



HTA Stakeholder Network

PCWP/HCPWP meeting - 14 November 2023

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SANTE C2: Health Technology Assessment

Regulation (EU) 2021/2282 on HTA

- ❖ Adoption 15 December 2021
- ❖ Entry into force 11 January 2022
- ❖ Entry into application 12 January 2025
- ❖ Main objectives: establishing a support framework and procedures for cooperation of Member States on health technologies at Union level; a mechanism for the submission of evidence for joint clinical assessments only once at Union level; common rules and methodologies for joint clinical assessments.

Joint HTA activities

Joint Clinical Assessments (JCA) on:

- **medicines** first 3 years: cancer medicines and advanced therapy medicinal products
following 2 years (3+2): + orphan medicinal products
after 5 years: full scope
- a selection of high-risk medical devices and in-vitro medical devices

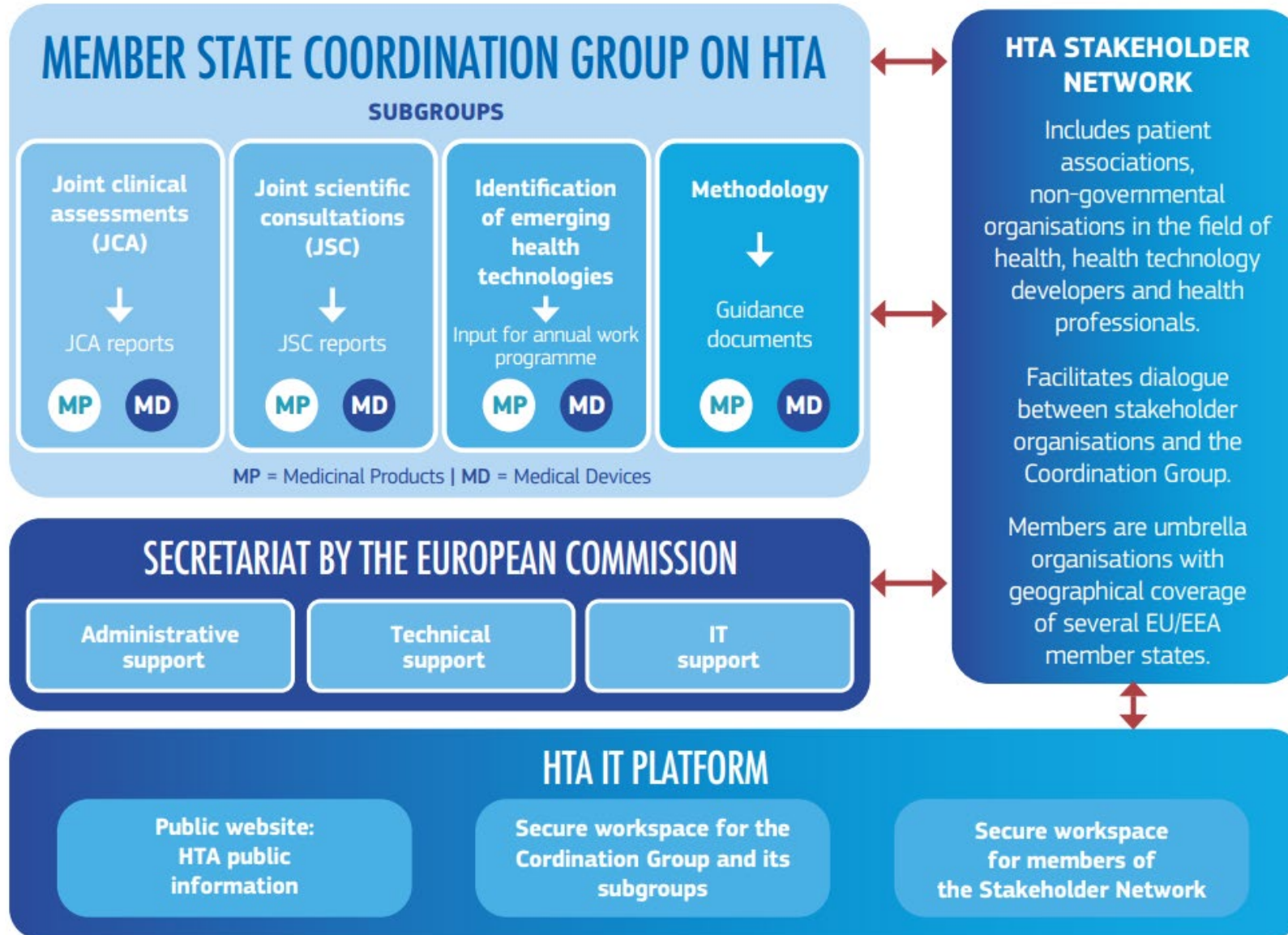
Joint Scientific Consultations (JSC)

