Ordinance on the Fees charged by the Swiss Agency for Therapeutic Products

(Therapeutic Products Fees Ordinance)

of 2 December 2011 (Stand am 1. Januar 2015)

The Agency Council of the Swiss Agency for Therapeutic Products (Agency Council),

having regard to Article 72 letter f of the Therapeutic Products Act of 15 December 2000[1] (TPA)

ordains:

Art. 1 Procedural and sales fees

[1] The Agency levies procedural fees for the following administrative actions that it performs under its executive powers in the area of therapeutic products and narcotics legislation and under the Transplantation Act of 8 October 2004[2]:

a. Official decisions;

b. Services;

c. Inspections;

d. Information.

[2] It levies a sales fee on the ex-factory price of medicinal products and transplant products authorised in Switzerland.

Art. 2 General Fees Ordinance

Unless this Ordinance provides otherwise, the provisions of the General Fees Ordinance of 8 September 2004 shall apply[3].

Art. 3 Payment obligation

[1] Any person who brings about the performance of an administrative action must pay a procedural fee.

[2] Sales fees must be paid by all authorisation holders that place authorised medicinal products and transplant products on the market in Switzerland.

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3 SR **172.041.1**

3 If several persons are jointly subject to fees, they are jointly liable for the whole fee.

Art. 4 Calculation

1 Fees are calculated using fixed fee rates (flat-rate fees) in accordance with Annexes 1, 3 and 5 or on the basis of the time involved. The hourly rate for fees based on the time involved is 200 francs.

2 The sales fee is a specific percentage of the ex-factory price. This percentage is determined in Annex 4.

Art. 5 Fee surcharges

1 For applications that are processed more quickly by the Agency in the interests of fast availability, a surcharge on the flat-rate fee is charged in accordance with Annex 2 A.

2 If an administrative procedure involves a considerable amount of additional work, either because documents relating to an application are inadequate or because additional documents are submitted, the Agency can charge a surcharge for the amount of additional work involved with the flat-rate fees. Such surcharges must be shown separately and accompanied by reasons justifying the additional charge.

3 If the additional work according to paragraph 2 is exceptionally extensive, the Agency shall inform the person liable to pay the fee in advance of the probable amount.

Art. 6 Fee reduction

1 The Agency shall reduce the procedural fees for cases listed in Annex 2 B by the percentages listed in this Annex.

2 If an application is withdrawn, the Agency can reduce the fees in response to a justified request.

3 The Agency can link the fee reduction to conditions and requirements.

Art. 7 Waiver of procedural and sales fees

The Agency can refrain from charging procedural and sales fees if:

a. there is overriding public interest in the exemption from fees;

b. the total amount is less than 100 francs.

Art. 8 Expenses

In addition to the expenses specified in Article 6 of the General Fees Ordinance of 8 September 2004[4], the following costs in particular are considered to be expenses:

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a. the costs incurred by the Agency itself in connection with administrative actions, namely the collection of evidence;

b. the costs of scientific investigations;

c. the costs of laboratory tests;

d. the costs of special tests.

Art. 9 Assessment of the sales fees

1 The Agency determines the sales fee by issuing an official decision on the basis of a self declaration provided by the authorisation holder.

2 The authorisation holder must submit a self declaration for every calendar year. This declaration should include the number of the packs of medicinal products and units of transplant products placed on the market in Switzerland in each price category and the corresponding documentation.

3 If the authorisation holder fails to submit the self declaration despite receiving a reminder, the Agency shall estimate the values to be declared according to Paragraph 2 and shall make the assessment on this basis.

Art. 10 Invoicing and official decisions

1 The Agency shall issue an invoice for the procedural fee immediately after the administrative action has been performed.

2 The sales fee is levied for the previous year and invoiced at the start of a calendar year.

3 In the event of disputes about the invoice, the Agency shall issue an official decision.

Art. 11 Advance payment

1 In justified cases, the Agency can demand advance payment from the person liable for the procedural and sales fee, particularly if the person in question has their place of residence or company headquarters outside Switzerland, or if that person is in arrears with payments.

2 The Agency can demand part-payments for the sales fee. However, these may not exceed two thirds of the fee estimated for the current calendar year.

