



**APPLICATION FOR REIMBURSEMENT STATUS AND
WHOLESALE PRICE FOR A MEDICINAL PRODUCT
SUBJECT TO MARKETING AUTHORIZATION**

Basic reimbursement status and wholesale price

Date of arrival

Special reimbursement status and wholesale price

Basic and special reimbursement status and wholesale price

Record No.

Restricted basic reimbursement status

Restricted special reimbursement status

Wholesale price increase

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 wholesale price, €					

4. Application type	Basic reimbursement status and wholesale price
	Special reimbursement status and wholesale price
	Basic and special reimbursement status and wholesale price
	Wholesale price increase
	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
	<p>Anterior pituitary hypofunction</p> <p>Diabetes insipidus</p> <p>Diabetes mellitus, insulin-treated</p> <p>Thyroid insufficiency</p> <p>Adrenal cortical hypofunction</p> <p>Hypoparathyroidism</p> <p>Pernicious anaemia and other vitamin B12 absorption disorders</p> <p>Myasthenia gravis</p> <p>Multiple sclerosis</p> <p>Parkinson's disease and other comparable movement disorders</p> <p>Epilepsy and comparable convulsive disorders</p> <p>Severe psychotic and other severe mental disorders</p> <p>Behavioural disorders associated with mental retardation</p> <p>Glaucoma</p> <p>Breast cancer</p> <p>Prostate cancer</p> <p>Leukaemias and other malignant diseases of the blood and bone marrow as well as malignant diseases of the lymphatic system</p> <p>Trigeminal neuralgia or neuralgia of the glossopharyngeal nerve</p> <p>Hypogammaglobulinaemia</p> <p>Severe hypofunction of sexual glands</p> <p>Aplastic anaemia</p> <p>Chronic disorders of vitamin D metabolism</p> <p>Congenital metabolic disorders</p> <p>Chronic coagulation defects</p>

	<p>Post-transplant conditions in organ or tissue transplants</p> <p>Cancers of female genital organs</p> <p>Idiopathic thrombocytopenia or granulocytopenia</p> <p>Other malignant tumours not mentioned under the Government decree</p> <p>Sarcoidosis</p> <p>Severe chronic pancreatic insufficiency</p> <p>General erythroderma</p> <p>Pemphigus</p> <p>Uraemia requiring dialysis</p> <p>Severe anaemia associated with chronic renal failure</p> <p>Lower special reimbursement</p> <p>Chronic cardiac insufficiency</p> <p>Disseminated connective tissue diseases, rheumatoid arthritis and comparable conditions</p> <p>Chronic asthma and similar chronic obstructive pulmonary diseases</p> <p>Chronic hypertension</p> <p>Chronic coronary heart disease</p> <p>Chronic arrhythmias</p> <p>Ulcerative colitis and Crohn's disease</p> <p>Severe hereditary disorders of lipid metabolism (familial hypercholesterolaemia and type III dyslipoproteinaemia)</p> <p>Gout</p> <p>Dyslipidaemia associated with chronic coronary heart disease</p> <p>Severe and long-lasting narcolepsy</p> <p>Diabetes mellitus, non-insulin-treated</p>
5. Application appendices	<p>Table of contents of the application</p> <p>Summary of the justifications presented in the application in regard to the reimbursement status for the product and the proposed wholesale price</p> <p>Valid summary of product characteristics</p> <p>Indications for which the medicinal product has been approved and for which basic reimbursement status is sought</p> <p>Benefits of reimbursement status compared with other medicinal products used for treating the same disease and with other treatments</p> <p>Clinical assessment by a marketing authorization authority if the medicinal product's active medicinal substance or combination of medicinal substances is not used in products that have been granted reimbursement status</p> <p>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</p> <p>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</p> <p>Health economic evaluation</p> <p>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</p> <p>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</p> <p>Copy of the valid marketing authorization decision</p> <p>Other specifications required by the Pharmaceuticals Pricing Board in its previous decision</p> <p>Other itemized specifications regarded as necessary by the applicant</p>

	<p>When applying for special reimbursement status append the following specifications in addition to the above mentioned appendices:</p> <p>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.</p> <p>Specification of the medicinal product's therapeutic value</p> <p>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</p> <p>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</p> <p>Other possible specifications</p> <p>The Pharmaceuticals Pricing Board may use appendices that we submitted in the earlier application to decide on this application matter.</p> <p>List of appendices:</p>
6. Invoicing	<p>Invoicing address</p> <p>Contact details for invoicing</p>
7. Consent	<p>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 include secret information as referred to in section 24 (1) (20) of the Act on the Openness of Government Activities (Finlex 621/1999)</p>
8. Signature	<p>Place and date</p> <p>Signature</p> <p>Clarification of signature</p>