- HTA Coordination Group only
- in parallel with EMA

Emerging Health Technologies

Methodology for joint HTA work

Governance



Involvement of stakeholders

In order to ensure the inclusiveness and transparency of the joint work, the Coordination Group should **engage and consult widely with stakeholder organisations** with an interest in Union cooperation on HTA, including patient organisations, healthcare professional organisations, clinical and learned societies, health technology developer associations, consumer organisations and other relevant non-governmental organisations in the field of health. A **stakeholder network should be set up to facilitate dialogue** between stakeholder organisations and the Coordination Group.

(Recital 44)

The HTA Stakeholder Network

Article 29

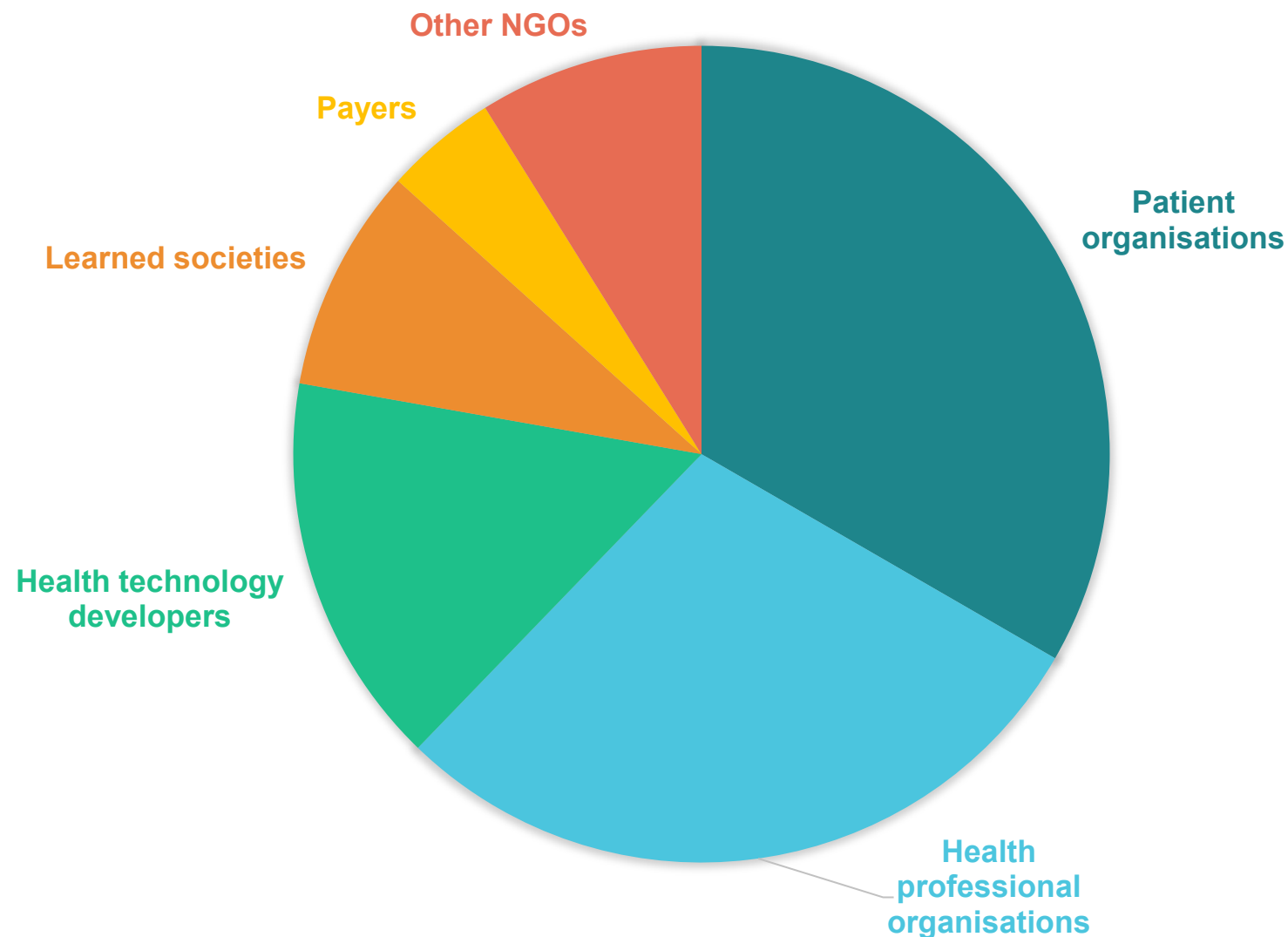
Stakeholder network

1. The Commission shall establish a stakeholder network. The stakeholder network shall support the work of the Coordination Group and its subgroups upon request.
2. The stakeholder network shall be established through an open call for applications addressed to all eligible stakeholder organisations, in particular patient associations, consumer organisations, non-governmental organisations in the field of health, health technology developers and health professionals. The eligibility criteria shall be set out in the open call for applications and shall include:
 - (a) proof of current or planned engagement in HTA development;
 - (b) professional expertise relevant to the stakeholder network;
 - (c) geographical coverage of several Member States;
 - (d) communication and dissemination capabilities.

The call for applications

- The call was open from 12 December 2022 to 17 February 2023
- 75 applications received
- 45 organisations selected as members
- 2 organisations offered observer status
- List of selected organisations was published on 5 May

Type of stakeholders in the network



Terms of Reference

