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Federal Act on Medicinal Products and Medical Devices
(Therapeutic Products Act, TPA)

of 15 December 2000 (Status as of 1 January 2018)

The Federal Assembly of the Swiss Confederation,

based on Article 95 paragraph 1 and 118 paragraph 2 of the Federal Constitution[1], and having considered the Federal Council Dispatch dated 1 March 1999[2],

decrees:

Chapter 1 General Provisions

Art. 1 Purpose

[1] The purpose of this Act is to protect human and animal health and to guarantee that only high quality, safe and effective therapeutic products are placed on the market.

[2] It shall furthermore:

a. protect the consumers of therapeutic products against fraud;

b. help to ensure that the therapeutic products placed on the market are used in accordance with their purpose and in moderation;

c. help to ensure that a reliable and well-organised supply of therapeutic products, together with the necessary technical information and advice, is available throughout the country.

[3] In the implementation of this Act, in particular in the enactment of the regulations and in the application to an individual case, it shall be necessary to ensure that:

a. the efficiency and independence of the control of therapeutic products is guaranteed in Switzerland;

b. favourable conditions exist for research and development in the therapeutic product sector;

c. all players competing in the market fulfil the same legal requirements of safety and quality.

AS **2001** 2790
1 SR **101**
2 BBl **1999** 3453

Art. 2 Applicability

[1] This Act applies to:

a. the handling of therapeutic products (medicinal products and medical devices), particularly in their manufacture and placing on the market;

b. narcotics as defined in the Narcotics Act of 3 October 1951[3], insofar as they are used as therapeutic products;

c. therapeutic treatments, such as gene therapy, insofar as they directly relate to therapeutic products; the Federal Council may enact provisions specific to this subject.

[2] The Federal Council may completely or partially exempt medical devices intended for use on animals or in veterinary diagnostics from the scope of this Act.

Art. 3 Due diligence

Any person handling therapeutic products must take all measures necessary according to the state of the art to ensure that human or animal health is not endangered.

Art. 4 Definitions

[1] In this Act:

a. *Medicinal products* means products of chemical or biological origin which are intended to have or are presented as having a medicinal effect on the human or animal organism, in particular in the diagnosis, prevention or treatment of diseases, injuries and handicaps; blood and blood products are also considered to be medicinal products.

b. *Medical devices* means products, including instruments, apparatus, in vitro diagnostics, software and other goods or substances which are intended to have or are presented as having a medical use and whose principal effect is not obtained with a medicinal product;

c. *Manufacture* means all stages in the manufacture of a therapeutic product, from the acquisition of the precursors and the processing to the packaging, storage and delivery of the end products, and including the quality controls and batch release;

d. *Placing on the market* means the distribution and dispensing of therapeutic products;

e. *Distribution* means the transfer or release, either free of charge or in return for payment, but not the dispensing, of a therapeutic product;

f. *Dispensing* means the transfer or release, either free of charge or in return for payment, of a ready-to-use therapeutic product destined for use by the purchaser or for use on a third party or on animals;

3 SR **812.121**

g. *Pharmacopoeia* (*Pharmacopoeia Europaea* and *Pharmacopoeia Helvetica*) means a collection of regulations on the quality of medicinal products, excipients and certain medical devices.

[2] The Federal Council may, by ordinance, distinguish between the terms used in this Act as well as those used in paragraph 1, define them in greater detail, and may provide for exceptions based upon new findings in science and technology as well as on international developments.

Chapter 2 Medicinal Products

Section 1 Manufacture

Art. 5 Mandatory licence

[1] A licence from the Swiss Agency for Therapeutic Products (Agency) shall be required by those who:

a. manufacture medicinal products;

b. add medicinal products to animal feed.

