for specific instances in case of pharmaceuticals, and only for medical devices with pharmaceutical character
- Ireland: NCPE does not have a set process for re-assessment of pharmaceuticals, whereas HIQA indicated having such a process for both types of technologies
- Sweden: TLV has a set process for re-assessment of both types of technologies; SBU indicated not having a set process for re-assessments.
- UK: a set process of re-assessment of pharmaceuticals was indicated for England and Wales, and no such process in Scotland.

Table 13. Presence of a set process for re-assessment (pharmaceuticals)

Yes	No	No information or n/a
Austria (HVB, outpatient), Belgium (INAMI-RIZIV), Bulgaria, Czech Republic, Estonia, Finland (outpatient), France, Germany (specific cases – see Country HTA Profile), Ireland (HIQA), Italy, Latvia,	Belgium (KCE), Finland (inpatient), Hungary, Ireland (NCPE), Lithuania, Malta, Poland, UK (Scotland), Sweden (SBU)	Cyprus, Greece, Denmark, Luxembourg, Romania

Netherlands, Portugal, Slovakia, Slovenia, Spain, Sweden (TLV), UK (England, Wales), Norway		
18 MS+Norway	9 MS	5 MS

Table 14. Presence of a set process for re-assessment (medical devices)

Yes	No	No information or n/a
Austria (LBI HTA, inpatient), Belgium (INAMI-RIZIV, invasive medical devices), Estonia, France, Germany (medical devices with pharmaceutical character), Ireland (HIQA), Latvia, Netherlands, Slovakia, Spain, Sweden (TLV), UK	Belgium (KCE, non-invasive medical devices – INAMI-RIZIV), Croatia, Denmark, Hungary, Italy, Lithuania, Luxembourg, Portugal, Sweden (SBU), Norway	Bulgaria, Cyprus, Czech Republic, Finland, Greece, Malta, Poland, Romania, Slovenia
12 MS	9 MS and Norway	9 MS

Estonia specifically indicated having a set re-assessment process, however, re-assessments as such are not required by any legislative acts.

The timing of performing re-assessment in relation to the initial assessment and criteria for re-assessment vary substantially within and across the countries, both in case of re-assessment of pharmaceuticals and medical devices. For example, in Czech Republic and France, the re-assessment of pharmaceuticals need to take place no later than 5 years after the initial assessment, and it is a compulsory evaluation for outpatient drugs to maintain the product on the list of reimbursed pharmaceuticals; in Germany, in some instances of assessment of pharmaceuticals, re-assessment date is specified in a resolution that ceases to be effective at that date. In Portugal re-assessment of pharmaceuticals are performed at least 2 years after the initial assessment. In the UK, the criteria for re-assessment of both pharmaceuticals and medical devices vary between different HTA products for each type of health technology.

Table 15 and 16 provide an overview of various types of HTA (i.e., STA, MTA; REA, REA and economic evaluation, Full HTA) used to perform re-assessments (only for the countries that provided such information; for details please consult individual Country HTA Profile). Ireland, Spain, UK specifically indicated that the choice of the type of HTA to perform re-assessment depends on the initial assessment.

Table 15. Type of HTA used to perform re-assessments (pharmaceuticals)

STA	MTA	REA	REA and economic evaluation	Full HTA
Austria, Belgium, Bulgaria, Finland, France, Italy, Latvia, Netherlands, Portugal, Slovakia, Slovenia, Spain,	Belgium, Czech Republic, France, Latvia, Portugal, Sweden, UK (England - specific HTA products)	Czech Republic, France, Germany, Italy, Netherlands, Portugal, Sweden (TLV)	Austria, Bulgaria, Czech Republic, Finalnd, Italy, Latvia, Netherlands, Portugal, Slovakia, Slovenia, Spain, Sweden (TLV),	Belgium, France, Netherlands, Sweden (SBU)

Sweden, UK (England – specific HTA products; Wales)			UK	
14 MS	7 MS	7 MS	13 MS	4 MS

