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.

In case the applicant/health technology developer declares to the EMA that their application falls under the scope of the HTA Regulation, the applicant/health technology developer is also requested to notify the secretariat of the Member State Coordination Group on Health Technology Assessment (HTACG) at the European Commission by sending an e-mail to the following e-mail address: SANTE-HTA-JCA@ec.europa.eu. The e-mail shall contain:

- A request by the applicant/health technology developer to access the HTA IT Platform to upload the EMA Letter of Intent (i.e. Pre-submission request form).
- Name, EU Login account user name and e-mail address (linked to the EU Login) of a contact person from the health technology developer for the purposes of the JCA under the HTA Regulation for the particular medicinal product. To create an EU Login account, please refer to this page: Help for external users (europa.eu)

No sensitive information shall be included in this e-mail about the product or applicant.

Following the receipt of the e-mail, the secretariat of the HTACG will instruct the health technology developer on how to upload on the HTA IT Platform a copy of the Letter of Intent which the health technology developer submitted to the EMA.

The secretariat of the HTACG will acknowledge the successful upload of the Letter of Intent by e-mail to the health technology developer.

Applicants/health technology developers are reminded to submit, in parallel to the notification procedures published by EMA, any updates on changes to the intended marketing authorisation application submission date and/or to inform of their intention to no longer pursue their application to the secretariat of the HTACG via the HTA IT Platform if the application was identified to fall under Article 7 of Regulation 2021/2282. The applicants/health technology developers are also reminded to contact the secretariat of the HTACG if their planned marketing authorisation submission for a product that was not originally envisaged to be

subject to JCA becomes subject to it due to a delay in the submission of the marketing authorisation application to EMA.