798/2022 (UNOFFICIAL TRANSLATION)

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 6 a 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 6 a 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 the supervision of medicines;
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 of 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 of the Medical Use of Human Organs and Tissues (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 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 or authorisation application relating to clinical trials on medicinal products in human subjects or clinical trials on a medical device or performance evaluation studies on in vitro diagnostic medical devices or processing and reviewing an application relating to clinical trials on veterinary medicinal products in animals conducted by an individual investigator, a trial group, a university department, a university hospital clinic, the veterinary teaching hospital or the Finnish 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 Project Authorisation Board;

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

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.

No processing fee will be charged for a shortage notification if the shortage can be proven to arise from:

1) a sudden, unpredictable increase in demand in Finland caused by a pandemic or other special situation;

2) a natural disaster that interrupted the production-supply chain,

3) a shortage of a competing product, if the market share of the competing product, based on the average sales of the five months prior to the time of notification, is greater than 20 percentage points; or

4) a large-scale withdrawal based on a decision by the authorities, which the marketing authorisation holder could not have foreseen.

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 September 2022 and will remain in force until 31 December 2023.

For performances concerning matters filed 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.

Helsinki, 30 August 2022

Minister of Social Affairs and Health Hanna Sarkkinen

Senior Officer, Legal Affairs 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** **Subsequent pharmaceutical forms or strengths**	 **€15,000** **€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	**€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: 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	**€10,000**
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. 2001/83/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	**€950**
Products containing more than 5 stock substances	**€1,200**

1.1.3 Mutual recognition procedure or decentralised procedure for medicinal products intended for human use, Finland as the 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 application 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 application fee will only be charged one.

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

1.2.1 National marketing authorisation or registration of medicinal products intended for human use: application 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: application 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 Additionally, an application fee in accordance with section 1.2.1 (National marketing authorisation or registration of medicinal products intended for human use)	**€2,000**
Type IB variations	
Process fee Additionally, a application fee in accordance with section 1.2.1 (National marketing authorisation or registration of medicinal products intended for human use)	**€900**
Type IA variations	**€500**
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 application 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 products intended for human use 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 the Reference Member State: process fee	
A process fee is payable for renewal when Finland acts as the 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	
■ Complete application / known active substance (Regulation (EU) 2019/6, Article 8) ■ Application based on bibliographic data (Regulation 2019/6, Article 22) ■ Combination veterinary medicinal products (Regulation 2019/6, Article 20) ■ Homeopathic products subject to marketing authorisation for which a therapeutic indication is stated (Regulation 2019/6, Article 5)	
For the first marketing authorisation applied for	**€9,750**
Subsequent pharmaceutical forms or strengths	**€6,000**
■ Application based on informed consent (Regulation 2019/6, Article 21) ■ Generic veterinary medicinal products (Regulation 2019/6, Article 18) ■ Hybrid veterinary medicinal products (Regulation 2019/6, Article 19)	
For each marketing authorisation applied for	**€6,000**
■ Applications for limited markets (Regulation 2019/6, Article 23) ■ Applications in exceptional circumstances (Regulation 2019/6, Article 25)	
For each marketing authorisation applied for	**€5,000**
■ Registration of homeopathic veterinary medicinal products (Regulation 2019/6, Article 86)	
Products containing 1 to 5 stock substances	**€850**
Products containing more than 5 stock substances	**€1,100**
2.1.2 Mutual recognition procedure, subsequent recognition procedure or decentralised procedure for veterinary medicinal products, Finland as a Concerned Member State: application-specific basic fee	
■ Complete application / known active substance (Regulation 2019/6, Article 8) ■ Application based on bibliographic data (Regulation 2019/6, Article 22) ■ Combination veterinary medicinal products (Regulation 2019/6, Article 20) ■ Homeopathic veterinary medicinal products subject to marketing authorisation for which a medicinal purpose is stated (Regulation 2019/6, Article 5)	
For the first marketing authorisation applied for	**€9,500**
Subsequent pharmaceutical forms or strengths	**€4,500**