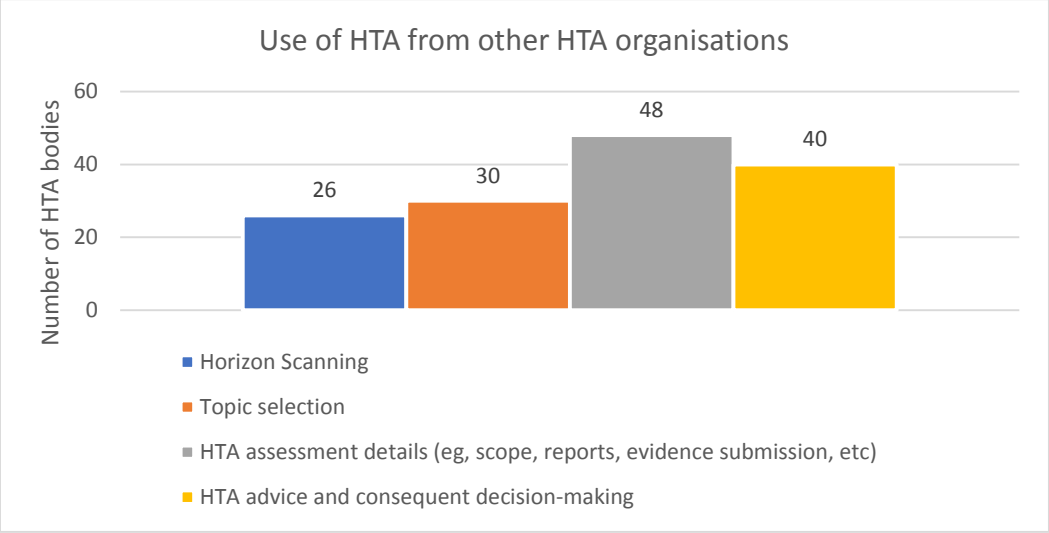
Table 16. Type of HTA used to perform re-assessments (medical devices)

STA	MTA	REA	REA and economic evaluation	Full HTA
Austria, Belgium, Estonia, France, Latvia, Netherlands, Norway, Slovakia, Spain, Sweden, UK (Scotland)	Belgium, Estonia, France, Latvia, Sweden, UK (England - specific HTA products)	France, Germany, Netherlands, Spain, Sweden (TLV)	Austria, Estonia, Latvia, Netherlands, Norway, Slovakia, Spain, Sweden (TLV), UK	Belgium, France, Netherlands, Sweden (SBU)
10 MS + Norway	6 MS	5 MS	9MS	4 MS

3.5 Use of HTA information from other jurisdictions

Forty-nine HTA organisations from 25 EU countries[58] and Norway indicated that they use HTA information from other jurisdictions – please see Appendix 6 for a detailed overview across all EU countries and Norway. The graph below indicates total number of the HTA bodies that use indicated type of the HTA information from other jurisdictions:

Diagram 12. Use of HTA information from other jurisdictions



3.6 Use of EUnetHTA tools and joint assessments

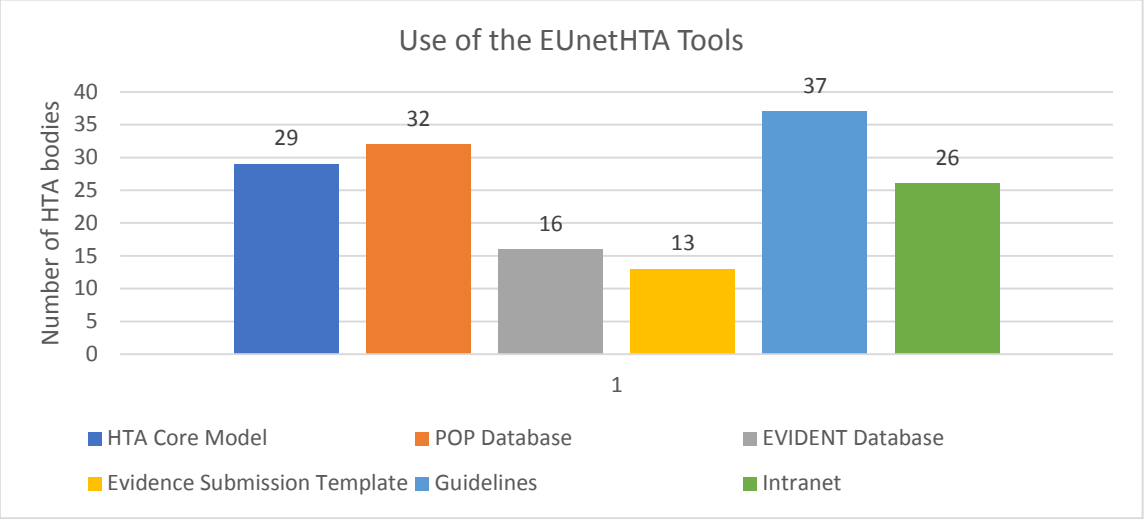
Thirty-eight HTA organisations from 23 EU countries[59] and 3 organisations from Norway indicated that they use **EUnetHTA tools** in their national HTA processes – please see Appendix 7 for a detailed overview across all EU countries and Norway.

