

Stakeholder Consultation Strategy

Strengthening of the EU cooperation on Health Technology Assessment (HTA)

1. Context

The present stakeholder consultation aims to provide broad and high quality information to support the Impact Assessment on Strengthening of the EU cooperation on Health Technology Assessment (HTA).¹ In particular the consultation aims to explore how a continued and sustainable EU cooperation could support the Member States in their HTA activities, taking into consideration the views of all key stakeholders. The Impact Assessment is foreseen to be carried out in 2017.

EU cooperation on HTA through projects/joint actions was essential for developing a collaborative spirit among HTA bodies and for the elaboration of common tools and methodologies. So far two Joint Actions were co-funded through the EU Health Programme and a **third Joint Action** is running until 2020. To complement the scientific and technical cooperation of the Joint Actions, an **HTA Network** was set up in 2013 to work on strategic and policy aspects. This Network provides guidance to HTA cooperation at EU level, as it involves representatives of health ministries or authorities responsible for HTA. Despite their voluntary nature, all Member States are involved in both mechanisms.² In addition to public authorities, key stakeholders are also involved in both.

A Steering Group has been set up to take into account the input of relevant Directorates-General of the European Commission throughout the process.

The current strategy document will (1) set out the objectives, scope of the public consultation, (2) map key stakeholders and (3) establish consultation methods and tools which ensure accessibility. A website will be set up to provide a centralised source of information on all stakeholder consultation activities and their outcomes. A synopsis report will document all consultation activities, summarise the responses and will give feedback to the stakeholders on how their input was used (and if not, why). This synopsis report will be discussed in the ISG and annexed to the Impact Assessment.

2. Stakeholder Consultation – Objectives and Scope

The aim of the stakeholder consultation on the future initiative on EU cooperation on HTA is to invite stakeholders to express their views on the European HTA cooperation: their experiences in the current system and the on-going cooperation mechanisms, their needs in the future and their opinion on the proposed approach in the Inception Impact Assessment. The

¹ Health Technology Assessment (HTA) determines 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.

² In EUnetHTA JA3, Norway is also participating as a non-EU country; Luxemburg's participation is being discussed. In the HTA Network in accordance with Article 15 of the Cross Border Healthcare Directive 2011/24/EU participation in the HTA Network is voluntary for Member States, it is worth noting that all Member States have applied for membership (as well as Norway and Iceland).

focus of the consultation is how the European cooperation could support the HTA processes in Member States and regions.

The following key aspects will be consulted on.

- Extent and impact of the current diversity of the national HTA system (*problem*)
- Subsidiarity, added EU value (*subsidiarity*)
- Scope for joint work on EU level, use in national decision-making, feasibility (*options*)
- Impacts of potential EU collaboration (both positive and negative) (*impacts*)

Studies are being launched to support the impact assessment with factual data. The stakeholder consultation will complement this by providing an insight to the perspectives of the stakeholders. Nonetheless, stakeholders will be encouraged to submit references to factual datasets.

It should be noted that the envisaged initiative will not affect national pricing and reimbursement decisions. The stakeholder consultation is a key tool to communicate consistently from the outset that areas of price-setting and reimbursement should clearly remain national responsibility in line with Article 168 (7) of the Treaty on the Functioning of the European Union (TFEU) and are not covered by any future initiative on HTA.³ Early and consistent communication throughout the process will be essential to avoid misunderstanding and ensure support.

3. Stakeholder Mapping

The next section will help to identify the key stakeholders, with particular attention to the groups that are often challenging to reach (e.g. patients, SMEs). The Inception Impact Assessment already contains a list of the key stakeholders and a summary of their positions previously expressed.

Stakeholders' categories:

Public authorities – are one of the key stakeholders. A variety of public bodies will be consulted, including MS representatives, National Governments, (in particular) Ministries of Health, regional and local authorities (if relevant), HTA agencies, and pricing and reimbursement authorities. Member States have expressed support for a sustained cooperation on health technology assessment,⁴ the extent of support, however, shows variation. In general, HTA agencies have demonstrated strong support for cooperation.

³ This article states: “Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them (...)”

⁴ [Strategy for EU Cooperation on HTA](#), [Council conclusions on innovation for the benefit of patients \(2014/C 438/06\)](#) and [Council conclusions on Personalised medicine for patients](#)

These agencies have a direct experience in EU collaboration as they have been actively working together in the frame of the EUnetHTA Joint Actions. The level of support also varies from MS to MS. It is important to make a distinction between MS with advanced and well-functioning HTA systems and MS who are now developing their systems or have limited resources to invest in HTA. Efforts will be made to ensure that all MS provide feedback.

Citizens and patients through civil society representatives (e.g. patients, public health organisations, etc.). Citizens and patients will be indirectly affected as cooperation on HTA can affect the availability and prices of health technologies. Patient representatives are consulted in the HTA process in some cases– the extent of their influence varies strongly. Individuals are not likely to provide input in the consultation, but EU representative organisations have already formulated positions regarding HTA. To ensure that all interested citizens can respond to the open public consultation, a translation to all official languages to the EU will be provided for the citizens' questionnaire.

Industry – The industry would be directly affected by a future initiative. There are EU level organisations representing the sector. The health technology sector is composed of two main groups: the **pharmaceutical industry** and the **medical technologies industry**. The market access paths of pharmaceutical and medical technologies are different – throughout the consultation the differences between these sectors will need to be duly accounted for. SMEs are strongly impacted, therefore it is a group that should be consulted. The consultation strategy will include measures to ensure their views are collected and taken into consideration.⁵

Payers (e.g. public and private health insurance representatives, 'mutualitiés') have been identified as a separate stakeholder group. They are also directly affected as HTA can provide an important input to pricing and reimbursement. It should be noted that there are differences in how the national systems are set up and how HTA inputs to the payers' decisions. European umbrella organisations representing the sector will also be consulted.

