Decree of the Ministry of Social Affairs and Health

on fees chargeable by the Finnish Medicines Agency

By decision of the Ministry of Social Affairs and Health and under section 8 of the Act on Criteria for Charges Payable to the State (150/1992), section 28 of the Medicines Act (395/1987) and section 6a of the Act on the Finnish Medicines Agency (593/2009), as they appear in section 8 of the Act on Criteria for Charges Payable to the State in Act 348/1994, section 28 of the Medicines Act in Act 773/2009 and in section 6a of the Act on the Finnish Medicines Agency in Act 1480/2019, the following is enacted:

Section 1

Performances chargeable under public law

Performances 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 that correspond to the average costs of the performances as specified in the enclosed table of fees, include the following:

1) marketing authorisations, registrations and special licences for medicinal products;
2) variations and other performances pertaining to medicinal products;
3) other authorisations, decisions, certificates and notifications related to pharmacovigilance;
4) scientific advice;
5) inspections related to the conduct 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) authorisation required under section 20b of the Act on the Medical Use of Human Organs and Tissues (101/2001), as well as the documents required under section 23a;
8) authorisation required under section 4 of the Blood Service Act (197/2005) as well as the authorisation required under section 22 for the import of blood or its components from third countries;
9) copies replacing the original decisions or corresponding documents kept at the Finnish Medicines Agency;
10) decisions concerning access to documents other than those under sections 9 and 11 of the Act on the Openness of Government Activities (621/1999);
11) statements given for the assessment and follow-up of agreements concerning the conditional reimbursement status pursuant to Chapter 6, section 6a of the Health Insurance Act (1224/2004);
12) the authorisations, decisions and certificates issued under the Narcotics Act (373/2008);
13) the authorisations and decisions issued under the Act on Mandatory Reserve Supplies (979/2008);
14) the permit issued under section 7 of the Act on the Medical Use of Human Organs, Tissues and Cells (101/2001), the permit and decision issued under section 11, the permits and decisions issued under section 19, the authorisation required under section 20b, the permit issued under section 21a, and the authorisation and certificates required under section 23a;
15) the decisions issued under the Biobank Act (688/2012) and the processing of notifications, the inspections related to the conduct of operations, and the biobank register maintenance and usage fee;

16) the licences granted under section 11 of the Medical Research Act (488/1999);
17) the authorisations and notifications issued under the Medical Devices Act (629/2010) as well as naming and supervision.

The fee charged for a performance referred to in section 1 or 2 of the Annex or the special authorisation fee referred to in section 4 may be waived if the demand for the medicinal product is negligible, but the medicinal product concerned must be deemed essential for treatment.

Section 2

Performances free of charge

No fee shall be charged for:
1) processing and reviewing a notification relating to clinical trials on medicinal products in human subjects or clinical trials on a medical device or clinical trials on veterinary medicinal products in 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 above in paragraph 1 of subsection 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 2a

Non-enforcement of a fee or charging it at less than cost price

For special reasons, the Finnish Medicines Agency Fimea may decide not to enforce a fee referred to in section 1 above or charge it at less than cost price if it is considered justified in view of the overall interest of the state and the equality of the operators.

Section 3

Charging of the fee in certain situations

The fee referred to in section 1(1) above shall also be charged if a negative decision is given on the application referred to therein.

Section 4

Performances priced according to commercial criteria

Other performances within the meaning of section 7 of the Act on Criteria for Charges Payable to the State, which the Finnish Medicines Agency shall price according to commercial criteria, include the following:
1) information services relating to data and information systems, except for minor guidance and advice;
2) training and consultation services;

3) specially ordered reports, investigations, inspections and analyses;
4) publications;
5) copies;
6) use of the premises occupied by the agency and agency services;
7) special services and performances ordered by clients other than, but comparable to, those referred to in points 1–5 above.

