# 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 hospital-only 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

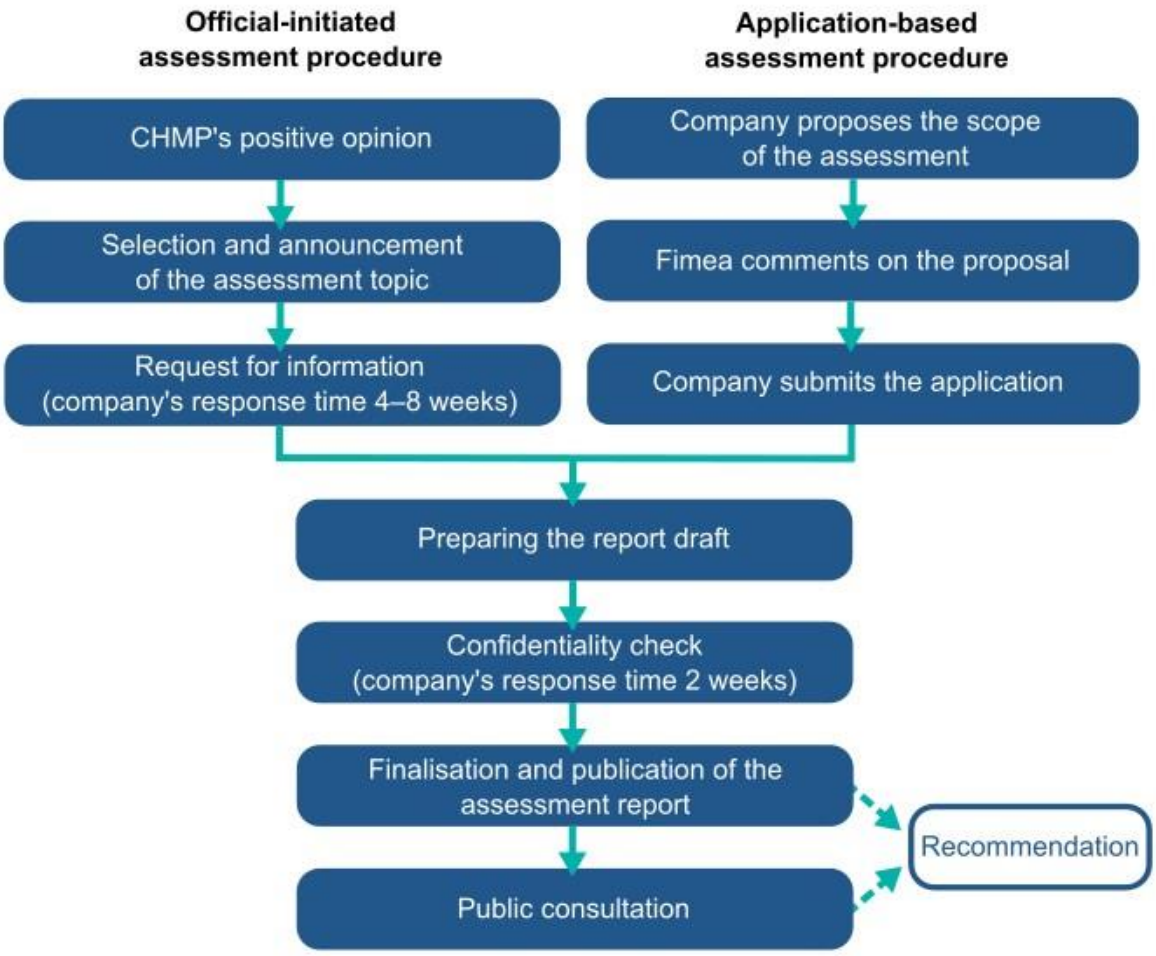
- Company (marketing authorisation holder or applicant)
    - may submit material for the assessment that can be used in the compilation of the assessment report
    - checks that the assessment report does not contain any confidential information provided by the Company
- Specific catchment areas' chief assessment physicians and other parties evaluating the introduction of medicinal products (FinCCHTA)
    - assist, if necessary, in questions related to topic selection
    - act as contact persons of specific catchment areas
    - bring the perspectives of specific catchment 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.

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.

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). If the company does not deliver a cost-effectiveness analysis, the cost-effectiveness will not be evaluated.

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.

[1] Contact: hta@fimea.fi

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. The delivery of the material and related practices are agreed upon with the company in a separate signed agreement (Annex 2).

