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Unofficial translation

THE STATUTES OF FINLAND

Adopted in Helsinki on 27 March 2014

252/2014

Decree of the Ministry of Social Affairs and Health
On fees chargeable by the Finnish Medicines Agency

Adopted in Helsinki on 28 March 2013

In accordance with Decision of the Ministry of Social Affairs and Health under Section 8 of the Act on Criteria for Charges Payable to the State (150/1992) as provided in Act 348/1994, the following provisions are laid down:

Section 1

Fees chargeable under public law

Fees chargeable under public law as defined in Section 6 of the Act on Criteria for Charges Payable to the State (150/1992), for which the Finnish Medicines Agency charges fixed fees corresponding to the average costs of the services according to the enclosed fee table, include the following:

1) marketing authorisations, registrations and special licences for medicinal products;

2) variations of medicinal products and other charges relating to medicinal products;

3) other authorisations, decisions, certificates and notifications relating to pharmacovigilance;

4) scientific advice;

5) inspections concerning the conducting of operations;

6) processing the application for approval of an authorised test laboratory as referred to in section 24 of the Chemicals Act (599/2013);

7) operating permits required under Section 20 b of the Act on the Medical Use of Human Organs and Tissues (101/2001);

8) operating permits required under Section 4 of the Blood Service Act (197/2005);

9) copies of original decisions or of corresponding documents kept at the Finnish Medicines Agency;

10) decisions concerning access to a document other than documents under Sections 9 and 11 of the Act on the Openness of Government Activities (621/1999).

The charge made for a service as referred to in paragraph 1 or 2 of the appendix or the special authorisation fee referred to in paragraph 4 may be waived if the sales of the medicinal product are negligible and the medicinal product is considered essential for treatment.

Section 2

Non-chargeable fees

No charge is payable for

1) processing and reviewing a notification relating to clinical trials on medicinal products in human subjects or clinical trials on veterinary medicinal products or animals conducted by an individual investigator, a trial group, a university department, a university hospital clinic, a university veterinary hospital or the National Institute for Health and Welfare if the trial has no outside financing or is financed by a non-profit organisation;

2) narcotics licences needed for animal experiments authorised by the Animal Experiment Board;

3) narcotics licences needed by the police, customs authorities or customs laboratories engaged in official duties, or for decisions concerning the classification of medicinal products.

In cases set out in subsection 1 of paragraph 1 the trial notification must be accompanied by a statement to the effect that the trial will not receive any outside financing or that outside financing will be provided by a non-profit organisation. Medicinal products received free of charge for the purpose of the trial are not considered as outside financing.

Section 3

Collection of charges in certain situations

The charges defined in subsection 1 of Section 1 will also be made if a negative decision is given on the application referred to in the said subsection.

Section 4

Services priced according to commercial criteria

Other services as referred to in Section 7 of the Act on Criteria for Charges Payable to the State, which the Finnish Medicines Agency prices according to commercial criteria, include the following:

1) information services relating to data and information systems, except for minor guidance and advice;

2) education and consultation services;

3) specially ordered reports, investigations, inspections and analyses;

4) publications;

5) copies.

Section 5

Other charges

Charges made for information retrieval as referred to in subsection 2 of Section 34 of the Act on the Openness of Government Activities, and for providing copies and printouts, as defined in subsection 3 of Section 34 of the same Act, are decided by the Finnish Medicines Agency, taking into account the terms set out in Section 34 of the Act on the Openness of Government Activities.

Section 6

Entry into force

This Decree enters into force on 1 April 2014 and will remain in force until 31 March 2015.

Fees concerning matters presented before the Decree's entry into force will be charged according to the regulations current at the time this Decree entered into force.

