HTA CG | MEMBER STATE COORDINATION GROUP ON HEALTH TECHNOLOGY ASSESSMENT

Annual Work Programme 2025

V1.0

28 November 2024

Adopted on 28 November 2024 by the HTA CG pursuant to Article 6 of Regulation (EU) 2021/2282 on Health Technology Assessment

Table of Contents

List of abbreviations

Abbreviation	Definition
HTA	Health Technology Assessment
EMA	European Medicines Agency
HTAR	Regulation on Health Technology Assessment ((EU) 2021/2282)
JCA	Joint Clinical Assessment
JSC	Joint Scientific Consultation
HTACG	Member State Coordination Group on Health Technology Assessment
JCA SG	Subgroup for Joint Clinical Assessments
JSC SG	Subgroup for Joint Scientific Consultations
EHT SG	Subgroup for the Identification of Emerging Health Technologies
MPG SG	Subgroup for the Development of Methodological and Procedural Guidance
HTA SN	Health Technology Assessment Stakeholder Network

1. Strategic direction for the HTACG and its subgroups

As of 12 January 2025, the Regulation on Health Technology Assessment ((EU) 2021/2282) becomes applicable. In 2025, joint clinical assessments will be carried out for medicinal products with new active substances for which the applicant declares in its application for authorisation submitted to the European Medicines Agency that it contains a new active substance for which the therapeutic indication is the treatment of cancer and medicinal products which are regulated as advanced therapy medicinal products pursuant to Regulation (EC) No 1394/2007 of the European Parliament and of the Council[1]. A selection of medical devices will also be subject to joint clinical assessments. From 2025, joint scientific consultations will be offered to health technology developers for their products which may be in scope for future joint clinical assessments.

Following the preparatory phase in 2022-2024 before the start of the application of the HTAR, the HTACG and its subgroups will prioritise the work on joint clinical assessments and joint scientific consultations to meet the requirements of the HTAR in 2025. The joint work also includes the identification of emerging health technologies.

The HTACG will continue working in joint configuration under the leadership of the same Chair and Co-chairs who were elected on 28 November 2022, during the preparatory phase. Meetings of the HTACG may be split into parallel sessions (one for medical devices and one for medicinal products) to allow for more detailed discussions on the two types of health technologies. The HTACG will have two quarterly meetings in the first half of the year and may decide to increase the frequency of meetings to monthly (in virtual format) in the second half of the year depending on the number of JCAs and JSCs initiated and the need for timely HTACG decisions for the ongoing joint work.

The JCA SG and JSC SG will meet monthly, except in August. The MPG SG and EHT SG will meet every two months. The subgroups will have the possibility to initiate the revision of their Terms of Reference, should changes become necessary during the practical implementation of the HTAR.

For the purposes of overall coordination as well as to ensure coherence and consistency between subgroups, the HTACG Chairs and Co-chairs and all subgroup Chairs and Co-Chairs will continue to exchange information as appropriate.

The JCA SG and JSC SG will focus their work on product specific joint clinical assessments and joint scientific consultations, respectively. The MPG SG will support product specific JCAs and JSCs by answering general methodological questions. The MPG SG will collect learnings from the JCAs and JSCs for the potential update of methodological guidance documents, as appropriate. The EHT SG will continue building intelligence and strategies/methods to gather information about emerging health technologies, resulting in their annual report on emerging health technologies which will inform the Annual Work Programme for 2026.

The HTACG welcomes the additional members joining the HTA SN in 2024 following a supplementary call for membership. The HTACG appreciates the active support from members of the HTA SN for the

[1] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

implementation of the HTAR. In 2025, the HTA SN members (in particular patient organisations and health professionals' associations) will be requested to support the joint work by proposing individual experts to be involved (subject to conflicts-of-interest checks) in product specific JCAs and JSCs and, where appropriate, provide input on the disease and therapeutic area in the context of JCAs and JSCs. The HTACG will actively engage with the HTA SN, with two face-to-face meetings (in July and in October). In addition, the webinars for stakeholders to raise awareness and build knowledge about the JCA and JSC processes may also be organised by the Commission as appropriate.

The joint work on medical devices will start with JSCs for medical devices. While no JCAs on medical devices will be carried out in 2025, the HTACG will continue working with Member States on procedures for the JCAs of medical devices. Health technology developers will be able to submit a request for JSCs for medical devices in the second half of the year.

In its meeting on 16 November 2023 the HTACG decided to form an interest group on voluntary cooperation. The HTACG discussed possible dimensions of interest in a voluntary work stream and some general topics have been identified for future discussions. Given the high workload in the HTACG and its subgroups, there is no expectation to start actual voluntary work production during 2025.

The main communication outlet on the implementation of the HTAR is the European Commission's HTA website. Methodological and other types of guidance as well as minutes of the meetings of the HTACG, its subgroups and minutes of the joint meetings with the HTA SN will be published on this website. The website will also act as the publicly accessible webpage of the HTA IT Platform and all public information as defined by Article 30 of the HTAR will be published there.

Member State representatives in the HTACG and, in particular, the Chair and Co-chairs, as well as Chairs and Co-chairs of the subgroups and the European Commission's HTA Secretariat actively participate in conferences and other communication activities to promote and explain the HTAR. The HTACG encourages members of the HTA SN to disseminate relevant information among their stakeholder constituencies via their own communication channels. The conferences, webinars and other events organised by members of the HTA SN provide a good opportunity to reach out to wider audiences and to raise awareness about the HTAR and its implementation.

The secure HTA IT Platform will be accessible to designated representatives of the HTACG, its subgroups and designated representatives in the HTA SN. Exchanges with health technology developers in the context of product specific JCAs and JSCs will take place on the HTA IT Platform, respecting confidentiality and security of information. Health technology developers will be able to notify the HTA Secretariat about planned marketing authorisation applications in line with the "Submission of early information" procedure established in 2024.

2. The planned number and type of joint clinical assessments

The HTACG has estimated that it will initiate 17 joint clinical assessments for medicinal products with new active substances for which the applicant declares in its application for authorisation submitted to the EMA that it contains a new active substance for which the therapeutic indication is the treatment of cancer.

The HTACG has estimated that it will initiate 8 joint clinical assessments for medicinal products which are regulated as advanced therapy medicinal products (ATMP). In case an ATMP has an indication for the treatment of cancer, it will be counted among the 17 JCAs planned for cancer medicines.

These estimates are based on information provided by the EHT SG on the predicted number of marketing authorisation application submissions to the EMA in 2025 and information provided by health technology developers on their intent to submit a marketing authorisation application.

The final number of JCAs will be based on the number of formal marketing authorisation submissions to EMA.

3. The planned number of updates of joint clinical assessments

As the work on joint clinical assessments is starting in 2025, it is unlikely that updates of joint clinical assessments will become necessary in 2025.

4. The planned number of joint scientific consultations

The HTACG is planning to initiate 5 to 7 joint scientific consultations for medicinal products and 1 to 3 joint scientific consultations for medical devices. This initial offering will be gradually increased over the next years.

The HTACG will invite health technology developers to submit requests for JSCs during the following periods:

- 3 February to 3 March 2025 for medicinal products only.
- 2 to 30 June 2025 for medicinal products and medical devices.

The request periods and instructions to submit the request for JSCs via the HTA IT Platform will be published by the HTA Secretariat in due course.

5. Work Programme 2026

The HTACG will approve the annual work programme for 2026 by 30 November 2025.

The EHT subgroup will seek input from members of the HTA SN on emerging health technologies which will feed into the annual work programme of the HTACG. The HTA SN will also be invited to give early input for the annual work programme at its meeting with the HTACG in July.