Developing health technology assessment in the European Union

SUMMARY

Health Technology Assessment (HTA) is a research-based tool to support decision-making in healthcare. HTA assesses the added value of new health technologies – medicines, medical devices and diagnostic tools, surgical procedures as well as measures for disease prevention, diagnosis or treatment – over existing ones.

HTA is used with a view to improving the quality and efficiency of public health interventions and the sustainability of healthcare systems. It has been growing in importance, given rising demand for healthcare and economic pressures.

HTA in the EU involves multiple national and regional players. European HTA cooperation consists of a strategic level (HTA Network) and a scientific and technical level (EUnetHTA Joint Action).

Efforts to advance certain aspects of voluntary cooperation on HTA are gaining momentum. Industry and non-industry stakeholders, as well as academia, generally agree on the benefit of stepping up EU cooperation on HTA. Members of the European Parliament have regularly asked for enhanced EU-level cooperation.

The European Commission has recently published an inception impact assessment for an initiative on HTA, planned for the fourth quarter of 2017. It will be preceded by a public stakeholder consultation due to be launched in autumn 2016.

In this briefing:

- What is health technology assessment?
- EU initiatives and cooperation on HTA
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Health technology assessment (HTA) is a cross-cutting field with a specific vocabulary. The most commonly used terms can be found in the following international online glossaries:

- International HTA glossary by the International Network of Agencies for Health Technology Assessment (INAHTA), Health Technology Assessment international (HTAi) and other partner organisations (available in English, French, Spanish and German);
- HTAi consumer and patient glossary;
- HTA 101 glossary by the US National Information Center on Health Services Research and Health Care Technology (NICHSR).

What is health technology assessment?

Definitions

According to Directive 2011/24/EU on patients’ rights in cross-border healthcare, the term health technology is used for designating 'a medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare'.

Health technology assessment has been defined in different ways. In the EU, the EUnetHTA definition is commonly used:

'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'.

HTA has been compared to a bridge between research and decision-making. Rooted in the scientific method, it can support healthcare decisions by providing decision-makers with the evidence to support more informed choices on access to innovative technologies and more efficient allocation of funds ('evidence-based decision-making').

Main objectives

HTA assesses the added value of new health technologies over existing ones. In other words, it provides information on how much better one health technology is compared to another. The European Commission's September 2016 inception impact assessment, which serves as a roadmap for an HTA initiative, considers HTA to be a tool that can contribute to the sustainability of the Member States' national healthcare systems, by helping them allocate resources to effective health technologies. This assessment also sees HTA as being capable of incentivising innovation by rewarding health technologies that bring high added value, while encouraging industry to address patients' unmet medical needs (health conditions that are not adequately addressed by existing treatments).

HTA process, players and methods

An HTA process generally has two main components: assessment (synthesising evidence or critically reviewing submitted evidence) and appraisal (considering the assessment in the light of additional inputs related to the local context). Assessment and appraisal feed into recommendations. These typically provide information on the benefits and harms of new health technologies compared to existing ones, and help determine the reimbursement status of a health technology in a particular country. They may also provide guidance to the price negotiation process.

HTAs are generally performed once a health technology has received regulatory approval. Most Member States have systems in place that provide for HTA bodies to give
recommendations for policy-making. There are currently more than 50 national or regional HTA bodies. In some countries, the assessment and appraisal functions may be carried out by separate bodies.

The approaches these HTA bodies follow vary according to the healthcare system in place. They differ in mandate (HTA is used with or without a formal link to reimbursement); scope (assessing all technologies or only medicines or new products); structure; funding; resources; expertise; and applicable methods and procedures.

In the European context, there are two types of assessment. A rapid relative effectiveness assessment (REA) focuses on the added clinical/therapeutic value of a health technology. It covers aspects such as safety (that is, any unwanted or harmful effects resulting from the use of a health technology) and clinical effectiveness (relative efficacy versus relative effectiveness). A full assessment covers the aforementioned elements plus further considerations, such as the cost-effectiveness of an intervention or its impact on healthcare budgets, its effects on patients and society and on how healthcare systems are organised, as well as ethical and legal aspects.

