ASSESSMENT OF NEW HOSPITAL-ONLY MEDICINAL PRODUCTS

1 Objectives of the assessment process

The goal of the process is to produce information about the therapeutic and economic effects of new hospital-only medicinal products. The results of the assessment are used by the Council for Choices in Health Care in Finland (COHERE Finland) in the preparation of recommendations regarding medicinal products as well as to support hospitals' implementation and procurement decisions. The assessment is partially based on different criteria than those used in the granting of a marketing authorization. In addition to the clinical effects, the assessment also takes into account the economic perspective, and if possible, the assessed medicinal product is compared against the treatment options already in use.

2 Medicinal products assessed

In Fimea's assessment process, mainly new, hospital-only medicinal products are assessed. In this context, a new medicinal product refers to a medicinal product that has recently received marketing authorisation or a medicinal product that has been granted a significant extension of the therapeutic indication. While no unequivocal definition exists for hospitalonly medicinal products, they can be characterised as follows:

- the medicinal product is primarily intended for use in public healthcare hospitals
- the principal purchaser of the medicinal product in Finland is a hospital
- the administration of the medicinal product usually requires a hospital-like setting

3 Assessment

3.1 Parties participating in the assessment

Company (marketing authorisation holder or applicant)

- may submit material for the assessment that can be used in the compilation of the assessment report
- checks that the public assessment report does not contain any confidential information provided by the Company

Chief assessment physicians of the collaborative areas for healthcare and social welfare and other parties evaluating the introduction of medicinal products (FinCCHTA)

- assist, if necessary, in questions related to topic selection
- act as contact persons of the collaborative areas
- bring the perspectives of the collaborative areas to assessment procedures, e.g., the selection of assessment topics

Fimea

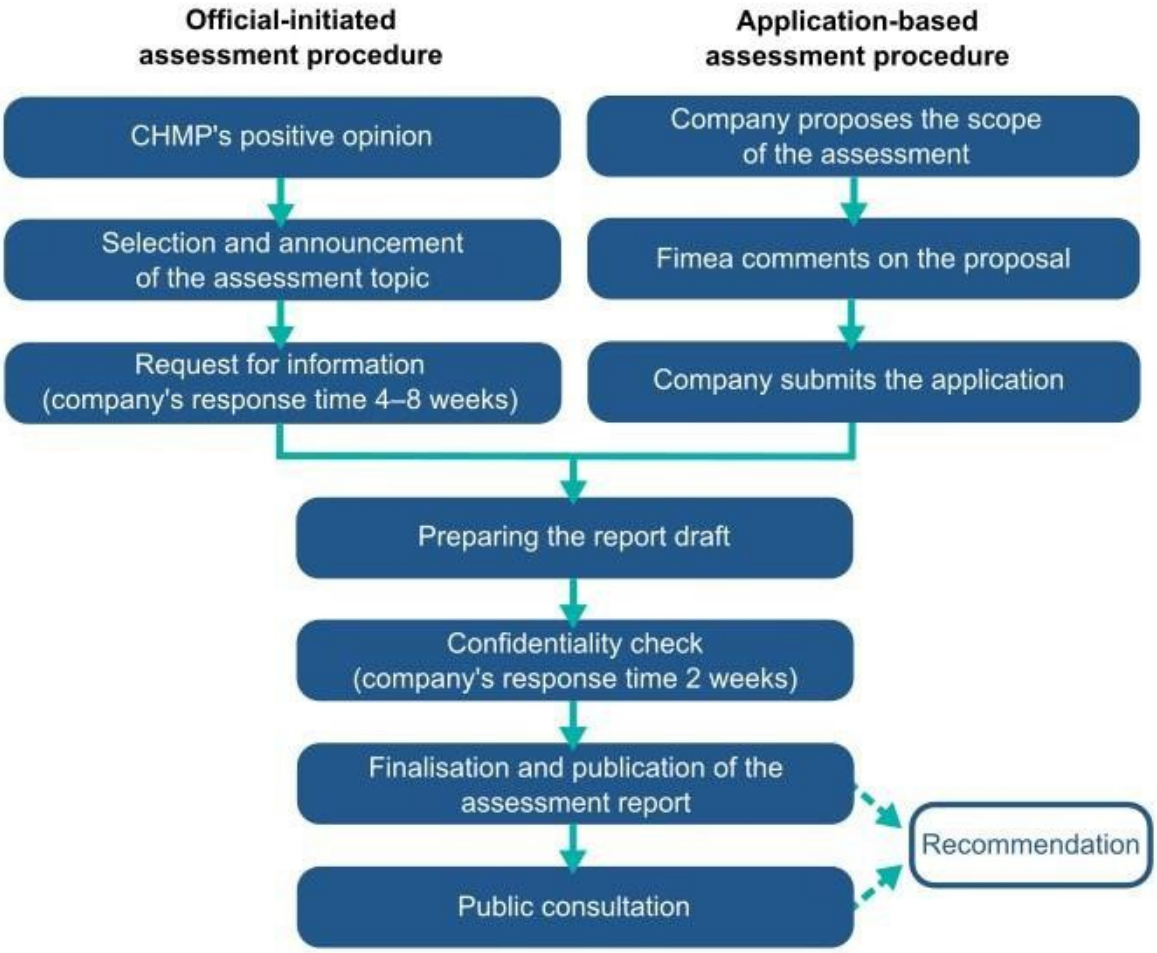
- decides on the initiation of assessments, according to the resources
- coordinates assessment activities
- produces and publishes the assessment reports
- participates, if necessary, in the assessment of the effects of contracts related to price negotiations

