PHARMACEUTICALS PRICING BOARD
Finland

APPLICATION INSTRUCTIONS

MEDICINAL PRODUCT SUBJECT TO MARKETING AUTHORISATION - APPLICATION FOR RENEWAL

APPLICATION FOR REIMBURSEMENT STATUS AND REASONABLE WHOLESALE PRICE FOR A MEDICINAL PRODUCT SUBJECT TO MARKETING AUTHORISATION, RENEWAL APPLICATION

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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. Apart from medicinal products belonging to the reference price system, decisions by the Pharmaceuticals Pricing Board on reimbursement status and wholesale prices are fixedterm in nature. These instructions apply to applications for the renewal of a reimbursement status and a reasonable wholesale price for medicinal products subject to marketing authorisation. These instructions also apply when applying for a reimbursement status and a reasonable wholesale price for a medicinal product subject to marketing authorisation during a so called reference price system transition period.

The holder of the marketing authorisation applies to the Pharmaceuticals Pricing Board for confirmation of a reimbursement status and a reasonable wholesale price for a medicinal product. Application consists of an application form (or forms) and specifications that lend support to the application. A separate form for each strength and pharmaceutical form of the product is filled in, but specifications are submitted for the whole product.

The application is submitted to the Pharmaceuticals Pricing Board 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 Application form

Fill in a separate form for each strength and pharmaceutical form of the product.

The application form includes information on

- the applicant,
- the medicinal product,
- the wholesale price,
- the application type,
- specifications related to the application,
- the processing fee's invoicing information
- consent for using email
- signature.

Instructions for filling in the form:

Section of the form	Instructions for completing the form
	Select the reimbursement status and wholesale price type for the medicinal product from the options in the left-hand corner on the first page of the form. If you are applying for restricted basic reimbursement status and/or restricted special reimbursement status, please mark the restriction by ticking the pertinent section. Define the proposed restriction in section 4 of the application form.
Section 1: Applicant	Fill in the following information on the applicant: • The holder of the marketing authorisation for the medicinal product, • the applicant, • the applicant's Business ID, • contact information, and • a contact person for correspondence with the Pharmaceuticals Pricing Board.

Section 2: Product	Fill in the following data on the medicinal product: • name, strength, pharmaceutical form, active substance and ATC class of the medicinal product; • product type; • date when the marketing authorisation was granted or date when it was renewed; • whether the medicinal product is included in the list of interchangeable medicinal products maintained by the Finnish Medicines Agency (Fimea); • validity period of patent or supplementary protection certificate or indication 'patent not valid'; and • marketing authorisation number and Nordic product number (Vnr) for each package.
Section 3. Wholesale price	Fill in the following data for each package: • the valid confirmed wholesale price (€) and • a proposal for a confirmed wholesale price (€).
Section 4: Type of application	Based on what is being applied for, choose the application type from the drop-down menu. When applying for restricted basic and/or restricted special reimbursement status, specify the verified restriction for the product. When applying for special reimbursement status, specify the disease which is to be treated with this product by choosing it from the list given on the form, which is based on a Government Decree.
Section 5: Appendices to the application	All the specifications listed in section 3 of these instructions must be included in the application. Tick all specifications presented in the application by marking an x on the form.
Section 6: 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: o invoicing address and o name and contact details for the invoicing contact person (phone number and email address).

Section 7: 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. Signature	The application form/s have to be signed.

3 Information to be presented in the application

The scope of reimbursement status is the same in the application for renewal as the valid reimbursement status. If you are applying for a wider scope of reimbursement status than in the existing one (e.g. a new indication), you must submit a separate application for extension of reimbursement status.

When drawing up the renewal application, please pay particular attention to any changes that might have taken place during the validity of the existing decision.

When submitting a renewal application for reimbursement status and reasonable wholesale price for a product, present the following information in the application:

Description	Specification
Table of contents	Table of contents of the application
Itemised and wellgrounded proposal for reimbursement status and wholesale price;	A summary of the justifications for the product's reimbursement status and for the proposed wholesale price. Therapeutic value • indications for which reimbursement status of the medicinal product is being applied; • description of the changes in the summary of product characteristics during the validity of the existing decision which impact the reimbursement status and/or costs ; • benefits to be achieved with the reimbursement status compared with other medicinal products or treatments used for treating the same disease; o changes in treatment practices, such as updated treatment guidelines; o changes in treatment options; and o summary of new clinical studies of the product carried out during the validity period in the indication being applied for and research publications. A summary of the product's indispensability and therapeutic value and replacement or remedial effect when applying for special reimbursement status. Information on the costs and economic value of the medicinal treatment • 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; • treatment costs for the indications being applied for with the dosages based on the summary of product characteristics compared to products subject to reimbursement that are on the market and are used for treating the same disease; o changes in comparable products and in their costs; • Health economic evaluation o A health economic evaluation must be included in renewal application whenever the Pharmaceuticals Pricing Board has requested one in its previous decision o A health economic evaluation may be included in the application in other cases too, if the applicant considers it necessary o The Pharmaceuticals Pricing Board gives further instructions on how to draw up a health economic evaluation on its website.

