

No 1252

**DECREE OF THE MINISTRY OF SOCIAL AFFAIRS AND HEALTH
CONCERNING ACTIVITIES OF THE NATIONAL AGENCY FOR
MEDICINES SUBJECT TO FEES**

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No 1252

Decree of the Ministry of Social Affairs and Health
concerning activities of the National Agency for Medicines
subject to fees

Issued in Helsinki on 12 December 2007

Having regard to §8 of the Government Basis of Payment Act (150/92), passed on 21 February 1992, as amended on 16 May 1994 (348/1994), the Ministry of Social Affairs and Health has decided the following:

Fee-related activities carried out under public law

§1

Activities carried out under public law as referred to in § 6 of the Government Basis of Payment Act, for which the National Agency for Medicines charges the fixed fees noted in the Annex, reflecting the average costs of the activities, shall include:

- (1) Marketing authorisations, registrations and permissions to release medicinal products for consumption;
- (2) Variations and other activities relating to marketing authorisations and registrations
- (3) Other authorisations, decisions, certificates and notifications relating to the control of medicines
- (4) Scientific advice
- (5) Inspections of traders
- (6) Decisions, notifications and certificates concerning medical devices;
- (7) Copies of documents available only from the National Agency for Medicines.
- (8) Decisions of access to other documents than those referred to in § 9 and 11 of the Act of the Openness of Government Activities

Fees for activities, annual fees and variation fees mentioned under point 1 and 2 in the Annex may not be charged, if demand for the medicinal product is small but the need for the product is therapeutically compelling.

No fee shall be charged for processing of notification of a clinical trial of a medicinal product in human subjects by an individual investigator or group of investigators, or by a university department, university hospital department, or the National Public Health Institute, or the National Research and Development Centre for Welfare and Health if there is no external sponsorship or if it is funded by a public non-profit organisation. In these cases evidence of no sponsorship or funding by a public non-profit organisation must be included. Free medicines

donated for the clinical trial are not regarded as external sponsorship. The fee shall neither be charged for notifications of clinical trials in animals nor licences concerning narcotic drugs in veterinary clinical trials performed by permission of Animal Ethics Committee. The fee shall not be charged for decisions concerning narcotic drugs and classification of products needed by the police or customs authorities in their official duties.

§2

Fees previously referred to in §1 Subsection 1 shall be charged also in cases when the decision is negative.

Fees calculated on commercial principles

§3

Other activities referred to in §7 of the Government Basis of Payment Act for which the National Agency for Medicines fixes fees on commercial principles, include:

- (1) provision of information services relating to data and information systems, except when they concern minor instruction and guidance;
- (2) provision of educational and consultancy services;
- (3) conduct of investigations, studies, inspections and analyses undertaken on request;
- (4) provision of publications;
- (5) provision of other copies than those referred to in §1 Subsection 1 under point 6.

§3a

Referring to §34 Subsections 2 and 3 of the Act on the Openness of Government Activities The National Agency for Medicines shall decide on fees charged for providing the information and submitting copies or printouts considering the legal provisions in §34 of the same law.

§4

This Decree will be effective from 1 of January 2008 until 31 December 2009.

