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Swedish code of statutes

Ordinance concerning fees for the governmental control of medicinal products:

Issued November 11, 2010

The government provides as follows.

Chapter 1, Initial provisions

§1 This ordinance contains directions concerning fees in accordance with § 25 of the Swedish Medicines Act (1992:859).

§2 The terms and expressions used in the Swedish Medicines Act (1992:859) have the same meaning in this ordinance. In addition

1. *natural remedies*: Medicinal products in which the active ingredient or ingredients derive from natural sources, have not been processed too highly and consist of part of an animal, bacterial cultures, minerals, salts or salt solutions. Natural remedies may only be products which are suitable for self-medication in accordance with tried and tested national tradition, or traditions in countries similar to Sweden with respect to drug usage,

2. *certain medicinal products for external use*

Medicinal products for external use for the treatment of mild diseases in humans or animals, such as ointments for wounds, oils for inhalation, antiseptic agents, liniments and similar preparations, in which the active ingredient or ingredients have well-established medicinal use with a recognised effect and an acceptable safety margin,

3. *parallel import*

Import to Sweden from a state within the European Economic Area (EEA) of medicinal products that are approved for marketing in Sweden and in the exporting state, but where importation is managed by another party than the manufacturer or the marketing authorisation holder,

4. *stock preparations*

A standardised medicinal product which is not approved for marketing and which is manufactured by a pharmacy,

5. *special permission (licence)*

Authorisation for the marketing of a medicinal product following the ordinance of the Medicinal Products Act, § 5, third section,

6. *special permission (licence) for stock preparations*

Authorisation concerning a stock preparation,

7. *duplicate application*

An application for marketing authorisation corresponding fully to an already existing approval or another application of approval, except for either the name of the medicinal product or the marketing authorisation holder,

8. *duplicate*

Medicinal product approved by the support of a duplicate application and which still corresponds to the reference medicinal product, except for either the name of the medicinal product or the marketing authorisation holder,

9. *major change type II:*

A change that is not an extension application and which can have a substantial impact on the quality, safety or efficacy of the concerned medicinal product,

10. *EU-certificate for batch release:*

A document stating that an official batch release for vaccines and blood products for the use of humans has been made before release on the Swedish market,

11. *abridged application:*

Application for marketing approval referring to the documentation of a reference medicinal product in accordance with The Swedish Medicines Act, § 8 a,

12. *approval or registration in accordance with the mutual recognition or decentralised procedure in which Sweden acts as concerned member state:*

An approval or registration based on the assessment of the reference member state in the decentralised procedure, or an acceptance of an approval or a registration in another member state in the European Economic Area,

13. *request for Sweden to act as reference member state in the decentralised or mutual recognition procedure:*

Request for Sweden to act as reference member state in the decentralised procedure in accordance with the Swedish Medicines Act, § 6 d or for the Medical Products Agency to compose or supplement an assessment report in association with an application in another member state for the acceptance of an approval or registration in Sweden.

§ 3 The medical products agency is the competent authority for issues concerning fees payable according to this ordinance.

§ 4 Fees are payable according to this ordinance.

Chapter 2. Application fees

Approval of marketing authorisation for medicinal products

§ 1 The application fee for the approval of marketing authorisation for medicinal products shall be paid as follows:

1. Medicinal products for human use	
a) complete application, with the exception of b-h	400 000 SEK
b) application concerning a generic medicinal product where the reference medicinal product is not authorised in Sweden	400 000 SEK
c) application concerning a radiopharmaceutical	65 000 SEK
d) application concerning an allergen	65 000 SEK
e) application concerning natural remedies or certain medicinal products for external use	100 000 SEK
f) abridged application where the reference medicinal product is authorised in Sweden	200 000 SEK
g) duplicate application	30 000 SEK
h) application concerning a parallel imported medicinal product	25 000 SEK
2. Medicinal products for veterinary use	
a) complete application, with the exception of b-f	200 000 SEK
b) application concerning a generic medicinal product where the reference medicinal product is not authorised in Sweden	200 000 SEK
c) application concerning natural remedies or certain medicinal products for external use	50 000 SEK

use	
d) abridged application where the reference medicinal product is authorised in Sweden	100 000 SEK
e) duplicate application	15 000 SEK
f) application concerning a parallel imported medicinal product	12 500 SEK

The fee covers all routes of administration, strengths and pharmaceutical forms of the same medicinal product (trade name) applied for at the same time.

The fee for applications for parallel imported medicinal products (section 1 h and 2 f), however, covers all strengths and pharmaceutical forms of the same medicinal product (trade name) from the same exporting country applied for at the same time.

