PHARMACEUTICALS PRICING BOARD
Finland

APPLICATION INSTRUCTIONS

MEDICINAL PRODUCT SUBJECT TO SPECIAL LICENCE

APPLICATION FOR BASIC / SPECIAL REIMBURSEMENT STATUS AND REASONABLE WHOLESALE PRICE FOR A MEDICINAL PRODUCT SUBJECT TO SPECIAL LICENCE

FOR APPLICATIONS BY MANUFACTURERS, IMPORTERS OR WHOLESALERS

Content of the instructions

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. Decisions by the Pharmaceuticals Pricing Board on reimbursement status and wholesale prices for a medicinal product subject to special licence are fixed-term in nature.

The manufacturer, importer or wholesaler may apply from the Pharmaceuticals Pricing Board for reimbursement status and reasonable wholesale price for the medicinal products dispensed subject to special licence referred to in section 21 f of the Medicines Act (395/1987). The applicant can also be a patient or a pharmacy on behalf of the patient, in which case separate instructions are applicable to the application procedure.

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. A valid special licence (for individual patient or temporary) granted by the Finnish Medicines Agency (Fimea) is a precondition for the application for reimbursement status and reasonable wholesale price.

Deliver the application to the Pharmaceuticals Pricing Board in an electronically saved format (memory stick). The application documents should be named as shown in Appendix 1 of these instructions.

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 and
- consent for using email.

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. There are three 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.

Section of the form	Instructions for completing the form
Section 1: Applicant	Fill in the following information on the applicant: • 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 and package size • active substance and ATC class of the medicinal product • manufacturer • importer and • validity period of patent or supplementary protection certificate or indication 'patent not valid'.
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. For instance, if the application concerns confirmation of basic reimbursement status and reasonable wholesale price choose the application type from the drop-down menu "Basic reimbursement status and reasonable wholesale price". Leave the other menu boxes empty. In case confirmation of both basic reimbursement status and special reimbursement status is applied for at the same time, the type of application is chosen from the menu "Basic reimbursement status, special reimbursement status and reasonable wholesale price", while the other menu boxes are left empty. Examples of the types of application that can be chosen from among include: new application, renewed application, subsequent strength, and subsequent dosage form. 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 of the form	Instructions for completing the form
Section 6: Invoicing details	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: Consent	Based on the consent given in the application form, messages and documents sent by unsecured email will be delivered to the email address of the contact person for the applicant given in section 1 of the application form. The Pharmaceuticals Pricing Board considers case by case whether documents are sent by email. It may also decide to send documents only by post in all cases. Final decision to an application matter is always sent by post. If email is used, the sender is always responsible for its use. The sender of the email is responsible for making sure the message is readable, that it reaches its destination and other similar factors, until confirmation of the email's receipt has been received. The Pharmaceuticals Pricing Board will notify of the arrival of the email message once it has been received.
Section 8. Signature	The application form (or forms) must be signed and dated.

3 Information to be presented in the application

When submitting an 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 well-grounded proposal for reimbursement status and wholesale price;	A summary of the justifications for the product's reimbursement status and for the proposed wholesale price. The number of special licences and price formation • the number of valid special licences granted for individual patients or information on the temporary special licence • a specification and calculation regarding circumstances affecting price formation

Description	Specification

	Therapeutic value
	• A summary of product characteristics, if available;
	  o for instance a summary of product characteristics approved in another country
	• indications for which reimbursement status of the medicinal product is being applied
	• benefits to be achieved with the reimbursement status compared with other medicinal products or treatments used for treating the same disease
	  o the application may present evidence of how patients benefit from the medicinal product and for which patient groups it is intended
	  o a comparison with medicinal products and/or treatments used for the treatment of the same disease.
	
	A summary of the product's indispensability and therapeutic value and replacement or remedial effect when applying for special reimbursement status.
	• a well-grounded proposal for the necessity of the medicinal product
	  o type of the disease
	  o 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
	  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 medicinal product’s therapeutic value proved in studies and in practice
	  o research-based evidence
	  – a summary of the findings of clinical studies with the product; publications, reports, assessments etc. are attached to the application
	  – the therapeutic value of the new product is assessed compared to other medicinal products and/or treatments with the same indication
	  o experience of use
	  – information on the extent to which the product is used and experience of use
	  o 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

Description	Specification
	○ treatment recommendations and systematic reviews – treatment recommendations and systematic reviews by a reliable, independent source (e.g. Duodecim, NICE, Cochrane) can be used for indicating the therapeutic value if they deal with the product of the application and the indication in question. 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 ○ with a normal treatment dosage ○ cost of treatment for a period of time essential for the treatment • treatment costs for the indications being applied for compared to products subject to reimbursement that are on the market and are used for treating the same disease • health economic evaluation ○ a health economic evaluation may be included in the application, if the applicant considers it necessary ○ the Pharmaceuticals Pricing Board gives further instructions on how to draw up a health economic evaluation on its website. Sales data and patient numbers • 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 ○ present the sales estimates for each pharmaceutical form, strength and package as well as by total sales of product (€) ○ the estimate of the sales and patient numbers is made for the current year and the following two years ○ the sales estimate applies to sales reimbursed under the Health Insurance Act • the actual sales reimbursed under the Health Insurance Act during the validity period of the previous decision ○ 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 (€) ○ if actual sales deviate significantly from those estimated in the previous application, give explanation on the deviation

Description	Specification

	• the table templates available on the website of the Pharmaceuticals Pricing Board should be used for reporting the sales data and patient numbers.
	
	Prices and reimbursement status in other European Economic Area states (EEA states)
	• 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
	  ○ if you do not provide price information for EEA states, include a relevant explanation of the missing prices
	  ○ prices should be in euros (€), using the exchange rates valid when submitting the application
	  ○ information on package sizes that are not marketed in Finland must also be given
	  ○ 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
	  ○ present a specification on in which EEA states the product is marketed as a product subject to marketing authorization and in which states subject to special licence
	• 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

Specifications required in a previous decision	Other specifications required by the Pharmaceuticals Pricing Board in its previous decision.
Other information	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) • changes in treatment practices, such as updated treatment guidelines; changes in treatment options; and summary of new clinical studies of the product carried out during the validity period in the indication being applied for and research publications • 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.

Submitting applications

Deliver the application and its attachments 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 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, • number of valid special licences and information on price formation, • 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 sales data and prices in EEA states, • other specifications required by the Pharmaceuticals Pricing Board in its previous decision.	pdf
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
Health economic evaluation	Health economic evaluation	pdf
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