Section 5

Other fees

The fees charged for information retrieval referred to in section 34(2) of the Act on the Openness of Government Activities, and for providing copies and printouts, as defined in section 34(3) of said act, shall be decided by the Finnish Medicines Agency, with due regard to the provisions of section 34 of the Act on the Openness of Government Activities.

Section 6

Entry into force

This Decree shall enter into force on 1 June 2021 and will remain in force until 31 August 2022.

For performances under a decree that was pending prior to the entry into force of this Decree, a fee shall be charged in accordance with the provisions that were in force upon entry into force of this Decree.

In Helsinki on 27 May 2021

Minister of Social Affairs and Health Aino-Kaisa Pekonen

Senior Secretary Mari Laurén-Häussler

Annex

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: application-specific basic fee	
▪ 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**	**€ 15,000**
Subsequent pharmaceutical forms or strengths	**€ 10,000**
▪ 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, Article 10.3) **For each marketing authorisation or registration applied for**	**€ 10,000**
▪ 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**	**€ 10,000**
▪ Homeopathic products subject to marketing authorisation for which no medicinal purpose is stated, including marketing authorisation extensions (Dir. 2001/83/EC, Article 16) **For each marketing authorisation or registration applied for**	**€ 2,100**
▪ Homeopathic products subject to registration, including registration extensions (Dir. 2001/83/EC, Article 14) **Products containing 1 to 5 stock substances** **Products containing more than 5 stock substances**	**€ 950** **€ 1,200**

1.1.2 Mutual recognition procedure or decentralised procedure for medicinal medicinal products, Finland as a Concerned Member State: application-specific basic fee	
▪ 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, Article 10.3) **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, including marketing authorisation extensions (Dir. 2001/83/EC, Article 16) **For each marketing authorisation or registration applied for**	**€ 2,100**
▪ Homeopathic products subject to registration, including registration extensions (Dir. 2001/83/EC, Article 14) **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 medicinal products, Finland as a Reference Member State: process fee	
Process fee for a mutual recognition procedure The process fee includes all pharmaceutical forms and/or strengths of the same trade name. The fee is charged for each process separately.	**€ 12,000**
0-day process fee for a mutual recognition procedure without updating the assessment report The process fee includes all pharmaceutical forms and/or strengths of the same trade name. The fee is charged for each process separately.	**€ 4,000**
Process fee for a decentralised procedure 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) for each marketing authorisation or registration applied for. The process fee includes all pharmaceutical forms and/or strengths of the same trade name. The fee is charged for each process separately. The process fee and application fee will be charged when the application has been accepted for processing.	**€ 12,000**

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 specified 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 (G), the processing 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 the processing fee will only be charged one.

In the worksharing procedure (WS), the processing fee pursuant to the Decree is payable for each variation applied for. The processing fee is payable depending on Finland's role in the process concerned.

1.2.1 National marketing authorisation or registration of medicinal products medicinal products: processing fee	
Type II variations (Commission Regulation (EC) No 1234/2008)	
Addition to therapeutic indication	**€ 4,000**
Other type II variations	**€ 1,000**
Type IB variations	**€ 430**

1.2.2 Mutual recognition procedure for medicinal products intended for human use, Finland as a Concerned Member State: processing fee	
Type II variations (Commission Regulation (EC) No 1234/2008)	
Addition to therapeutic indication	**€ 3,000**
Other type II variations	**€ 800**
Type IB variations	**€ 340**

1.2.3 Mutual recognition procedure for medicinal products intended for human use, Finland as Reference Member State: process fee	
Type II variations (Commission Regulation (EC) No 1234/2008)	
Process fee	**€ 2,000**
Additionally, a processing fee in accordance with section 1.2.1 (National marketing authorisation or registration of medicinal products intended for human use)	