Approval of marketing authorisation for medicinal products in accordance with the decentralised or mutual recognition procedure in which Sweden acts as concerned member state

§ 2 The application fee for the approval of a medicinal product for marketing in accordance with the mutual recognition or decentralised procedure in which Sweden acts as the concerned member state shall be paid as follows:

1. Medicinal products for human use	
a) complete application, with the exception of b-d	100 000 SEK
b) application concerning a generic medicinal product where the reference medicinal product is not authorised in Sweden	100 000 SEK
c) abridged application where the reference medicinal product is authorised in Sweden	65 000 SEK
d) duplicate application	30 000 SEK
2. Medicinal products for veterinary use	
a) complete application, with the exception of b-d	50 000 SEK
b) application concerning a generic medicinal product where the reference medicinal product is not authorised in Sweden	50 000 SEK
c) abridged application where the reference medicinal product is authorised in Sweden	32 500 SEK
d) duplicate application	15 000 SEK

The fee covers all routes of administration, strengths and pharmaceutical forms of the same medicinal product (trade name) applied for at the same time.

Extension of an existing marketing authorisation

§ 3 Application fee concerning the extension of an existing marketing authorisation shall be paid as follows:

1. Medicinal products for human use	
a) extension application, with the exception of b and c	200 000 SEK
b) extension application for natural remedies or certain medicinal products for external use	50 000 SEK
c) extension application through the decentralised or mutual recognition procedure in which Sweden acts as concerned member state	65 000 SEK
2. Medicinal products for veterinary use	
a) extension application, with exceptions of b and c	100 000 SEK
b) extension application for natural remedies, traditional herbal medicinal products and certain medicinal products for external use	50 000 SEK
c) extension application via decentralised or mutual recognition procedure in which	

Sweden acts as concerned member state

32 500 SEK

The fee covers all routes of administration, strengths and pharmaceutical forms of the same medicinal product (trade name) applied for at the same time and which concerns the same type of change of the terms of the authorisation.

Registration of traditional herbal medicinal products and the extension of such registrations

§ 4 The registration fee for traditional herbal medicinal products and the extension of such registrations shall be paid as follows:

1	Application for the registration of a traditional herbal medicine	100 000 SEK
2	Application for the registration of a traditional herbal medicine containing plant based material or a preparation or a combination of these that are listed by the European commission	50 000 SEK
3	Application for the approval of a registration of a plant based medicinal product in accordance with the decentralised or mutual recognition procedure in which Sweden acts as concerned member state	32 500 SEK
4	Duplicate application	30 000 SEK
5	Application for parallel imported traditional herbal medicinal products	25 000 SEK

The fee covers all routes of administration, strengths and pharmaceutical forms of the same medicinal product (trade name) applied for at the same time.

The fee for applications for parallel imported medicinal products (section 5), however, covers all strengths and pharmaceutical forms of the same medicinal product (trade name) from the same exporting country, applied for at the same time.

5§ The application fee for an extension of an existing registration of a traditional herbal medicine is 50 000 SEK. The application fee for the approval of an extension registration of a traditional herbal medicine in accordance with the decentralised or mutual recognition procedure in which Sweden acts as concerned member state is 16 250 SEK.

Registration of homeopathic medicinal products SFS 2010:1167

§ 6 Application fees for the registration of homeopathic medicinal products intended for human or veterinary use shall be paid as follows:

1	Application for the registration of a homeopathic medicinal product in accordance with SFS 1992:859 Medicinal Products Act, § 2 b	4 000 SEK
2	Application for the acceptance of a registration of a homeopathic medicinal product in accordance with the decentralised or mutual recognition procedure in which Sweden acts as concerned member state	2 000 SEK

The fee applies to a separate single-component product, single-component products in a dilution series or a composite product with several components.

Special permission and special permission for stock preparations

§ 7 Fees for special permission and special permission for stock preparations shall be paid as follows:

1. Medicinal products for human use		
a)	application for special permission for stock preparations	65 000 SEK
b)	application for special permission to meet special needs for a medicinal product in individual cases	220 SEK

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|---|------------|
| 2. Medicinal products for veterinary use | |
| a) application for special permission for stock preparations | 32 500 SEK |
| b) application for special permission to meet special needs for a medicinal product in individual cases | 220 SEK |

Manufacturing authorisation of medicinal products

§ 8 Fees for the application of an authorisation for the manufacturing of medicinal products for human and veterinary use shall be paid as follows for each production site:

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|---|------------|
| 1. Manufacturing of medicinal products, except 2 | 65 000 SEK |
| 2. Manufacturing of natural remedies, traditional herbal medicinal products or homeopathic medicinal products | 30 000 SEK |

§ 9 Application fees for the approval of facilities for the manufacturing of extemporaneous preparations. (Excluding manufacturing performed at a local pharmacy).