HTA is based on a systematic evaluation of the use of a health technology, and mainly relies on:

- **primary data methods**, which involve collection of original data from clinical trials or other study designs;
- **integrative methods** (also referred to as secondary or synthesis methods), which consist of combining data or information from existing sources (including from primary data studies) and systematic reviews and meta-analyses; and
- **economic analysis methods**, which cover primary data collection and integrative methods, as well as modelling. Common approaches used for estimating cost-effectiveness of interventions include, for instance, the quality-adjusted life-year (QALY) measure, which gauges health gains, and the disability-adjusted life-year (DALY) measure, which takes stock of the number of QALYs lost because of illness or disability.

**Efficacy, effectiveness and efficiency**

Efficacy refers to the benefit of using a health technology under 'ideal' conditions (such as in a randomised controlled clinical trial).

(Clinical) effectiveness is the benefit of using a health technology under the 'real-world' conditions of routine healthcare practice.

Relative efficacy/effectiveness denotes the relative benefits of health technologies compared with one or more alternatives.

Efficiency can be defined as obtaining the greatest benefit from a health technology using the resources available, or achieving a given benefit in a way that minimises costs.

**EU initiatives and cooperation on HTA**

**European Commission**

The Commission considers HTA to be an important element of evidence-based health decision-making, promoting it as a means of improving the resilience of healthcare systems. There have been repeated references to HTA in recent Commission documents.

A 2014 Commission staff working document on the pharmaceutical industry states that, in the context of sustainable healthcare systems and in view of maximising patient benefits, enhanced cooperation between EU Member States and pooling of resources in the implementation of HTA is crucial. It recalls that the Commission has been supporting cooperation on scientific issues between national and regional agencies since the late 1990s, in order to facilitate more consistent approaches in HTA.
A 2014 communication on healthcare systems stresses that 'HTA has proved to be an efficient tool for improving access to innovative technologies for patients and for supporting more efficient allocation of funds'. It reaffirms that the Commission 'supports an ambitious goal for the HTA network' and that 'a more ambitious and stable structure to support scientific cooperation on HTA will be developed'.

The Commission’s 2016 work programme of October 2015 announced that the Commission would launch preparatory work and enhance consultation on HTA ‘to improve the functioning of the single market for health products’.

A 2015 communication on upgrading the Single Market, published in the same month, stated that the Commission would introduce an HTA initiative for more coordination so as to avoid multiple – and sometimes contradictory – assessments of a product in different Member States. The accompanying analysis and evidence document pinpointed the lack of 'binding mechanisms for mutual recognition of joint assessments' in the EUnetHTA Joint Action.

The 2016 work plan for the EU Health programme envisages a study exploring the different options on how to maintain EU cooperation on HTA post-2019, when the third Joint Action ends. The plan mentions that by 2019, the Commission will have invested about €50 million in support for EU-level cooperation and research in HTA.

Lastly, a 2016 Commission staff working document addresses the issue of 'very high' HTA fragmentation and its implications for companies and the healthcare sector:

>'Each Member State carries out assessments individually, under different legal frameworks. The varying results between countries raise the question of objectivity and accuracy of assessments... In particular, for medicines multiple assessments impose a high cost on the industry which needs to submit its application multiple times, according to varying requirements. ... [S]eparate assessments by individual Member States mean duplication of work. ... [C]omplex and fragmented post-market approval processes and reimbursement decisions could have a restraining effect on research and innovation in the healthcare sector. ... Delays also affect companies' revenues...'

**European and international cooperation on HTA**

European HTA cooperation consists of a strategic level (HTA Network) and a scientific and technical level (EUnetHTA Joint Action), which complement each other. Member States participate on a voluntary basis, and decide whether or not they wish to use the output of the cooperative work (known as 'reuse' or 'uptake' of 'joint work').