The HTA Stakeholder Network shall:

- Support the work of the Coordination Group and its subgroups upon request;
- Provide advice and expertise as required on issues of general relevance for the joint work and for the implementation of the Regulation;
- Facilitate dialogue between stakeholder organisations and the Coordination Group;
- Provide input as appropriate, on relevant outputs of the Coordination Group;
- Contribute to identifying experts for the joint work upon request;
- Be consulted and comment on the annual work programme and annual report of the Coordination Group;
- Share expertise on state of the art of HTA;
- Meet with the Coordination Group at least once a year.

1st meeting on 14 June

- 59 representatives from 43 stakeholders and two observer organisations.
- CG was represented by 16 Member States, including the Chair and Co-Chairs of the Coordination Group.
- Chairs and Co-Chairs of the four sub-groups.
- European Medicines Agency.



Key points raised by stakeholders...

- Expertise in the network on oncology and advanced therapy medicinal products (ATMPs).
- Contributing to the identification of emerging health technologies.
- Capacity building in HTA agencies as well as among local stakeholders, incl. patients and health professionals.
- Recommending experts for the joint work.
- Stakeholders' role in the consultation on the upcoming implementing acts.

Follow up actions with stakeholders

- Targeted consultation on the concepts of the Implementing Act on JCA for medicinal products – 3 October
- Co-created workshop on oncology and ATMPs – 25 October
- Publication of DoI and sources of funding – upcoming
- Onboarding of the Stakeholder Network on the HTA IT Platform – upcoming
- **Next Stakeholder Network meeting: 17 November**
- **Next HTA Information days with local stakeholders (3rd Seville on [22.11](#), 4th Utrecht on 30.01, etc.)**

Thank you for your attention

Any question?

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