



**PHARMACEUTICALS PRICING BOARD**  
Finland

## **APPLICATION INSTRUCTIONS**

### **REIMBURSEMENT STATUS AND WHOLE-SALE PRICE FOR A MEDICINAL PRODUCT SUBJECT TO MARKETING AUTHORIZATION**

#### **APPLICATION FOR BASIC / SPECIAL REIMBURSEMENT STATUS AND REASONABLE WHOLESALE PRICE FOR A MEDICINAL PRODUCT SUBJECT TO MARKETING AUTHORIZATION**

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## **1**

### **General**

The condition for payment of reimbursement under the Health Insurance Act (1224/2004) for a medicinal product is that the product has a reimbursement status and a wholesale price confirmed by the Pharmaceuticals Pricing Board. These application instructions are applied to applications for reimbursement status and reasonable wholesale price for medicinal products subject to marketing authorization. In a situation where a medicinal product subject to marketing authorization would belong or belongs to an existing reference price group in the reference price system separate instructions and application form (application for reimbursement status and wholesale price in the reference price system) are applicable to the application procedure.

The holder of marketing authorization for a medicinal product applies for confirmation of reimbursement status and reasonable wholesale price for the product from the Pharmaceuticals Pricing Board. Application consists of an application form/application forms and their appendices. Fill out a separate form for each strength and dosage form, but submit appendices for each product.

Application forms include information on

- the applicant,
- the product,
- the wholesale price,
- the application type,
- the appendices to the application, and
- the processing fee's invoicing information.

Include other specifications, such as justifications for the application, sales estimates, and information on prices and reimbursement status in other EEA states, in the appendices to the application (cf. section 3 for instructions).

Sign and date the application.

Submit the application with appendices to the Pharmaceuticals Pricing Board in an electronically saved format (memory stick). Use the attached instructions for naming the electronic versions of application documents (Appendix 1).

## 2 Filling in application forms

A separate form should be filled in for each strength and dosage form.

Choose on the first page of the form, at the top on the right-hand side, which reimbursement status and wholesale price is applied for the medicinal product. There are four alternatives:

- confirmation of basic reimbursement status and reasonable wholesale price,
- confirmation of special reimbursement status and reasonable wholesale price,
- confirmation of basic reimbursement status, special reimbursement status and reasonable wholesale price, and
- increase of the reasonable wholesale price on which the reimbursement status is based.

In case it is question of applying for restricted basic reimbursement status and/or restricted special reimbursement status, mark the section, in addition, with an x. Define the proposed restriction in section 4 of the form.

### Section 1 on the form. Applicant

Fill in the following data on the applicant:

- the holder of the marketing authorization for the medicinal product,
- the applicant,
- the business identity code of the applicant,
- contact data, and
- a contact person whom the Pharmaceuticals Pricing Board may contact.

### Section 2 on the form. Product

Fill in the following data on the medicinal product:

- the product's name, strength, dosage form, active substance, ATC class,
- the type of product,
- the date of issue of the marketing authorization,
- information on whether the product is included in the Finnish Medicines Agency's (Fimea) list of interchangeable medicinal products,
- validity and validity period of patent or supplementary protection certificate, and
- the package size-specific marketing authorization number and the Nordic product number (Vnr).

### Section 3 on the form. Wholesale price

Fill in the following data according to package

- the valid confirmed wholesale price (€) and - a proposal for a confirmed wholesale price (€).

### Section 4 on the form. Application type

Choose the application type in accordance with what is applied for the product. For instance, if the application concerns confirmation of basic reimbursement status and wholesale price choose the application type "Basic reimbursement status and reasonable wholesale price" from the drop-down menu. Leave the other menu boxes empty. If confirmation of both basic reimbursement status and special reimbursement status is applied for at the same time, choose "Basic

reimbursement status, special reimbursement status and reasonable wholesale price” from the menu, while the other boxes are left empty.

Examples of the types of application that can be chosen from among are: new active substance, new dosage form, new generic product, renewed application for the original product, renewed application for parallel imported product, extension of reimbursement status, and subsequent strength.