**HTA Network**

Operating on a voluntary basis, the HTA Network was set up by Directive 2011/24/EU on patients’ rights in cross-border healthcare. It involves mainly ministries of health or national authorities responsible for decisions on HTA from the EU Member States, Norway and Iceland. It also includes observer stakeholders representing patients/consumers, healthcare providers, the healthcare industry and social payers (statutory health insurance). The HTA Network focuses on strategic issues relevant to HTA. According to the Commission, its aim is to facilitate efficient use of HTA resources in Europe; create a sustainable system of HTA knowledge-sharing; and promote good practices in HTA methods.

The 2014 HTA Network strategy for EU cooperation on HTA defines a vision for European cooperation (‘evidence is global, decision is local’) and calls upon the various actors involved in HTA to implement the principles and actions outlined. The strategy expects
that, beyond 2020, scientific activities will continue to be carried out by national and regional HTA bodies and that administrative coordination may be performed 'within suitable structures and possibly be supported by the EU budget'.

A 2015 reflection paper by the HTA Network gives recommendations on the reuse of joint work in national HTA activities. It also identifies possible barriers to developing and testing joint products and to increasing the use and further development of HTA tools.

Specific tasks under the HTA Network's 2016-2020 work programme focus on: the production of reflection/discussion papers on the interaction between regulatory and HTA issues; how to facilitate stakeholder involvement; efficient HTA cooperation on medical technologies (medical devices, in vitro diagnostics, medical imaging and health ICT), including the role of procurement processes; and communicating HTA reports to a broader audience. The work programme proposes further possible activities for the HTA Network. These include its acting as a platform for strengthening cooperation in 'areas of common interest', such as: horizon-scanning initiatives; discussions on technologies (other than medicines and medical devices) for which HTA may be useful; economic assessments of new technologies; and a mapping on how ethical issues regarding prioritisation and decision-making are handled in the EU.

**EUnetHTA Joint Action**

The HTA Network is supported by a mechanism for scientific and technical cooperation, the EUnetHTA Joint Action. EUnetHTA is organised as a network of government-appointed organisations, as well as regional agencies and not-for-profit organisations, which produce or contribute to HTA in Europe. EUnetHTA activities (or joint work) include developing methodological guidelines (for example, on rapid REA) and tools (such as databases, templates and the HTA Core Model®), as well as piloting joint assessments (of which 20 were finalised by March 2016).

The current EUnetHTA Joint Action 3, which commenced in June 2016 and will end by 2020, builds on the previous Joint Actions 1 (2010-2012) and 2 (2012-2015). With a budget of €20 million, EUnetHTA Joint Action 3 aims to increase the use, quality and efficiency of joint HTA work at European level, and to support structural voluntary cooperation at scientific and technical level between HTA bodies. It involves almost 80 participants, mostly from the EU, and will be coordinated by the National Health Care Institute of the Netherlands (Zorginstituut Nederland, ZIN).

EUnetHTA Joint Actions are co-funded by the EU Health programme. According to the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA), which implements Joint Actions, consolidating the permanent network for HTA in Europe will enable national agencies to achieve more efficient and comparable HTAs, avoiding duplication of work and increasing information exchange.

**Inception impact assessment on HTA cooperation**

According to the Commission's above-mentioned inception impact assessment (HTA roadmap), EU-level cooperation on HTA has an important role to play, but its full benefits have not yet been exploited. The roadmap identifies four problems that an initiative on HTA could address:

i. low uptake of joint work at EU level into national decision-making, leading to duplication of efforts (each national HTA is estimated to cost around €30 000 to national HTA bodies and €100 000 to industry);
ii. differences in the Member States’ procedural framework and administrative capacity (given the high number of national or regional HTA bodies), which have an impact on the duration of procedures, the scope of health technologies assessed and the number of assessments carried out;

iii. differences in national methodologies, which lead to divergent data requirements for the industry (with negative impacts on the investment climate, especially for small and medium-sized enterprises) and divergent outcomes of HTA assessments;

iv. lack of long-term financial sustainability, given that the current Joint Action 3 ends in 2020 and that, without EU funding, cooperation is unlikely to continue.