Clinical experts

- assist in the specification of the objectives of the assessment (PICO)
- comment on the material produced by the assessment team and respond to the questions of the assessment team, in particular with regard to the current treatment practices and applicability of evidence

3.2 Assessment process

A flowchart of the progress of the assessment process is presented in the figure below (CHMP = Committee for Medicinal Products for Human Use).



3.2.1 Selection and announcement of the assessment topic

In the selection of topics, the focus is on the assessment of new medicinal products entering the market for the first time, and the aim is to evaluate all new medicinal products either through an official-initiated or application-based procedure. In the official-initiated assessment procedure, Fimea first goes through the positive opinions issued monthly by the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP), selects suitable topics and sends requests for information to associated companies. In the

application-based assessment procedure, the company first informs Fimea[1] about the new hospital-only medical product and the anticipated date of the application submission, and proposes the scope of the assessment (PICO definition). When contacting Fimea, the company must have a good understanding of the expected date of the opinion issued by the CHMP and the indication for use. If the company has not contacted Fimea before the CHMP's positive opinion, Fimea will reach out to the company regarding matters related to initiating the assessment.

In the beginning of the assessment, an initial meeting can be arranged with the company in order to discuss the scheduling, content and scope of the assessment as well as the request for information directed to the company or the company's application. The aim is to start the assessment so that the result of the assessment is available as soon as possible after the application submitted by the company, the granting of the marketing authorization or the extension of a therapeutic indication. Fimea schedules the progress of the assessment and informs the parties involved about the start of the assessment. The start of the assessment will also be announced on Fimea's website. For assessments conducted in accordance with the European Union HTA mechanism, a separate guideline is followed, which is available on Fimea's website.[2]

In order to plan and anticipate the assessment activities, Fimea organizes horizon scanning events for pharmaceutical companies at suitable intervals. In these events, new hospital-only medicinal products, which are potentially entering the market in the near future, are mapped.

3.2.2 Requests for information and material used in the assessment

The assessment is primarily based on published studies, the public assessment report produced by the European Medicines Agency, and material available from other sources. In addition, material provided by the company can be used in the assessment. For this reason, at the beginning of the assessment

1) Fimea sends the marketing authorization holder (or applicant) a request for information (official-initiated assessment procedure), or
2) the company submits an application to Fimea as agreed in advance (application based assessment procedure).

The request for information related to the official-initiated assessment procedure is always prepared on a case-by-case basis and may include a request for additional information on, for example, clinical studies, subgroup analyses, duration of treatment, costs of treatment, estimated number of patients in Finland and the budget impact of treatment. In addition, the company is requested to provide Fimea with a cost-effectiveness analysis and model, as well as related material (hereinafter referred to only as cost-effectiveness analysis).

In the official-initiated assessment procedure, the company is given four weeks to submit the answers and materials. If the company is prepared to deliver a cost-effectiveness analysis and model and related material, the response time for delivering this information is eight weeks. However, the company has no obligation to deliver the material. The assessment can also be performed without the material provided by the company.