Type IB variations Process fee Additionally, a processing fee in accordance with section 1.2.1 (National marketing authorisation or registration of medicinal products intended for human use)	**€ 900** **€ 500**
Type IA variations Process fee For grouped variation applications, the process fee is only paid once based on the most significant variation (II/IB/IA). An exception to the above are type IA grouped variation applications that include several processes.	 **€ 1,000**
Type IA grouped variation applications including more than one process (FI/H/XXXX/IA/G) Process fee	 **€ 4,000**
Worksharing procedure Process fee Additionally, a processing fee in accordance with section 1.2.1 (National marketing authorisation or registration of medicinal products intended for human use)	

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	**€ 250**

1.2.5 Transfer of marketing authorisation or registration of medicinal medicinal products to a new holder	
Transfer of a marketing authorisation or registration to another holder	**€ 200**

1.3 ANNUAL FEES FOR MEDICINAL PRODUCTS INTENDED FOR HUMAN USE

▪ The fee is charged for each marketing authorisation and registration. ▪ 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, maintenance of ATC classification and dose registers (DDD), and medicine consumption statistics. ▪ The fee is determined according to the average costs arising from the performance of above-mentioned duties for each marketing authorisation or registration.	
Medicinal products referred to in sections 21–21c and 21e of the Medicines Act	**€ 1,400**
Parallel import products	**€ 680**
Registered traditional herbal medicinal products	**€ 200**
Herbal medicinal products, homeopathic and anthroposophic products subject to marketing authorisation	**€ 200**
Registered homeopathic and anthroposophic products	**€ 200**

1.4 RENEWAL OF A MARKETING AUTHORISATION OF MEDICINAL PRODUCTS INTENDED FOR HUMAN USE

1.4.1 Mutual recognition procedure for medicinal products intended for human use, Finland as Reference Member State: process fee	
A process fee 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 fee is charged for each process separately.	
Renewal process fee	**€ 2,000**
Renewal process fee, abridged renewal application	**€ 1,000**

1.5 APPLICATION FOR WAIVER OF THE MARKETING AUTHORISATION AND REGISTRATION OF MEDICINAL PRODUCTS INTENDED FOR HUMAN USE

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

2 VETERINARY MEDICINAL PRODUCTS

2.1 MARKETING AUTHORISATION AND REGISTRATION APPLICATIONS FOR VETERINARY MEDICINAL PRODUCTS

2.1.1 National marketing authorisation and registration procedure for veterinary medicinal products: application-specific basic fee	
▪ 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	**€ 9,750**
Subsequent pharmaceutical forms or strengths	**€ 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 authorisation or registration applied for	**€ 6,000**
▪ Extensions to a marketing authorisation	

(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, including marketing authorisation extensions (Dir. 2001/82/EC, Article 19) **For each marketing authorisation or registration applied for**	**€ 1,680**
▪ Homeopathic products subject to registration, including registration extensions (Dir. 2001/82/EC, Article 17) **Products containing 1 to 5 stock substances** **Products containing more than 5 stock substances**	**€ 850** **€ 1,100**

2.1.2 Mutual recognition procedure or decentralised procedure for veterinary medicinal products, Finland as a Concerned Member State: application-specific basic fee	
▪ 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, Article 13.3)	**€ 4,500**

For each marketing authorisation applied for	
▪ Extensions to a marketing authorisation (Commission Regulation (EC) No 1234/2008) **For each marketing authorisation applied for**	**€ 4,500**
▪ Homeopathic products subject to marketing authorisation for which no medicinal purpose is stated, including marketing authorisation extensions (Dir. 2001/82/EC, Article 19) **For each marketing authorisation or registration applied for**	**€ 1,680**
▪ Homeopathic products subject to registration, including registration extensions (Dir. 2001/82/EC, Article 17) **Products containing 1 to 5 stock substances** **Products containing more than 5 stock substances**	**€ 850** **€ 1,100**

