Q&A: Commission proposal on Health Technology Assessment

Brussels, 31 January 2018

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What is Health Technology Assessment?

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 and robust manner. It answers clinical questions like: How well does a new technology work compared with existing alternative health technologies? For which patients does it work best? HTA can also answer economic questions like: What costs are entailed for the health system? It is therefore a key tool for Member States to ensure the accessibility, quality and sustainability of healthcare. The Commission proposal focuses on clinical aspects of HTA, i.e. problem definition, and the relative safety and clinical effectiveness of a health technology as compared with existing technologies.

What problem/gap does the proposal seek to address?

Currently, **market access** for innovative technologies is **impeded and distorted** due to differing national or regional processes and methodologies for HTA across Europe. This situation also contributes to lack of business predictability, higher costs for industry, delays in access to technologies, and negative effects on innovation. Moreover, it can result in **duplication of work** for national HTA bodies, inefficient use of resources and **limited transparency** for patients. As several decades of project-based EU-cooperation on HTA have shown, these issues cannot be sufficiently addressed by the purely voluntary approach on joint work taken to date. The current project-based EU-level cooperation on HTA also suffers from a **lack of sustainability**, as funding is short-term and needs to be renegotiated and secured in every financial cycle.

What are the main objectives of the Commission's proposal?

The proposed mechanism for EU cooperation on HTA aims to help to make innovative health technologies available to Europe's patients, make better use of available resources and improve business predictability. The proposal seeks to ensure that when HTA is performed, the methodologies and procedures applied are more predictable across the EU and that joint clinical assessments are not repeated at national level, thereby avoiding duplication and discrepancies.

What will EU cooperation on HTA entail?

The proposal includes provisions for the use of common HTA tools, methodologies and procedures across the EU. It sets out four pillars for joint work of Member States at EU-level. These are:

- **Joint clinical assessments** focusing on the most innovative and potentially impactful health technologies for maximum EU-added value;
- **Joint scientific consultations** whereby developers of a health technology can seek the advice of HTA authorities on what type of data and evidence is likely to be required in the submission for HTA;
- **Identification of emerging health technologies** to help ensure that the most promising health technologies for patients and health systems are identified early and included in the joint work; and
- **Voluntary cooperation** in areas outside the scope of mandatory cooperation, for example on health technologies other than medicines and medical devices (e.g. surgical procedures), or on economic aspects of health technologies.

Who will coordinate this work?

The proposal establishes a Member State Coordination Group on HTA (the 'Coordination Group') composed of representatives from national HTA authorities and bodies. The Coordination Group will be responsible for overseeing the joint clinical assessments and other joint work carried out by designated national experts organised in sub-groups dedicated to the specific types of joint work (e.g. sub-group on joint clinical assessments, sub-group on joint scientific consultations).

Which health technologies are covered by joint clinical assessments?

Joint clinical assessments are limited to the most innovative technologies with the most potential EU-wide public health impact, also taking into account the specific characteristics of the different health technology sectors. They fall under two main categories:

- **Medicines**: which undergo the EU's central marketing authorisation procedure, including new active substances and existing products that seek to extend the marketing authorisation to a new therapeutic indication.
- **Medical devices**: certain medical devices, including in vitro diagnostic medical devices, which have received an opinion of relevant experts at EU-level under the new EU Regulations on medical devices (EU/2017/745 and EU/2017/746). From among these products, the Coordination Group will further select those for which a joint clinical assessment at EU level will bring most added value, based on criteria such as unmet medical need and the potential impact on health systems.

Will joint clinical assessments affect market approval?

No. The joint clinical assessments for HTA purposes will only be completed **after** the products have obtained a marketing authorisation (for medicines) or a CE mark (for medical devices). HTA does not interfere with marketing authorisation assessments (of medicines) or conformity assessments (of medical devices).

How will Member States use joint clinical assessments?

Member States HTA authorities will use the reports of joint clinical assessments conducted at EU-level as part of their national or regional HTA processes. While Member States shall not repeat the joint clinical assessment, they can complement it with assessments of non-clinical HTA aspects (e.g. economic, social, ethical). Member States will also continue to draw conclusions on the overall added value of a health technology and take related decisions for their health systems (e.g. on pricing and reimbursement).

How many joint clinical assessments are expected for medicines and medical devices?

The proposal includes provisions for a step-by-step build-up of the new EU system for joint work during its first years until it becomes fully operational. For both medicines and medical devices we expect the number of joint clinical assessments to gradually increase during this transitional period, taking into account the capacities and priorities of Member States. For instance, the system could start performing 10 to 15 assessments in the first year, reaching a number of around 65 joint clinical assessments towards the end of the transitional period. After the transitional period, joint clinical assessments on all medicines and the medical devices included in the scope of the proposal should be carried out.

What is the role of the European Commission?

The Commission will support the work of the Coordination Group by hosting the meetings of national HTA experts carrying out the joint work, providing scientific, secretarial and IT support, and facilitating cooperation with other EU organisations, such as the European Medicines Agency (e.g. for joint scientific consultations). While the scientific-technical work is Member State-driven, the Commission's role is to make sure that the work of the Coordination group is carried out independently and transparently, and the timing and quality of the joint work complies with the requirements set in the Regulation.

Who will benefit from this cooperation?

Patients will benefit from faster uptake of promising innovative technologies, to the extent that Member States – who are in the driver's seat as concerns uptake of these technologies in national health systems as well as national pricing and reimbursement policies – take account of the results of

the joint clinical assessments. For **Member States**, the key benefits are the ability to improve the sustainability of their health systems by selecting technologies for which HTA has shown an added value. In addition, national authorities will be able to pool their expertise and avoid duplication of efforts on clinical assessments, making better use of human and financial resources. **Industry**, including SMEs, will benefit from clearer rules and greater predictability for their business planning, and cost savings. All three of these groups will benefit from greater transparency.

What are the financial implications of this proposed legislation?

The implementation of this proposal has no impact on the current Multiannual Financial Framework 2014-2020, as the proposal is aimed at a cooperation mechanism post-2020. The financial impact on the EU budget post-2020 will be part of the Commission's proposals for the next Multiannual Financial Framework.

When will the new rules take effect?

The rules will become applicable **three years after entry into force** which is 20 days after the adoption by both the European Parliament and the Council. This will allow for all the planned implementing and delegated acts to be prepared and adopted as well as for the preparatory steps necessary for the joint work.

Following the date of application, **a further three-year transitional period** is granted for EU countries to fully adapt to the new system. During this transition period we expect the number of joint clinical assessments to gradually increase.

The proposal also includes a **safeguard clause** that allows Member States, in justified situations agreed by the Commission, to revert to carrying out clinical assessments at national level.

For more information:

https://ec.europa.eu/health/technology_assessment/eu_cooperation_en

MEMO/18/487

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