Helsinki, 12 December 2007

Minister of Social Affairs and Health

Liisa Hyssälä

Financial Secretary

Tuula Karhu

ANNEX

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(1) Marketing authorisations, registrations and permissions to release medicinal products for consumption	
Fee category I	
New active substance/known active substance (Dir.2001/83/EC article 8, Dir.2001/82/EC article 12)	
Applications based on well-established medicinal use (Dir. 2001/83/EC Article 10(a), Dir. 2001/82/EC Article 13(a))	
Applications for 'fixed combinations' (Dir. 2001/83/EC Article 10(b), Dir. 2001/82/EC Article 13(b))	
Applications for similar biological medicinal products (Dir. 2001/83 EC Article 10.4, Dir.2001/82/EC article 13.4)	
Marketing authorisation applications for homeopathic preparations with therapeutic indication (Dir. 2001/83/EC Article 16)	
for the first authorisation	9,500.00
each additional strength and/or pharmaceutical form,	4,000.00
Fee category II	
"Informed consent" applications (Dir. 2001/83/EC Article 10 c, Dir. 2001/82/EC Article 13 c)	
"Generic" applications (Dir. 2001/83/EC Article 10.1 Dir. 2001/82/EC Article 13.3)	
Hybrid abridged applications (Dir. 2001/83/EC Article 10.3, Dir 2001/82/EC Article 13.3)	
Registrations for traditional herbal medicinal products (Dir. 2004/24/EC)	
Marketing authorisation applications for herbal medicinal products for which Community herbal monograph exists (Dir 2004/27/EC Article 10 a)	
for each authorisation or registration applied	4,000.00

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Immunological veterinary medicinal products	
for each authorisation applied	1,100.00
Extensions	
(Commission Regulation (EC) No 1084/2003, Annex II)	
for each authorisation or registration applied	4,000.00
Extra fee is charged in cases of Finland acting as a Reference Member State in the Mutual Recognition Procedure (MRP) or in Decentralised Procedure (DCP)	
One procedure covers all pharmaceutical forms and/or strengths of the same trade name. The fee is charged for each procedure. If the number of procedures started simultaneously for the same product (under different trade names) is more than three, only three fees are collected	
The fee is charged before initiation of the MRP- or DCP-procedure	9,000.00
Marketing authorisation applications for homeopathic preparations without therapeutic indication	
(Dir.2001/83/EC Article 16, Dir.2001/82/EC Article 19)	
including extensions	1,680.00
Registrations for homeopathic preparations	
(Dir 2001/83/EC Article 14, Dir. 2001/82/EC Article 17)	
preparations with 1-5 homeopathic stocks	850.00
preparations with more than 5 homeopathic stocks	1,100.00
Extra fee is charged in cases of Finland acting as a Reference Member State in the Mutual Recognition Procedure (MRP) or in Decentralised Procedure (DCP)	
One procedure covers all pharmaceutical forms and/or strengths of the same trade name. The fee is charged for each procedure. If the number of procedures started simultaneously for the same product (under different trade names) is more than three, only three fees are collected	
The fee is charged before initiation of the MR-or DCP- procedure	9,000.00
Marketing authorisation for a parallelly imported medicinal product for the first country of acquisition	1,680.00
each additional country of acquisition	755.00

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Permission for release for consumption of a medicinal product as referred to in § 21 f of the Medicines Act (licence for compassionate use)	10.00
(2) Variations and other activities relating to marketing authorisations	
Type II variations (Commission Regulation (EC) nr 1084/2003)	
Change of therapeutic use	3,750.00
Other type II variations excluding applications for a change of the cycle in submitting periodic safety update reports (PSURs); these applications are free of charge	600.00
Transfer of marketing authorisation or registration to a new holder	170.00
The fee is charged for each marketing authorisation or registration. In the event of the same variation being applied to another pharmaceutical form and/or strength of the same trade name, the fee shall be charged for only one marketing authorisation or registration.	
Extra fee is charged for type II variations and for renewals in cases of Finland acting as a Reference Member State in the Mutual Recognition Procedure (MRP)	
One procedure covers all pharmaceutical forms and/or strengths of the same trade name. The fee is charged for each MR-procedure. If the number of MR-procedures started simultaneously for the same product (under different trade names) is more than three, only three fees are collected	1,500.00
Annual fees	
Medicinal product referred to in §21-21 c and §21 e of the Medicines Act	970.00
Registered traditional herbal medicinal product	200.00
Herbal medicinal products and registered and authorised homeopathic and antroposophic products	100.00
Medicinal product subject to parallel import	420.00