■ Application based on informed consent (Regulation 2019/6, Article 21) ■ Generic veterinary medicinal products (Regulation 2019/6, Article 18) ■ Hybrid veterinary medicinal products (Regulation 2019/6, Article 19) **For each marketing authorisation applied for**	**€4,500**
■ Applications for limited markets (Regulation 2019/6, Article 23) ■ Applications in exceptional circumstances (Regulation 2019/6, Article 25) **For each marketing authorisation applied for**	**€3,500**
2.1.3 Mutual recognition procedure, subsequent recognition procedure or decentralised procedure for veterinary medicinal products, Finland as the 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 2.1.1 (National marketing authorisation procedure for veterinary medicinal products) for each marketing authorisation 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**
Subsequent 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**
2.1.4 Licence for parallel trade in veterinary medicinal products (Regulation 2019/6, Article 102)	
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 application fee pursuant to the Decree on Fees will be payable for each variation. This does not apply to a grouped application for variations concerning the trade name, for which the application fee will only be charged one.

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

2.2.1 Variation applications for veterinary medicinal products, national marketing authorisation or registration: application fee	
Variation applications requiring assessment Extended timetable[1)] Standard timetable[2)] Reduced timetable	 **€3,850** **€800** **€340**
Variation application for a nationally registered homeopathic veterinary medicinal product	**€800**
1) For example, addition of a therapeutic indication or target species, changes in active substance(s), strength, pharmaceutical form or route of administration 2) Also a change in the withdrawal period	
2.2.2 Variation applications for veterinary medicinal products, mutual recognition procedure, Finland as a Concerned Member State	
Variation applications requiring assessment Extended timetable Standard timetable Reduced timetable	 **€3,100** **€600** **€250**
2.2.3 Variation applications for veterinary medicinal products, mutual recognition procedure, Finland as the Reference Member State: process fee	
Variation applications requiring assessment ■ Extended timetable ■ Standard timetable Process fee Additionally, a processing fee in accordance with section 2.2.1 (National marketing authorisation of veterinary medicinal products)	 **€2,000**
Variation applications subject to assessment ■ Reduced timetable Process fee Additionally, an application fee in accordance with section 2.2.1 (National marketing authorisation of veterinary medicinal products)	 **€900**
Worksharing procedure Process fee Additionally, an application fee in accordance with section 2.2.1 (National marketing authorisation of veterinary medicinal products)	**€4,000**
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 Variation applications for veterinary medicinal products, parallel trade	

■ **Type II variations**	**€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, processing of product defects, processing of variation applications not requiring assessment, processing of Type IA variation applications for parallel trade products, monitoring of medicinal product advertising, maintenance of ATC classification and dose registers (DDD), and medicine consumption statistics. ■ In the case of a national marketing authorisation granted based on applications for limited markets and in exceptional circumstances, the annual fee also includes the re-examination procedure. ■ The fee is determined according to the average costs arising from the performance of above-mentioned duties for each marketing authorisation or registration.	
Annual fee for a veterinary medicinal product subject to marketing authorisation	**€1,500**
Annual fee for homeopathic veterinary medicinal products registered for veterinary use and subject to marketing authorisation	**€200**
Licence for parallel trade, annual fee	**€680**

2.4 RE-EXAMINATION PROCEDURE FOR A MARKETING AUTHORISATION OF A VETERINARY MEDICINAL PRODUCT

2.4.1 Mutual recognition procedure for veterinary medicinal products, Finland as the Reference Member State: process fee	
The re-examination procedure pertains to applications for limited markets and in exceptional circumstances. A process fee is payable for the re-examination procedure when Finland acts as the 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.	
Re-examination procedure process fee	**€2,000**