When applying for restricted basic and/or restricted special reimbursement status, specify the restriction that is proposed (a new restriction or a restriction confirmed before) in this section. If you propose abolishment of an existing restriction or a new indication for which extended reimbursement status is applied for, specify that also in this section. Present itemized grounds for restriction or extension of reimbursement status in appendices justifying the product's reimbursement status. When applying for special reimbursement status, specify the disease which is to be treated with this product by choosing it from the list on the form based on the Government Decree.

#### Section 5 on the form. Application appendices

Attach all the required specifications (cf. section 3 for instructions) to the application. The appendices should be marked on the form with an x. Here the applicant may also inform which parts of the documents earlier submitted to the Pharmaceuticals Pricing Board can be used in processing the application concerned.

#### Section 6 on the form. Invoicing

The fee laid down in the Decree of the Ministry of Social Affairs and Health on the priced services of the Pharmaceuticals Pricing Board will be charged for the processing of the application.

The application must contain invoicing details:

- invoicing address and
- name and contact details for the invoicing contact person (phone number and email address).

#### Section 7 on the form. Consent

On the basis of the consent given on the application form the messages and documents sent via unprotected e-mail communication will be sent to the e-mail address of the contact person for the applicant given in section 1 on the application form. The Pharmaceuticals Pricing Board considers case by case whether to send documents by e-mail, and it may in any case decide to send the documents only by post. The decision by which the application matter is finally solved is always sent by post.

The sender is always responsible for the use of e-mail. The sender is responsible for the readability of the message, that it reaches its destination and other comparable circumstances, until the sender has been informed that the message has arrived successfully. The Pharmaceuticals Pricing Board notifies the sender of the arrival of the message once it has been received.

#### Section 8 on the form. Signature

The application form/s have to be signed.

### **3**

#### **Application appendices**

##### **a) Basic reimbursement status and wholesale price**

Append the following specifications to the application for basic reimbursement status and wholesale price for the medicinal product:

- ❑ Table of contents of the application

An itemized and well-grounded proposal concerning the medicinal product's basic reimbursement status and wholesale price

- ❑ A summary of the justifications presented in the application as regards the product's reimbursement status and a proposal for a reasonable wholesale price

The medicinal product's therapeutic value

- ❑ A valid summary of product characteristics
- ❑ Indications for which the medicinal product has been approved and for which basic reimbursement status is sought
  - The summary of product characteristics may be referred to
- ❑ The benefits of reimbursement status compared with other medicinal products or treatments used for treating the same disease
  - A summary of clinical studies on the product and research publications
  - The applicant may present evidence of how patients benefit from the medicinal product and for which patient groups it is intended
  - A comparison with medicinal products and/or treatments used for the treatment of the same disease
- ❑ Clinical assessment by a marketing authorization authority if it is question of a new product or of extending the reimbursement status to a new indication
  - A European public assessment report (EPAR) by the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency (EMA); or
  - The reference member state's (RMS) clinical assessment report for products authorised by the mutual recognition procedure or decentralised marketing authorisation.

Treatment costs

- ❑ A statement of the average daily dosage and the resulting medicinal treatment costs calculated on the basis of the proposed wholesale price and retail price including value added tax
  - The most common daily dosage
  - The applicant may present a comparison of treatment costs for a period of time essential for the treatment
- ❑ A statement of the cost-effectiveness of the medicinal product and a market forecast compared with other medicinal products used for treating the same disease
  - The market forecast must specify the group of medicinal products with similar indications within which the medicinal product will be marketed, what similar products there already are within the group, and how the use of medicinal products is expected to change within the group
  - The market forecast uses retail prices including value added tax
  - An assessment of the extent to which the medicinal product is expected to replace other medicinal substances or products in the group and whether the product is supplementary to an already existing medicinal treatment
- ❑ A health economic evaluation
  - A health economic evaluation must always be attached

