



Application of the EU Regulation on Health Technology Assessment to the assessment of hospital-only medicinal products at Fimea

Fimea's assessment of hospital-only medicinal products is described in the assessment process description¹, which is available on Fimea's website. This memorandum describes the changes caused by the application of the European Union's (EU) Regulation on Health Technology Assessment (HTA Regulation, 2021/2282/EU) to the assessment of hospital-only medicinal products.

Under the EU HTA Regulation, joint clinical assessments (JCAs) will be carried out on medicines approved through the centralised procedure of the European Medicines Agency (EMA) as of January 2025. For the purposes of the JCA, the Member States' information needs will be determined by means of a PICO survey, which will be organised shortly after the marketing authorisation process has begun at the EMA.² In order to respond to the PICO survey, the Member States will receive a PICO proposal prepared by JCA assessors on the basis of European treatment guidelines.

Definition of PICO for joint clinical assessment

For medicines, either Fimea or the Pharmaceuticals Pricing Board (HILA) respond to the PICO surveys in Finland. Who responds to a PICO survey is determined by which party is more likely to assess the medicine in question.

Fimea responds to PICO surveys based on a PICO proposal. In normal marketing authorisation procedures, the PICO proposal is submitted to the Member States 22 days after the marketing authorisation application is submitted to EMA, with 21 days allowed for a response. In the accelerated procedure, the proposal is submitted after 8 days and response time is 14 days.³

If a company so wishes, it may, on its own initiative, provide Fimea with its own views on how PICO should be defined for the medicine in question in Finland. This information must be made available to Fimea while the process of responding to the PICO survey is ongoing in Fimea, at the latest. Due to the time limits specified above, the company must submit its views within three weeks, or within one week in an accelerated procedure, from submitting the marketing authorisation application. The most helpful resource is a PICO

¹ Process description of the assessment of hospital-only medicines. Available on the Fimea website.

² Guidance on the scoping process. Available on the European Commission website.

³ Procedural guidance for JCA medicinal products. Available on the European Commission website.



proposal that justifies the selection of comparators used in Finland with references, for example.

Fimea does not make a specific request for information to the companies for responding to the PICO survey. We request that you submit any comments related to the definition of PICO to Fimea's HTA service email within the time limits specified above (hta@fimea.fi).

In addition to the PICO proposal, Fimea will use any information provided by the company and other sources of information, such as data on the reimbursement and consumption of medicines, when formulating the response to the PICO survey. We will also consult Fimea's internal clinical experts. Fimea will respond to the PICO survey via the IT platform referred to in the HTA Regulation. The responses of the Member States will be consolidated into assessment PICOs, which are then submitted to the company for the preparation of the JCA dossier.

Assessment of hospital-only medicinal products at Fimea when a joint clinical assessment is available

Fimea's assessment of hospital-only medicinal products follows the procedures presented in the process description for the assessment of hospital-only medicinal products, also when a JCA is available. It is possible to submit material even before the JCA is published, and Fimea can take preparatory measures based on the materials. However, the assessment proper will only begin once the JCA is available.

We will carry out the assessment of hospital-only medicinal products based on the information presented in the JCA as far as possible. At the initial meeting mentioned in the process description, we will discuss the PICO of the assessment with the company. We will pay special attention to the information available in the JCA. However, we will examine the suitability of the information available in the JCA for the assessment of hospital-only medicinal products when the assessment is launched in light of the current information and situation.

According to Article 10 of the HTA Regulation, the company shall not submit any information on national level that has already been submitted at Union level. Fimea will not ask the company to provide information that the company has already submitted for the JCA and that is available to Fimea on the Commission's IT platform.

The first JCA reports will be available at the end of 2025, at the earliest. The implementation of the joint assessment as a part of the national assessment will be further specified at a later date, if necessary.