The graph below indicates total number of the HTA bodies that use indicated type of the EUnetHTA tool:

[58] Cyprus, Greece, Romania were not included due to lack of specific information on the subject.

[59] Greece, Romania – no specific information; Czech Republic, Malta, Slovenia – no use at present

Diagram 13. Use of EUnetHTA tools



Out of 11 organisations from the EU countries that indicated non-use of the EUnetHTA tools six organisations are not nominated by the MoH to participate in the EUnetHTA JA3. In three cited instances of the current non-use of the EUnetHTA tools, the organisation indicated that they are ready to explore or are already exploring possibilities of their application.

Thirty HTA organisations from 19 EU countries and 2 organisations from Norway indicated that they use elements of **EUnetHTA joint assessments** in their national HTA processes. Several countries (Austria, Belgium, Croatia, Portugal, Spain, Norway) indicated that use of the EUnetHTA joint assessment reports is a part of their national practice of utilising HTA information from other jurisdictions. Please see appendix 7 for detailed overview of the EUnetHTA joint assessments use in the EU countries and Norway.

Among the most often cited reasons for not using the EUnetHTA joint assessments were their timing, topic and scope of assessment not being in line with national HTA process requirements. The governance aspects of EUnetHTA joint assessment utilisation were not addressed by the respondents except for these two comments: insufficient transparency of the EUnetHTA joint reports as they lack company's submission evidence inclusion, and the HTA body's internal governance process and procedures inflexibility to readily implement use of EUnetHTA reports in the HTA body's assessment practice.

4. CONCLUSIONS

The purpose of this mapping study was to survey, examine and document organisational and processual /procedural aspects of the HTA process and delivery of HTA results to inform decision-making in the EU Member States and EEA countries at national (country) level. While the study confirms diversity of HTA processes across EU countries and Norway, it also indicates that there is an opportunity to practically explore appropriate and effective convergence of procedures.

4.1 Organisation of HTA systems in EU Member States and Norway

At least 89% of EU MS (25) and Norway indicated that they have and HTA system with HTA bodies having a clearly defined role in the HTA production process informing decision-making at national level.

Half of the EU MS (15) have a singular national body whose main role includes development of HTA recommendations. Among these, only 6 EU MS (Bulgaria, Denmark, France, Poland, Slovakia, United Kingdom) indicated having among these HTA bodies, a national HTA body with a singular remit that exclusively focuses on the development of HTA recommendations. HTA bodies in the remaining countries combine in various constellations HTA, regulatory, pricing and/or reimbursement functions.

Twelve EU MS and Norway have HTA system model with two or more national HTA bodies that combine in various constellations HTA, regulatory, pricing and/or reimbursement functions.

Majority of the EU countries (17 countries) and Norway have an HTA system where at least one of the national HTA bodies has pricing and/or reimbursement decision-making functions in addition to the development of HTA recommendations. Thus, further clarification of the boundaries between the HTA process and the decision-making process that the HTA process informs will help identifying appropriate and effective modes and levels of engagement in the European cooperation on HTA in the EU countries and Norway.

Majority of EU MS and Norway indicated having an HTA system that includes assessment of pharmaceuticals (23) and medical devices (20). Slightly fewer EU MS (17) and Norway indicated having an HTA system that also includes assessment of other technologies.

Majority HTA bodies in the EU countries and Norway perform REA (15 EU MS) and REA and economic evaluations (24 EU MS); minority (12 EU MS and Norway) indicated producing full HTA.

