Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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

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Conflict of interest disclosure

I have no actual or potential conflict of interest in relation to this program/presentation

What is Health Technology Assessment?

- **"Health technology"** comprises:
  - medicines,
  - medical devices,
  - in vitro diagnostics devices,
  - medical and surgical procedures, measures for disease prevention, vaccination, treatments - used in healthcare.

- **HTA an evidence-based process that assesses the added value (relative effectiveness)** of a given health technology/health interventions and compares it with other health technologies and / or the current standard of care.

- **HTA can cover different aspects:** from clinical domains (e.g. safety, clinical effectiveness) to non-clinical domains (e.g. economic, ethical, organisational).

Health Technology Assessment (HTA)

HTA domains	
Health problem and currently used technologies	Clinical domains
Description of technology under assessment	
Relative clinical effectiveness	
Relative safety	
Economic evaluation	Non-clinical domains
Ethical aspects	
Organisational aspects	
Social aspects	
Legal aspects	

Key principles I

- **Provides support framework** for EU cooperation on HTA
- **Joint work on scientific, clinical aspects** — Articles 5-11
  - Joint clinical assessments/JCA (REA)
  - Joint scientific consultations/JSC (early dialogues) — Articles 12-17
  - Horizon scanning/Emerging health technologies
  - Voluntary cooperation — Article 18 -19
- **Well defined scope** (MP- Centrally authorised; MD – selection of Class II and IIIb + IVD) — Article 5
- Joint scientific work **driven by Member State HTA bodies** (Coordination group and subgroups) — Articles 3-7,13
- Ensure **high quality and transparency** of joint work (involvement of patients and clinical experts + publication + CoI) — Article 22.1.

Key principles II

- Ensure **use of joint work in national HTA processes** — **Article 8**
- **Member States** remain **responsible for** — **Recital 16**
  - Drawing the overall **conclusions on added value** in the context of their healthcare system
  - Taking subsequent **decisions on pricing & reimbursement** — **Article 6,11,16**
- Enable **synergies** between regulatory and HTA issues
- **Progressive implementation** — **Articles 33, 36**

Expected benefits of Commission proposal

Member State decision-makers

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

Patients

- ✓ **Improved transparency** and engagement in the HTA process **for EU patients**
- ✓ Contribute to improved availability of **technologies with true added value** for patients across the EU (due to more timely, evidence-based decision-making)

Industry

- ✓ **Clearer evidence requirements/predictability**
- ✓ **More efficient evidence** generation and **submission**

High scientific quality and transparency

- **Ensuring appropriate evidence for HTA**
  Joint scientific consultations
  Submission requirements for industry (joint clinical assessments)
- **Pooling resources/expertise of HTA bodies across EU**
  Selection of HTA bodies with appropriate expertise/capacity as lead assessors (e.g. joint clinical assessments)
- **Consultation of external clinical experts**:
  Specialist clinicians and patients in particular therapeutic areas (joint clinical assessments, joint scientific consultations)
- Rules to ensure **avoidance of conflicts of interest**
- **Publication of joint clinical assessments**

Thank you!

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