

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

EU HTA
Emerging Health Technologies (EHT) Subgroup
Objectives and mandate

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HORIZON SCANNING IN EUROPEAN INITIATIVES AND LEGISLATION

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- STRATEGY FOR EUROPEAN LIFE SCIENCES
- EUROPEAN BIOTECH ACT
- MEDICAL COUNTERMEASURES STRATEGY
- EUROPEAN INNOVATION COUNCIL: FUTURRINOV

- HTA REGULATION

HTA REGULATION: EMERGING HEALTH TECHNOLOGIES

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Legal basis:

- Art 22 and Art 7 (3) of Regulation (EU) 2021/2282 HTA
- Art 23: Voluntary cooperation on clinical assessments of health technologies not yet in scope but expected to have a major impact on patients, public health or healthcare systems.

HTA COORDINATION GROUP (CG) AND EHT Subgroup

- EHT Subgroup informs the HTACG Annual Work Programme
- HTACG guides the EHT Subgroup mandate continually

Article 22

Identification of emerging health technologies

1. The Coordination Group shall ensure the preparation of reports on emerging health technologies expected to have a major impact on patients, public health or healthcare systems. Those reports shall in particular address the estimated clinical impact and the potential organisational and financial consequences of emerging health technologies for national healthcare systems.

2. The preparation of the reports referred to in paragraph 1 shall be based on existing scientific reports or initiatives on emerging health technologies and information from relevant sources including:

(a) clinical study registers and scientific reports;

(b) the European Medicines Agency in relation to upcoming submissions of applications for marketing authorisation for medicinal products referred to in Article 7(1);

(c) the Medical Device Coordination Group;

(d) health technology developers on the health technologies they are developing;

(e) members of the stakeholder network referred to in Article 29.

3. The Coordination Group may consult stakeholder organisations which are not members of the stakeholder network referred to in Article 29 and other relevant experts, as appropriate.

Article 7

Health technologies subject to joint clinical assessments

3. By way of derogation from paragraph 2 of this Article, the Commission, upon a recommendation from the Coordination Group, shall adopt a decision by means of an implementing act establishing that medicinal products referred to in that paragraph shall be subject to joint clinical assessment at a date earlier than the dates set out in that paragraph, provided that the medicinal product, in particular according to Article 22, has the potential to address an unmet medical need or a public health emergency or has a significant impact on healthcare systems.

Scope of EHT reports 2026-2028

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1. The **expected number of products** within the mandatory scope of the HTAR expected to submit for MA in the following calendar year including product specific information
2. Extension of indication of already authorised medicinal products, for which a JCA report has been published, if data is available; and
3. **Future trends in innovation** expected to have a major impact on patients, public health and healthcare systems.

Scope 2026-2028

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Product specific information

mandatory scope of HTAR

- Medicinal Products (MP)
- Medical Devices class IIb and III and *In-vitro* diagnostics (MD/IVD) class D



Emerging trends

- Health technologies or approaches/tools with a major impact
- Therapeutic areas, drug classes or MD/IVD classes

Emerging trends

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- The scope of “emerging trends” in the EHT reports will be a high-level overview highlighting:
    1. Innovative health technologies and approaches/tools with a major impact, including a description of the technology/approach/tool and considerations on potential impact.
    2. Therapeutic areas or drug classes or MD/IVDs classes, or other relevant areas of particular interest in terms of emerging trends and considerations on potential impact.
- Time horizon of 10 years
- Based on information from different sources e.g.; EHT SG members, the MDCG, HTDs, the Stakeholder Network, EMA, EU-Innovation Network, IHSI.



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Thank you for your attention