[2] The Federal Council regulates exemptions from the licence requirement. In particular, it may:

a.[4] make the manufacture of medicinal products under Article 9 paragraph 2a–c^{bis} and Article 14 paragraph 1c subject to a mandatory cantonal licence or reporting requirement.

b. exempt from the licence requirement livestock holders who add medicinal products to animal feed intended for their own livestock.

Art. 6 Conditions

[1] The licence shall be issued if:

a. the necessary technical and operational conditions are fulfilled;

b. an appropriate system of quality assurance exists.

[2] The competent authority shall verify by inspection that the conditions are fulfilled.

Art. 7 Manufacturing standards

[1] The manufacture of medicinal products must conform to the recognised rules of good manufacturing practice.

[2] The Federal Council shall specify the recognised rules of good manufacturing practice. In doing so, it shall take account of internationally recognised guidelines and standards.

4 Amended by No 1 of the FA of 13 June 2008, in force since 1 Oct. 2010 (AS **2008** 4873, **2010** 4027; BBl **2007** 2393).

Section 2
Principle for Placing Products on the Market and Authorisation Procedure

Art. 8 Principle for placing products on the market

Medicinal products and excipients placed on the market must meet the requirements of the Pharmacopoeia provided that such requirements exist.

Art. 9 Marketing authorisation

[1] Ready-to-use medicinal products and veterinary medicinal products intended for the manufacture of medicinal foodstuffs (premixed medicinal products) may be placed on the market only if authorised by the Agency, subject to international agreements on the recognition of marketing authorisations.

[2] The following shall be exempt from authorisation:

a.[5] medicinal products prepared according to a doctor's prescription by a public pharmacy or a hospital pharmacy, or under mandate to the latter by another establishment holding a manufacturing authorisation, and for a given person or group of persons or for a given animal or livestock (magistral formula); on the basis of a prescription, the medicinal product may be manufactured by the public pharmacy or the hospital pharmacy as required or on a small industrial scale but may only be dispensed on a doctor's prescription.

b.[6] medicinal products prepared as required or on a small industrial scale by a public pharmacy, a hospital pharmacy, a drugstore or by another establishment holding a manufacturing licence, conforming to a special monograph of the Pharmacopoeia or another pharmacopoeia or a formulary recognised by the Agency, and which are supplied to their own customers (officinal formula);

c.[7] non-prescription medicinal products prepared as required or on a small industrial scale by a public pharmacy, a hospital pharmacy, a drugstore or by another establishment holding a manufacturing licence, within the limits of the establishment's right to dispense in compliance with Article 25, according to its own formula or a formula published in the specialised literature, which are intended for dispensing to the establishment's own customers;

c[bis].[8] medicinal products for which it is proven that there is no authorised or available alternative medicinal product that is applicable and equivalent and which are manufactured in a hospital pharmacy in accordance with the hos-

5 Amended by No 1 of the FA of 13 June 2008, in force since 1 Oct. 2010 (AS **2008** 4873, **2010** 4027; BBl **2007** 2393).
6 Amended by No 1 of the FA of 13 June 2008, in force since 1 Oct. 2010 (AS **2008** 4873, **2010** 4027; BBl **2007** 2393).
7 Amended by No 1 of the FA of 13 June 2008, in force since 1 Oct. 2010 (AS **2008** 4873, **2010** 4027; BBl **2007** 2393).
8 Inserted by No I of the FA of 13 June 2008, in force since 1 Oct. 2010 (AS **2008** 4873, **2010** 4027; BBl **2007** 2393).

pital's own pharmaceuticals list, on a small industrial scale, and are intended for dispensing to its own customers;

d. medicinal products intended for clinical trials;

e. medicinal products which cannot be standardised.

f.[9] medicinal products that were authorised in a canton on 1 January 2002 and which are still on the market when the Amendment of 18 March 2016 comes into force; they must be labelled accordingly and may only be placed on the market in the canton concerned and only supplied by person entitled to supply medicinal products under this Act.