Minister of Social Affairs and Health *Paula Risikko*

Ministerial Secretary Ulla Närhi

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Appendix

1 MEDICINAL PRODUCTS INTENDED FOR HUMAN USE

1.1 MARKETING AUTHORISATION AND REGISTRATION APPLICATIONS FOR MEDICINAL PRODUCTS INTENDED FOR HUMAN USE

1.1.1. National marketing authorisation and registration procedure for medicinal products intended for human use	
▪ New active substance/known active substance (Dir. 2001/83/EC article 8) ▪ Applications based on established medicinal use (Dir. 2001/83/EC article 10 (a)) ▪ Combination products (Dir. 2001/83/EC article 10(b)) ▪ Applications for similar biological medicinal products (Dir. 2001/83/EC article 10.4) ▪ Homeopathic products subject to marketing authorisation for which a medicinal purpose is stated (Dir. 2001/83/EC article 16) **For the first marketing authorisation applied for**	€ 13,000
Subsequent pharmaceutical forms or strengths	€ 8,000
▪ Applications where the applicant has obtained the consent of the original marketing authorisation holder to refer to the marketing authorisation documentation (Dir. 2001/83/EC article 10c) ▪ Generic products (Dir. 2001/83/EC article 10.1) ▪ Abridged applications of mixed type (Dir. 2001/83/EC article10.3) **For each marketing authorisation or registration applied for**	€ 8,000
▪ Traditional herbal medicinal products to be registered (Dir. 2004/24/EC) ▪ Herbal medicinal products subject to marketing authorisation for which a community monograph exists (Dir. 2004/27/EC article 10 a) **For each marketing authorisation or registration applied for**	€ 6,000
▪ Extensions to a marketing authorisation and registration (Commission Regulation (EC) no 1234/2008) **For each marketing authorisation or registration applied for**	€ 8,000
▪ Homeopathic products subject to marketing authorisation for which no medicinal purpose is stated (Dir. 2001/83/EC article 16) including marketing authorisation extensions	€ 2,100
▪ Homeopathic products subject to registration (Dir. 2001/83/EC article 14) including registration extensions **Products containing 1 to 5 stock substances**	€ 950
Products containing more than 5 stock substances	€ 1,200

1.1.2. Mutual recognition procedure or decentralised procedure for medicinal products intended for human use, Finland as a Concerned Member State	
▪ New active substance/known active substance (Dir. 2001/83/EC article 8) ▪ Applications based on established medicinal use (Dir. 2001/83/EC article 10 (a)) ▪ Combination products (Dir. 2001/83/EC article 10(b)) ▪ Applications for similar biological medicinal products (Dir. 2001/83 EC article 10.4) ▪ Homeopathic products subject to marketing authorisation for which a medicinal purpose is stated (Dir. 2001/83/EC article 16) **For the first marketing authorisation applied for** **Subsequent pharmaceutical forms or strengths**	 € 10,000 € 6,000
▪ Applications where the applicant has obtained the consent of the original marketing authorisation holder to refer to the marketing authorisation documentation (Dir. 2001/83/EC article 10c) ▪ Generic products (Dir. 2001/83 EC article 10.1) ▪ Abridged applications of mixed type (Dir. 2001/83/EC article10.3) **For each marketing authorisation or registration applied for**	 € 6,000
▪ Traditional herbal medicinal products to be registered (Dir. 2004/24/EC) ▪ Herbal medicinal products subject to marketing authorisation for which a community monograph exists (Dir. 2004/27/EC article 10a) **For each marketing authorisation or registration applied for**	 € 6,000
▪ Extensions to a marketing authorisation and registration (Commission Regulation (EC) no 1234/2008) **For each marketing authorisation or registration applied for**	 € 6,000
Homeopathic products subject to marketing authorisation for which no medicinal purpose is stated (Dir. 2001/83/EC article 16) including marketing authorisation extensions	€ 2,100
▪ Homeopathic products subject to registration (Dir. 2001/83/EC article 14) including registration extensions **Products containing 1 to 5 stock substances** **Products containing more than 5 stock substances**	 € 950 € 1,200