2.1.3 Mutual recognition procedure or decentralised procedure for veterinary medicinal products, Finland as a Reference Member State: process fee	
Process fee for a mutual recognition procedure The process fee includes all pharmaceutical forms and/or strengths of the same trade name. The fee is charged for each process separately. **0-day process fee for a mutual recognition procedure without updating the assessment report** The process fee includes all pharmaceutical forms and/or strengths of the same trade name. The fee is charged for each process separately.	**€ 12,000** **€ 4,000**
Process fee for a decentralised procedure In addition to the process fee, a basic fee according to section 2.1.1 (National marketing authorisation or registration procedure for veterinary medicinal products) for each marketing authorisation or registration. The process fee includes all pharmaceutical forms and/or strengths of the same trade name. The fee is charged for each process separately.	**€ 12,000**

The process fee and application fee will be charged when the application has been accepted for processing.	

2.1.4 Marketing authorisation for veterinary medicinal products, parallel import	
For the first country of acquisition	**€ 1,900**
For each subsequent country of acquisition	**€ 1,100**

2.2 VARIATION APPLICATIONS FOR VETERINARY MEDICINAL PRODUCTS

The fees specified 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 (G), the processing 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 the processing fee will only be charged one.
In the worksharing procedure (WS), the processing fee pursuant to the Decree is payable for each variation applied for. The processing fee is payable depending on Finland's role in the process concerned.

2.2.1 National marketing authorisation or registration of veterinary medicinal products: processing fee	
Type II variations (Commission Regulation (EC) No 1234/2008)	
Addition to therapeutic indication and variation to withdrawal period	**€ 3,750**
Other type II variations	**€ 800**
Type IB variations	**€ 340**

2.2.2 Mutual recognition procedure for veterinary medicinal products, 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	 **€ 3,000** **€ 600**
Type IB variations	**€ 250**

2.2.3 Mutual recognition procedure for veterinary medicinal products, Finland as Reference Member State: process fee	
Type II variations (Commission Regulation (EC) No 1234/2008) Process fee Additionally, a processing fee in accordance with section 2.2.1 (National marketing authorisation or registration of veterinary medicinal products)	**€ 2,000**
Type IB variations Process fee Additionally, a processing fee in accordance with section 2.2.1 (National marketing authorisation or registration of veterinary medicinal products)	**€ 900** **€ 500**
Type IA variations Process fee For grouped variation applications, the process fee is only paid once based on the most significant variation. An exception to the above are type IA grouped variation applications that include several processes.	
Type IA grouped variation applications including more than one process (FI/V/XXXX/IA/G) Process fee	**€ 500** **€ 4,000**
Worksharing procedure Process fee Additionally, a processing fee in accordance with section 2.2.1 (National marketing authorisation or registration of veterinary medicinal products).	

2.2.4 Transfers of marketing authorisation or registration of veterinary medicinal products to a new holder	
Transfer of a marketing authorisation or registration to another holder	**€ 200**

2.2.5 Parallel import of veterinary medicinal products	
Type II variations (Commission Regulation (EC) No 1234/2008)	**€ 600**
Type IB variations	**€ 250**

2.3 ANNUAL FEES FOR VETERINARY MEDICINAL PRODUCTS

▪ The fee is charged for each marketing authorisation and registration. ▪ 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, maintenance of ATC classification and dose registers (DDD), and medicine consumption statistics. ▪ The fee is determined according to the average costs arising from the performance of above-mentioned duties for each marketing authorisation or registration.	
Veterinary medicinal products referred to in sections 21–21c and 21e of the Medicines Act	**€ 1,400**
Homeopathic and anthroposophic products registered for veterinary use and subject to marketing authorisation	**€ 200**

2.4 RENEWAL OF MARKETING AUTHORISATIONS FOR VETERINARY MEDICINAL PRODUCTS

2.4.1 Mutual recognition procedure for veterinary medicinal products, Finland as Reference Member State: process fee	
A process fee 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 fee is charged for each process separately.	
Renewal process fee	**€ 2,000**
Renewal process fee, abridged renewal application	**€ 1,000**