Art. 12 Due dates

1 The procedural and sales fee are payable:

a. in the case of official decisions: when they acquire legal force;

b. in the case of administrative actions with no official decision: when the invoice is issued;

c. in the case of a disputed invoice: when the official decision on the fee acquires legal force.

2 The period for payment is 30 days from the due date. The Agency may extend the period for payment in special cases.

3 After this period expires, default interest of 5 percent per year is payable.

Art. 13 Limitation period

The limitation period for the sales fees, like that for procedural fees, is based on Article 14 of the General Fees Ordinance of 8 September 2004[5].

Art. 14 Repeal of current legislation

The Ordinance of 22 June 2006[6] on the Fees of the Swiss Agency for Therapeutic Products is hereby repealed.

Art. 15 Transitional provisions

The provisions of this Ordinance shall apply to administrative actions that are subject to a fee and not yet concluded when this Ordinance comes into force.

Art. 16 Commencement and repeal

1 This Ordinance enters into force, subject to Paragraph 2, on 1 January 2013.

2 Annex 1, as attached, enters into force on 1 January 2015.

3 Annex 5, as attached, is repealed on 1 January 2015.

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6 [AS **2006** 3681, **2007** 2041, **2010** 459 Annex]

Annex 1
(Art. 4, para. 1)

Procedural fees for medicinal and transplant products

A. Market access

I. Authorisation fees

		Francs
1.	Authorisation fees	
1.1	Authorisation of medicinal products for human use (excluding complementary and herbal medicinal products) and transplant products	
	a. New active substance	70,000
	b. Similar biological medicinal products according to Art. 12, para. 4 of the Ordinance of the Swiss Agency for Therapeutic Products of 22 June 2006[7] on the Simplified Licensing of Therapeutic Products and the Licensing of Therapeutic Products by the Notification Procedure (TPLO)	70,000
	c. Known active substance with innovation	28,000
	d Known active substance without innovation	15,000
1.2	Authorisation of complementary and herbal medicinal products and review of basic documentation	
	a. Complementary and herbal medicinal product with indication: new active substance	6,000
	b. Complementary and herbal medicinal product with indication: known active substance	3,000
	c. Homeopathic, anthroposophic or Asian medicinal product without indication	1,500
	d. Master dossier for homeopathic or anthroposophic medicinal product	1,000
	e. Basic company dossier for homeopathic, anthroposophic or Asian medicinal product	1,000
	f. Homeopathic or anthroposophic medicinal products without indication, with submission of a reduced dossier	500
	g. Notification for a homeopathic, anthroposophic or Asian medicinal product without indication, per 20 notifications or	

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		Francs
	parts thereof	200
	h. Quality documentation for an Asian medicinal product	3,000
1.3	Authorisation of veterinary medicinal products	
	a. New active substance	8,000
	b. Known active substance	3,000
	b. Complementary and herbal medicinal product with indication	1,500
	d. Notification according to Art. 39 TPLO	500
	e. Notification for a homeopathic or anthroposophic medicinal product without indication, per 20 notifications or parts thereof	200
1.4	Authorisation of special medicinal product categories or of medicinal products in special procedures	
	a. Allergen preparation	3,000
	b. Allergen follow-on preparation	1,000
	c. Imported medicinal product (Art. 14 para. 2 TPA)	4,000
	d. Co-marketing of a medicinal product for human use	2,500
	e. Co-marketing of a complementary and herbal medicinal product	500
	d. Co-marketing of a veterinary medicinal product	500
	g. Sample pack	1,000
1.5	Temporary authorisation of medicinal products for the treatment of life-threatening diseases (Art. 9 para. 4 TPA).	
	a. Medicinal products for human use or transplant products	15,000
	b. Veterinary medicinal products	2,000
2.	Fees for major variations (Art. 12 of the Therapeutic Products Ordinance of 17 Oct. 2001[8]; TPO)	
2.1	Major variations of medicinal products for human use (excluding complementary and herbal medicinal products) and transplant products	
	a. Change of a genetically modified organism in a medicinal product or of active substances manufactured using recombinant technologies or processes	70,000
	b. Change of active substance	25,000
	c. Change of pharmaceutical form	20,000