1.1.3. Mutual recognition procedure or decentralised procedure for medicinal products intended for human use, Finland as a Reference Member State	
Process fee for a mutual recognition procedure The process fee includes all pharmaceutical forms and/or strengths of the same trade name. The charge is payable for each process separately.	€ 12,000

Process fee for a decentralised procedure	€ 12,000
The process fee is payable as follows:	
Upon approval of a schedule request	€ 1,500
Upon process initiation	€ 10,500
In addition to the process fee, a basic fee according to section 1.1.1 (National marketing authorisation and registration procedure for medicinal products intended for human use).	
The process fee includes all pharmaceutical forms and/or strengths of the same trade name. The charge is payable for each process separately.	
The fee payable upon approval of a schedule request will not be returned in the event of a cancellation.	

1.1.4. Marketing authorisation for medicinal products intended for human use, parallel import	
For the first country of acquisition	€ 1,900
For each subsequent country of acquisition	€ 1,100

1.2. VARIATION APPLICATIONS FOR MEDICINAL PRODUCTS INTENDED FOR HUMAN USE

The fees mentioned below will be charged separately for each marketing authorisation and registration. If the same variation of other pharmaceutical forms and/or strengths of the same trade name is being applied for in one application, the fee will only be charged for one marketing authorisation or registration. **In the grouping of the variations, the handling fee pursuant to the Decree will be payable for each variation.** This does not apply to a grouped application for variations concerning the trade name, for which only one handling fee is payable. **In the worksharing procedure, the handling fee pursuant to the Decree is payable for each variation applied for.**

1.2.1. National marketing authorisation or registration of medicinal products intended for human use	
▪ Type II variations (Commission Regulation (EC) No 1234/2008)	
Addition to therapeutic indication	€ 4,000
Other type II variations	€ 1,000
Type IB variations	€ 500

1.2.2. Mutual recognition procedure for medicinal products intended for human use, Finland as a Concerned Member State	
▪ Type II variations (Commission Regulation (EC) No 1234/2008)	
Addition to therapeutic indication	€ 3,000

Other type II variations	€ 800
Type IB variations	€ 400

1.2.3. Mutual recognition procedure for medicinal products intended for human use, Finland as a Reference Member State	
Type II variations (Commission Regulation (EC) No 1234/2008) **In addition to the process fee, a variation application charge in accordance with** **section 1.2.1** (National marketing authorisation or registration of medicinal products intended for human use).	€ 2000
Worksharing procedure **In addition to the process fee, a variation application charge in accordance with section 1.2.1** (National marketing authorisation or registration of medicinal products intended for human use).	€ 4,000
Type IB variations **In addition to the process fee, a variation application charge in accordance with section 1.2.1** (National marketing authorisation or registration of medicinal products intended for human use).	€ 1,000
Type IA variations **No separate variation application fee**.(section 1.3).	€ 500
Type IA grouped variation applications including more than one process (FI/H/XXXX/IA/G) **No separate variation application (section 1.3)** For grouped variation applications, the process fee is paid once on the basis of the most significant variation.	€ 1,000

1.2.4. Parallel import of medicinal products intended for human use	
Type II variations (Commission Regulation (EC) no 1234/2008)	€ 600
Type IB variations	€ 300

1.2.5. Transfer of marketing authorisation or registration holder of medicinal products intended for human use	
Transfer of a marketing authorisation and registration to a new holder	€ 200

1.3. ANNUAL CHARGES FOR MEDICINAL PRODUCTS INTENDED FOR HUMAN USE

▪ Medicinal products referred to in Sections 21–21c and 21e of the Finnish Medicines Act	€ 1,350
▪ Parallel import products	€ 680
▪ Registered, traditional herbal medicinal products	€ 200
▪ Herbal medicinal products, homeopathic and anthroposophic products subject to marketing authorization	€ 200
▪ Registered homeopathic and anthroposophic products	€ 200
▪ The fee is charged for each procedure. ▪ The annual fee includes the cost of register maintenance, medical information produced by the Finnish Medicines Agency, adverse effect monitoring with the associated PSURs, processing of product defects, marketing authorisation or registration renewal, processing of Type IA applications, monitoring of medicinal product advertising, processing of variations other than those mentioned above, maintenance of ATC classification and dose registers (DDD), and medicine consumption statistics. The fee is determined according to the average costs of the above-mentioned services for each marketing authorization or registration.	