Healthcare providers (e.g. professional associations, hospitals, healthcare managers) will also be indirectly affected as cooperation on HTA can affect the availability of technologies and the clinical protocols. Similarly to patients, they are only likely to provide input through EU representative organisations.

Science, Research and innovation community (e.g. academia and scientific societies) is indirectly affected as they are involved in developing the methodologies used in the HTA. This category also includes experts, either from the academia or the private sector who are subcontracted to develop methodologies or assessments of technologies for industry or public authorities.

Relevant **international organisations** such as WHO, OECD, INAHTA (International Network of Agencies for Health Technology Assessment), Health Technology

⁵ It should be added that there is an industry of specialised consultancies producing health technology assessment. They will also be strongly impacted, but the size of the sector is smaller and the EU representation is not as organised as in the case of the pharmaceutical and medical technologies industry. Therefore, they are grouped under the category research and innovation community.

Assessment international (HTAi) and International Society for Pharmacoeconomics and Outcomes Research (ISPOR) have demonstrated their interest in the topic.

The **media** has already demonstrated a strong interest in the subject. Even though they have low stake, their influence is high and so they should be considered in the stakeholder mapping.

While the stakeholder consultation does not cover inter-institutional consultations, the importance of the European Parliament should be noted in this document as they have demonstrated an interest in HTA cooperation at EU level. The same applies to relevant EU bodies, such as the European Medicines Agency (EMA).⁶

4. Methods & Tools

The combination of consultation methods will support reaching the stakeholders and ensuring a high quality and balanced input. If a compelling need emerges during the process, the stakeholder consultation methods will be modified. Such changes will be announced on the consultation website.

1. The key tool of the consultation will be the open public stakeholder consultation.

The purpose of the consultation will be to collect information, views and opinions. Through the current cooperation the European Commission already has a good first indication of the needs and the concerns of the main stakeholder groups, and studies are being launched to provide further data. Yet, understanding and assessing the views and opinion of the broader constituency of stakeholders will be crucial in order to develop an initiative that meets expectations, demonstrates EU added value and allows for effective implementation.

An online questionnaire will be prepared on Your Voice in Europe. The launch of the public consultation is foreseen in Q4 of 2016 and will be announced in the consultation planning that can be found at: http://ec.europa.eu/yourvoice/consultations/index_en.htm.

As the timing of the publication of the Inception Impact Assessment will coincide with the launch of the public consultation, the Inception Impact Assessment will be used as one of the key the supporting documents for the open public stakeholder consultation.

2. Experts Consultation will be carried out also through the existing cooperation mechanisms, such as **EUnetHTA Joint Action** and the **HTA Network**, where many of the key stakeholders are present.

⁶ In its joint motion for a resolution on the Commission Work Programme 2016, the European Parliament called for "a step forward towards a common European Health Technology Assessment" (European Parliament resolution on the Commission Work Programme for 2016 (2015/2729(RSP)). Some MEPs have repeatedly suggested stepping up cooperation at EU level. Moreover the European Parliament commissioned a study on HTA highlighting its interest in the subject (final study: "Towards a Harmonised EU Assessment of the Added Therapeutic Value of Medicines", Report commissioned by the committee of Environment, Public Health and Food Safety at the European Parliament, 2015).

The purpose of these meetings will be to discuss the options proposed in the Inception Impact Assessment for the future EU cooperation in HTA. Since these are the stakeholders who are already participating in the cooperation and they will be the ones who continue cooperating after 2020, their views on the added value, the feasibility, the costs and the potential issues of subsidiarity related to the options are of particular relevance.

In particular, the next HTA Network meeting (planned for 10th of November) will be an important forum for input from a group of responsible national officials/experts. The EUnetHTA plenary is planned for second half of October for key stakeholders; it is also expected to be a major event for the stakeholder consultation. Smaller focus group discussions or workshops are envisaged. The exact format and the topics of the meeting will be developed around the main issues emerging in the first phases of the policy making cycle.

3. In addition to these two stakeholder consultation tools, a number of **consultation channels** will be used to reach out to stakeholders, invite them to participate in the public consultation, and listen to their views and opinions. **External events** provide ample opportunities to reach out to and request the input of a broad range of stakeholders. Examples of such events are the ISPOR (International Society for Pharmacoeconomics and Outcomes Research) meeting or the European Health Forum Gastein. In addition, larger national events may also be included in the consultation efforts to facilitate direct interaction in some MS.

Ad hoc meetings with stakeholder representatives have been going on and will be continued to allow in-depth discussion on specific topics and the expression of non-organized interests. The unit responsible for the HTA initiative (SANTE B4) publishes the summary records for all meetings with stakeholders on the SANTE website.

To reach out to **SMEs**, the SME Panel Consultations conducted through the Enterprise Europe Network (DG GROW) will be used. In addition, we will also use the channels of the EMA office for SMEs to reach out to a high number of SMEs in the sector.

To allow opportunities for in-depth discussion, **senior level meetings with the Ministry of Health and HTA bodies** in a number of MS are foreseen.

5. Website and dissemination

DG SANTE will set up webpages dedicated to the stakeholder consultation strategy which will serve as the major information tool concerning the consultation process. It will contain subpages for the different types of consulting work performed, inform about the envisaged timeframes and all relevant information on the consultation activities planned.

The Communication unit (SANTE 02) will provide support to disseminate the launch of the consultation as well as the results through the regular channels (SANTE website, newsletters, Twitter etc.)