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|--|------------|
| 1. When another approval for the manufacturing of the medicinal product exists | 26 000 SEK |
| 2. When another approval for the manufacturing of the medicinal product does not exist | 58 500 SEK |

Authorisation to conduct clinical trials

§ 10 The application fee for authorisation to conduct clinical trials is 45 000 SEK for medicinal products for human use and 22 500 SEK for medicinal products for veterinary use.

Chapter 3. Additional fees

Sweden acting as reference member state in the decentralised or mutual recognition procedure:

Approval of marketing authorisation for medicinal products

§ 1 Fee for marketing authorisation of medicinal products via the decentralised or mutual recognition procedure when Sweden is requested to act as reference member state, in association with an application for marketing authorisation in another member state shall be paid as follows:

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|--|-------------|
| 1. Medicinal products for human use | |
| a) a request where the medicinal product comes with complete documentation | 200 000 SEK |
| b) abridged application | 200 000 SEK |
| c) duplicate application (both in Sweden and the concerned member states) | 30 000 SEK |
| 2. Medicinal products for veterinary use | |
| a) a request where the medicinal product comes with complete documentation | 100 000 SEK |
| b) abridged application | 100 000 SEK |
| c) duplicate application (both in Sweden and the concerned member states) | 15 000 SEK |

The fee covers all routes of administration, strengths and pharmaceutical forms of the same medicinal product (trade name) applied for at the same time. In addition to the fee above, the fee for approval of marketing authorisation for medicinal products as detailed in Chapter 2, § 1 of this ordinance shall also be paid.

Extension of an existing authorisation

§ 2 The fee when Sweden is requested to act as reference member state in the decentralised or mutual recognition procedure, in association with an application for the extension of an existing authorisation in

another member state is 200 000 SEK for medicinal products for human use and 100 000 SEK for medicinal products for veterinary use. The fee covers all routes of administration, strengths and pharmaceutical forms of the same medicinal product (trade name) applied for at the same time and which concerns the same type of modification of the terms of the authorisation.

In addition to the fee according to this paragraph, the fee detailed in Chapter 2, § 3 of this ordinance shall also be paid.

Registration of traditional herbal medicinal products and the extension of such an authorisation

§ 3 Fee for marketing authorisation of medicinal products via the decentralised or mutual recognition procedure, in which Sweden is requested to act as reference member state, in association with an application for marketing authorisation in another member state shall be paid as follows:

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|--|-------------|
| 1. Registration of a traditional herbal medicinal product | 100 000 SEK |
| 2. Extension of a registration of a traditional herbal medicinal product | 50 000 SEK |

In addition to the fees according to this paragraph, the fee detailed in Chapter 2, § 4 and 5 of this ordinance shall also be paid.

Registration of homeopathic medicinal products

§ 4 The fee for when Sweden is requested as reference member state in the decentralised or mutual recognition procedure, in association with an application for the authorisation of a homeopathic medicinal product in another member state is 4 000 SEK. The fee covers a separate single-component product, single-component products in a dilution series or a comprised product with several components. In addition to the fees according to this paragraph, fee in accordance with Chapter 2, § 6 of this ordinance shall also be paid.

Variation of approval of marketing authorisation

Variation type II change of an existing approval

§ 5 The fee for a major variation, type II, of medicinal products for human or veterinary use is as follows:

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|--|------------|
| a) national procedure | 10 000 SEK |
| b) mutual recognition procedure with Sweden acting as reference member state | 20 000 SEK |
| c) mutual recognition procedure with Sweden acting as concerned member state | 6000 SEK |

The fee covers all routes of administration, strengths and pharmaceutical forms of the same medicinal product (trade name) applied for at the same time.

Change in legal status

§ 6 The application fee for changed legal status in accordance with SFS 1992:859 Medicinal Products Act, § 8 g is 100 000 SEK. The fee for a medicinal product for veterinary use is 50 000 SEK.

The application fee for changed legal status where the substance has been previously changed in the same way, and where the summary of product characteristics and package leaflet are essentially the same is 10 000 SEK.

Type II variation for an existing registration of a traditional herbal medicinal products or homeopathic medicinal product

7§ The fee for a major variation, type II, of a registration is as follows:

1. Traditional herbal medicinal products through	
a) national procedure	10 000 SEK
b) mutual recognition procedure in which Sweden acts as reference member state	20 000 SEK
c) mutual recognition procedure in which Sweden acts as concerned member state	6 000 SEK
2. Homeopathic medicinal products (for both human and veterinary use)	2 000 SEK

The fee for a variation of an existing registration of a traditional herbal medicinal product covers all routes of administration, strengths and pharmaceutical forms of the same medicinal product (trade name) applied for at the same occasion. For homeopathic medicinal products the fee covers a separate single-component product, single-component products in a dilution series or a composite product with several components.