4.2 Role of HTA in decision-making in EU Member States and Norway

HTA is indicated to be used by majority of EU MS and Norway to inform decision-making on reimbursement of pharmaceuticals (24 EU MS) and medical devices (19 EU MS). Only 12 EU MS and Norway indicated to use HTA to inform reimbursement of other technologies. The organisation of the HTA process informing reimbursement decisions differs substantially from country to country, eg, different types of HTA with regards to its scope (i.e., REA, REA and economic evaluation, full HTA) might be utilized for different types of technologies by different countries.

HTA is indicated to be used by majority of EU MS (20) and Norway to inform decision-making on pricing of pharmaceuticals and by minority of EU MS to inform pricing decisions on medical devices (9 EU MS) and other technologies (7 EU MS).

There is a prevalence of advisory weight of HTA (20 EU MS and Norway) over obligatory weight (16 EU MS and Norway) in relation to the decision-making processes. Thirteen EU MS indicated more than one kind of HTA influence on decision-making (informative, advisory, obligatory). The weight of the HTA is associated with different type and kind of technology, decision-making or even scope of the HTA performed (REA, REA and economic evaluation, or full HTA).

4.3 Organisational framework of HTA bodies in the EU MS and Norway

All 56 HTA organisations from 27 EU Member States and Norway are public bodies. Majority of the organisations indicated “mostly budget” or “budget only” as forms of financing HTA activities - budget and service fees were indicated among the methods to finance HTA activities in 5 MS only.

Half of the organisations (27 HTA bodies) did not provide information on the size of the budget for their HTA activities. Thus, there is very restricted opportunity to draw any comparative conclusions across EU MS based on the size of the budget.

The number of staff (full-time equivalents, FTEs) differ greatly between the HTA organisations – from no dedicated to HTA activities staff at all (e.g., HIIS, Slovenia) to 604 total FTEs of permanently employed staff across the whole organisation (NICE, UK). Four EU MS have HTA staff capacity above 100 FTEs (per country). Remaining EU MS and Norway have fewer than 100 FTEs per country.

HTA expertise is present in all EU countries and Norway, however, the staff and financial capacities of the HTA organisations differ across the countries, which makes assistance with building staff capacities to do HTA a helpful undertaking.

Forty-nine organisations indicated that they have procedures to handle conflict of interest issues when performing HTA.

4.4 National HTA processes in the EU Member States and Norway

Majority of those countries that provided differentiated data (22 countries including Norway) on the number of assessments of pharmaceuticals apply a single technology assessment approach (11 EU MS).

Clear majority of the HTAs of pharmaceuticals are ***REAs with economic evaluation*** – as indicated by 16 MS and Norway.

Eight of 19 countries including Norway that provided differentiated data on the number of assessments of medical devices and other technologies combine both single and multiple technology assessment. Only 6 countries apply STA to assess medical devices.

There is a great variety of HTA types in terms of the scope of HTA domains covered when medical devices are assessed by the EU countries' HTA bodies. However, full HTA is used notably more often than when pharmaceuticals are assessed. Full HTA is used in Austria, Belgium, Denmark, Estonia, France, Netherlands, Sweden to assess medical devices.

Twenty and seventeen countries including Norway indicated having a specific topic election process for pharmaceuticals and medical devices respectively.

When explicitly indicated by the respondents, the most frequently cited (ie, by 4 or more countries) criteria for topic selection were existence of EMA/national authorisation, therapeutic value claims and perceived economic impact on health system - for pharmaceuticals, and CE-mark presence before the start of an assessment, existence of sufficient evidence to perform HTA, perceived economic impact, professional uncertainty regarding clinical effect, and impact on organisation of care – for medical devices.

During the scoping phase of an HTA assessment, "HTA body" was indicated most frequently both in HTA of pharmaceuticals (10 countries) and of medical devices (15 countries). When comparing the distribution of responsible parties for scope definition between HTA of pharmaceuticals and medical devices, an "HTA body and company" and "Company" is indicated more often for the assessment of pharmaceuticals (6 vs 1 and 7 vs 2 respectively). The status of scope contents indicates a prevalence of the mandatory nature both for HTA of pharmaceuticals and medical devices (13 countries for each of the assessment types).