As the roadmap explains, a European initiative on HTA would be supportive of three main EU policies: the internal market strategy, by reducing national differences in access of health technologies to the market; fiscal stability and sustainability, since HTA can help Member States improve the allocation of resources; and research and innovation, where HTA could guide industry to invest in innovations with therapeutic benefits for patients.

**European Medicines Agency**

The European Medicines Agency (EMA) has been working with HTA bodies since 2008. EMA-EUnetHTA collaboration is aimed at creating synergies between regulatory evaluation and HTA. In 2010, EMA and EUnetHTA established a pilot project on parallel (that is, regulatory and HTA) **scientific advice**, also known as early dialogue. Regulatory scientific advice implies advice from the EMA to a pharmaceutical company on the appropriate tests and studies required in the development of a medicine. Aimed at facilitating the development and availability of medicinal products, the procedure can also help reduce delays in marketing them. Parallel scientific advice means that companies receive feedback from regulators and HTA bodies simultaneously, at any point in the development lifecycle of a medicine. According to the EMA, this fosters a more rational approach by bringing together requirements of regulators and HTA bodies in a single development programme and will ultimately improve ‘timely access by patients to meaningful new medicines’.

The April 2016 report on the joint EMA-EUnetHTA work plan for the 2013-2015 period states that the pilot ‘has demonstrated positive outcomes and should now continue on an operational basis’. The EMA has expressed its willingness to work with EUnetHTA and all stakeholders to ‘move forward’. Other current EMA initiatives relevant to HTA include:

- the Prime (Priority Medicines) scheme, based on enhanced interaction and early dialogue with developers of promising medicines, which aims to speed up evaluation and patient access to medicines;
- pilot projects on **adaptive pathways**, an approach to medicines development and data generation that allows for early and progressive patient access to new medicines under well-defined conditions;
- the **Adapt Smart** multi-stakeholder consortium under the Innovative Medicines Initiative (IMI), which acts as an enabling platform for Medicines Pathways to Patients activities. These seek to foster access to treatments for targeted patient groups at the earliest appropriate time in the lifecycle of a medicine;
- EUnetHTA pilot projects for rapid REA of pharmaceuticals, which means assessing a specific technology within a limited timeframe while comparing it with one or more alternative interventions;
- possible collaboration on 'late dialogues' (such as parallel scientific advice on post-
Other European and international initiatives for HTA collaboration

Examples of HTA initiatives at European and international level linked to the HTA Network or EUnetHTA include:

**Networks:** the Network of Competent Authorities on Pricing and Reimbursement (CAPR), some of which have been involved in the HTA Network or in EUnetHTA; the European Social Insurance Platform’s Medicine Evaluation Committee (MEDEV), whose members are HTA bodies and payers; and the International Network of Agencies for Health Technology Assessment (INAHTA) with 52 member agencies from 32 countries.

**Scientific societies:** Health Technology Assessment international (HTAi), a forum for collaboration and sharing of expertise among members from more than 65 countries; and the International Society of Pharmacoeconomics and Outcomes Research (ISPOR), with members from 114 countries.

**Projects:** completed projects that were funded under the seventh research framework programme, such as: AdvanceHTA on strengthening methodological tools and practices for HTA; AdHopHTA on HTA for hospitals; and MEDTECHTA on HTA for medical devices; SEED, funded in the framework of the second EU Health programme (2008-2013), on early dialogue between health technology assessors and healthcare product developers during the development phase of medicines and medical devices; or GetReal, an ongoing project funded by the Innovative Medicines Initiative (IMI), a public-private partnership, on incorporating real-life clinical data into medicines development.