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The fee is charged for each authorisation and registration.	
The annual fee is intended to cover costs associated with maintenance of the registers, drug information produced by the National Agency for Medicines, pharmacovigilance activities including evaluation of periodic safety update reports, processing of notifications of product defects, renewal of marketing authorisation or registration , supervision of advertising of medicinal products, processing of variations excluding those mentioned above, maintenance of the ATC classification and DDD dose registers, and compilation of statistics concerning consumption of medicinal products. The fee is calculated on the basis of the average costs of the above-mentioned activities per marketing authorisation or registration.	
(3) Other authorisations, decisions, certificates and notifications relating to the control of medicines;	
Certificates relating to exportation, industrial manufacture and wholesale of medicinal products	40.00
Processing of notifications concerning clinical trials on medicinal products for human use	1,350.00
Authorisations of clinical trials on medicinal products for human use	1,450.00
Decision concerning classification of products	85.00
Licences relating to industrial manufacture of medicinal products, pharmaceutical wholesaling, blood transfusion, tissue establishment, contract laboratory and manufacture for clinical trials	
Pharmaceutical manufacturing licence	1,200.00
Pharmaceutical wholesale licence	200.00
Licences relating to blood transfusion, tissue establishment, contract laboratory and manufacture for clinical trials	450.00
Change to the above licences, import and export licences concerning tissue establishment or blood transfusion	100.00
Inspection fee is charged in case of application for the licence or change to the licence requires pre-inspection	
Pharmacy licence	1,685.00

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Licence to operate a subsidiary pharmacy	840.00
Approval of establishment of a hospital pharmacy or dispensary	420.00
Permission to distribute medicinal products referred to in §62 of the Medicines Act except for that concerning the treatment of an individual patient or vaccines used in prevention of diseases as referred to in Contagious Diseases Act	420.00
Permission to keep stocks lower than obligatory reserve levels for the supply of medicinal products, exemption from reserve-supply obligation, or storage of an active substance instead of a medicinal product	40.00
Licences concerning narcotic drugs and substances used in the illicit manufacture of narcotic drugs except for that concerning the treatment of an individual patient	100.00
(4) Scientific advice human medicinal products	1,360.00
(5) Inspection of traders:	
Inspection of pharmaceutical plant	
One-day	1,200.00
Each extra day	400.00
For inspections abroad travel expenses will be charged extra on the basis of the actual cost	
Inspection of pharmaceutical wholesaler	
Wholesaler engaging in storage and distribution of medicinal products of several pharmaceutical manufacturers/importers	950.00
Wholesaler engaging only in importation or storage and distribution of medicinal products imported by itself and wholesaler engaging only in storage and distribution of medicinal gases	350.00
Inspection of blood transfusion, tissue establishment, contract laboratory and manufacturer for clinical trials	500.00

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Inspection of pharmacy, hospital pharmacy, military pharmacy and dispensary	800.00
Inspection of subsidiary pharmacy	400.00
Inspections of a laboratory as referred to in §57 of the Chemicals Act	
Approval related inspection of long duration	5,045.00
Approval related inspection of short duration	3,365.00
Changes related inspection of short duration	840.00
(6) Decisions, notifications and certificates concerning medical devices;	
Decisions concerning application of the Medical Devices Act referred to in § 30 under point 1 and decisions concerning classification of products referred to in §30 under point 2 of the Medical Devices Act	85.00
Exemption permit referred to in §30 under point 4 of the Medical Devices Act	1,680.00
Notifications concerning clinical investigations of medical devices	
Class A (non-risk products)	335.00
Class B (risk products)	840.00
Certificates relating to exportation of medical devices each duplicate issued simultaneously	85.00 15.00
(7) Copies of documents available only from the National Agency for Medicines; for each 10 pages or part thereof	5.00
(8) Decisions of access to other documents than those referred to in § 9 and 11 of the Act of the Openness of Government Activities	500.00