



**APPLICATION INSTRUCTIONS
REIMBURSEMENT STATUS AND
WHOLESALE PRICE FOR A CLINICAL
NUTRITIONAL PREPARATION**

**APPLICATION FOR REIMBURSEMENT STATUS AND REASONABLE WHOLESALE PRICE
FOR A CLINICAL NUTRITIONAL PREPARATION**

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1 General

Reimbursement status and reasonable wholesale price for clinical nutritional preparations may be applied for from the Pharmaceuticals Pricing Board. Clinical nutritional preparations can be reimbursed when they are used in the treatment of a serious disease to replace or complement the diet or its part. The diseases in whose treatment costs of clinical nutritional preparations are reimbursed up to 40 or 65 per cent are specified in Government Decree.

Applications, which are delivered to the Pharmaceuticals Pricing Board, consist of an application form/s and their appendices. Fill in a separate form for each dosage form, but submit appendices for each product.

Application forms include information on

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

Other specifications, such as justifications for the application, sales estimates and information on prices and reimbursement status in other EEA state, are presented in appendices (Cf. section 3 for instructions).

Date and sign the application.

Deliver 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 the application form

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

Choose on the first page of the form, at the top on the right-hand side, what is applied for the clinical nutritional preparation. There are two alternatives:

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

Section 1 on the form. Applicant

Fill in the following data on the applicant:

- the applicant,
- the business identity code,
- contact information, and
- a contact person whom the Pharmaceuticals Pricing Board may contact.

Section 2 on the form. Product

Fill in the following data on the clinical nutritional preparation:

- the name of the product,
- the dosage form,
- the manufacturer,
- the importer, and
- the package sizes.

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 type of application in accordance with what is applied for the product. For instance, if the application concerns confirmation of reimbursement status and reasonable wholesale price choose the application type from the drop-down menu "Reimbursement status and reasonable wholesale price". The menu box "Wholesale price increase" is then left empty.

Examples of the types of application that can be chosen from among include: new preparation, new dosage form, renewed application, wholesale price increase.

In addition, specify the disease which is to be treated with this preparation by choosing it from the list on the form based on the Government Decree.

Section 5 on the form. Application appendices

Attach to the application all the required specifications (Cf. section 3 for instructions). The appendices attached to the application should be marked with an x on the form.

Section 6 on the form. 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 on the form. Consent

Messages and documents sent in an unsecure email connection on the basis of the consent given in the application will be sent to the email address of the contact person for the applicant specified in section 1 of the application form. On a case-by-case basis, the Pharmaceuticals Pricing Board will consider the submission of documents by applicants via email, and the Board may only ever send documents by post. The final decision on the application will always be delivered by post.

The use of email is always at the sender's own risk. The sender of an email message is responsible for the readability of the message, the delivery of the message and other comparable matters until the sender has been informed of the successful delivery of the message. The Pharmaceuticals Pricing Board will notify the sender when they have received the sender's email.

Section 8 on the form. Signature

The application form/s have to be signed.

3 Appendices to the application**a) Reimbursement status and wholesale price**

- Table of contents of the application
- A summary of the grounds presented in the application in regard to the preparation's reimbursement status and a proposal for a reasonable wholesale price
- A well-grounded proposal for reimbursement status for the clinical nutritional preparation in regard to the disease proposed by the applicant, a specification of the use of the preparation, and an itemized and well-grounded proposal for reasonable wholesale price
- A well-grounded estimate of the expected sales of the product on the basis on the proposed wholesale price
 - The sales estimates presented in the previous application and actual sales during the validity of a price confirmed by a decision; if the estimate given in the previous application differs significantly from actual sales, an explanation of the reasons for the difference must be provided
 - An estimate on sales at wholesale price (€) during the current year and the following three years for each dosage form and package, and there must also be an estimate of total sales
 - The table formats available from the website of the Pharmaceuticals Pricing Board can be used for reporting the information
 - The sales estimate concerns the sales reimbursed under the Health Insurance Act
- Product specification
- Valid wholesale prices and reimbursement bases in other states of the European Economic Area (EEA)
 - Wholesale prices for all package sizes, i.e. the purchasing prices that the pharmacies pay (not ex factory prices) in EEA states
 - Prices should be wholesale prices in euros (€), using the exchange rates valid at the time of application
 - Also provide information on package sizes that are not marketed in Finland
 - The table format available from the website of the Pharmaceuticals Pricing Board can be used for reporting the prices of EEA states
 - 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 in an appendix; The statement must report whether the preparation 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

- Other possible specifications
- Other specifications required by the Pharmaceuticals Pricing Board in its previous decision
- Other specifications that the applicant considers necessary
 - E.g. a specification of the preparation's research, product development and production costs to the extent to which the applicant wishes to appeal to them and 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)

b) Wholesale price increase

When applying for increase of the confirmed reasonable wholesale price for the 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 took place in circumstances affecting the price formation of the preparation while the wholesale price was in force. In addition, the appendices referred to in section a) must be appended to the application as appropriate; for instance, a statement of how the price increase would change the sales estimates.

4 Sending the application

Deliver the application with appendices 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*.

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

Appendices to application (from the application form):

Document	Name of the file	File format
- Table of contents of the application	Table of contents	pdf
The following Appendices to the application for reimbursement status are saved in one file:	Application memorandum	pdf

- A summary of the grounds presented in the application in regard to reimbursement status for the clinical nutritional preparation and a proposal for a wholesale price		
- A well-grounded proposal for reimbursement status for the clinical nutritional preparation in regard to the disease proposed by the applicant, a specification of the use of the preparation, and an itemized and well-grounded proposal for reasonable wholesale price		
- Product specification	Product specification	pdf
- A well-grounded estimate of the expected sales of the product on the basis of the proposed wholesale price	Sales estimates [The table format available on the website of the Pharmaceuticals Pricing Board can be used for submitting the information]	xls
- Valid wholesale prices and reimbursement bases in other states of the European Economic Area (EEA)	Prices in EEA states [The table format available on the website of the Pharmaceuticals Pricing Board can be used for submitting the information]	xls
- Other possible specifications	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_Smith" or "Source_1_ Smith]	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