**Council of the European Union**

HTA is specifically mentioned in the Council conclusions of 1 December 2014 on innovation for the benefit of patients. The conclusions recall that ‘European cooperation on HTA can promote more consistent approaches to HTA as a health policy tool to support evidence-based, sustainable and equitable choices in healthcare and health technologies’. They recognise that early dialogue between technology developers as well as regulatory, HTA and pricing bodies 'may promote innovation and quicker access to medicines at affordable prices'. The Council invites the Member States and the Commission to further enhance joint work on HTA and to support collaboration between regulators, HTA bodies, the EMA and the HTA Network throughout the lifecycle of medicines, 'without compromising the independence and respective prerogatives of regulatory and HTA processes'. The Commission is asked, inter alia, to explore options for sustainable financing, 'including considerations on how to make the best use of existing bodies that could facilitate cooperation, efficiency gains and scientific synergies'.

The Council conclusions of 7 December 2015 on personalised medicine for patients invite Member States to 'develop or adjust ... procedures aiming to evaluate the impact of personalised medicine, in particular ... HTA procedures, to the specific nature of
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personalised medicine, taking into account, inter alia, added value from the patients perspective as well as enhanced cooperation and exchange of best practices'.

The references to HTA in the Council conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the EU and its Member States are, as expressly stated, not only applicable to medicinal products, but also to medical devices and in vitro diagnostic medical devices. The Council invites the Member States to exchange HTA methodologies and assessment outcomes through EUnetHTA and the HTA Network, recognising that 'financial impact and pricing must be addressed separately from the HTA'. The Member States and the Commission are also invited to reflect about the future of European HTA cooperation after the current Joint Action has ended, notably to assess the relevance and functioning of the various bodies operating at EU level and to clarify existing tasks and mandates so as to avoid duplication and fragmentation of work.

European Parliament

Members of the European Parliament have regularly asked for enhanced EU-level cooperation on HTA. A written declaration of 7 September 2015 on the rights of cancer patients calls for more cooperation among the Member States' national HTA bodies as well as for 'research on possible scenarios for the creation of a European HTA reference assessment'.

In a resolution of 16 September 2015 on the Commission's work programme 2016, Parliament 'stresses the need for a step forward towards a common European ... HTA at EU level that does not create an extra layer of administrative burden'.

A Parliament amendment to the proposal for a regulation amending Regulation (EC) No 726/2004 on the rules governing marketing authorisation for medicines entrusts the EMA with the additional task of 'cooperating with the Health Technology Assessment Network, with health technology assessment bodies and other national authorities involved in market access, in particular to facilitate their assessment and reduce disparities in patients' access to health technologies'.

Moreover, a 2015 study commissioned by Parliament investigates the possibility of a harmonised EU approach to the assessment of the added therapeutic value of medicines.

Stakeholder views on European HTA cooperation

Patients/consumers, healthcare professionals, payers, public health organisations

In a joint position paper, non-industry stakeholders involved in EUnetHTA Joint Action 2 have underlined the importance of HTA 'in helping national authorities to make better decisions and generate more health from their investments in healthcare'. They argue that, to maximise the added value of HTA, non-industry stakeholders need to be actively engaged in several HTA processes, and that, through their involvement, transparency as regards reimbursement decisions and the decision-making process could be enhanced.

The European Cancer Patient Coalition (ECPC) advocates in a letter to Health Commissioner Vytenis Andriukaitis that 'Europe needs a strong and clear message in favour of the harmonisation of HTA at the European level', asking the Commissioner to 'take a clear position ... in favour of cutting the wastes of time and resources related to the implementation of 28 different HTA approaches in Europe'.

According to the European Patients' Forum (EPF), 'patients are the ultimate users of health technologies' and as such, have 'a crucial role in the assessment process'. EPF has identified two main ways of involving patients in HTA: by providing quantitative (through
surveys and health records) and qualitative (through patients’ stories and testimonies) evidence. EPF contends that the patients' perspective 'has a long way to go' before being fully integrated in HTA processes, while recognising that some improvements have been achieved, such as the involvement of EPF in EUnetHTA and in the HTA Network.