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 PERMITS AND CLASSIFICATION

Special permits referred to in section 21f of the Medicines Act	**€20**
Special permits requiring urgent processing	**€40**
Product classification decisions	**€500**

5 EXPORT CERTIFICATES

Certificates concerning the industrial manufacture and wholesale of medicinal and veterinary medicinal products related to the export of medicinal and veterinary medicinal products	
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	**€300**
First copy	**€60**
Duplicates ordered in the same connection	
Official certificate of devices in the medical device register	
First copy	**€150**
Duplicates ordered in the same connection	**€30**

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

Processing of notifications related to clinical trials	**€3,000**
Processing of applications related to veterinary clinical trials (Regulation 2019/6, Article 9)	**€800**
Processing of authorisations related to clinical trials	**€3,300**
Notification of a substantial amendment to a clinical trial protocol	**€900**
Application for a substantial amendment to a veterinary clinical trial protocol	**€240**

Processing of a shortage notification concerning a medicinal or veterinary medicinal product made pursuant to section 27 of the Medicines Act	**€280**

Authorisations or registrations concerning the industrial manufacture of medicinal products, veterinary medicinal products, active substances, pharmaceutical wholesaling and industrial manufacture of advanced therapy medicinal products, registration concerning the brokering of medicinal products, and changes to authorisations and registrations:	
Authorisation for the industrial manufacture of medicinal and veterinary medicinal products (Medicines Act, section 8; Veterinary Medicines Regulation, Article 88)	**€3,000**
Authorisation for the contract analysis of medicinal and veterinary medicinal products (Medicines Act, section 10; Veterinary Medicines Regulation, Article 88)	**€1,500**
Authorisation for the manufacture of medicinal or veterinary medicinal products for clinical trials and/or veterinary clinical trials (Medicines Act, section 15 a)	**€1,500**
Manufacturing authorisation of advanced therapy medicinal products (Medicines Act, sections 8 and 15c)	**€1,500**
Registration of the manufacturer of the active substance of a veterinary medicinal products	**€2,000**
Manufacturer of an active substance used in a veterinary clinical trial	**€1,000**
Changes to registration data	**€500**
Wholesale distributor authorisation for medicinal or veterinary medicinal products	**€1,750**
Wholesale distributor authorisation for anthroposophic and homeopathic products	**€1,000**
Registration of an EEA importer and of a distributor of the active substance of a veterinary medicinal product The fee will not be charged to authorisation holders who import active substances for their in-house manufacture referred to in section 8 of the Medicines Act or Article 88 of Regulation (EU) 2019/6.	**€1,000**
Changes to registration data	**€500**
Registration of a broker of medicinal products	**€1,000**
If an application for an operating authorisation, registration, or a change thereto requires pre-inspection, the inspection will be subject to a separate charge.	

Authorisations for tissue establishment or blood establishment operations and changes to them	**€3,000**
Import and export licences related to tissue establishment or blood establishment operations	**€500**
Import certificate related to tissue establishment operations	**€500**

Patient-specific import and export licences If the application for an authorisation or for changes to an authorisation requires pre-inspection, the inspection will be subject to a separate charge.	**€100**

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 each following application for the use of 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**
Permission to underrun the mandatory reserve minimum or to store active substances instead of medicinal or veterinary 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 mandatory reserve supplies or alternate way of maintaining mandatory reserve supplies; as a whole or for each group of medicinal/veterinary medicinal products containing the same active 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 narcotics manufacturing with the exception of licences needed for the treatment of an individual patient	**€200**
Clearance certificates required by other countries for the import of pharmaceuticals, narcotics or precursors of narcotics	**€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 charged for each member of the inspection team who travelled on site, 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 (distant assessments) performed in real time over a remote connection, in part or in whole, 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 and interpretation service costs 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 on medicinal or veterinary medicinal products	**€6,000**
For 1 day	**€3,000**
Additional days	
In inspections carried out abroad, the fee for additional days will be charged for each member of the inspection team who travelled on site	