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		Francs
	d. Change or addition of an indication	20,000
	e. Change or addition of doses (= dosage strength)	15,000
	f. Change or addition of recommended dose	10,000
	g. Change or addition of route of administration	10,000
2.2	Major variations of complementary and herbal medicinal products with indication	3,000
2.3	Major variations of veterinary medicinal products	2,000
3.	Fees for variations requiring approval and notification	
3.1	Variations requiring approval with scientific evaluation	
	a. Major variation of product information (safety-relevant variations and variations in more than two sections)	5,000
	b. Minor variation of product information (variations in max. two sections or variations in the Patient Information only)	1,500
	c. Major quality variation	4,000
	d. Minor quality variation	1,500
	e. Extension of supplementary first applicant protection from 3 to 5 years	4,000
3.2	Variations requiring approval without scientific evaluation	
	a. Change to information and text on container and packaging material (excl. package leaflet)	500
	b. All other changes without scientific evaluation	1,000
3.3	Changes requiring notification	500
4.	Fees for other applications	
4.1	Application for fast-track procedure for medicinal products for human use and transplant products	5,000
4.2	Recognition of the status as an important medicinal product or transplant product for rare diseases	
	a. Medicinal products for human use and transplant products	3,000
	b. Veterinary medicinal products	300
4.3	Reclassification in another dispensing category	
	a. Human medicinal product	8,000
	b. Complementary or herbal medicinal products	2,000
5.	Fees for extensions and discontinuations	

		Francs
5.1	Extension of the authorisation of:	
	a. Medicinal products	500
	b. Complementary and herbal medicinal products	200
	c. Notification for homeopathic, anthroposophic or Asian medicinal products without indication, per 20 notifications or parts thereof	200
	d. Transplant products	200
	e. Allergen preparations	200
	f. Veterinary medicinal products	200
5.2	Discontinuation of the authorisation	200

II. Fees for batch releases

		Francs
1.	Fees for reviewing quality specifications in connection with a batch release application	2,000
2.	Fees for reviewing a plasma pool in connection with a batch release application	300

III. Fees for clinical trials

		Francs
1.	Fees for approvals of a clinical trial	
	a. of somatic gene therapy or with medicinal products containing genetically modified microorganisms	5,000
	b. of somatic gene therapy with transplant products containing genetically modified microorganisms	2,000
	c. with medicinal products (notification)	1,000
	d. with transplant products (notification)	1,000
2.	Fees for variations of a clinical trial	
	a. of somatic gene therapy or with medicinal products containing genetically modified microorganisms	1,000
	b. of somatic gene therapy with transplant products containing genetically modified microorganisms	500
	c. with transplant products	200

IV. Fees for operating licences

		Francs
1.	Fees for the granting of operating licences for	
	a. the manufacture of medicinal products or transplant products	500
	b. wholesale trading in medicinal products or transplant products	500
	c. the import or export of finished medicinal products or transplant products	500
	d. trading in medicinal products or transplant products in foreign countries from Switzerland	500
	e. the withdrawal of blood for transfusions or for the manufacture of medicinal products according to Article 34 TPA	500
	f. the handling of controlled substances	500
	g. the admixture of veterinary medicinal products on the company's own systems	500
2.	Fees for the variation of operating licences for	
	a. the manufacture of medicinal products or transplant products	200
	b. wholesale trading in medicinal products or transplant products	200
	c. the import or export of ready to-use medicinal products or transplant products	200
	d. trading in medicinal products or transplant products in foreign countries from Switzerland	200
	e. the withdrawal of blood for transfusions or for the manufacture of medicinal products according to Article 34 TPA	200
	f. the handling of controlled substances	200
	g. the admixture of veterinary medicinal products on the company's own systems	200
3.	Fees for import or export	
3.1	Import of medicinal products, transplant products, blood or blood products	100
3.2	Import or export of controlled substances	
	a. General import or export	200
	a. One-off import or export	100

V. Fees for certificates

		Francs
1.	Fees for operating licence certificates	100
2.	Fees for product certificates	200
3.	Fees for batch release certificates	100
4.	Fees for other confirmations	
	a. Appendices to a certificate	100
	b. General confirmations	100