[2bis] An establishment with a manufacturing licence may be commissioned to manufacture medicinal products in accordance with paragraph 2 a–c[bis].[10]

[2ter] The Federal Council shall lay down the qualitative and quantitative criteria for the medicinal products manufactured in accordance with paragraph 2 a–c[bis] and paragraph 2[bis].[11]

[3] The Federal Council may make provision for a requirement of authorisation for the production or manufacturing process used in making medicinal products which cannot be standardised.

[4] The Agency may authorise, for a limited period, the distribution or dispensing of unauthorised medicinal products to treat life-threatening diseases if such an authorisation is compatible with the protection of health, if a significant therapeutic benefit is to be expected from the administration of these medicines, and if no comparable medicine exists.

Art. 10 Conditions for granting a marketing authorisation

[1] Any person applying for a marketing authorisation for a medicinal product or procedure must:

a. prove that the medicinal product or procedure is of high quality and is safe and effective;

b. be a holder of an authorisation to manufacture, import or conduct wholesale trade issued by the competent authority;

c. have a registered address, registered office or a branch office, in Switzerland.

[2] The Agency shall verify that the conditions for granting the marketing authorisation are fulfilled. To this effect, it may carry out product-specific inspections.

9 Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2018 (AS **2017** 2745; BBl **2013** 1).

10 Inserted by No I of the FA of 13 June 2008, in force since 1 Oct. 2010 (AS **2008** 4873, **2010** 4027; BBl **2007** 2393).

11 Inserted by No I of the FA of 13 June 2008, in force since 1 Oct. 2010 (AS **2008** 4873, **2010** 4027; BBl **2007** 2393).

Art. 11 Application for a marketing authorisation

[1] The application for a marketing authorisation must contain all of the data and documents necessary for its assessment, in particular:

a. the brand name of the medicinal product;

b. the name of the manufacturer and the distribution company;

c. the manufacturing process, the composition, the quality and the stability of the medicinal product;

d. the attestation of residues and the withdrawal period for medicinal products intended for animals kept for the production of foodstuffs;

e. the therapeutic effects and adverse events;

f. the labelling, the medical information, the dispensing method and the method of administration;

g. the results of physical, chemical, galenic and biological or microbiological tests as well as of pharmacological and toxicological tests;

h. the results of clinical trials.

[2] The Federal Council shall:

a. lay down, taking into account the recognised international guidelines and standards, the requirements for organising, carrying out and recording the pharmacological and toxicological tests referred to in paragraph 1 letter g, and shall adopt provisions for the control procedure;

b. stipulate the languages to be used for labelling and information leaflets.

[3] The Agency shall define in greater detail the data and documents mentioned in paragraph 1. It may make provision for further data and documents.

Art. 12 Second notification

[1] An application for a marketing authorisation for a medicinal product which is essentially the same as an already authorised medicinal product (original preparation) and is intended for the same use, may be based on the results of the pharmacological, toxicological and clinical tests of the already authorised medicinal product if:

a. the applicant for the original preparation provides written permission; or

b. the protection period for the original preparation has expired.

[2] The protection period shall be ten years. The Federal Council may also grant an appropriate protection period for the test results for the original preparation referred to in paragraph 1 for new indications, new modes of administration, new preparation forms, or new dosages.

Art. 13 Medicinal products and procedures authorised in foreign countries

If a medicinal product or procedure is already authorised in a country having equivalent medicinal product control, the results of tests carried out for this purpose shall be taken into account.