Inspection of a marketing authorisation holder of a medicinal or veterinary medicinal product and a registration holder of traditional herbal medicinal product	
For 1 day	**€4,000**
Additional days	**€2,000**
Inspection of a medicinal/veterinary medicinal product factory, active substance manufacturer or excipient manufacturer	
For 1 day	**€6,000**
Additional days	**€3,000**
In inspections carried out abroad, the fee for additional days will be charged for each member of the inspection team who travelled on site	
Inspection of a medicinal/veterinary medicinal product factory active substance manufacturer or excipient manufacturer carried out at the operator's own request	
For 1 day	**€10,000**
Additional days for each member of the inspection team who travelled on site	**€5,000**

Inspection of an operator manufacturing medicinal products, veterinary medicinal products or active substances for clinical trials or veterinary clinical trials and a laboratory engaged in contract analysis, domestic	
For 1 day	**€3,000**
Additional days	**€1,500**
Inspection of an operator manufacturing medicinal products for clinical trials or veterinary clinical trials and a laboratory engaged in contract analysis, abroad	
For 1 day	**€6,000**
Additional days for each member of the inspection team who travelled on site	**€3,000**
Inspection of a pharmaceutical and veterinary medicinal product wholesaler	
For 1 day	**€6,000**
Additional days	**€3,000**
Inspection of pharmaceutical wholesaler operations targeted at a single area of operations with duration of not more than 4 hours	**€3,000**
Inspection of a pharmaceutical and veterinary medicinal product wholesaler, if the operations do not include warehousing and possession of medicinal or veterinary medicinal products or if the warehousing and possession is only limited to homeopathic products or samples of pharmaceuticals referred to in section 35(2) of the Medicines Act or pharmaceutical preparations that are not intended for human or veterinary use	
For 1 day	**€4,000**
Additional days	**€2,000**
Inspection of pharmaceutical wholesaler operations targeted at a single area of operations with duration of not more than 4 hours	**€2,000**
Inspection of an anthroposophic or homeopathic product wholesaler or inspection of a medicinal product broker	
For 1 day	**€2,000**
Additional days	**€1,000**
Inspection of an EEA importer and/or distributor of active substances conducted separately	**€3,000**
Inspection of blood establishment and tissue establishment operations and an organ transplantation centre	
For 1 day	**€3,000**
Additional days	**€1,500**
Inspection of blood establishment or tissue establishment operations targeted at a single area of operations with duration of not more than 4 hours	**€2,000**
Inspection of tissue establishment operations as a desk-based documents review	**€1,000**
Inspection of an organ donation hospital	**€2,000**
Inspection of an organ donation hospital as a desk-based documents review	**€1,000**

Inspection related to the manufacturing authorisation of an advanced therapy medicinal product manufactured under a national manufacturing authorisation	
For 1 day	**€3,000**
Additional days	**€1,500**

Inspection of a pharmacy, hospital pharmacy, military pharmacy or dispensary	
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 of a subsidiary pharmacy	
In connection with the main pharmacy inspection	**€1,000**
As a separate inspection	**€2,000**
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, abroad	
For 1 day	**€6,000**
Additional days for each member of the inspection team who travelled on site	**€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**
Inspection of the repository system of medicinal products safety features and of the repository system administrator	**€6,000**
Inspection of a biobank's facilities and operations	
For 1 day	**€2,500**
Additional days	**€1250**
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 as a desk-based documents review	**€500**

Inspection of manufacturers of medical devices and products listed in Annex XVI to the MD Regulation (EU) 2017/745	
For 1 day	**€5,000**
Additional days	**€2,500**
Inspection with total duration of not more than 4 hours	**€2,500**
Inspections of authorised representatives, importers, system and procedure pack assemblers, sterilisation service providers and distributors of medical devices	
For 1 day	**€2,500**
Additional days	**€1,500**
Inspection with total duration of not more than 4 hours	**€1,500**
Inspection of in-house manufacture of devices by professional users and health care units	
For 1 day	**€2,500**
Additional days	**€1,500**
Inspection with total duration of not more than 4 hours	**€1,500**
Inspection of clinical device investigations and performance studies on IVD devices	
For 1 day	**€6,000**
Additional days	**€3,000**
Inspection with total duration of not more than 4 hours	**€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	**€3,000**
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.	