- To a basic reimbursement status and wholesale price application for a new active substance
- When applying for a significant extension of reimbursement status for a medicinal product
- When the Pharmaceuticals Pricing Board has specifically demanded such an evaluation in its decision.
- A health economic evaluation can also otherwise be appended to an application for reimbursement status and reasonable wholesale price, if the applicant considers it necessary. The applicant may submit a health economic evaluation e.g. when applying for a special reimbursement status or a reasonable wholesale price for a new dosage form of the product
- The health economic evaluation has to be drawn up according to the guidelines appended to the Decree of the Ministry of Social Affairs and Health on applications and price notifications made to the Pharmaceuticals Pricing Board
- Pharmaceuticals Pricing Board has given separate detailed application instructions for a health economic evaluation

#### Sales information

- ☐ A well-grounded estimate of the medicinal product's sales on the basis of the proposed wholesale price and retail price including value added tax and an estimate of the number of patients expected to use the product
- The sales estimates presented in the previous application and actual sales during the validity of a price confirmed by a decision and during the current year; if the estimate given in a previous application differs significantly from actual sales, an explanation of the reasons for the difference must be provided
- An estimate is presented on sales at wholesale price (€) and at retail price including value added tax (€) during the current year and the following three years for each dosage form, strength, and package, and there must also be an estimate of total sales
- The sales forecast concerns the sales reimbursed under the Health Insurance Act.
- An estimate of the number of patients expected to use the product must be provided for the current year and the following three years
- The table format available in the website of the Pharmaceuticals Pricing Board must be used for reporting the sales information and number of patients

#### Prices in other EEA states

- ☐ Other trade names of the medicinal product used in other European Economic Area (EEA) states, existing wholesale prices and the reimbursement bases of the medicinal product
- Valid wholesale prices for all package sizes, i.e. the purchasing prices that the pharmacies pay in EEA states
  - If no wholesale prices are available, ex factory prices should be provided
  - Prices must be presented in euros (€), using the exchange rates valid at the time of application
  - Also provide information on package sizes that are not marketed in Finland
- If you do not provide price information for EEA states, include a relevant explanation of the missing prices
- Provide an itemized statement of the reimbursement status of the product in EEA states. The statement must report whether the medicinal product is included in a reimbursement system and the structure of the reimbursement system, e.g. percentage or cost-based system, reference price-based system or profit control system
- The table format available in the website of the Pharmaceuticals Pricing Board must be used for reporting the prices of EEA states

#### Other specifications

- ☐ A copy of the valid marketing authorization decision

- If the product has been granted a central marketing authorisation, the information of all package sizes with their marketing authorization numbers (all authorized presentations) provided by European Medicines Agency (EMA) should be attached to the marketing authorization decision
- ☐ Other specifications required by the Pharmaceuticals Pricing Board in its previous decision
- ☐ Other specifications regarded as necessary by the applicant, such as:
  - An expert opinion that must clearly state the expert's ties (see instructions for preparing an expert opinion and an example for declaration of interests)
  - An itemised specification of the research, product development and manufacturing costs for the medicinal product to the extent to which the applicant wishes to appeal to them.

## **b) Special reimbursement status and wholesale price**

When applying for special reimbursement status and reasonable wholesale price, append the following specifications to the application **in addition to the appendices** to the application for basic reimbursement status and wholesale price **referred to in section a)**:

### A well-grounded proposal for the necessity of the medicinal product

- ☐ Type of the disease
- ☐ Why is this particular medicinal product needed for the treatment of the chronic and severe disease in question and for which patient group is it needed
- ☐ When 100 per cent is reimbursed for a medicinal product in excess of the product-specific deductible, a specification must be presented on the replacement or remedial effect of the medicinal product

### A specification of the medicinal product's therapeutic value proved in studies and in practice

- ☐ Research-based evidence
  - A summary of the clinical studies carried out on the product related to the special reimbursement status applied
  - Clinical assessment report by the marketing authorization authority assessing studies carried out and/or published before the granting of the marketing authorization
  - Any studies published after the granting of the marketing authorization related to the special reimbursement status applied
    - New original studies that have been published in peer review journals
    - In the first place, the effect of the therapy is indicated by randomised controlled trials (RCT) with clear, acceptable primary endpoints
    - Studies in which the product has been compared to other products with the same indication (active treatment, comparative treatment studies)
    - Open studies
    - Reviews combining different research material (*review articles, meta-analyses*); it is however desirable to append to the application in the first place the original studies, instead of reviews and analyses
    - If there are plenty of publications that have been published after the granting of the marketing authorization, the publications should be placed in a priority order and it should be informed clearly which of them are the most important articles; when assessing the articles, attention should be given to possible ties of the authors with a company and in which papers the outcomes have been published

