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Authorised medicinal product – new medicinal product

These instructions apply when the marketing authorisation holder seeks basic reimbursement status or special reimbursement status and a wholesale price for a new original product (new active pharmaceutical ingredient or other new medicinal product).

If you are applying for different reimbursement statuses for different packages of the same medicinal product and/or their therapeutic indications differ from each other, the indications and the reimbursement status you are applying for must be separately detailed for each package.

Products that have undergone a joint clinical assessment (JCA) referred to in the HTA regulation (EU) 2021/2282 have partially different application requirements. These differences are detailed as part of these instructions.

See also the general instructions for the application at applying for reimbursement status and reasonable wholesale price (The information is in Finnish).

Application documents

- Attach the following documents to your application:
    - valid summary of product characteristics
    - valid marketing authorisation decision (if the marketing authorisation was granted in a centralised authorisation procedure, also attach the information published by the European Medicines Agency on the different product packages and their marketing authorisation numbers)
    - clinical assessment by a marketing authorisation authority
    - statement of therapeutic value
    - statement of costs and cost-effectiveness
    - health economic evaluation
    - market forecast
    - sales volumes and number of patients
    - information on prices and reimbursement statuses in EEA states
    - any other specifications
    - list of sources and sources
        - The list of sources must contain all documents referred to in the application. In the case of a product that has undergone a joint clinical assessment (JCA), documents found on the joint assessment IT platform should not be included. However, these must be presented and specified

in the list of sources and clear references to them must be provided.

- Give the following information in the application memorandum:
  - statement of the product's therapeutic value
  - grounds for seeking special reimbursement status
  - information on the costs and cost-effectiveness of medicinal treatment
  - basis for the market forecast and the estimates of sales and patient volumes.

- Name the files as follows:
  - Application memorandum
  - Sales data and number of patients
  - Market forecast
  - Prices in EEA states
  - Summary of product characteristics
  - Clinical assessment
  - Marketing authorisation decision
  - Health economic evaluation
  - List of sources
  - Source_Lastname_Year
  - Source_TT_Lastname_Year
  - Name other attachments appropriately, for example: Expert Opinion_Lastname

Therapeutic value

- Provide information about the therapeutic indications for which reimbursement status is sought.
- If you are applying for restricted reimbursement status (the medicinal product is particularly expensive), present
  - proposed restriction of the reimbursement status (therapeutic indication specified in detail)
  - grounds for the therapeutic value within the indication
  - grounds for the appropriateness of the proposed restriction as regards the implementation of pharmacotherapy.
  - Present a summary of the clinical studies carried out on the product to the extent of the sought reimbursement status and attach the relevant research publications to the application.
    - In the case of a product that has undergone a joint clinical assessment (JCA), only if the corresponding summary is not included in the JCA report

- In the case of a product that has undergone a joint clinical assessment (JCA), present a statement of the suitability of the joint assessment as a basis for a Finnish assessment to the extent of the sought reimbursement status at the time of the application.
    - Determine whether the patient groups and comparative treatments covered in JCA correspond to the sought reimbursement status and are they essential concerning Finnish treatment practices at the time of the application.
    - Also determine which of the assessment frameworks (PICO) specified in the joint assessment best corresponds to the sought reimbursement status.
    - Present the references to the JCA report by specifying the sections of the report to which references have been made and the sources provided in the joint assessment.
- Present a statement on the benefits of reimbursement status compared with other medicinal products or treatments used for treating the same disease.
    - Describe the current treatment of the disease and attach any treatment recommendations to the application.
        - In the case of a product that has undergone a joint clinical assessment (JCA), describe the possible differences between European treatment practices and recommendations described in the JCA report and Finnish practices.
    - Describe how patients benefit from the medicinal product and for which patient groups it is intended.
        - In the case of a product that has undergone a joint clinical assessment (JCA), a separate statement is presented only to the extent that the Finnish treatment practice or the patient group that takes into account the scope of the reimbursement status differs from that covered in the JCA report. In other respects, references can be made to the JCA report.
- In addition to the above, the application for special reimbursement status must also
    - Describe the type of the disease
        - If the product has undergone a joint clinical assessment, references can be made to the JCA report where applicable.
    - Present a specification of the necessity and the remedial or replacement effect of the product in the treatment of the disease in question.
    - Present a specification of the experience of the use of the product. Attach the following documents to your application:
        - patient exposure or sales information from Finland and worldwide, as well as how the information has been estimated or counted
        - assessment report by the marketing authorisation authority of the latest periodic safety update report

        - the latest periodic safety update report if a new safety update report has been prepared after the latest assessment report by the marketing authorisation authority
        - information about adverse events reported after the granting of the marketing authorisation entered into the summary of product characteristics
        - if desired, research information about the use of the product in real-life treatment contexts.