9 COPIES REPLACING THE ORIGINAL DECISIONS OR CORRESPONDING DOCUMENTS 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	**€200**
Research is considered a thesis when it is a thesis of an individual researcher. If an authorisation is applied for a thesis that is prepared as part of a larger research project or for several theses under a single application, a fee of €350 will be charged.	
Continuation of a previously granted data access authorisation or its review, or a decision on the supplementing of the research team	**€50**

11 AUTHORISATIONS, NOTIFICATIONS AND APPLICATIONS CONCERNING MEDICAL DEVICES

11.1. Authorisations and notifications concerning medical devices	
Operators' role-specific first registration fee: - manufacturers established in Finland; - manufacturers of custom-made devices; - system or procedure pack assemblers; - sterilisation service providers; - authorised representatives; - importers; - distributors who distribute medical devices to retailers, healthcare and social welfare operators and other professional users; and - healthcare units that engage in in-house device manufacturing	**€500**
Application and classification decisions under the MD Regulation (EU) 2017/745: - Decision on the application of the Act pursuant to Article 4 of the MD Regulation - Decision on classification pursuant to Article 51 of the MD Regulation	**€2,000** **€500**
Application and classification decisions under the IVD Regulation (EU) 2017/746: - Decision on the application of the Act pursuant to Article 3 of the IVD Regulation - Decision on classification pursuant to Article 51 of the IVD Regulation	**€2,000** **€500**

Exemption orders:	
- Exemption order concerning a medical device of MD Regulation risk class I IIa in Finland	**€1,850**
- Exemption order concerning a medical device of MD Regulation risk class IIb III in Finland	**€3,700**
- Exemption order concerning an in vitro diagnostic device of IVD Regulation risk class A in Finland	**€1,750**
- Exemption order concerning an in vitro diagnostic device of IVD Regulation risk class B, C and D in Finland	**€3,500**
11.2. Notifications and applications concerning clinical investigations of medical devices and performance studies on IVD devices	
Clinical investigations of medical devices:	
- Application pursuant to the MD Regulation on a clinical investigation of a medical device in risk class I, including corresponding clinical investigations of products listed in Annex XVI	**€700**
- Application pursuant to the MD Regulation on a clinical investigation of a medical device in risk class IIa - III, including corresponding clinical investigations of products listed in Annex XVI	**€1,750**
- Notification of a post-market clinical follow-up where the subject is submitted to invasive or burdensome procedures pursuant to Article 74(1) of the MD Regulation	**€700**
- Substantial modifications to clinical investigations	**€300**
Performance studies on IVD devices:	
- Application for a performance study on an IVD device pursuant to Article 58(1) of the IVD Regulation	**€1,750**
- Notification pursuant to Article 58(2) of the IVD Regulation and section 23 of the Medical Devices Act (719/2021) of an IVD device performance study involving companion diagnostics which only uses samples not obtained from the study subjects or where such a study is carried out using samples obtained under the Biobank Act (688/2012)	**€200**
- Notification of a post-market clinical follow-up performance study where the subject is submitted to invasive or burdensome procedures pursuant to Article 70(1) of the IVD Regulation	**€700**
- Substantial modifications to an IVD device performance study	**€300**

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 re-assessment or extension of competence area 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	**€1,000**
Permission to transfer a biobank abroad in whole or in part	**€1,000**
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	**€1,000**
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**

PUBLISHED BY MINISTRY OF JUSTICE ISSN 1455-8904