PHARMACEUTICALS PRICING BOARD
Finland

APPLICATION FOR REIMBURSEMENT STATUS AND WHOLESALE PRICE IN THE REFERENCE PRICE SYSTEM FOR A MEDICINAL PRODUCT SUBJECT TO MARKETING AUTHORIZATION

- ☐ Basic reimbursement status
- ☐ Special reimbursement status
- ☐ Basic and special reimbursement status
  - ☐ Restricted basic reimbursement status
  - ☐ Restricted special reimbursement status

Date of arrival

Record No.

Clear | Print

1. Applicant	Marketing authorization holder					
	Applicant				Business ID	
	Contact person					
	Postal address					
	Telephone number					
	E-mail address					
2. Product	Name of the medicinal product					
	Strength					
	Dosage form					
	Active substance					
	ATC class			Product type		
	Date of issue of the marketing authorization			☐ The product is included in the Finnish Medicines Agency's (Fimea) list of interchangeable medicinal products		
	Validity period of patent or supplementary protection certificate expires (dd.mm.yyyy)					
	Package size					
	Marketing authorization number					
	Vnr number					
3. Wholesale price	Valid confirmed wholesale price, €					
	Proposed new wholesale price, €					

4. Application type	Basic reimbursement status
	Special reimbursement status
	Basic and special reimbursement status
	Proposed restriction / abolishment of restriction / extension of basic reimbursement status
	Proposed restriction / abolishment of restriction / extension of special reimbursement status
	Disease / -s under the Government decree for which special reimbursement status is sought:
	Higher special reimbursement
	☐ Anterior pituitary hypofunction ☐ Diabetes insipidus ☐ Diabetes mellitus, insulin-treated ☐ Thyroid insufficiency ☐ Adrenal cortical hypofunction ☐ Hypoparathyroidism ☐ Pernicious anaemia and other vitamin B12 absorption disorders ☐ Myasthenia gravis ☐ Multiple sclerosis ☐ Parkinson's disease and other comparable movement disorders ☐ Epilepsy and comparable convulsive disorders ☐ Severe psychotic and other severe mental disorders ☐ Behavioural disorders associated with mental retardation ☐ Glaucoma ☐ Breast cancer ☐ Prostate cancer ☐ Leukaemias and other malignant diseases of the blood and bone marrow as well as malignant diseases of the lymphatic system ☐ Trigeminal neuralgia or neuralgia of the glossopharyngeal nerve ☐ Hypogammaglobulinaemia ☐ Severe hypofunction of sexual glands ☐ Aplastic anaemia ☐ Chronic disorders of vitamin D metabolism ☐ Congenital metabolic disorders ☐ Chronic coagulation defects

	☐ Post-transplant conditions in organ or tissue transplants ☐ Cancers of female genital organs ☐ Idiopathic thrombocytopenia or granulocytopenia ☐ Other malignant tumours not separately mentioned under the Government decree ☐ Sarcoidosis ☐ Severe chronic pancreatic insufficiency ☐ General erythroderma ☐ Pemphigus ☐ Uraemia requiring dialysis ☐ Severe anaemia associated with chronic renal failure
	Lower special reimbursement
	☐ Chronic cardiac insufficiency ☐ Disseminated connective tissue diseases, rheumatoid arthritis and comparable conditions ☐ Chronic asthma and similar chronic obstructive pulmonary diseases ☐ Chronic hypertension ☐ Chronic coronary heart disease ☐ Chronic arrhytmias ☐ Ulcerative colitis and Crohn's disease ☐ Severe hereditary disorders of lipid metabolism (familial hypercholesterolaemia and type III dyslipoproteinaemia) ☐ Gout ☐ Dyslipidaemia associated with chronic coronary heart disease ☐ Severe and long-lasting narcolepsy ☐ Diabetes mellitus, non-insulin-treated
5. Application appendices	☐ Table of contents of the application ☐ Summary of the justifications presented in the application in regard to the reimbursement status for the product ☐ Valid summary of product characteristics ☐ Indications for which the medicinal product has been approved and for which reimbursement status is sought ☐ Copy of the valid marketing authorization decision ☐ Other itemized specifications regarded as necessary by the applicant
	When applying for an extension of reimbursement status append also the following specifications:
	☐ Benefits of reimbursement status compared with other medicinal products used for treating the same disease and with other treatments ☐ Clinical assessment by a marketing authorization authority regarding the benefits and risks of the product in the new indication ☐ Statement of the average daily dosage and the resulting medicinal treatment costs calculated on the basis of the maximum wholesale price and retail price including value added tax ☐ Statement of the cost-effectiveness of the medicinal product and a market forecast compared with other medicinal products used for treating the same disease ☐ Health economic evaluation ☐ Well-grounded estimate of the medicinal product's sales on the basis of the maximum wholesale price and retail price including value added tax and an estimate of the number of patients expected to use the product

	When applying for new special reimbursement status append the following specifications in addition to the above mentioned appendices:
	☐ Well-grounded proposal for the necessity and cost-effectiveness of the medicinal product. 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. ☐ Specification of the medicinal product's therapeutic value ☐ The treatment dosage of the medicinal product, the treatment costs of the product compared with products with special reimbursement status on the market and used for treating the same disease and market forecast on the cost effects of potential approval of special reimbursement status ☐ Itemized specification of the costs and benefits of the medicinal treatment and a report on the product's status in relation to alternative medicinal and other treatments
	☐ The Pharmaceuticals Pricing Board may use appendices that we submitted in the earlier application to decide on this application matter. List of appendices:
6. Invoicing	Invoicing address
	Contact details for invoicing
7. Consent	☐ In its contacts with the applicant the Pharmaceuticals Pricing Board may use unprotected e-mail communication in all matters related to the processing of this application, which may inlude secret information as referred to in section 24 (1) (20) of the Act on the Openness of Government Activities (Finlex 621/1999)
8. Signature	Place and date
	Signature
	Clarification of signature