Implementing the EU regulation on health technology assessment

SME info day @ EMA
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European Commission

Regulation on Health Technology Assessment (HTA)

- Regulation (EU) 2021/2282 – Adoption 15.12.2021; in force 11.01.2022; in application **12.01.2025**
- **Deliverable in the EU Pharmaceutical Strategy 2020**
- 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.
- Vision: improve **patient access** to innovative technologies, strengthen the **quality** of HTA across the EU, avoid duplication and ensure **efficiency** (incl. on clinical evidence generation), secure the **long-term sustainability** of EU HTA cooperation.

HTA Regulation – Key principles

- **Joint work** on common **scientific, clinical aspects** of HTA
- Ensure **high quality, evidence-based** decision-making;
- Ensure **transparency & inclusiveness** (stakeholders' engagement)
- **Driven by Member State HTA bodies**
- 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**

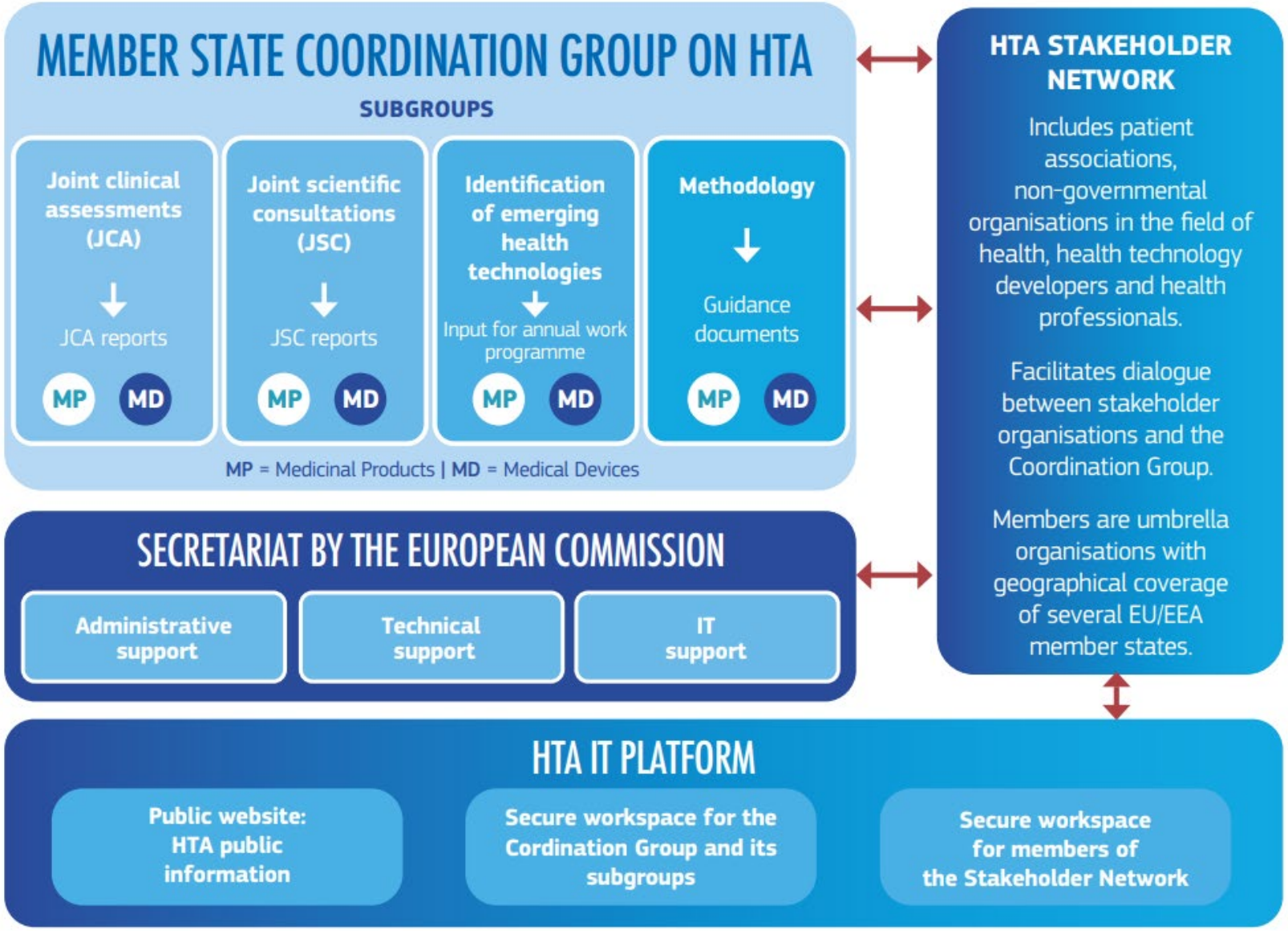
Joint HTA activities

- **Joint Clinical Assessments (JCA)** on:
  - **medicines** first 3 years: New cancer medicines and advanced therapy medicinal products

    from January 2028: + orphan medicinal products

    from 2030: full scope
  - **a selection of high-risk medical devices and in-vitro medical devices**
- **Joint Scientific Consultations (JSC)**
  - in parallel with the European Medicines Agency (scientific advice)
- **Emerging Health Technologies (horizon scanning)**

Governance of EU HTA Framework



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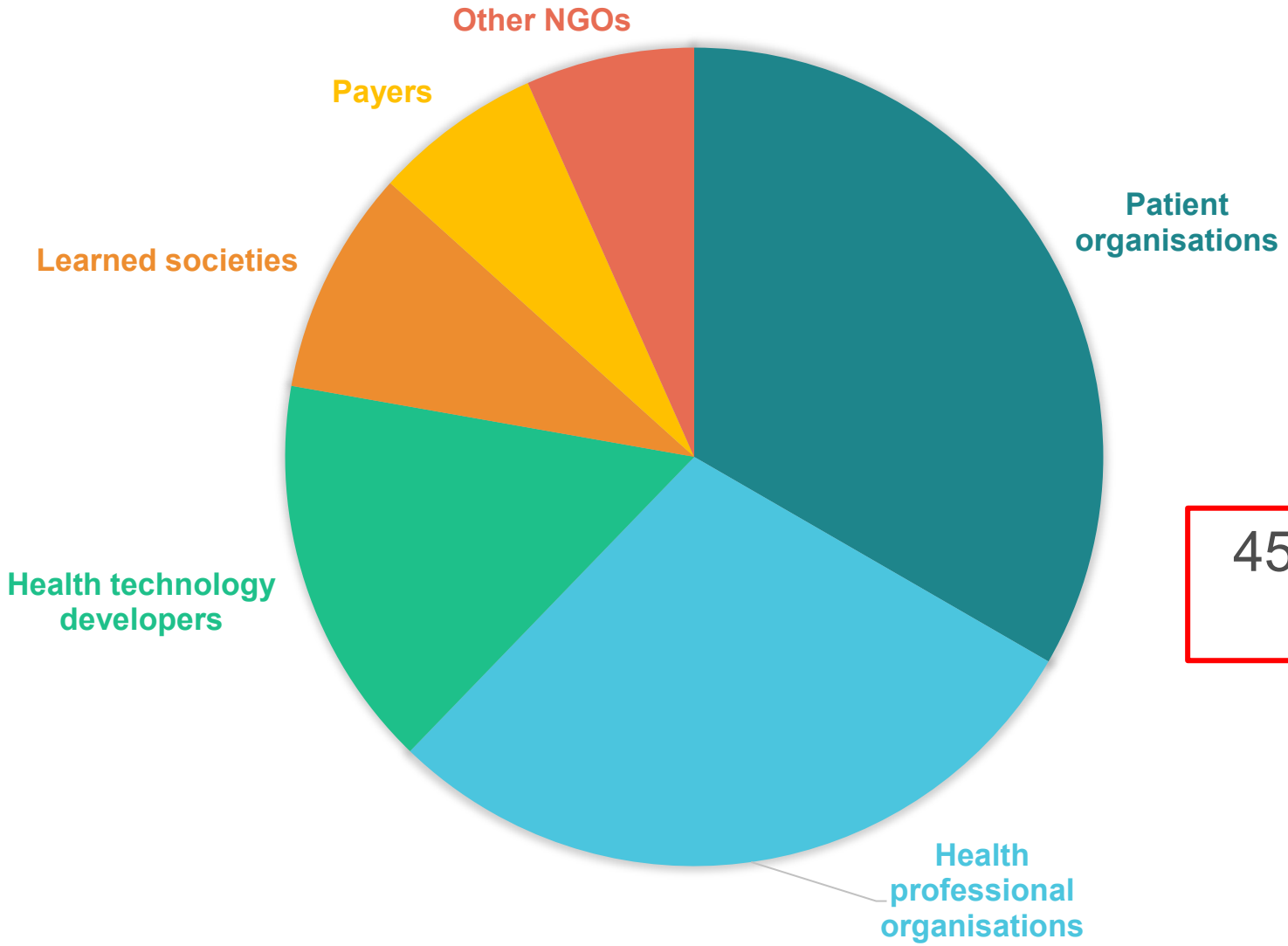
Role of the HTA secretariat by the EC