2.5 APPLICATION FOR WAIVER OF THE MARKETING AUTHORISATION AND REGISTRATION OF VETERINARY MEDICINAL PRODUCTS UNDER SECTION 29(3) OF THE MEDICINES ACT

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

3 SCIENTIFIC ADVICE

Scientific advice on medicinal products intended for human use	**€ 5,000**
Scientific advice on medicinal products intended for veterinary use	**€ 750**

4 SPECIAL AUTHORISATIONS AND CLASSIFICATION

Authorisation (special authorisation) referred to in section 21f of the Medicines Act	**€ 20**
Special authorisations requiring urgent processing	**€ 40**
Product classification decisions	**€ 500**

5 EXPORT CERTIFICATES

Certificates concerning the export, industrial manufacture and wholesale of medicines	
A certificate requested in regular schedule	**€ 150**
Request for express delivery of a certificate with a delivery time less than 2 weeks from the order	**€ 300**

Medical device, certificate of free sale	
First copy	**€ 150**
Duplicates ordered in the same connection	**€ 30**
Request for express delivery of a certificate of free sale for a medical device with a delivery time of less than 2 weeks from the order	
First copy	**€ 300**
Duplicates ordered in the same connection	**€ 60**
Official certificate of devices in the medical device register	**€ 150**

6 OTHER AUTHORISATIONS, DECISIONS, CERTIFICATES AND NOTIFICATIONS RELATED TO PHARMACOVIGILANCE

Processing of notifications related to clinical trials	**€ 3,000**
Processing of notifications related to veterinary clinical trials	**€ 750**
Processing of authorisations related to clinical trials	**€ 3,300**
Notification of a substantial amendment to a clinical trial protocol	**€ 900**
Processing of a shortage notification made pursuant to section 27 of the Medicines Act	
Processing of a notification made at least two months prior to the interruption of sales The fee is also charged for cancelled notifications made before the start of the shortage	**€ 70**
Processing of a notification made less than two months before the interruption of sales for special reasons.	**€ 200**
Processing of a notification made less than two weeks before the interruption of sales for special reasons.	**€ 1,000**

Licences concerning the industrial manufacture of medicinal products, pharmaceutical wholesaling and industrial manufacture of advanced therapy medicinal product, registration concerning the distribution of medicinal products, and changes to licences and registrations:	
Licence for the industrial manufacture of medicinal products Medicines Act, section 8	**€ 3,000**
Licence for the contract analysis of medicinal products Medicines Act, section 10	**€ 1,500**
Licence for the manufacture of medicinal products for clinical trials (Medicines Act, section 15a)	**€ 1,500**
Manufacturing authorisation of advanced therapy medicinal products (Medicines Act, section 15c)	**€ 1,500**
Pharmaceutical wholesale licence	**€ 1,750**
Pharmaceutical wholesale licence for anthroposophic and homeopathic products	**€ 1,000**
Registration of a distributor of medicinal products	**€ 1,000**
If the application for an operating licence or for changes to an operating licence requires pre-inspection, the inspection will be subject to a separate charge.	
Operating licences for tissue establishment or blood service operations and changes to them	**€ 3,000**
Import and export licences related to tissue establishment or blood service operations	**€ 500**
Import certificate relate to tissue establishment operations	**€ 500**
Patient-specific import and export licences	**€ 100**
If the application for an operating licence or for changes to an operating licence requires pre-inspection, the inspection will be subject to a separate charge.	
Pharmacy licence	**€ 5,000**
Pharmacy service point licence	**€ 1,250**
Running a pharmacy service point as a precondition for a pharmacy licence	**€ 1,250**