1.4. RENEWAL OF A MARKETING AUTHORIZATION OF A MEDICINAL PRODUCT INTENDED FOR HUMAN USE

1.4.1 Mutual recognition procedure for medicinal products intended for human use, Finland as a Reference Member State	
A charge is payable for renewal when Finland acts as a Reference Member State in the mutual recognition procedure The process fee includes all pharmaceutical forms and/or strengths of the same trade name. The charge is payable for each process separately.	€ 2,000

1.5. APPLICATION FOR WAIVER OF THE MARKETING AUTHORIZATION AND REGISTRATION OF A MEDICINAL PRODUCT INTENDED FOR HUMAN USE

1.5.1 Application for waiver of the marketing authorization and registration of medicinal products under section 29, sub-section 3 of the Medicines Act	
Application for waiver (sunset clause) The fee includes all pharmaceutical forms and/or strengths of the trade name.	€ 100

2. MEDICINAL PRODUCTS INTENDED FOR VETERINARY USE

2.1. MARKETING AUTHORIZATION AND REGISTRATION APPLICATIONS FOR MEDICINAL PRODUCTS INTENDED FOR VETERINARY USE:

2.1.1. National marketing authorisation or registration procedure for medicinal products intended for veterinary use	
▪ New active substance/known active substance (Dir. 2001/82/EC article 12) ▪ Applications based on established medicinal use (Dir. 2001/82/EC article 13 (a)) ▪ Combination products (Dir. 2001/82/EC article 13(b)) ▪ Applications for similar biological medicinal products (Dir. 2001/82/EC article 13.4) **For the first marketing authorisation applied for** **Subsequent pharmaceutical forms or strengths**	 € 9,750 € 6,000
▪ Applications where the applicant has obtained the consent of the original marketing authorisation holder to refer to the marketing authorisation documentation (Dir. 2001/82/EC article 13c) ▪ Generic products (Dir. 2001/82/EC article 13.3) ▪ Abridged applications of mixed type (Dir. 2001/82/EC article 13.3) **For each marketing authorization applied for**	 € 6,000
▪ Extensions to a marketing authorization (Commission Regulation (EC) no 1234/2008) **For each marketing authorization applied for**	 € 6,000
▪ Homeopathic products subject to marketing authorization, for which no medicinal purpose is stated (Dir 2001/82/EC Article 19) including extensions of marketing authorizations	€ 1,680
▪ Homeopathic products subject to registration (Dir 2001/82/EC Article 17) including registration extensions **Products containing 1–5 stock substances** **Products containing more than 5 stock substances**	 € 850 € 1,100

2.1.2. Mutual recognition procedure or decentralised procedure for medicinal products intended for veterinary use, Finland as a Concerned Member State	
▪ New active substance/known active substance (Dir. 2001/82/EC article 12) ▪ Applications based on established medicinal use (Dir. 2001/82/EC article 13 (a)) ▪ Combination products (Dir. 2001/82/EC article 13(b)) ▪ Applications for similar biological medicinal products (Dir. 2001/82/EC article 13.4) **For the first marketing authorisation applied for** **Subsequent pharmaceutical forms or strengths**	€ 9,500 € 4,500