The European Public Health Alliance (EPHA) has expressed support for strengthening EU cooperation on HTA. It sees HTA as a 'gatekeeper' in increasing accessibility to medicines while ensuring innovation. EPHA is in favour of protecting the integrity and independence of the HTA bodies vis-à-vis the industry, and considers the current separation of the marketing authorisation and HTA processes as 'the correct approach'. While acknowledging the advantages of parallel regulatory and HTA advice, EPHA considers it essential to address potential conflicts of interest facing experts: for instance, those providing advice during early dialogue on a given product should not be involved in the assessment of that product. Moreover, EPHA has underlined the need for transparency and openness involving all relevant stakeholders, especially patients, and also questioned whether the EMA can ensure adequate independence from the industry.

In a 2015 joint position on access to innovative medicines, the European Social Insurance Platform (ESIP) and the International Association of Mutual Benefit Societies (AIM) state that 'the development and use of transparent HTA tools and processes should be promoted at national and EU level to support Member States in their evidence-based pricing and reimbursement decisions'. ESIP and AIM argue that 'new medicines that do not demonstrate measurable benefits for patients should not be reimbursed'. When added benefit is proven, 'reasonable pricing should be expected'. In case of unmet medical need, 'potential flexible pricing and reimbursement models might be explored'.

Eurordis Rare Diseases Europe contends that the most important contribution patients can make to the HTA process is 'the description of the benefits or unwanted effects of a healthcare technology'. According to Eurordis, the fact that HTA can be used, for instance, for a cost-benefit analysis of medicines to determine prices and reimbursement of orphan drugs 'is something that has long been crucial to many rare disease patient advocates'.

The Standing Committee of European Doctors (CPME) takes the view that HTA plays an important role in translating scientific knowledge on medicines and devices for use in decision-making in medical practice. According to CPME, the transparency of procedures and outcomes as well as the 'meaningful consideration of the ethical and social dimensions of technologies must be guiding principles for HTA'.

The European Association of Hospital Pharmacists (EAHP) believes that, in the context of medicines pricing, the development of HTA protocols across Europe is encouraging. EAHP states that moves by governments to better match the reimbursement price for medicines and the evidence of their value and benefit are 'generally welcomed as an advance in evidence-based policy'. EAHP cautions nonetheless that 'scrutiny of the evaluation methodologies must be maintained', so as to ensure an appropriate 'balance of considerations from the patient perspective'.

The European Society for Medical Oncology (ESMO) supports the HTA Network's aim of 'developing reliable, timely, transparent and transferable information for HTA bodies in each European country' and considers itself 'instrumental to achieving EUnetHTA’s goal of improving patient access to effective cancer medicines'.

Pharmaceutical and medical technology industry
The European Federation of Pharmaceutical Industries and Association (EFPIA) sees a need for creating a permanent EU cooperation structure after EUnetHTA Joint Action 3 ends, whether attached to the EMA or in the form of another sustainable solution. EFPIA maintains that the various approaches that different HTA agencies apply to the rating and interpretation of the data studied 'are confusing, lead to avoidable redundancies and thereby to unnecessarily lengthier procedures'. EFPIA argues that this heterogeneity in the appraisal of the same clinical data contributes to the divergence in the reimbursement status of medicines and delays the accessibility of novel medicines in different Member States. EFPIA believes that 'efficient and high quality European REAs of new pharmaceuticals at time of launch are essential', and that 'decision-making on pricing, reimbursement and access should remain a national competence'.

The medical technology industries – the European Coordination Committee of the radiological, electromedical and healthcare IT Industry (COCIR), the European Diagnostic Manufacturers Association (EDMA) and the association representing the European medical devices industry (Eucomed) – have issued recommendations on stakeholder involvement in the EU HTA cooperation. Among other things, the industries wish to see a multi-stakeholder dialogue platform within the current HTA Network structure, to discuss topics focused on medical technologies and not only on pharmaceuticals technology. EDMA calls for 'market access processes that are suitable for the specificities of the IVD [in vitro diagnostics] technologies' and requests 'appropriate timelines for market access decisions'. Eucomed asks for a 'device specific assessment paradigm' to be recognised, since a 'pharmaceutical paradigm, based on an expectation of multiple randomised controlled trials being available at the time of launch, may lead to restrictions on access to many new medical technologies'. HTA bodies should be 'pragmatic in their consideration of other sources of evidence', such as observational studies.