Costs and cost-effectiveness

- Present a statement on the average dosage based on the summary of product characteristics as well as the common dosages used in treatment practice and/or clinical studies and the resulting medicinal treatment costs calculated on the basis of the proposed wholesale price and retail price including VAT per a day of treatment and a period of time essential for the treatment.
- Compare the treatment costs at wholesale prices with other products subject to reimbursement that are in the market and that are used in the treatment of the same disease with a dosing as described in summary of product characteristics and with the most common treatment dosage per a day of treatment and a period of time essential for the treatment.

Health economic evaluation

- Attach a health economic evaluation to the application
    - when applying for basic reimbursement status or a wholesale price for a new active pharmaceutical ingredient
    - to the basic reimbursement status or wholesale price application if no reimbursement status has been approved to the same extent for other products containing the same active substance
    - in any other situation where the marketing authorisation holder considers it necessary; for instance, when applying for special reimbursement status or a reasonable wholesale price for a new dosage form of a product.
- Prepare the health economic evaluation in accordance with the instructions appended to the Decree of the Ministry of Social Affairs and Health on applications and price notifications made to the Pharmaceuticals Pricing Board. The Pharmaceuticals Pricing Board has provided more detailed instructions on the preparation of a health economic evaluation on its website.

Market forecast

- Describe the group of medicinal products with similar therapeutic indications within which the product will be marketed, what similar products there already are within the group, how the use of medicinal products is expected to change within the group, and what changes are anticipated in the market conditions. Is the product expected to replace other available medicinal treatments or will it supplement them?
- Present an estimate of the total sales of the group of medicinal products in retail prices including VAT in the current year and the three years following it
    - in a situation where the product subject to the application is reimbursed and
    - in a situation where the product subject to the applicationis not reimbursed.
- Estimate the share of the product/products of total sales (in EUR and %) and present the change that will result from the reimbursement of the product subject to the application (in EUR and %) of the total sales in the group.
- Present the market forecast using the pre-formatted tables available on the Pharmaceuticals Pricing Board website and select 'sales estimate' as the type of the attachment in the e-service.

Sales and number of patients

- Estimate the future sales of the product at the proposed wholesale price and retail price including VAT per package and as total sales. Estimate the number of patients using the product. The sales forecast concerns the sales reimbursed under the Health Insurance Act and must be provided for the current year and the three years following it.
- Report the sales volume and patient numbers using the pre-formatted tables available on the website of the Pharmaceuticals Pricing Board.
- In addition to the above, the application for special reimbursement status must also contain
    - an estimate of the effect of the special reimbursement status on the sales of the product
    - an estimate of the costs resulting from the special reimbursement status to health insurance.

Prices and reimbursement statuses in other EEA states

- List any other trade names of the medicinal product used in other EEA states.
- State the existing wholesale prices in euros, using the exchange rates valid at the time of submitting the application. If no wholesale prices are available, give

the ex factory prices of the packages. Also provide this information for packages that are not sold in the Finnish market. Report if the product is subject to an agreement (publicly available information).
- State if the product is reimbursed in other EEA states and if the reimbursement status is general or patient specific. Also give any restrictions and conditions for reimbursement.
- Report the prices and reimbursement statuses in EEA states using the pre-formatted tables available on the website of the Pharmaceuticals Pricing Board.

Other specifications

- When an application for special reimbursement status concerns a product that has been approved for conditional reimbursement status and the applicant proposes an extension of conditional reimbursement, the application must include the ordinary application documents and a separate document containing a proposal for conditional reimbursement status. The Pharmaceuticals Pricing Board has published on its website instructions on the procedure for the conditional reimbursement status.
- Attach any other specifications you consider necessary to your application, such as
    - an expert opinion, which must clearly state any conflicts of interest (see instructions for preparing an expert opinion and an example of a disclosure form on the Pharmaceuticals Pricing Board's website)
    - detailed specification of the research, product development and manufacturing expenses for the product if you wish to refer to them.
- When reimbursement status and wholesale price are sought for a product whose previous reimbursement status and wholesale application has been rejected, present a summary of the changes and updates made to your application.
- When applying for an increase in the approved reasonable wholesale price, in addition to the aforementioned attachments, submit a detailed and reasoned proposal for a new reasonable wholesale price and details of the permanent changes in the factors affecting the price formation of the product during the validity of the wholesale price.

List of sources and sources

- Attach to the application a list containing all the sources referred to in the application. The sources must be presented in a logical order, for instance alphabetically.
- All sources referred to in the application must be attached, excluding those freely available on the internet, for which an exact reference and a hyperlink must be provided. If the source is extensive, indicate the page number, table

number or similar in the reference. If the source publication includes an appendix, you should also attach this appendix to the application.

- In the case of a product that has undergone a joint clinical assessment (JCA) under the EU HTA regulation, the application documentation should not include sources available through the joint assessment IT platform, but the sources referred to should be included in the list of sources, named individually, and the previous submission to the IT platform should be mentioned (for example, 'submitted in JCA assessment').