B. Controls

I. Fees for inspections

	Francs
Fees for inspections per hour and inspector	200

II. Fees for checking authorisation conditions

		Francs
1.	Fees for a Periodic Safety Update Report (PSUR)	1,500
2.	Fees for preclinical or clinical conditions	
	a. Human medicinal product	4,000
	b. Transplant product	1,000
	c. Veterinary medicinal product	750
3.	Fees for Plasma or Vaccine Antigen Master File	3,000
4.	Fees for quality condition	500

Annex 2
(Art. 5, para. 1)

Fee surcharges and fee reductions

A. Fee surcharges

1. Fast-track authorisation procedure for medicinal products for human use and transplant products

For applications in the fast-track authorisation procedure (Art. 5 TPO[9]), the fees for authorisations and major variations according to Article 12 TPO are increased by:	50 %

2. Procedures with prior notification for medicinal products for human use with a new active substance

When the following applications are submitted with prior notification and processed 20 % faster, the fees are increased by:	100 %
– authorisation,	
– addition of an indication.	

B. Fee reductions

1. Medicinal products for treating rare diseases (Art. 14 para. 1 f TPA)

Once recognised as important medicinal products for rare diseases (orphan drug, MUMS), the fees for applications for medicinal products for human and veterinary use are reduced by:	100 %

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2. Transplant products

1.	For transplant products, fees for authorisations, major variations and the following applications are reduced by:	90 %
	– fast-track authorisation procedure	
	– recognition of the status as an important transplant product for rare diseases	
	– reclassification in another dispensing category	
2.	For transplant products, fees for variations requiring approval and notification are reduced by:	50 %

3. Complementary and herbal medicinal products

For complementary and herbal medicinal products, fees for variations requiring approval and notification are reduced by:	50 %

4. Allergen preparations

1.	For allergen preparations for in-vivo diagnosis, the procedural fees are reduced by:	90 %
2.	For allergen preparations, fees for variations requiring approval and notification are reduced by:	50 %

5. Radiopharmaceuticals

1.	For radiopharmaceuticals, fees for authorisations and major variations are reduced by:	90 %
2.	For radiopharmaceuticals, fees for variations requiring approval and notification are reduced by:	50 %

6. Medicinal products indicated exclusively for paediatric use

For medicinal products indicated exclusively for paediatric use, fees for authorisations and major variations are reduced by:	90 %

7. Veterinary medicinal products

For veterinary medicinal products, fees for variations requiring approval and notification are reduced by:	50 %

8. Application of Article 13 Therapeutic Products Act

Fees for applications processed in accordance with Art. 13 TPA are reduced by:	50 %

9. Collective applications (Annexes 7 and 8 of the Ordinance of the Swiss Agency for Therapeutic Products of 9 Nov. 2001[10] on the Licensing Requirements for Therapeutic Products; TPLRO)

If the same variation is requested simultaneously for several medicinal products with identical documentation, the fee for the second and every subsequent application is reduced by:	80 %

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Annex 3
(Art. 4, para. 1)

Procedural fees for medical devices

	Francs
1. Designation of a conformity assessment body for medical devices	5,000
2. Change in the designation of a conformity assessment body for medical devices	1,000
3. Receipt of a notification for a clinical trial with a medical device	1,000
4. Review of an application for the issuing of an "exceptional permit" to market a non-conforming medical device	1,000
5. Issuing of an import or export certificate for a medical device	300

Annex 4
(Art. 4, para. 2)

Sales fee on medicinal products and transplant products

Level	Ex-factory price of the medicinal product or transplant product in francs	Fee per pack sold (per unit of transplant product) in francs
1	0– 1.99	–.014
2	2– 4.99	–.042
3	5– 10.99	–.084
4	11– 16.99	–.14
5	17– 21.99	–.196
6	22– 27.99	–.252
7	28– 41.99	–.35
8	42– 55.99	–.49
9	56– 90.99	–.56
10	91-121.99	–.7
11	122-194.99	–.98
12	195-364.99	1.4
13	365-499.99	2.1
14	500-999.99	3.1
15	as of 1000	5

Annex 5[11]

[11] This annex is no longer effective. See Art. 16 para. 3 above.