Short-term pharmacy service point licence (duration less than 1 month)	**€ 500**
Subsidiary pharmacy authorisation	**€ 2,500**
Running a subsidiary pharmacy as a precondition for a pharmacy licence	**€ 2,500**
Changing the location area of a subsidiary pharmacy at the subsidiary pharmacy authorisation holder's request	**€ 2,500**
Processing of a prior notification of a pharmacy web service or other means of distance communication	**€ 1,000**
Processing of an application for the use of each following means of distance communication by the pharmacy	**€ 400**
Extension of the time limit granted for pharmacy business	**€ 1,000**
Granting a pharmacy licence pursuant to section 54(2) of the Medicines Act	**€ 5,000**
Authorisation for setting up a hospital pharmacy, dispensary or military pharmacy	**€ 5,000**
Licence for non-industrial manufacture under section 12a of the Medicines Act	**€ 2,000**
Authorisation referred to in section 62 of the Medicines Act to supply medicinal products, 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 or to store medicinal substances instead of medicinal products, for each product applied for	
Application filed at least 2 weeks prior to the date of commencement of the underrun or replacement applied for	**€ 600**
Application filed less than 2 weeks prior to the date of commencement of the underrun or replacement applied for	**€ 1,200**

Exemption from maintaining obligatory reserve supplies of medicinal products or alternate way of maintaining obligatory reserve supplies; as a whole or for each group of medicinal products containing the same medicinal substance	**€ 600**
Application filed at least 2 weeks prior to the date of commencement of the exemption or alternative arrangement applied for	**€ 1,200**
Application filed less than 2 weeks prior to the date of commencement of the exemption or alternative arrangement applied for	

Licences and decisions in accordance with the Narcotics Act including decisions on the registration concerning the conduct 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	**€ 200**
Clearance certificates for the import of pharmaceuticals, narcotics or precursors of narcotics required by other countries	**€ 100**
Decision concerning approval of a GLP testing laboratory and changes to the decision	**€ 1,000**

7 INSPECTIONS RELATED TO THE CONDUCT OF OPERATIONS

In inspections carried out abroad, the fee for additional days will be changed for each inspector, and in addition to the inspection fee, the actual travel and accommodation costs as well as potential interpretation costs will be charged.

The charge for remote inspections performed in real time over a remote connection is the same as if the inspection were performed on site. If the target of inspection is located in Finland, the fee for an inspection performed entirely as a remote inspection is discounted by 10%.

The inspection fee chargeable for the first day plus actual travel expenses will be charged for each and every inspection cancelled on the operator's initiative after the inspection was agreed upon in writing and the preparations were started.

Inspections related to clinical trials	
For 1 day	**€ 6,000**
Additional days	**€ 3,000**
Inspections related to clinical trials, abroad	
For 1 day	**€ 6,000**
Additional days for each inspector	**€ 3,000**
Inspection of a marketing authorisation holder of a medicinal product and a registration holder of traditional herbal medicinal product, the domestic	
For 1 day	**€ 4,000**
Additional days	**€ 2,000**
Inspection of a marketing authorisation holder of a medicinal product and a registration holder of traditional herbal medicinal product, rest of the world	**€ 4,000**
For 1 day	**€ 2,000**
Additional days for each inspector	
Inspection of a pharmaceutical or excipient manufacturer, domestic	
For 1 day	**€ 6,000**
Additional days	**€ 3,000**
Inspection of a pharmaceutical manufacturer based on documents	**€ 2,500**
Inspection of a pharmaceutical or excipient manufacturer, abroad	
For 1 day	**€ 6,000**
Additional days for each inspector	**€ 3,000**
Inspection of a pharmaceutical or excipient manufacturer at the operator's request, abroad	
For 1 day	**€ 10,000**
Additional days for each inspector	**€ 5,000**