- The therapeutic value of the new product is assessed compared to other medicinal products and/or treatments with the same indication
- ❑ Experience of use
  - A specification of the extent of the use of the product and experience of its use
    - Patient exposure and sales information in Finland, as well as how the information has been estimated or counted
    - The latest assessment report by the marketing authorization authority for the periodic safety update report [EMA/RMS assessment report for periodic safety update report (PSUR)]. The assessment report must state:
      - Global patient exposure and sales information, as well as how the information has been estimated or counted
      - The countries in which the product has a marketing authorization
      - The countries in which the product has been placed on the market
      - Harmful effects reported after the granting of the marketing authorization grouped in known and unknown, and in serious and non-serious
      - Changes related to the product's safety made after the granting of the marketing authorization and
      - Information on the ongoing and completed studies regarding the product.
    - The latest periodic safety update report (PSUR) if a new safety update report has been prepared after the latest assessment report by the marketing authorization authority
- ❑ Dosage
  - The dosage of the medicinal product in the disease or indication entitling to special reimbursement status; grounds should be presented if the proposed dosage or way of administration deviates from the information given in the summary of product characteristics or from what is used in the studies appended to the application
- ❑ Treatment recommendations and systematic reviews
  - Treatment recommendations and systematic reviews by a reliable, independent source can be used for indicating the therapeutic value (e.g. Current Care Guideline, European/international treatment guidelines, Cochrane Reviews)

#### A specification of the costs and cost-effectiveness of the medicinal treatment

- ❑ An itemized specification of the costs of the treatment at wholesale prices and retail prices including value added tax with a normal treatment dosage
- ❑ Treatment costs compared to products or treatments subject to special reimbursement that are on the market and that are used in the treatment of the same disease (cost of treatment for a period of time essential for the treatment, e.g. for one year, at wholesale price with a normal treatment dosage)
- ❑ In regard to a health economic evaluation, reference to a specification submitted in connection with an application for basic reimbursement status and wholesale price if it is a fairly recent one, or a new health economic evaluation if the applicant considers it necessary

#### Market forecast

- ❑ An estimate of the sales of the medicinal product during the current year and the following three years after the approval of the product for special reimbursement status (both the total sales and the sales based on special reimbursement status); in regard to a new product an estimate of the expected impact of special reimbursement status on the sales of the product
- ❑ The market forecast must show a group of medicinal products with similar indications within which group the medicinal product in question will be marketed with special reimbursement status, what similar products are already in the group, and how the use of these medicinal

products is expected to change within the group. The market forecast is presented in retail prices including value added tax

- ❑ An estimate of to which extent the medicinal product would replace the use of other medicinal substances in the group and if the preparation complements a medicinal treatment already in use

#### Other specifications

- ❑ When an application for special reimbursement status concerns a product with confirmed conditional reimbursement status and the applicant proposes a continuation of the conditional reimbursement status, the application must include the ordinary application documents and a separate document containing a proposal for a conditional reimbursement status. The Pharmaceuticals Pricing Board has published on its website instructions on the procedure for the conditional reimbursement status.
- ❑ Any other specifications, such as:
  - An expert opinion that must clearly state the expert's ties (see instructions for preparing an expert opinion and an example for declaration of interests)

### **c) Restricted reimbursement status and wholesale price**

Reimbursement status is mainly applied to the extent of the approved indication in the summary of product characteristics. The reimbursement status applied can also be limited if the medicinal product is particularly expensive and the use of which results in the exceeding of a patient's annual deductible (the medicine reimbursement ceiling). If the reimbursement status applied for is more limited than the approved indication, the following must be appended to the application in addition to the appendices referred to in sections a) and b):

- ❑ the proposed restriction of basic/special reimbursement status (indication specified in detail)
- ❑ Grounds for the proposed restriction of reimbursement status
  - The therapeutic value, necessity and cost-effectiveness of the medicinal product within the indication applied for/the concerned condition as proven in the product's use and research
  - The appropriateness of the proposed restriction as regards the implementation of the pharmacotherapy.