▪ Applications where the applicant has obtained the consent of the original marketing authorisation holder to refer to the marketing authorisation documentation (Dir. 2001/82/EC article 13c) ▪ Generic products (Dir. 2001/82 EC article 13.3) ▪ Abridged applications of mixed type (Dir. 2001/82/EC article13.3) **For each marketing authorization applied for**	€ 4,500
▪ Extensions of a marketing authorization (Commission Regulation (EC) no 1234/2008) **For each marketing authorization applied for**	€ 4,500
▪ Homeopathic products subject to marketing authorization, for which no medicinal purpose is stated (Dir 2001/82/EC Article 19) including extensions of marketing authorizations	€ 1,680
▪ Homeopathic products subject to registration (Dir 2001/82/EC Article 17) including extensions of registration. **Products containing 1–5 stock substances** **Products containing more than 5 stock substances**	€ 850 € 1,100

2.1.3. Mutual recognition procedure or decentralised procedure for medicinal products intended for veterinary use, Finland as a Reference Member State	
Process fee for a mutual recognition procedure The process fee includes all pharmaceutical forms and/or strengths of the same trade name. The charge is payable for each process separately. **Process fee for a decentralised procedure** **The process fee is payable as follows:** **Upon approval of a schedule request** **Upon process initiation** In addition to the process fee, a basic fee according to section 2.1.1. (**National marketing authorisation or registration procedure for medicinal products intended for veterinary use).** The process fee includes all pharmaceutical forms and/or strengths of the same trade name. The charge is payable for each process separately. The fee payable upon approval of a schedule request will not be returned in the event of a cancellation.	€ 12,000 € 12,000 € 1,500 € 10,500

2.2. VARIATION APPLICATIONS FOR MEDICINAL PRODUCTS INTENDED FOR VETERINARY USE

The fees mentioned below will be charged separately for each marketing authorisation and registration. If the same variation of other pharmaceutical forms and/or strengths of the same trade name is being applied for in one application, the fee will only be charged for one marketing authorisation or registration. **In the grouping of the variations, the handling fee pursuant to the Decree will be payable for each variation.** This does not apply to a grouped application for variations concerning the trade name, for which only one handling fee is payable. **In the worksharing procedure, the handling fee pursuant to the Decree is payable for each variation applied for.**

2.2.1. National marketing authorization and registration of medicinal products intended for veterinary use	
Type II variations (Commission Regulation (EC) no 1234/2008) ▪ **Addition to therapeutic indication or variation to withdrawal period** ▪ **Other type II variations** **Type IB variations**	 € 3,750 € 750 € 375

2.2.2. Mutual recognition procedure for medicinal products intended for veterinary use, Finland as a Concerned Member State	
Type II variations (Commission Regulation (EC) no 1234/2008) ▪ **Addition to therapeutic indication or variation to withdrawal period** ▪ **Other type II variations** **Type IB variations**	 € 3,000 € 600 € 300

2.2.3. Mutual recognition procedure for medicinal products intended for veterinary use, Finland as a Reference Member State	
Type II variations (Commission Regulation (EC) No 1234/2008) **In addition to the process fee, a variation application fee in accordance with section 2.2.1** (National marketing authorization and registration of medicinal products intended for veterinary use).	€ 2,000
Worksharing procedure **In addition to the process fee, a variation application fee in accordance with section 2.2.1** (National marketing authorization and registration of medicinal products intended for veterinary use).	€ 4,000
Type IB variations **In addition to the process fee, a variation application fee in accordance with section 2.2.1** (National marketing authorization and registration of medicinal products intended for veterinary use).	€ 1,000
Type IA variations **No separate variation application** (section 2.3).	€ 500
Type IA grouped variation applications including more than one process (FI/V/XXXX/IA/G) **No separate variation application fee (section 2.3)** For grouped variation applications, the process fee is paid once on the basis of the most significant variation.	€ 1,000

2.2.4. Transfers of marketing authorization or registration holder of medicinal products intended for veterinary use	
Transfer of a marketing authorization and registration to a new holder.	€ 200