### 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

Fimea provides the Company with a draft of the assessment report, if unpublished material submitted by the Company was utilised in its preparation. The Company is given two weeks to mark on the draft any previously unpublished information the Company considers confidential or to declare that the draft does not contain any confidential information. In the published version of the assessment report, all information the Company has marked as confidential will be concealed. The procedure is described in more detail in Annex 2.

### 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 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). COHERE Finland is fully responsible for preparing the recommendations and the recommendation process.

## 5 National price negotiations

If COHERE gives a conditional recommendation, which requires a price reduction, the assessed medicinal product can proceed to national price negotiation. In this case, Fimea may have a role in evaluating the effects of the proposed agreement. However, Fimea does not participate in the actual price negotiations. The processes related to national price negotiation are not yet established in all respects, and efforts are being made to develop them with the experience 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[2] and the instructions for preparing a health economic evaluation[3], 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[4].

### 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.

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

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.

**ANNEX 2. Agreement on the submission and use of information for the assessment of pharmacotherapies**

**1. Parties**

xxxxxx, (hereinafter Company)
(business ID xxx)
Address

Finnish Medicines Agency (hereinafter Fimea)
(business ID 0921536-6)
P.O. Box 55, FI-00034 FIMEA

The Finnish Medicines Agency and the Company will, hereinafter, collectively be referred to as the Parties.

**2. Contact persons**

Fimea contact person(s):
First name Last name
Position
Phone
E-mail

Contact person(s) in company:
First name Last name
Position
Phone
E-mail

In matters pertaining to this Agreement, Fimea will deal only with the Company and its contact persons.

It is the duty of the contact persons to keep track of and monitor compliance with the Agreement, to furnish information on the Agreement within their own organisations and to the other Party, as well as submitting and receiving notifications and requests for information under the Agreement. The contact person of the other Party shall be informed of any changes of contact persons or any change to a contact person's contact information without delay. The contact person shall not have the right to amend the content of this Agreement.

**3. Definitions**

In this Agreement

*assessment* refers to the assessment of the therapeutic and economic value of a medicine subject to assessment by Fimea;

*an assessment report* refers to the Fimea publication relating to the assessment;

*information* refers to any material provided by the Company to Fimea that can be used for the assessment or the preparation of the assessment report;

*a clinical expert* refers to a separately assigned expert involved in the assessment, who is obliged to keep secret and not to take advantage of what they have learned about the Company's trade or professional secrets or other confidential matters. The professional confidentiality is also binding after the end of the assignment.

## 4. Background and purpose of Agreement

Under Section 2(1)(8) of the Act on the Finnish Medicines Agency (593/2009), the duties of Fimea include producing and compiling assessments on the therapeutic and economic value of medicines, as well as coordinating the cooperation involved. In executing its duty, Fimea performs therapeutic and economic assessments of medicines in cooperation with operators in this field. Assessments made by Fimea will be published.

This Agreement includes provisions regarding the submission of information for assessment, and regarding practical procedures and confidentiality in a situation where a company has decided to submit information to Fimea.

The assessment may involve other companies. Fimea may conclude separate agreements with such companies regarding the submission and use of information for the assessment of pharmacotherapies.

## 5. Medicine subject to assessment

The present assessment concerns the therapeutic and economic effects of medicine x in the treatment of disease z. The Company is the marketing authorisation holder for medicine x.

## 6. Information to be submitted to Fimea

Fimea shall gain the right to use the information. The information may include an IT application and written reports to be used in the economic evaluation. The right to use such information includes the right to use, copy, edit and publish it.

The information shall only be used, to the extent deemed necessary by Fimea, in an assessment covered by the present Agreement. Fimea may decide to make no use of the information in the assessment.

The Company shall be responsible for ensuring that the information submitted to Fimea does not infringe the existing patent, copyright or other immaterial rights of any third party.

The Company shall, at its own cost, indemnify Fimea against any claims that may be made against Fimea regarding immaterial rights. The Company shall further indemnify Fimea against any legal costs, compensation or any other costs or liabilities towards third parties arising from claims or liabilities pertaining to immaterial rights.

## 7. Publicity and confidentiality

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, guidelines on how to use the model and a health-economic report relating to it, and, for example, a pricing scheme based on something other than the published listed price. Fimea shall comply with the Act on the Openness of Government Activities in matters of the confidentiality of documentation.