### **d) Application for renewal of a fixed-term decision**

The decisions of the Pharmaceuticals Pricing Board on reimbursement status and wholesale price are issued for a fixed period of time. When applying for renewed confirmation of reimbursement status and reasonable wholesale price please see application instructions for renewal.

### **e) Generic product and parallel imported product**

Appendices referred to in sections a) through c) must be appended to applications regarding generic products or parallel imported products, as appropriate. In addition, a specification on the wholesale price proposed for the product compared with the price of the original product / directly imported product must be included in the application.

### **f) Extension of reimbursement status**

The Pharmaceuticals Pricing Board confirms the reimbursement status of a medicinal product to the extent referred to in the summary of product characteristics that is valid at the date of issuing



the decision on reimbursement status, unless otherwise mentioned in the decision. If the marketing authorization authority later approves an extended indication for the medicinal product, the product is not reimbursable within its new indication unless extension of reimbursement status is applied from the Pharmaceuticals Pricing Board. It is also question of extension of reimbursement status if abolishment of a valid restriction for a medicinal product is applied for.

Attach to an application for an extension of reimbursement status the appendices referred to in sections a) through c) above. Give specifications concerning the new indication for which reimbursement status is applied. Any sales estimates should be specified as total sales and, as regards the new indication, estimating the share of the new indication (€ / %) of the sales. Also the clinical assessment report by the marketing authorization authority about the benefits and risks of the product in the new indication should be appended to the application.

A health economic evaluation must be appended to the application as grounds for the suggested wholesale price in case of a substantial extension of reimbursement status and if no reimbursement status has been confirmed in the same extent for other products containing the same active substance. A health economic evaluation is necessary in order to assess the product's economy and cost-effectiveness. The Pharmaceuticals Pricing Board has provided more detailed instructions on the preparation of a health economic evaluation in separate application instructions.

A health economic evaluation must generally be appended to an application, for example: -

When the case concerns

- a different illness,
  - a different treatment line for the same illness or
  - a different patient group for the same illness and
  - the comparative treatments,
  - the costs of the applied product and/or comparative treatments or
  - the health effects of the applied product and/or comparative treatments
- differ from the indication previously approved for reimbursement.

- When applying for a removal of a reimbursement restriction.

By default, a health economic evaluation does not need to be appended to applications that concern an extension of indication to the treatment of paediatric patients, for example. In these cases, the extension of reimbursement has little impact on the product's reimbursed sales, and the comparative treatments may also not necessarily diverge from earlier.

If a health economic evaluation is not appended to an application for an extension of reimbursement status, the applicant must state grounds for this.

When an application concerns a product with confirmed conditional reimbursement status and the applicant proposes a continuation of the conditional reimbursement status, the application must include the ordinary application documents and a separate document containing a proposal for a conditional reimbursement status. The Pharmaceuticals Pricing Board has published on its website instructions on the procedure for the conditional reimbursement status.

The processing fee for an application for an extension of reimbursement status is paid based on extended processing when a health economic evaluation has been appended to the application. Otherwise, the processing fee is paid based on restricted processing by default, and the Secretariat for the Pharmaceuticals Pricing Board will contact the applicant if the application is found to require extended processing.

## **g) Wholesale price increase**

When applying for an increase of the reasonable wholesale price confirmed for a product, include an itemized and well-grounded proposal for a new reasonable wholesale price. Include a specification to support the application on changes of a permanent nature that have taken place in circumstances affecting the price formation of the medicinal product during the validity of the wholesale price. In addition, the appendices referred to in sections a) and b) must be appended to

the application as appropriate; for instance, a statement of how the increase of the price would change the market forecast and sales estimates.

#### **h) Sources**

The list of references must include all the sources that have been referred to in the application. The sources must be presented in a logical order, for instance in the order they are referred to or in alphabetical order. If a source publication is extensive, page number, table number or other similar reference should be given.