2.3. ANNUAL CHARGES FOR MEDICINAL PRODUCTS INTENDED FOR VETERINARY USE

Medicinal products intended for veterinary use referred to in Sections 21–21c and 21e of the Finnish Medicines Act	€ 1,200
Homeopathic and anthroposophic products registered for veterinary use and subject to marketing authorization	€ 200
The fee is charged for each procedure. The annual fee includes the cost of register maintenance, medical information produced by the Finnish Medicines Agency, adverse effect monitoring with the associated PSURs, processing of product defects, marketing authorisation or registration renewal, processing of Type IA applications, monitoring of medicinal product advertising, processing of variations other than those mentioned above, maintenance of ATC classification and dose registers (DDD), and medicine consumption statistics. The fee is determined according to the average costs of the above-mentioned services for each marketing authorisation or registration.	

2.4. RENEWAL OF MARKETING AUTHORIZATIONS FOR MEDICINAL PRODUCTS INTENDED FOR VETERINARY USE

2.4.1 Mutual recognition procedure for medicinal products intended for veterinary use, Finland as a Reference Member State	
A charge is payable for renewal when Finland acts as a Reference Member State in the mutual recognition procedure The process fee includes all pharmaceutical forms and/or strengths of the same trade name. The charge is payable for each process separately.	€ 2,000

2.5. APPLICATION FOR WAIVER OF THE MARKETING AUTHORIZATION AND REGISTRATION OF A MEDICINAL PRODUCTS INTENDED FOR VETERINARY USE UNDER SECTION 29, SUB-SECTION 3 OF THE MEDICINES ACT

2.5.1 Application for waiver of the marketing authorization and registration of medicinal products under section 29, sub-section 3 of the Medicines Act	
Application for waiver (sunset clause) The fee includes all pharmaceutical forms and/or strengths of the trade name	€ 100

3. SCIENTIFIC ADVICE

Scientific advice on medicinal products intended for human use.	€ 2,500
Scientific advice on medicinal products intended for veterinary use.	€ 750

4. SPECIAL AUTHORIZATIONS AND CLASSIFICATION

Authorization referred to in Section 21 (f) of the Medicines Act	€ 12
Special authorizations requiring urgent processing	€ 18
Product classification decisions	€ 150

5. EXPORT CERTIFICATES

Certificates concerning the export, industrial manufacture and wholesale of medicines	€ 50

6. OTHER AUTHORIZATIONS, DECISIONS, CERTIFICATES AND NOTIFICATIONS RELATING WITH PHARMACOVIGILANCE

Processing of notifications concerning clinical research studies	€ 2,200
Processing of notifications concerning veterinary clinical research studies	€ 750
Processing of authorisations concerning clinical research studies	€ 2,500
Licences for the industrial manufacture of medicines, pharmaceutical wholesaling, blood as well as tissue services, and manufacturing authorisations for units that manufacture medicinal products for clinical trials or contract analytical laboratories and changes to them:	
▪ Pharmaceutical manufacturing licence	€ 3,000
▪ Pharmaceutical wholesale licence	€ 1,750
▪ Pharmaceutical wholesale licence for anthroposophic and homeopathic products	€ 1,000
▪ Registration of a medicine distributor	€ 1,000
Operating licences for blood and tissue services, units producing pharmaceuticals for clinical research studies and laboratories engaged in contract analysis and licences other than industrial manufacturing licences for pharmaceuticals used in advanced therapy and changes to them.	€ 1,500
Import and export licences relating to tissue or blood services	€ 100
If the application for an operating licence or for changes to an operating licence requires preliminary inspection, a separate charge is made for this	
▪ Pharmacy licence	€ 5,000
▪ Auxiliary pharmacy licence	€ 2,500
▪ Running an auxiliary pharmacy as a condition for licence	€ 2,500
▪ Pharmacy service point licence	€ 1,500
▪ Running a pharmacy service point as a condition for licence	€ 1,500
▪ Short-term pharmacy service point licence (duration less than 1 month)	€ 500
▪ Processing of pharmacy online service notifications	€ 1,000
▪ Extension of the time limit granted for pharmacy business	€ 1,000
▪ Granting a pharmacy licence on the basis of section 54:2 of the Medicines Act	€ 5,000
▪ Changing the location of an auxiliary pharmany at the licence holder’s request	€ 2,500
▪ Licence for non-industrial manufacture under section 12a of the Medicines Act	€ 2,000