In HTA of pharmaceuticals, 23 EU countries and Norway indicated that company provides information on a technology to undergo HTA. Ten of these countries (Austria, Belgium, Croatia, Estonia, Finland, France, Ireland, Poland, Sweden, UK (England)) also exercise an approach where an HTA body carries out its own HTA and itself identifies the evidence to use (i.e., not using evidence submitted from the company). What approach is used and when is influenced by different circumstances across the countries.

In HTA of medical devices, 12 EU countries and Norway indicated that company provides information on a technology to undergo HTA while 17 countries (including Norway) indicated that it is the HTA body that carries out its own HTA and itself identifies the evidence to use (not using evidence submitted from the company). Eight countries (Belgium, Croatia, France, Germany, Poland, Portugal, Sweden, United Kingdom (England, Scotland)) indicated that both approaches are used, however, the choice of approach might be influenced by different circumstances across the countries.

All EU countries (except for the United Kingdom (England) that indicated commissioning of the reviews to other organisations for certain NICE HTA products, and for Cyprus, Greece and Romania where detailed information on the subject is not available) and Norway perform the review of information for HTA themselves.

The results of the review of information for HTA in assessment of pharmaceuticals are mostly made public by majority of the countries – 9 MS made them fully publicly available while 9 MS and Norway remove confidential information before making it publicly available. In 7 MS the results of the review are confidential information.

The results of the review of information for HTA of medical devices are made public by 11 MS, and 6 MS and Norway remove confidential information prior to publication. Three MS keep this information confidential.

With regards to stakeholder engagement, more countries indicated that they have a system of stakeholder engagement for HTA of pharmaceuticals (20) than for HTA of medical devices (13). The most frequently engaged groups in HTA of pharmaceuticals are clinical experts (23 countries), industry (22 countries) and payers (22) – the same pattern is observed for HTA of medical devices: 18, 17 and 16 countries respectively indicate these groups organised engagement in the HTA process.

Majority of the EU countries that perform assessment of pharmaceuticals (17 countries, 74%) and Norway indicated having a set process for re-assessment.

Only slightly more than half the EU countries that perform assessment of medical devices (12 countries, 60%) indicated having such a process.

The timing of performing re-assessment in relation to the initial assessment and criteria for re-assessment vary substantially within and across the countries, both in case of re-assessment of pharmaceuticals and medical devices.

4.5 Use of HTA information from other jurisdictions

Forty-nine HTA organisations from 25 EU countries and Norway indicated that they use HTA information from other jurisdictions. HTA assessment details like scope, evidence tables, etc were mentioned by the highest number of HTA bodies (48) as the type of HTA information used from other jurisdictions.

4.6 Use of EUnetHTA tools and joint assessments

Thirty-eight HTA organisations from 23 EU countries and 3 organisations from Norway indicated that they use **EUnetHTA tools** in their national HTA processes. EUnetHTA Guidelines, POP Database and HTA Core Model are most frequently used EUnetHTA tools as indicated by 37, 32 and 29 HTA bodies respectively.

Thirty HTA organisations from 19 EU countries and 2 organisations from Norway indicated that they use elements of **EUnetHTA joint assessments** in their national HTA processes. Several countries (Austria, Belgium, Croatia, Portugal, Spain, Norway) indicated that use of the EUnetHTA joint assessment reports is a part of their national practice of utilising HTA information from other jurisdictions

A large number of HTA organisations indicated use of the EUnetHTA joint assessments. The commonly cited reasons for not using the EUnetHTA joint assessments include timing, topic and scope of assessment not being in line with national HTA process requirements. However, a clear majority of the countries indicated use of the EUnetHTA tools in their national HTA processes.

Sufficient procedural commonalities can be found in the processes of HTA of pharmaceuticals across the EU countries and Norway in terms of type of HTAs (REA, REA and economic evaluation), processes to define the scope of the assessment, provision of information for HTA, delivery of HTA advice/recommendation to inform decision-making, stakeholder engagement and re-assessment practices. Further comparative analysis of the process steps in HTA of pharmaceuticals, paying focused attention to the specific legal framework issues would be helpful in identifying desirable and feasible level of cooperation on HTA of pharmaceuticals.

More diversity and procedural complexity can be observed in the HTA of medical devices. Nevertheless, sharing best practices and assisting with capacity building in this area could bring common benefit.

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