Inspection of a unit manufacturing medicinal products for clinical trials and a laboratory engaged in contract analysis, domestic	
For 1 day	**€ 3,000**
Additional days	**€ 1,500**
Inspection of a unit manufacturing medicinal products for clinical trials and a laboratory engaged in contract analysis, abroad	
For 1 day	**€ 6,000**
Additional days for each inspector	**€ 3,000**
Inspection of a pharmaceutical wholesaler	
For 1 day	**€ 6,000**
Additional days	**€ 3,000**
Inspection based on documents	**€ 2,000**
Inspection of a pharmaceutical wholesaler, if the operations do not include warehousing and possession of pharmaceuticals or if the warehousing and possession is only limited to homeopathic products or samples of pharmaceuticals or pharmaceutical preparations referred to in section 35(2) of the Medicines Act that are not intended for human or veterinary use	**€ 4,000**
For 1 day	**€ 2,000**
Additional days	**€ 2,000**
Inspection based on documents	
Inspection of an anthroposophic or homeopathic product wholesaler or inspection of a medicinal product distributor	**€ 2,000**
For 1 day	**€ 1,000**
Additional days	**€ 1,000**
Inspection based on documents	
Inspection of blood service and tissue establishment operations and an organ transplantation centre	**€ 3,000**
For 1 day	**€ 1,500**
Additional days	**€ 2,000**
Inspection of blood service or tissue establishment operations targeted at a single area of operations with duration of not more than 4 hours	**€ 1,000**
Inspection of blood service or tissue establishment operations based on documents	

Inspection of an organ donation hospital	**€ 2,000**
Inspection of an organ donation hospital based on documents	**€ 1,000**
Inspection related to the manufacturing authorisation of an advanced therapy medicinal product manufactured under a national manufacturing authorisation	**€ 3,000**
For 1 day	**€ 1,500**
Additional days	
Inspection of a pharmacy, hospital pharmacy, military pharmacy or dispensary	**€ 4,000**
For 1 day	**€ 2,000**
Additional days	**€ 2,000**
Inspection targeted at a single operation with a duration of not more than 4 hours	**€ 1,500**
Pharmacy inspection based on documents	
Inspection of a subsidiary pharmacy	**€ 2,000**
In connection with the main pharmacy inspection	**€ 3,000**
As a separate inspection	
Inspection related to the approval or supervision of a GLP test laboratory, domestic	
For 1 day	**€ 4,000**
Additional days	**€ 2,000**
Inspection targeted at a single operation with a duration of not more than 4 hours	**€ 2,000**
Inspection related to the approval or supervision of a GLP test laboratory, rest of the world	
For 1 day	**€ 6,000**
Additional days	**€ 3,000**

A charge is payable for the following inspections if no inspection under the Medicines Act is carried out in connection with the inspection:	
Inspections performed pursuant to the legislation on narcotics or mandatory reserve supplies	
For 1 day	**€ 2,000**
Additional days	**€ 1,000**
Verification of the safety features of a medicinal product, repository system and repository system administrator	**€ 6,000**
Inspection of a biobank's facilities and operations	
For each inspection day	**€ 1,000**
Inspection of the operations of a unit that performs research on embryos pursuant to section 11 of the Medical Research Act (488/1999) or provides teaching pursuant to section 11 of the Act of the Medical Use of Human Organs and Tissues (101/2001)	
For each inspection day	**€ 1,000**
Inspection based on documents	**€ 500**
Inspections of medical device manufacturers	
For 1 day	**€ 5,000**
Additional days	**€ 2,500**
Inspection targeted at a single operation with a duration of not more than 4 hours	**€ 2,500**
Inspection based on documents	**€ 2,000**
Inspections of authorised representatives, importers and distributors of medical devices	
For each inspection day	**€ 2,500**
Inspection targeted at a single operation with a duration of not more than 4 hours	**€ 1,500**
Inspection based on documents	**€ 1,000**

Inspections of clinical trials of medical devices For 1 day Additional days	 **€ 6,000** **€ 3,000**

8 ASSESSMENT AND FOLLOW-UP OF AGREEMENTS ON CONDITIONAL REIMBURSEMENT OF A MEDICINAL PRODUCT

Assessment report on the feasibility of conditional reimbursement agreement, for each medicinal product separately	**€ 3,500**
Assessment report on the implementation of conditional reimbursement agreement, for each medicinal product separately The fees include all pharmaceutical forms and/or strengths of the same trade name, provided that they are covered by the same conditional reimbursement agreement.	**€ 3,000**