- Central hub for information exchange among all parties involved
- Preparing, organizing and hosting all the meetings of HTACG and sub-groups
- Completeness check of HTD dossier and procedural check of JCA reports
- Identification of patients, clinical experts and other experts to be involved in the joint clinical assessments and joint scientific consultations
- Managing the conflict-of-interest framework for the HTACG and subgroup members, assessors/co-assessors and individual experts
- Chairing the HTA Stakeholder Network

Stakeholder Network distribution

New call for members closed 9 October

36 applications received



45 organisations
2 observers

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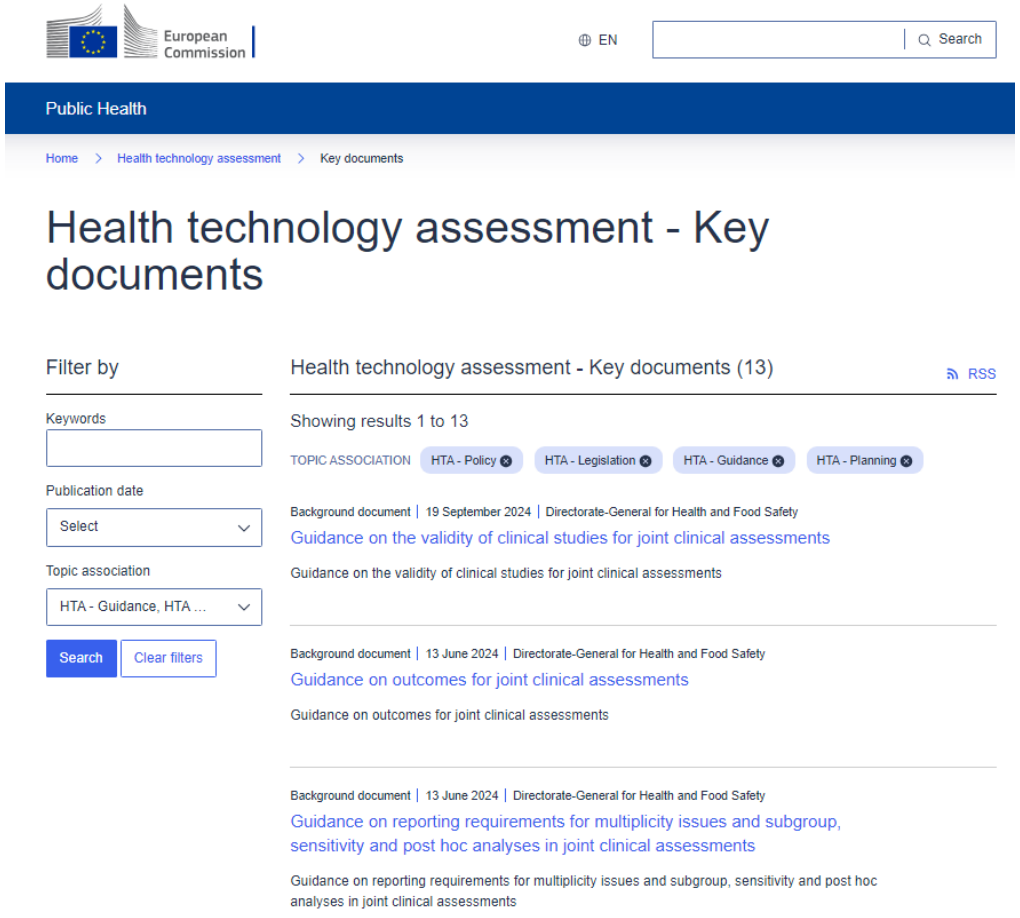
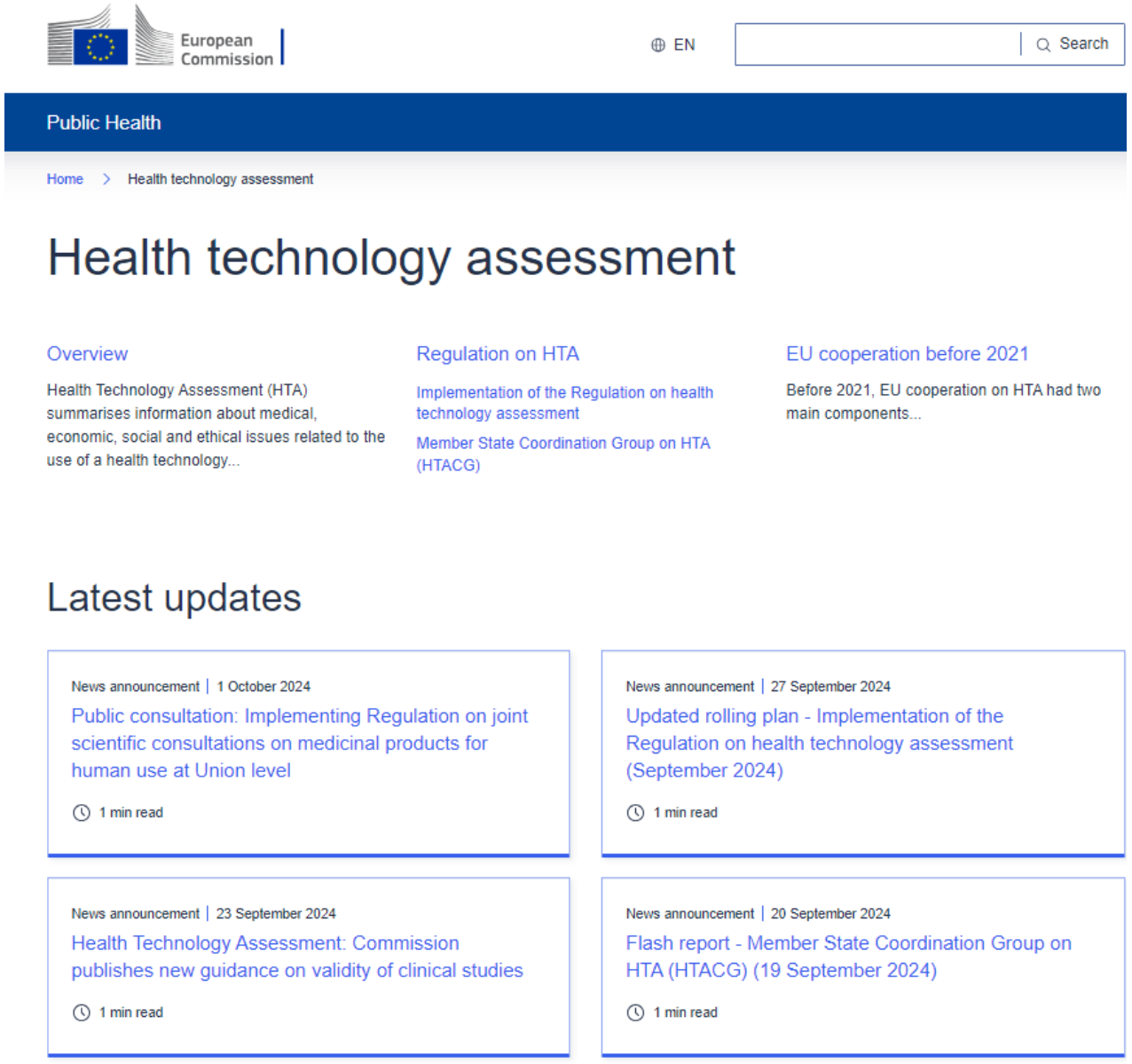
Implementing acts to be adopted by 2025

