

On 23 May 2024, the European Commission adopted the implementing regulation ((EU) 2024/1381) laying down procedural rules for the interaction during, exchange of information on, and participation in, the preparation and update of joint clinical assessments (JCA) of medicinal products, as well as templates for those joint clinical assessments.

The Heads of Health Technology Assessment Agencies Group (HAG) welcomes the adoption of this first implementing regulation pursuant to regulation EU 2021/2282 by the Commission. This text was prepared in close coordination with the Health Technology Assessment committee composed of representatives of member states and following an extensive public consultation with over 125 contributions received.

This implementing regulation establishes the basis to start JCAs for medicinal products in January 2025 that must be achieved with the highest level of quality, transparency, and independence. It not only describes the mechanism of JCA for medicinal products, but also details plans for interactions with patients and clinical experts, stakeholders, and health technology developers. The HAG wishes to underscore that while this document lays out the main principles for conducting a JCA for medicinal products, it remains a legal document describing a new process which may have to be updated in the future depending on the experience gained by the HTA Coordination Group. Furthermore, this implementing regulation needs to be supplemented by the HTA Coordination Group's procedures, methodological guidance, and other supporting documents, which will contain more details and technical recommendations for assessors, health technology developers and users of JCA reports.

This publication is the first major piece of regulation since the passing of the regulation EU 2021/2282, and it marks a pivotal point in the implementation of the regulation. The HAG reiterates its support for the HTA Regulation and will continue to engage actively in its implementation to achieve a European HTA system built on the principles of solidarity, inclusiveness, and impartiality.