Art. 14 Simplified authorisation procedure

[1] The Agency shall make provision for simplified procedures for the authorisation of certain categories of medicinal products where this is compatible with the quality, safety and efficacy requirements, and where there is no conflict with Swiss interests or international agreements. In particular, this applies in the case of:

a. medicinal products made with known active pharmaceutical ingredients;

b. medicinal products of complementary medicine;

c. medicinal products prepared for stocks by a public pharmacy, a drugstore or by another establishment holding a manufacturing licence, according to its own formula (specialities of the house), conforming to the Pharmacopoeia or another pharmacopoeia, or a formula recognised by the Agency, and which are dispensed to its own customers;

d.[12] medicinal products prepared by a hospital pharmacy or in the hospital's own radiopharmaceutical unit for the needs of the hospital;

e. medicinal products prepared by the army and used in the context of the co-ordinated army medical corps;

f. important medicinal products for rare diseases;

g. veterinary medicinal products, which are intended exclusively for animals not kept for the production of foodstuffs.

[2] The Agency shall make provision for a simplified authorisation procedure in the case of an application from another person responsible for the placing on the market of a medicinal product which is already authorised in Switzerland and which is imported from a country with an equivalent authorisation system:

a. if the medicinal product satisfies the same requirements as the medicinal product already authorised in Switzerland, in particular in regard to the labelling and the medical information mentioned in Article 11;

b. if the other person responsible for placing the medicinal product on the market can continue to guarantee that all the authorised medicinal products that he distributes fulfil the same requirements of safety and quality as those of the first applicant.

[3] ...[13]

12 Amended by No 1 of the FA of 13 June 2008, in force since 1 Oct. 2010 (AS **2008** 4873, **2010** 4027; BBl **2007** 2393).

13 Repealed by No II of the FA of 19 Dec. 2008, with effect from 1 June 2009 (AS **2009** 2615; BBl **2008** 303).

Art. 15[14] Mandatory notification

When certain medicinal products or categories of medicinal products, in particular medicinal products for hospital use, fulfil the conditions for a simplified marketing authorisation and yet the implementation of such a procedure is not deemed appropriate, the Agency may require only a mandatory notification.

Art. 16 Authorisation decision

[1] The Agency shall grant a marketing authorisation if the conditions are fulfilled. It may attach conditions and requirements to the authorisation.

[2] The authorisation is valid for five years. During this period, the Agency may, on its own initiative or upon request, adapt the marketing authorisation to changes in circumstances or revoke it.

[3] The Agency may, independently of the validity period of the authorisation, re-examine the medicinal products by groups and if necessary adapt or revoke the authorisation.

[4] On request, it shall renew the authorisation if the conditions are still fulfilled.

Art. 16*a*[15] Revocation of the authorisation

[1] The Agency shall revoke the authorisation for a medicinal product if:

a. it is not actually placed on the market within three years of the granting of the authorisation;

b. it is no longer actually on the market during a period of three successive years after it has been placed on the market.

[2] The Federal Council may provide for exceptions from paragraph 1.

[3] It may provide that, in the case of medicinal products for severe illnesses, injuries or handicaps, the authorisation is revoked before the period mentioned in paragraph 1 has expired. It decides the duration of such periods and lays down the criteria for revocation.

Art. 17 Official batch release

[1] If the manufacture of a medicinal product requires special measures to be taken, in particular to guarantee safety, then a release authorisation must be obtained from the Agency for each batch before distribution. This shall be subject to international agreements on batch release recognition.

[2] The Agency shall determine the categories of medicinal products for which official batch release is required, as well as procedure and the requirements to be fulfilled.

14 Amended by No 1 of the FA of 13 June 2008, in force since 1 Oct. 2010 (AS **2008** 4873, **2010** 4027; BBl **2007** 2393).
15 Inserted by No 1 of the FA of 13 June 2008, in force since 1 Oct. 2010 (AS **2008** 4873, **2010** 4027; BBl **2007** 2393).

[3] It shall publish a list of medicinal products which require a batch release for their distribution.

Section 3 Imports, Exports and Foreign Trade

Art. 18 Mandatory licence

[1] A licence granted by the Agency shall be required by any person who in a professional capacity:

a. imports ready-to-use medicinal products intended for distribution or dispensing;

b. exports ready-to-use medicinal products intended for distribution or dispensing;

c. trades medicinal products in foreign countries from Switzerland, without their entering Switzerland.