1st	Procedural rules for JCA of medicinal products	Adopted 23 May
2nd	Procedural rules for the management of conflicts of interest	Positive opinion of the HTA Committee on 27 September
3rd	Procedural rules on the cooperation with the EMA	Adopted on 18 October
4th	Procedural rules for JSC of medicinal products	Published for public feedback DDL: 29 October
5th	*Procedural rules for JSC of medical devices and IVD medical devices*	*In preparation*
6th	*Procedural rules for JCA of medical devices and IVD medical devices*	*In preparation*

Information on the HTA website





https://health.ec.europa.eu/health-technology-assessment_en

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Information events

[HTA information event in Paris]
5 November

[Webinar for health technology developers]
15 November

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Contact for questions

SANTE-HTA@ec.europa.eu

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Conclusions: Co-creation of a new system

Quality, inclusivity and **transparency** as key principles of the joint work on HTA

Commitment of all Member States and all stakeholders is essential to secure smooth implementation

3 months left until the application

Thanks

Any questions?

You can find me at:
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Submission of early information for JCA

- Possibility to send the EMA Letter of Intent to the HTA Secretariat
- Secure upload link via the HTA IT Platform

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
State of Health, European Semester, Health technology assessment

Joint clinical assessment of medicinal products: Submission of early information by health technology developers

After 12 January 2025, medicinal products falling under the scope of Article 7(2), point (a) of Regulation (EU) 2021/2282 (the HTA Regulation) will be subject to a Joint Clinical Assessment (JCA). Initially, the JCA will concern medicinal products with new active substances for which the therapeutic indication is the treatment of cancer as well as advanced therapy medicinal products. As of 13 January 2028, all medicinal products designated as orphan medicinal products and, as of 13 January 2030, all other medicinal products falling under the scope of Article 7 of Regulation 2021/2282 are also subject to JCA.

The EMA published guidance on 21 June 2024 to applicants/health technology developers on how to declare in the EMA Letter of Intent (via the Pre-submission request form) whether their application falls under the scope of the Health Technology Assessment Regulation ((EU) 2021/2282 Article 7) and, therefore, is subject to JCA. The Member State Coordination Group on Health Technology Assessment published a document entitled *"Scientific specifications of medicinal products subject to joint clinical assessments"* to support identification of products subject to JCA from 2025.

Pre-authorisation guidance

2.4.1.2 Declaring a product in scope of Joint Clinical Assessment (JCA) under the HTA Regulation (Regulation (EU) 2021/2282) in the Letter of Intent NEW June 2024

As of 13 January 2025, all medicinal products falling under the scope of Article 7 of Regulation (EU) 2021/2282, for which the applicant declares in its application for marketing authorisation that it contains a new active substance and the therapeutic indication is the treatment of cancer and those that concern ATMPs are subject to JCA. As of 14 January 2028, all medicinal products designated as orphan medicinal products and, as of 14 January 2030, all other medicinal products falling under the scope of Article 7 of Regulation (EU) 2021/2282 are also subject to JCA.

To facilitate and prepare the respective assessments, EMA and the secretariat of the Member State Coordination Group on HTA (HTACG) have agreed to use the same form for respective notifications. Therefore, on the basis of the type of submission for a marketing authorisation application and the planned submission time, applicants should declare in the Pre-submission request form whether their application falls under the scope of Article 7 of Regulation (EU) 2021/2282 and therefore is subject to JCA. This declaration shall be made alongside the request under section 1.1.1 (when selecting the indent "Intent to submit MA").