Description	Specification
	Market forecast • describe the group of medicinal products with similar indications within which the medicinal product is marketed, what similar products there exist within the group, and how the use of medicinal products is expected to change within the group; • include total sales of the medicinal product group using retail prices including value added tax and the product's market share of total sales both in euros (€) and percentages (%); • the market forecast is made for the current year and the following four years; • if changes are expected in the market situation, an account of the changes should be included; • the table templates available on the website of the Pharmaceuticals Pricing Board can be used for drawing up the market forecast. Sales data and patient numbers • the actual sales reimbursed under the Health Insurance Act during the validity period of the previous decision; o sales estimates given in the previous application and actual sales figures over the validity period of the previous decision and the current year broken down into pharmaceutical form, strength and package as well as by total sales of product (€); o if actual sales deviate significantly from those estimated in the previous application, give explanation on the deviation and refer to the notification of exceeding the sales estimates; • estimate of the sales of the medicinal product based on the proposed wholesale price and the retail price including value added tax, and an estimate of the number of patients expected to use the product; o present the sales estimates for each pharmaceutical form, strength and package as well as by total sales of product (€); o the estimate of the sales and patient numbers is made for the current year and the following four years; o the sales estimate applies to sales reimbursed under the Health Insurance Act; • the table templates available on the website of the Pharmaceuticals Pricing Board should be used for reporting the sales data and patient numbers.

Description	Specification
	Prices and reimbursement status in other European Economic Area states (EEA states) o trade names of the medicinal product, existing wholesale prices and reimbursement in other EEA states; if wholesale prices are unavailable, give ex factory prices for the packages. o prices should be in euros (€), using the exchange rates valid when submitting the application; o information on package sizes that are not marketed in Finland must also be given; o the reimbursement status of the product in EEA states; specify whether the product is included in the reimbursement system, its reimbursement percentage and the basis for reimbursement; • the table templates available on the website of the Pharmaceuticals Pricing Board should be used for reporting the prices and reimbursement data in EEA states; • short summary of the changes in prices and reimbursement statuses in EEA states.
Summary on product characteristics;	Most recently updated valid summary of product characteristics.
Valid marketing authorisation decision	A copy of the valid decision on marketing authorisation If the product has been granted a centralised marketing authorisation, information on all package sizes including their marketing authorisation numbers (all authorised presentations) provided by the European Medicines Agency (EMA) should be appended to the marketing authorisation.
Specifications required in a previous decision	Other specifications required by the Pharmaceuticals Pricing Board in its previous decision.
Other information	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. Other information the applicant considers necessary, such as

	• an expert opinion that must clearly state the expert's conflicts of interest (see instructions on the Pharmaceuticals Pricing Board website for drawing up an expert opinion and example of declaration of interests); • itemised specification of the medicinal product's research, product development and production costs to the extent that the applicant wishes to appeal to them.
Description	Specification
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 application documents

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

Name of the file	Document	File format
Covering letter	Covering letter and possible forms related to confidentiality	pdf
Application form	Application form(s)	pdf
Table of contents	Table of contents of the application	pdf
Application memorandum	The following are saved in one file: • summary of the justifications for the product's reimbursement status and for the proposed wholesale price, • therapeutic value, • summary of the product's indispensability and therapeutic value and replacement or remedial effect (special reimbursement status), • information on the costs and economic value of the medicinal treatment, • summary of the market forecast, sales data and prices in EEA states; and • other specifications required by the Pharmaceuticals Pricing Board in its previous decision.	pdf
Market forecast	Market forecast □ The table template available on the website of the Pharmaceuticals Pricing Board can be used for submitting this information.	xlsx
Sales data and patient numbers	Sales data and patient numbers □ The table template available on the website of the Pharmaceuticals Pricing Board must be used for submitting this information.	xlsx
Prices in EEA states	Prices and reimbursement status in other EEA states □ The table template available on the website of the Pharmaceuticals Pricing Board must be used for submitting this information.	xlsx
Summary of product characteristics	A valid summary of product characteristics	pdf
Marketing authorization	Valid marketing authorisation decision	pdf
Health economic evaluation	Health economic evaluation	pdf

Name of the file	Document	File format
Other data expediently named [e.g. clinical expert opinions “Expert opinion_Surname”]	Other information that the applicant considers necessary	pdf
List of sources	List of sources	pdf
In the manner mentioned in the list of sources [e.g “Source_Surname”]	Sources	pdf