[2] The Federal Council may also make provision for a requirement of licence for the import or export of non-ready-to-use medicinal products.

[3] It may issue exemptions from the requirement of licence for:

a. medical professionals who work across borders;

b. international organisations.

[4] Goods stored in a customs warehouse or a bonded warehouse shall be considered to be imported.[16]

[5] The Federal Council may issue special regulations for goods in transit.

[6] If another State requests export certificates and attestations for the importing of medicinal products, the Agency may issue such documents to persons holding an authorisation to export.

Art. 19 Licensing conditions

[1] The licence shall be issued if:

a. the necessary technical and operational conditions are fulfilled;

b. an appropriate system of quality assurance exists.

[2] The licence shall also be issued to the applicant who already possesses a manufacturing licence for medicinal products. Furthermore, the licence referred to in Article 18 paragraphs 1 letters b and c shall be issued to the applicant already possessing a licence for the import or wholesale trade of medicinal products.

[3] The competent authority shall verify by inspection that the conditions are fulfilled.

16 Amended by Annex No 17 of the Customs Act of 18 March 2005, in force since 1 May 2007 (AS **2007** 1411; BBl **2004** 567).

Art. 20 Special provisions for imports

[1] Medicinal products which have been authorised, or which are not subject to authorisation, may be imported.

[2] The Federal Council may permit the importing of small quantities of non-authorised ready-to-use medicinal products by:

a. private individuals for their personal use;

b. medical professionals.

[3] It may:

a. stipulate that the licence to import certain medicinal products requiring a specific control for the protection of health be granted in particular cases by the Agency;

b. restrict or prohibit the importing of certain medicinal products if circumstances suggest that they could be intended for illegal purposes or misuse.

[4] The Agency shall draw up a list of medicinal products for which imports shall be restricted or prohibited.

Art. 21 Restrictions on export and foreign trade

[1] The exporting of medicinal products and their foreign trade from Switzerland shall be prohibited if:

a. they are prohibited in the target country;

b. circumstances suggest that they could be intended for illegal purposes.

[2] The Federal Council may stipulate that in particular cases the export of medicinal products which are not authorised in Switzerland or in the target country is prohibited by the Agency or subject to restrictions.

[3] The Agency shall draw up a list of medicinal products for which export shall be restricted or prohibited.

[4] In particular cases, it may grant exemptions from export restrictions or bans, in particular if the authority of the target country agrees to the import.

Art. 22 Duties of diligence at the time of export

[1] Any person exporting ready-to-use medicinal products, whether pre-packaged or not, should provide the recipient, without being asked, with the appropriate basic medical and pharmaceutical information.

[2] Any person exporting medicinal products intended for use in clinical trials must demand proof that the rules of good clinical trial practice are applied.

Section 4 Distribution, Prescription and Dispensing

Art. 23 Categories of medicinal products

[1] Medicinal products shall be classified into categories according to whether or not they are subject to prescription.

[2] A category of over-the-counter medicinal products shall be created. Articles 24 to 27 and 30 do not apply to this category.

[3] The Federal Council shall lay down the classification criteria. The Agency shall categorise each medicinal product for which it has granted a marketing authorisation.

Art. 24 Dispensing of medicinal products subject to prescription

[1] The following persons shall be entitled to dispense prescription-only medicinal products:

a. pharmacists, on presentation of a doctor's prescription and, in justified exceptional cases, without a doctor's prescription;

b. all other medical professionals in accordance with the provisions on pro-pharmacy;

c. all duly trained professionals, under the supervision of a person specified in paragraphs 1a and b.

[2] Prescription-only medicated foodstuffs for animals may also, on presentation of a prescription from a veterinary surgeon, be dispensed by persons licensed to add medicinal products to animal foodstuffs.