Think-tanks
In the context of considerations regarding innovation and sustainability in European healthcare systems, Bruegel refers to HTAs – 'which assess the ways science and technology are used in healthcare and disease prevention' – as a means for the EU to support the Member States' efforts in reforming their healthcare systems.

According to the European Policy Centre (EPC), more cooperation on exchanging information and developing methodologies is needed. The EPC pleads for a more comprehensive approach to assessing a medicine's value and effects, asserting that HTAs should, 'in addition to cost-effectiveness, take into account factors such as the lack of alternative treatments and the severity of the disease, and thus enhance a true value-based approach'. The EPC argues that 'creating an EU body to conduct the HTAs would prevent costly duplication and turn them into a valuable tool for decision-making'.

Next steps
The indicative planning for the Commission's legislative or non-legislative initiative is the fourth quarter of 2017. The inception impact assessment maps out five options for this initiative:

- status quo – Joint Action until 2020;
- long-term voluntary cooperation (financed by the EU beyond 2020);
- cooperation on collection, sharing and use of common tools and data;
- cooperation on production of joint REA reports and their uptake (cooperation on
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- Clinical/medical matters;
- Cooperation on production of joint full HTA reports and their uptake (cooperation on cost-effectiveness).

An online public stakeholder consultation is scheduled to be launched in autumn 2016. Targeted events for in-depth discussions are planned as well. The Commission has expressed particular interest in the views of patients' organisations, for instance on patient involvement in the HTA process or the interplay between HTA; access to innovative technologies for patients; and the sustainability of healthcare budgets.

Main references


Inception Impact Assessment on Strengthening of the EU cooperation on Health Technology Assessment, European Commission, DG SANTE, 2016.


Endnotes

1 Examples of the main categories of health technologies include: medicines; biologics (vaccines, blood products); devices, equipment and supplies (cardiac pacemakers, diagnostic test kits, surgical gloves); medical and surgical procedures; public health programmes (screening, prevention); and support and organisational systems used in healthcare (telemedicine systems, medication adherence programmes).

2 Healthcare expenditure in the EU is estimated to account for 10% of EU GDP. It is likely to increase in the coming years, inter alia due to: the ageing of the population; the rise in chronic diseases; and the acceleration of medical innovation fuelling the demand for state-of-the-art health technologies. In particular, the market entry of novel high-cost medicines, such as in oncology, for hepatitis C or for rare diseases, is thought to be a major driver of healthcare spending. As argued in the Commission's inception impact assessment on the basis of data from France and Germany, many new and expensive health technologies appear to have no or minor added therapeutic value compared with existing alternatives, and their reimbursement would put pressure on national health budgets.

3 In accordance with Article 168 of the Treaty on the Functioning of the EU, decisions on pricing and reimbursement of medicines are prerogatives of the Member States.

4 Such as a marketing authorisation for medicinal products or CE marking for medical devices, in vitro diagnostics and active implantable devices.

5 A study to map the national organisations, programmes and processes in the EU dedicated to HTA (‘atlas’) is currently underway.

6 Based on the HTA Core Model®, a methodological framework developed by the EUnetHTA Joint Action.

7 Defined as 'a technique for detecting early signs of potentially important developments through a systematic examination of potential threats and opportunities, with emphasis on new technology and its effects on the issue at hand'.

8 The International Association of Mutual Benefit Societies (AIM); the European Hospital and Healthcare Federation (HOPE); the European Consumer Organisation (BEUC); the Standing Committee of European Doctors (CPME); the European Organisation for Rare Diseases (Euordis); and the European Social Insurance Platform (ESIP).