All sources used should be attached to the application. If there is a supplement or an appendix connected with an article, include also the supplementary material. Where necessary, the applicant may only submit the used parts of very extensive sources. For sources that are only available on the Internet, the precise source reference and hyperlink shall be given. The Internet source must be freely available.

### **4 Submitting applications**

The applications with appendices are submitted to the Pharmaceuticals Pricing Board.

Postal address:

Pharmaceuticals Pricing Board

PO Box 33

FI-00023 Government, Finland

Street address:

Prime Minister's Office Registry Office

Ritarikatu 2B

FI-00170 Helsinki, Finland

**APPENDIX 1. Instructions for naming the application documents**

All the documents mentioned in column *Document* are saved in one file, which is named in the way referred to in column *Name of the file*.

<b>Document</b>	<b>Name of the file</b>	<b>File format</b>
- Covering letter, possible forms regarding confidentiality	Covering letter	pdf
- Application form/forms	Application form	pdf

**Appendices to application (from the application form):**

<b>Document</b>	<b>Name of the file</b>	<b>File format</b>
- Table of contents of the application	Table of contents	pdf

The following Appendices to the application for basic reimburse-status are saved in one file:

- A summary of the grounds presented in the application in regard to the product's reimbursement status and a proposal for a wholesale price
- Indications for which the medicinal product has been approved and for which basic reimbursement status is applied
- The benefits of reimbursement status compared with other medicinal products used for treating the same disease and with other treatments
- A statement of the average daily dosage and the resulting medicinal treatment costs calculated on the basis of the proposed wholesale price and retail price including value added tax
- A statement of the cost-effectiveness of the medicinal product and a market forecast compared with other medicinal products used for treating the same disease
- Other specifications required by the Pharmaceuticals Pricing Board in its previous decision

In case it is, in addition, question of an application for special reimbursement status, also the following appendices are saved in the file *Application memorandum*:

- A well-grounded proposal regarding the necessity and cost effects of the medicinal product
  - o When 100 per cent is reimbursed for a medicinal product in excess of the product-specific deductible, a specification must be presented on the replacement or remedial effect of the medicinal product
- A specification of the therapeutic value of the medicinal product
- The treatment dosages of the medicinal product, the treatment costs of the product compared with products with special reimbursement status on the market used for treating the same disease and market forecast on the cost effect of potential approval of special reimbursement status

- An itemized specification of the costs and benefits of the medical treatment and a report on the product's status in relation to alternative medicinal and other treatments

Document	Name of the file	File format
- A valid summary of product characteristics	Summary of product characteristics	pdf
- Clinical assessment by a marketing authorization authority	Clinical assessment	pdf
- A health economic evaluation	Health economic evaluation	pdf
- A well-grounded estimate of the medicinal product's sales on the basis of the proposed wholesale price and retail price including value added tax and an estimate of the number of patients expected to use the product	Sales estimates [The table format available on the website of the Pharmaceuticals Pricing Board can be used for submitting the information]	xlsx
- Other trade names of the medicinal product used in other European Economic Area states, existing wholesale prices and the reimbursement bases of the medicinal product	Prices in EEA countries [The table format available from the website of the Pharmaceuticals Pricing Board can be used for submitting the information]	xlsx
- A copy of the valid decision on marketing authorization	Marketing authorization	pdf
- Other specifications that the applicant considers necessary	Other specifications named appropriately [e.g. clinical expert opinions "Expert opinion_Surname"]	pdf
- Table of sources	Table of sources	pdf
- Sources etc.	In the manner mentioned in the table of sources [The first author in the table of sources or, if the sources are numbered, the number first and then the first author, e.g. "Source_Surname" or "Source_1_ Surname"]	pdf

#### Other documents:

Document	Name of the file	File format
- Supplementary information to the application material (before starting the processing of the application)	Name of the supplemented file + _supplement [e.g. "Sales estimates_supplement"]	pdf
- Additional specification (during the processing of the application)	Additional specification	pdf
- The applicant's response to statement of the Social Insurance Institution (Kela)	Response to statement of Kela	pdf
- The applicant's response to statement of the expert group	Response to statement of the expert group	pdf