[3] The cantons may license the persons referred to in Article 25 paragraph 1c, to use certain prescription-only medicinal products.

Art. 25 Dispensing of non-prescription medicinal products

[1] The following shall be entitled to dispense non-prescription medicinal products:

a. persons entitled to dispense prescription medicinal products;

b. drugstore assistants holding a federal diploma, within the limits of their right to dispense medicinal products;

c. all other duly trained persons, within the limits of their right to dispense medicinal products;

d. all duly trained professionals, under the supervision of persons referred to in letters a and b.

[2] The Federal Council shall determine the categories of duly trained persons which are referred to in paragraph 1 letter c.

[3] The Agency shall determine the categories of medicinal products which may be dispensed by the persons referred to in paragraphs 1 letters b and c.

[4] The cantons may grant to drugstore assistants holding a federal diploma the right to dispense all non-prescription medicinal products insofar as the dispensing of medicinal products of this type is not guaranteed over the whole of the cantonal territory. The Federal Council shall lay down the conditions for this.

[5] Subject to the provisions of paragraphs 2 and 3, the cantons may grant to persons holding a qualification recognised by the canton the right to dispense certain groups of medicinal products, such as those pertaining to complementary medicine. The Agency must be informed of this.

Art. 26 Principle of prescription and dispensing

[1] The recognised rules of pharmaceutical and medical sciences must be respected when prescribing and dispensing medicinal products.

[2] A medicinal product may only be prescribed if the state of health of the consumer or patient is known.

Art. 27 Mail-order trade

[1] In principle, mail-order trade in medicinal products is prohibited.

[2] A licence may only be issued under the following conditions:

a. there is a doctor's prescription for the medicinal product;

b. no safety requirements oppose it;

c. appropriate consultation is guaranteed;

d. sufficient medical supervision of the effect of the medicinal product is guaranteed.

[3] The Federal Council shall regulate the details.

[4] The cantons shall issue the authorisation.

Art. 28 Licence for wholesale trade

[1] Any person engaged in the wholesale trade of medicinal products must possess a licence issued by the Agency.

[2] The licence shall be issued if:

a. the necessary technical and operational conditions are fulfilled;

b. an appropriate system of quality assurance exists.

[3] The licence shall also be issued if the applicant already possesses a manufacturing or import licence for medicinal products.

[4] The competent authority shall verify by inspection that the conditions are fulfilled.

Art. 29 Wholesale standards

[1] Any person engaged in the wholesale trade of medicinal products must respect the recognised principles of good wholesale trade practice.

[2] The Federal Council shall specify the recognised principles of good wholesale trade practice. In doing so, it shall take account of internationally recognised guidelines and standards.

Art. 30 Licence for retail trade

[1] Any person dispensing medicinal products in a pharmacy, a drugstore or another retail trade establishment, must possess a cantonal licence.

[2] The cantons shall lay down the conditions and procedures for granting the licence for retail trade. It shall carry out periodical inspections.

Section 5 Advertising and Price Comparisons

Art. 31 Principle

[1] In principle, it shall be permitted to:

a. advertise all types of medicinal products if the advertising is directed exclusively at persons who prescribe or dispense them;

b. advertise non-prescription medicinal products to the general public.

[2] The Federal Council shall lay down the conditions for the publication of price comparisons for prescription medicinal products.

[3] It may, in order to protect health and prevent fraud, restrict or prohibit the advertising of certain medicinal products or groups of medicinal products and enact regulations concerning cross-border advertising.

Art. 32 Unlawful advertising

[1] Advertising shall be deemed unlawful:

a. if it is misleading or contrary to public order and morality;

b. if it may incite an excessive, abusive or inappropriate use of medicinal products;

c. if it is for medicinal products which may not be placed on the market in Switzerland.