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[1] Contact: hta@fimea.fi

[2] Taking the EU HTA Regulation into consideration in the assessment of hospital-only medicinal products (pdf)

In the application-based assessment procedure, a separate guideline has been prepared for applications sent to Fimea for the assessment of hospital-only medicinal products (Annex 1).

The material or application submitted by the company may contain information that is considered confidential based on trade secrets or other sensitive information. Before the assessment begins, the company grants Fimea permission to deliver the full assessment report to COHERE for use in the recommendation process, without redacting confidential information from the report. The company provides details of a contact person and the signatory of the waiver form described in Annex 2, as well as a power of attorney if necessary, at the time of the submission at the latest.

3.2.3 Preparing the report draft

Once the responses to the request for information or the application and its materials have been received, the following steps in the assessment process are similar between the official-initiated and application-based assessment procedures. Fimea prepares a draft of the assessment report using all available material.

3.2.4 Confidentiality check

The public availability and confidentiality of materials released to Fimea shall be determined in all respects with reference to the Act on the Openness of Government Activities (621/1999). Under section 24 of the Act, material may contain confidential information on a private business secret or other confidential information under the same section. This might, for example, include the unpublished results of research, a decision analytic model used as an IT application in cost-effectiveness analysis and a health-economic report relating to it, and, for example, a pricing scheme based on something other than the published listed price.

In order to facilitate the assessment process, Fimea requests that the company marks those sections or entire parts of the submission which, in the company’s view, are entirely confidential and for which no assessment can therefore be included in the published assessment report.

If the company submits a cost-effectiveness or budget impact model to Fimea for economic evaluation, the purpose of this submission is for Fimea to include in the assessment report a description of the methods used in the modelling, the results of the modelling, and an assessment of these. Fimea may also publish results and analyses it has produced itself using the model provided by the company, which are not directly apparent in the material submitted by the company.

The company receives a draft of the assessment report from Fimea for review, specifically as regards sections reporting unpublished material submitted by the company. The company then has two weeks to mark in the draft any individual data or figures it considers, under the Act on the Openness of Government Activities, to be confidential due to business or other secrets, or to declare that the draft does not contain any confidential information.
Fimea assesses the confidentiality of the information marked by the company on the basis of the Act on the Openness of Government Activities.

Before the confidential information is marked, Fimea may, at its discretion, share the draft assessment report and relevant information from the material submitted by the company with clinical experts involved in the assessment, whom Fimea has specifically appointed and who have signed a confidentiality agreement, to the extent deemed necessary.

If a request for information concerning the material is made to Fimea, the public availability and confidentiality of the information contained therein are determined according to the provisions of the Act on the Openness of Government Activities. The Act always takes precedence in evaluating the public status of material to be disclosed. The company's wishes regarding confidentiality are used as a basis for assessing the public status of the documents.

3.2.5 Finalisation and publication of the assessment report

As a final step, Fimea finalises the assessment report, publishes it on its website and notifies the associated parties of the assessment. A version of the assessment report is published in which any information considered confidential under the Act on the Openness of Government Activities is redacted. A template for the structure of an assessment report and the matters to be addressed in it is provided in Annex 3.

3.2.6 Public consultation

The assessment report is publicly available and open to comments. Comments may be submitted to Fimea's registry office. The comments and the details of the party submitting them are public and can be published.

4 Preparing a recommendation

Fimea presents the assessment results to the Council for Choices in Health Care in Finland (COHERE Finland). The assessment report and the results of the evaluation are presented to COHERE in their entirety, without redacting or removing any confidential information. Before the evaluation begins, the company provides Fimea with permission to disclose this information using a separate consent form (Annex 2). COHERE Finland is fully responsible for preparing the recommendations and the recommendation process.

5 National price negotiations

Fimea may have an expert role in assessing the impacts of a proposed managed entry agreement during national price negotiations. However, Fimea does not act as a party to procurement nor does it conclude any agreements related to procurement. The processes related to national price negotiations are not yet fully established and efforts are being made to develop them as experience is gained.

