



Council of the
European Union

Brussels, 2 February 2018
(OR. en)

**Interinstitutional File:
2018/0018 (COD)**

**5844/18
ADD 2**

**PHARM 6
SAN 49
MI 61
COMPET 53
CODEC 133**

COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	1 February 2018
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2018) 42 final
Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU

Delegations will find attached document SWD(2018) 42 final.

Encl.: SWD(2018) 42 final



Brussels, 31.1.2018
SWD(2018) 42 final

COMMISSION STAFF WORKING DOCUMENT
EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

**Proposal for a Regulation of the European Parliament and of the Council
on health technology assessment and amending Directive 2011/24/EU**

{COM(2018) 51 final} - {SWD(2018) 41 final}

Executive Summary Sheet

Impact assessment on Strengthening EU cooperation on Health Technology Assessment (HTA)

A. Need for action

Why? What is the problem being addressed?

HTA is considered a valuable tool for ensuring the sustainability of health systems and stimulating innovation at EU level, but a series of shortcomings have prevented the full potential of HTA being reached for Member States and economic operators with subsequent negative consequences also for EU patients and healthcare professionals: **1) Impeded and distorted market access**, results from different national HTA processes and methodologies meaning that economic operators who want to introduce a health technology in multiple Member States are confronted with various data requests. **2) Duplication of work for national HTA bodies** means that they carry out in parallel or within a similar time-frame, clinical assessments on the same health technologies. In addition, the results of joint clinical assessments (relative effectiveness assessments - REA) carried out by a group of HTA bodies in the framework of the current Union-funded cooperation (EUnetHTA Joint Action 3) have not been used at national level ("low uptake"), which has resulted in additional duplication, extra work and supplementary costs. **3) Unsustainability of the current HTA cooperation.** The current EU cooperation on HTA is project-based with no guarantee for the continuation of activities or their financing in the long-term.

What is this initiative expected to achieve?

The **general objectives** of the initiative are to ensure a better functioning of the internal market of health technologies and to contribute to a high level of human health protection.

The **specific objectives** of the initiative are: to promote convergence in HTA tools, procedures and methodologies; to ensure efficient use of resources and strengthen the quality of HTA across the EU and to improve business predictability.

What is the value added of action at the EU level?

While the on-going cooperation (i.e. EUnetHTA Joint Actions and HTA Network) has illustrated benefits of EU cooperation, the current model has not contributed to the removal of the fragmentation of the internal market, or the duplication of assessments. Without an EU initiative, it is unlikely that long-term cooperation on HTA between Member States would be strengthened, with a potential risk of losing the results achieved until now. By carrying joint clinical assessments, economies of scale, greater business predictability, increased quality and consistency and improved transparency for patients would be achieved in the long run.

B. Solutions

What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why?

Two non-legislative options were considered. **Policy option 1** supposes that when EUnetHTA Joint Action 3 ends in 2020 the EU funding for the scientific and technical cooperation is discontinued. The cooperation would be voluntary, relying on national resources and is expected to remain sporadic. **Policy option 2** provides for a voluntary cooperation model, implemented through EU-funded projects other than Joint Actions. It is dependent on the willingness of HTA bodies to participate, with no guarantee for the implementation of joint outputs. Additionally, **three legislative** policy options were considered. **Policy option 3** provides for a permanent cooperation mechanism allowing for the harmonisation of common HTA tools, procedures, methodology and joint Early Dialogues with health technology developers. **Policy option 4** builds on option 3, to which joint clinical assessments (i.e. joint REA) are added. This policy option could be applied through an 'opt-in' system (**option 4.1**) or to all Member States with no possibilities to opt-in later or stay out (**option 4.2**). **Policy option 5** which extends option 4 by including the joint full HTA (i.e. REA plus an economic assessment and other non-clinical domains) was not considered feasible and was discarded at the start of the process. The preferred option is a **revised Option 4.2** which integrates elements from other policy options (i.e. 2 and 4.1) and also some adjustments (i.e. progressive implementation of the product scope, inclusion of transitional arrangements for Member States and specific approach for medical technologies). The preferred governance option includes a central secretariat to be hosted by the European Commission.

Who supports which option?

Most **Member States' public administrations** support options 3-4, favouring a stepwise approach/transitional regime. **Payers** expressed concerns about mandatory use of economic assessments. **Patients** are strong supporters of option 5, or at least option 4. Healthcare professionals and academia advocate for options 4-5, and

together with patients' representatives support a legal framework to secure their participation in the HTA process. The **pharmaceutical industry** supports option 4 advocating for a legal framework to guarantee uptake of joint clinical assessments by Member States. The **medical technologies industry** expressed concerns regarding a "one size fits all" solution and a legally mandated joint clinical assessment (REA) at the time for market launch.

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise main ones)?

The preferred option is considered to provide for the best combination of effectiveness and efficiency and is the most proportionate one:

- It allows for the best possible achievement of the internal market objective by promoting convergence in procedures and methodologies, reducing duplications/parallel REA and thereby the risk of divergent outcomes, thus contributing to improving the availability of innovative health technologies for patients;
- It provides Member States with a sustainable framework allowing them to pool expertise, reinforce evidence-based decision making, supporting them in their efforts to ensure sustainability of national health systems;
- It respects the subsidiarity principle, taking into account the time needed for adapting/aligning to the system and leaving the economic/non-clinical assessment to national or regional level;
- It is cost efficient in the sense that the costs are significantly outweighed by savings for Member States and industry, as a result of pooling of resources, avoiding duplications and improving business predictability;
- It provides useful input to and synergies with the Digital Single Market agenda and play an important role in supporting innovation by influencing longer-term R&D investment decisions by industry. It is fully coherent with other EU legislation in the field of medicinal products and medical devices.

What are the costs of the preferred option (if any, otherwise main ones)?

Economic impacts. The cost **savings** related to the joint clinical assessments (REA) could reach over time EUR 2 670 000 per year for *HTA bodies*. A high quality joint REA is also expected to contribute to better allocation of resources and more efficient healthcare investments decisions, but these benefits are difficult to quantify at this stage. For *industry*, the most important economic impact is related to the expected benefits in terms of predictability, leading to better innovation and increased competitiveness. **Social impacts.** The availability of timely and good quality joint REAs mean better evidence available for national decision-making, sustainability of health systems, and ultimately improved public health. The joint REA will further improve the participation of patients and transparency. It has the potential to speed up assessment timelines and thereby reduce delays in the availability of innovative medicines.

Costs. The overall costs of the preferred option were estimated at approximately EUR 16 million, of which 7 million represent the running costs and the rest the costs of the joint outputs.

How will businesses, SMEs and micro-enterprises be affected?

In the area of pharmaceuticals SMEs are mostly engaged in the discovery phase of new molecules, and a very low number apply for central marketing authorisation. The number of applications for joint REA from SMEs is expected to be very low, and since no fees are foreseen for this type of joint output, the compliance costs are expected to be low. Similar treatment would be applied for SMEs in the field of medical technologies (no compliance fee in case of a joint REA).

Will there be significant impacts on national budgets and administrations?

The planned work-sharing is expected to result in cost savings for public administrations. It is expected, however, that in the short run national administrations would be faced with limited administrative costs/burden as they have to adapt to the joint system.

Will there be other significant impacts?

No other significant impacts have been identified.

D. Follow up

When will the policy be reviewed?

Continuous monitoring and evaluation is planned. A review of the scope and governance structure, including the possibility of introducing fees for joint clinical assessments is planned.