9 COPIES REPLACING THE ORIGINAL DECISION OR CORRESPONDING DOCUMENT KEPT AT THE FINNISH MEDICINES AGENCY

For each commencing 10 pages	**€ 7**
For each commencing 10 pages subject to confidentiality of information	**€ 12**

10 DECISIONS CONCERNING ACCESS TO DOCUMENTS OTHER THAN THOSE UNDER SECTIONS 9 AND 11 OF THE ACT ON THE OPENNESS OF GOVERNMENT ACTIVITIES

Decisions concerning access to documents other than those under sections 9 and 11 of the Act on the Openness of Government Activities	

Data access authorisation or extension of data materials concerning new scientific research, except when the decision concerns a thesis	**€ 350**
Data access authorisation or extension of data materials associated with a thesis Research is considered a thesis when the research is the thesis of an individual researcher. If an authorisation is sought for a thesis that is performed as part of a larger research project or for several theses with a single application, a fee of € 350 will be charged.	**€ 200**
Continuation of a previously granted data access authorisation or its review, or a decision on the supplementing of the research team	**€ 50**

11 AUTHORISATIONS AND NOTIFICATIONS CONCERNING MEDICAL DEVICES

First registration of a manufacturer, importer, authorised representative, assembler of a system and a procedure pack, provider of sterilisation services, manufacturer of custom-made devices, on-site manufacturer and a distributor referred to in the Regulation (EU) of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (hereinafter MD Regulation)	**€ 500**
Notification pursuant to the Act on certain medical devices regulated by EU directives (629/2010) or an application for a performance assessment of an IVD device pursuant to the IVD Regulation (2017/746/EU)	**€ 500**
Exemption concerning a medical device	**€ 1,750**
Application pursuant to the MD Regulation (2017/745/EU) on a clinical investigation of a medical device in product class I	**€ 700**
Application pursuant to the MD Regulation (2017/745/EU) on a clinical investigation of a medical device in product class IIa–III	**€ 1,750**

Decision on the application of the Act pursuant to Article 4 of the MD Regulation (2017/745/EU)	**€ 2,000**
Decision on classification pursuant to Article 51 of the MD Regulation (2017/745/EU)	**€ 500**

12 NAMING AND ASSESSMENT FEES CONCERNING NOTIFIED BODIES

Processing of an application by a notified body	**€ 30,000**
Naming fee for a notified body	**€ 1,000**
Statutory periodic assessment of a notified body	**€ 10,000**
Statutory full re-assessment of a notified body	**€ 20,000**

13 AUTHORISATIONS AND NOTIFICATIONS RELATED TO BIOBANKING ACTIVITIES

Notification of commencement of biobanking activities	**€ 3,000**
Notification of alteration to biobanking activities	**€ 300**
Biobank's notification of merging of activities	**€ 500**
Permission to transfer a biobank abroad in whole or in part	**€ 500**
Annual fee arising from the maintenance and operating costs of the biobank register	**€ 800**
Decision on the fulfilment of the prerequisites for a public disclosure	**€ 665**
Decision issued in response to a negative decision by an ethics committee	**€ 3,000**

14 AUTHORISATIONS PURSUANT TO THE ACT ON THE MEDICAL USE OF HUMAN ORGANS AND TISSUES

Permissions issued for the medical collection or use of human organs, tissues and cells in connection with the termination of pregnancy or miscarriage	**€ 700**
Permissions issued for the use of cadavers in medical teaching activities	**€ 700**
Permits issued for the change in the purpose for which organs, tissues, cells and tissue samples will be used	**€ 700**
Decision issued in response to a negative decision by an ethics committee	**€ 3,000**
Medically or societally significant research	**€ 700**

15 LICENCES GRANTED UNDER THE MEDICAL RESEARCH ACT (488/1999)

Licence for an agency engaging in research on embryos	**€ 3,000**