ANNEX 1. Guidelines on the application of the Pharmaceuticals Pricing Board's application instructions

General

This guideline is applied when the marketing authorisation holder applies for an HTA assessment of a new hospital-only medicine from Fimea through the application procedure. The contents of the application material follow the Pharmaceuticals Pricing Board's application instructions for the reimbursement status of a new medicinal product[3] and the instructions for preparing a health economic evaluation[4], the application of which in Fimea's hospital-only medicine assessments is described in these guidelines. Guidelines concerning the use of the Pharmaceuticals Pricing Board's e-services do not apply to material submitted to Fimea. The companies are asked to contact Fimea at hta@fimea.fi. The actual application material is submitted to the designated contact persons through Fimea's Secure Mail service[5].

Application of the application instructions for the reimbursement status of a new medicinal product

At least the following attachments listed in the application instructions are sent to Fimea:

- a valid marketing authorisation decision or the CHMP's positive opinion concerning the granting of a marketing authorisation
- a valid SPC (a summary of product characteristics) or a draft SPC
- a clinical assessment report of the marketing authorisation official or its draft
- a report on the therapeutic value, including a list of references
- a report on costs and economic efficiency
- a health economic evaluation, including a list of references
- references

In the report on the therapeutic value, the guidelines for the application of a special reimbursement status are followed. The market forecast and the information on sales and patient numbers can be reported in a manner that deviates from the Pharmaceuticals Pricing Board's application instructions, but in a manner that the information presented contains sufficient grounds for the assessment of the budget impact. To assess costs and economic efficiency, the company has the opportunity to present a proposal for a confidential price or pricing model. However, the reports must also always present the information on the basis of the public wholesale price of the product.

In addition, the company is requested to provide references (links) to ongoing HTA assessments in other EEA countries and Canada as well as information on the results of completed recommendations or the stage of their processing.

Application of the instructions for preparing a health economic evaluation

Comparators according to the PICO procedure should be used as treatment options.

All information in the health economic evaluation must be primarily based on the information presented in the therapeutic value report. The results can also be presented using a confidential contract price or pricing model.

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[3] https://www.hila.fi/content/uploads/2021/05/Uusi_valmiste_ohje_250521.pdf (in Finnish)
[4] https://www.hila.fi/content/uploads/2020/01/Instructions_TTS_2019.pdf
[5] https://www.fimea.fi/web/en/about_us/contact_information/secure-mail

ANNEX 2. Consent for Disclosure of Confidential Information from Fimea to COHERE

(The Company) hereby grants Fimea permission to disclose to the Council for Choices in Health Care (COHERE), for the preparation of a recommendation regarding the case *(subject and case number),* an assessment report or statement, including any parts that contain confidential information as defined by the Act on the Openness of Government Activities (621/1999) (Openness Act).

The information may be disclosed in writing or verbally. The company's contact person may, by email, extend this consent to cover other information provided by the company.

COHERE and Fimea will comply with the Openness Act when processing information received from the Company and in all other activities.

The company's contact person for this matter is

First name Surname
email
Telephone

Date and signature

First name Surname
Job title
XX Ltd
Business ID xxx
Address
Phone number

ANNEX 3. Content of assessment and the structure of the assessment report An assessment report is divided into the sections described below.

1 Scope of the assessment and assessment question definition

P	Population, patients
I	Intervention
C	Comparison, comparators
O	Outcomes

2 Health problem and medicinal product to be assessed

- Health problem (disease under assessment)
- Treatment options (current treatment)
- The medicinal product being assessed and its indication for use

3 Clinical effectiveness and safety

- Published clinical studies of the medicinal product being assessed
- The effect of the medicinal product being assessed on the final outcomes of the treatment. The most important outcomes are presented as their own subsections. For example: ○ overall survival (OS) ○ progression-free survival (PFS) ○ response to treatment ○ health-related quality of life
- Subgroup analyses
- Indirect comparisons (presented if necessary)
- Safety
- Ongoing clinical studies
- Discussion

4 Cost-effectiveness

- Methods used in the marketing authorization holder’s/applicant’s analysis
- Results presented by the marketing authorization holder/applicant
- Fimea's assessment of the marketing authorization holder's/applicant’s model and the assumptions made in the modelling
- Fimea's own scenarios for the cost effectiveness analysis of the marketing authorization holder/applicant (presented if necessary)
- Discussion

5 Costs and budget impact

- Methods used in cost estimation
- Costs per patient
- Number of patients
- Budget impact
- Discussion

6 Conclusions