Chapter 4. Annual fees

Approved and registered medicinal products

§1 Annual fees shall be paid as follows:

1. Medicinal products for human use	
a) medicinal product, with the exception of b-h	46 000 SEK
b) additional strength or pharmaceutical form, with the exception of special permission for stock preparations	22 500 SEK
c) duplicate	22 500 SEK
d) traditional herbal medicinal products, natural remedies and certain medicinal products for external use	14 000 SEK
e) radiopharmaceutical and allergen products	8 000 SEK
f) dilution of stock extract of allergen (for each additional dilution)	250 SEK
g) homeopathic medicinal product (a separate single-component product, a single-component product in a dilution series or a composite product with several components)	250 SEK
h) parallel imported medicinal product (per exporting country, pharmaceutical form, strength and marketing authorisation number)	6 000 SEK
2. Medicinal products for veterinary use	
a) medicinal products for veterinary use, with the exception of b-f	15 000 SEK
b) additional strength or pharmaceutical form, with the exception of special permission for stock preparations	7 500 SEK
c) duplicate	7 500 SEK
d) natural remedies and certain medicinal products for external use	14 000 SEK
e) homeopathic medicinal product (a separate single-component product, a single-component product in a dilution series or a composite product with several components)	250 SEK
f) parallel imported medicinal product (per exporting country, pharmaceutical form, strength and marketing authorisation number)	2 000 SEK

Manufacturing

§ 2 Unless otherwise specified in § 3-5, the annual fee for the manufacturing of medicinal products for human or veterinary use is 46 000 SEK. The fee covers the manufacturing of up to three pharmaceutical forms. For the manufacturing of additional pharmaceutical forms an additional annual fee of 14 000 SEK shall be paid. For the manufacturing of sterile medicinal products an additional annual fee of 30 000 SEK shall be paid. For manufacturing requiring only a limited amount of supervision, the annual fee is 14 000 SEK.

§3 The annual fee for the production of medicinal gas, traditional herbal medicinal products, natural remedies and certain medicinal products for external use or homeopathic medicinal product is 30 000 SEK. For manufacturing requiring only a limited amount of supervision, the annual fee is 14 000 SEK. The same fees given in the first and second paragraphs apply to medicinal products for veterinary use.

§4 The annual fee for radiopharmaceutical or medicinal products for dialysis treatment manufactured within a hospital is 14 000 SEK. The same fee applies to medicinal products for veterinary use.

§5 The annual fee for facilities intended for the manufacturing of extemporaneous preparations of medicinal products, where there is no other authorisation for the production, is 32 500 SEK. If another authorisation for production already exists, the annual fee is 13 000 SEK.

Chapter 5 Special fees

Scientific advice

§ 1 The application fee for scientific advice is 45 000 SEK.

Certificate

§ 2 Application fee for a certificate of authorisation to manufacture medicinal products and application for certificate to export medicinal products is 950 SEK.

§3 The fee for issuing a batch release certificate for vaccines and blood products for human use prior to release on the Swedish market in cases where an EU-certificate for batch release is missing is 2 000 SEK. The application fee for a certificate of export of a certain batch of a medicinal product is 2 000 SEK.

Chapter 6 Payment

Payment of application fee, additional fee and special fee

§ 1 The application fee, additional fee and special fee shall be paid by the applicant.

Payment of annual fee

§2 Annual fee shall be paid for:

1. the approval of marketing authorisation of medicinal product: by the authorisation holder from the month after the product is authorised for marketing until and including the year the authorisation ceases to be valid,
2. registration of traditional herbal medicinal products: by the authorisation holder from the month after the medicinal product is authorised for marketing until and including the year when the authorisation ceases to be valid,
3. registration of homeopathic medicinal product: by the authorisation holder from the year in which the medicinal product is authorised for marketing until and including the year when the authorisation ceases to be valid,
4. manufacturing of medicinal product: by the authorisation holder from the month following the month in which the medicinal product is authorised for marketing until and including the year when the authorisation ceases to be valid.

Annual fee according to the first section 1-3 shall not be paid if the medicinal product is deregistered no later than January 31.

§3 Payment shall be made when the applicant receives an invoice for the fee from the Medical Products Agency.

§4 The Medical Products Agency can, under certain circumstances where special reasons apply, decide on partial or full reduction or refund of the application fee.

Chapter 7 Other provisions

Authorisation

§1 The Medical Products Agency may publish statutes needed for the execution of this ordinance.

Appeal

§2 § 22 a in the administrative law (1986:223) contains provisions for appeals through the general Administrative Court.

1. This ordinance becomes effective January 1, 2011, when the ordinance (1993:595) of fees for the governmental control of medicinal products ceases to apply.
2. The invalid ordinance still applies to fees derived from the time before the new ordinance came into effect.