



Strengthening EU cooperation on Health Technology Assessment

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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on health technology assessment and amending Directive 2011/24/EU

Objectives

- **Reduce duplication** of efforts for HTA bodies and industry
- **Promote convergence** in HTA tools, procedures and methodologies
- **Strengthen the quality** of HTA **across the EU**
- Ensure the **uptake of joint outputs** in Member States
- Ensure the long-term **sustainability** of EU cooperation



Key principles

- **Joint work** on common **scientific, clinical aspects** of HTA
- Joint work **driven by Member State HTA bodies**
- Ensure **high quality, timeliness and transparency**
- Ensure **use of joint work in national HTA processes**
- **Member States** remain responsible for:
 - Drawing **conclusions on added value** for their health system
 - Taking **decisions on pricing & reimbursement**
- **Progressive implementation**

Main areas of joint work

- **Joint clinical assessments (medicines, medical devices)**
- **Joint scientific consultations**
(scientific advice to health technology developers)
- **Identification of emerging health technologies**
("horizon scanning")
- **Voluntary cooperation in other areas**
(e.g. on other health technologies or non-clinical HTA aspects)



Expected benefits of strengthened EU HTA cooperation

Member State decision-makers

- ✓ High quality, timely scientific reports (pooling of HTA resources and expertise; better evidence base for HTA across EU)
- ✓ Supports **evidence-based decision-making** at national level

Patients across the EU

- ✓ Improved **transparency** and engagement in the HTA process
- ✓ Contribute to facilitating patient access to truly innovative technologies (due to more timely, evidence-based decision-making)

Industry

- ✓ **Clearer evidence requirements**, facilitating investment decisions for R&D of innovative technologies
- ✓ More efficient evidence submission (single EU-wide dossier for joint clinical assessment)



Involvement of patients and clinical experts – EC Proposal

- **Joint Clinical Assessments**

The designated sub-group shall ensure that stakeholders, including **patients and clinical experts**, are given an **opportunity to provide comments** during the preparation of the draft joint clinical assessment report

- **Joint Scientific Consultation**

The designated sub-group shall ensure that stakeholders, including **patients and clinical experts** are given an opportunity to provide comments during the preparation of the draft joint scientific consultation report

- Consultation of patients and clinical experts in clinical assessments carried out by Member States

procedural rules to be developed for the consultation of patients, clinical experts and other stakeholders

Stakeholder Network – EC Proposal

- Established by the Commission through an **open call for applications** and a selection procedure (list of included stakeholder organisations is published)
- **Meetings** between **Stakeholder Network** and **Coordination Group** (updates and information exchange)
- **Support Coordination Group** in the **identification of patient and clinical expertise** for the work of its subgroups

Stakeholder Involvement

Ongoing discussion

- **Shared Objective :**

Involving stakeholders EU HTA cooperation - welcomed and acknowledged

- Involvement of stakeholders experts in products specific output
- Involvement of stakeholders representatives in overall/general output

- **Challenge :**

How to combine inclusiveness , high quality with timeliness and resources availability

Co-decision procedure: Negotiations in Council

➤ Council

- **BG Presidency (Jan.-June 2018):** 3 Working Party meetings and EPSCO debate (June)
- **AT Presidency (July-Dec. 2018):** 7 Working Party meetings, AT Presidency proposal for compromise text (Art 1-8), Progress Report
<http://data.consilium.europa.eu/doc/document/ST-14694-2018-INIT/en/pdf>
- **RO Presidency (Jan.-June 2019):** 8 Working Party meetings (8 held)

Progress report to be presented at the EPSCO council 13&14 June

- FI Presidency (July – Dec 2019) expressed commitment to progress with the negotiations 7 Working Party meeting scheduled



Co-decision procedure: Parliament

- **Lead committee:** ENVI
- **Rapporteur:**
Soledad Cabezon Ruiz (S&D, ES, ENVI)
- **Vote:**
3 October 2018 - Plenary adopted amendments on and referred back to ENVI
- 13 February 2019 - adopted its report on HTA proposal, thus concluding its first reading
 - <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P8-TA-2019-0120>



Thank you

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