If the material contains items or longer sections that are entirely confidential in the opinion of the company, so that no assessment of them can be included in any assessment report for publication, the company shall mark such sections clearly when the material is made available. Nevertheless, the company may permit Fimea to pass on confidential data or assessments based on it to separately designated Parties. Fimea is not responsible for the use or confidentiality of data passed on with the company’s permission.

If the company makes available to Fimea a cost-effectiveness or budget impact model for economic evaluation to be conducted, the purpose of doing so shall be that Fimea shall incorporate in its assessment report a description of the methods used in the model, its results and an assessment of them. In such cases, Fimea shall also be entitled to publish the results and analyses produced using the model made available by the Company, such results and analyses not being directly apparent in the material for economic evaluation provided.

Fimea shall provide the Company with a draft of the assessment report as regards the unpublished material made available by the Company described in it. The Company shall be allowed two weeks to mark on the draft any information or figures the Company considers should be kept confidential as it constitutes a business or some other secret under the Act on the Openness of Government Activities, or declare that the draft does not contain any confidential information. The confidential information so marked in the draft report may, for example, be estimates of market shares, the results of calculations based on prices other than those publicly listed, or the individual unpublished results of research. In the published version of the assessment report, all the information the Company has marked as confidential and which is confidential under the Act will be concealed. If the company does not provide the details of the confidential sections of the report within two weeks, this shall be regarded as a declaration that the report does not contain any confidential parts. If Fimea decides not to use any unpublished material submitted by the Company in the report, it will not provide the Company with a draft for the identification of confidential information.

Notwithstanding the non-disclosure provisions described here, Fimea may, prior to the marking of confidential information, provide separately designated clinical experts participating in the assessment with access to a draft of the

assessment report and information contained in the material submitted by the Company to the extent it deems necessary.

The Parties undertake to keep confidential any information and documents received from the other Party that may be considered confidential and are to be kept confidential pursuant to the legislation on the openness of government activities, and further undertake not to use said information and documents for any purpose other than that specified in the Agreement. If there is a request for information relating to the material, the public availability and confidentiality of the material shall be decided with reference to the Act on the Openness of Government Activities. This Act must always apply in the first instance in any evaluation of the public availability of material released. This agreement confirms the desire for confidentiality on the part of the Parties. However, it cannot serve to define in any binding way the confidentiality of information more widely than what is referred to in the Act on the Openness of Government Activities. The company's desire for confidentiality shall be used as a reference point for the assessment of the public availability of documents. Fimea shall, in all respects, comply with the provisions of the Act on the Openness of Government Activities, as a result of which Fimea's assessment of the confidentiality of information with reference to the Act shall not result in any breach of this agreement, even if the assessment does not entirely reflect the company's desire for confidentiality.

Furthermore, the Parties confirm separately that the agreement and its annexes shall be made public.

**8. Costs**

The Parties shall each be liable for any costs incurred by them in relation to the Agreement.

**9. Validity and termination of the Agreement**

This Agreement shall terminate upon the completion of the assessment and the publication of the assessment report.

The termination of the Agreement upon the publication of the assessment report shall have no effect on the provisions of the Agreement concerning the information to be submitted to Fimea, publicity and confidentiality, costs, indemnity from compensation, the transfer of the Agreement, language, applicable legislation and resolution of disputes.

**10. Transfer and amendment of Agreement**

The Parties are entitled to transfer the Agreement to a third party on which the duties carried herein are vested either fully or partly. Each Party shall notify the other Party of any transfer of the Agreement.

All amendments shall be made in writing. Any electronic amendments to the Agreement shall be deemed written amendments.

**11. Language**

This Agreement has been drawn up and signed in Finnish. An unsigned, unofficial English translation of the Agreement may be prepared if required. In the event of any conflict between the Finnish and English text, the Finnish version shall take precedence.

## 12. Applicable legislation and resolution of disputes

This Agreement shall be governed by the laws of Finland. Any disputes arising from the Agreement shall principally be resolved through negotiation. If such a dispute cannot be settled, it shall be resolved at Helsinki District Court as the court of first instance.

## 13. Entry into force and signatures

This Agreement shall enter into force when signed by competent representatives of both Parties.

The Agreement has been executed in two (2) identical copies, one for each Party.

**FINNISH MEDICINES AGENCY FIMEA**

_____

Place and date

| | |
|---|---|
| _____ | _____ |
| NN | NN |
| position | position |

**COMPANY**

_____

Place and date

| | |
|---|---|
| _____ | _____ |
| NN | NN |
| position | position |

## 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