▪ Authorisation to establish a hospital pharmacy or dispensary	€ 1,500
A licence to supply medicinal products as referred to in Section 62 of the Finnish Medicines Act, except for the supply of medicines for the treatment of an individual patient or for the supply of vaccines for the prevention of communicable diseases under the Communicable Diseases Act	€ 1,000
A licence to store less medicines than the statutory minimum for each product applied for and exemption from maintaining obligatory supplies of medicines, and a licence to store medicinal agents instead of medicinal products	€ 600
Licences and decisions in accordance with narcotics legislation including decisions on notification regarding conducting of operations, decisions relating to persons in charge, and licences concerning substances used in drug manufacturing with the exception of licences needed for the treatment of an individual patient Certificates of free sale for medicines, narcotics and narcotics precursors for import required by other countries and the registration of precursor users as specified in Article 3 of regulation (EC) 273/2004.	€ 200 € 100
Decision concerning approval of a GLP testing laboratory and changes in the decision.	€ 1,000

7. INSPECTIONS CONCERNING CONDUCTING OF OPERATIONS

Inspection of a pharmaceutical or excipient manufacturer ▪ One day ▪ Additional days or inspection based on documents In addition, the actual travel costs will be charged for inspections abroad.	 € 5,000 € 2,500
Inspection of a pharmaceutical wholesaler ▪ One day ▪ Additional days Inspection of an anthroposophic or homeopathic product wholesaler or inspection of the medicinal product distributor ▪ One day ▪ Additional days or inspection of medicinal product wholesale or distribution based on documents	 € 4,000 € 2,000 € 2,000 € 1,000
Inspection of blood and tissue services, organ transplantation centres, units that manufacture clinical-trial medicinal products and contract analytical laboratories as well as inspections relating to the manufacturing authorisation of advanced therapy medicinal products manufactured under a national manufacturing authorization ▪ One day ▪ Additional days	 € 1,200 € 600
Inspection of tissue services on the basis of documents and inspection of an organ donation hospital	€ 500
Inspection of a pharmacy, hospital pharmacy, military pharmacy or dispensary	

▪ One day ▪ Additional days	€ 3,000 € 1,500
Inspection of an auxiliary pharmacy Pharmacy inspection on site, duration maximum 4 hours, or a pharmacy inspection based on documents	€ 1,500 € 1,500
Inspection concerning the approval or supervision of a GLP test laboratory ▪ One day ▪ Additional days A charge is payable for the following inspections where the inspection is not carried out under the Medicines Act:	 € 4,000 € 2,000
Inspections performed in accordance with narcotics legislation ▪ One day ▪ Additional days	 € 2,000 € 1,000
Inspections concerning a licence to store less medicines than the statutory minimum ▪ One day ▪ Additional days	 € 2,000 € 1,000
Inspections concerning clinical research studies ▪ One day ▪ Additional days	 € 4,000 € 2,000
Inspection concerning pharmacovigilance of the marketing authorisation holder ▪ One day ▪ Additional days	 € 4,000 € 2,000

8. COPIES OF ORIGINAL DECISIONS OR CORRESPONDING DOCUMENTS KEPT AT THE FINNISH MEDICINES AGENCY

per each 10 pages or part thereof per each 10 pages or part thereof requiring confidentiality	€ 5 € 10

9. DECISIONS CONCERNING SHARING INFORMATION FROM DOCUMENTS OTHER THAN THOSE UNDER SECTIONS 9 AND 11 OF THE ACT ON THE OPENNESS OF GOVERNMENT ACTIVITIES

Decisions concerning sharing information from documents other than those under Sections 9 and 11 of the Act on the Openness of Government Activities	€ 500