[2] Advertising directed at the general public shall be deemed unlawful for medicinal products which:

a. may only be supplied on a prescription;

b. contain narcotic or psychotropic substances as referred to in the Narcotics Act of 3 October 1951[17];

[17] SR **812.121**

c. may not, on account of their composition and their intended use, be used without the intervention of a doctor for the necessary diagnosis, prescription or treatment;

d. are frequently the object of abuse or which lead to an addiction or dependence.

Art. 33 Promises and acceptance of material benefits

[1] It shall be prohibited to grant, offer or promise material benefits to persons who prescribe or dispense medicinal products or to the organisations which employ them.

[2] It shall be prohibited for persons who prescribe or dispense medicinal products as well as for the organisations which employ them, to solicit or accept material benefits.

[3] However, the following shall be permitted:

a. material benefits of modest value and which are related to medical or pharmaceutical practice;

b. commercially and economically justified discounts which directly reflect on the price.

Section 6 Special Provisions on Blood and Blood Products

Art. 34 Operating licence

[1] Anyone drawing blood from persons for the purpose of transfusion or the manufacture of therapeutic products or for supply to a third party must possess an operating licence issued by the Agency.

[2] The licence shall be issued if:

a. the necessary technical and operational conditions are fulfilled;

b. an appropriate system of quality assurance exists.

[3] The Agency shall verify by inspection that the licensing conditions are fulfilled.

[4] Establishments such as hospitals which only stock blood or blood products must possess a cantonal operating licence. The cantons shall lay down the conditions and the procedure for granting this licence. They shall carry out periodical inspections.

Art. 35 Licence for individual imports

[1] An import licence is required for each individual batch of imported blood and blood products. Storage in a customs warehouse shall be deemed to be importing.

[2] The Federal Council may make provision for exemptions from an import licence if all danger to persons is excluded.

Art. 36 Fitness of the donor to give blood

[1] The holder of the licence referred to in Article 34 paragraph 1 must verify that the donor is fit to give blood.

[2] Persons excluded from donating blood shall be those:

a. whose health could suffer from the extraction of blood;

b. whose blood may transmit pathogens.

[3] The Federal Council shall lay down the requirements relating to the donor's fitness to give blood, the competence to establish this fitness and the data which must be recorded at the time of the blood donation.

Art. 37 Rules of good manufacturing practice in the handling of blood and blood products

[1] Any operations relating to blood and labile blood products, in particular the extraction, manufacture, processing, storage and the placing on the market, must be conducted in accordance with the principles of quality management and the recognised principles of good manufacturing practice in the handling of blood and blood products.

[2] Blood and labile blood products as well as associated blood samples must be labelled such that they can be unambiguously identified at any time.

[3] The Federal Council shall specify the recognised rules of good manufacturing practice. In doing so, it shall take account of internationally recognised guidelines and standards.

Art. 38 Obligation to test

[1] Donated blood must be tested for the presence or signs of pathogens and examinations must be carried out in order to guarantee compatibility.

[2] The Federal Council shall specify:

a. for which pathogens or which signs of their presence the blood should be tested;

b. the procedure to be followed when a test result is positive;

c. the examinations to be carried out in order to guarantee compatibility;

d. the regulations concerning the execution of tests.

[3] It may grant exemptions to the obligation to test in the case of autologous transfusions.

Art. 39 Obligation to record

[1] Any person handling blood or blood products must:

a. record all of the processes which are important for safety;

b. maintain the records in such a manner as to be able to trace the data back to the person who donated or received the blood;

[2] For each extraction of blood, the following shall in particular be recorded:

a. the surname, first name and the date of birth of the blood donor;

b. the date on which the blood was taken;

c. the test results and their interpretation.

[3] For a person excluded from donating blood, the following shall be recorded:

a. the surname, first name and the date of birth;

b. the date and the reasons for exclusion.

[4] For a person to whom blood or blood products are to be administered, the following shall be recorded:

a. the surname, first name and the date of birth;

b. the date of administration;

c. the labelling and the origin of the blood or blood products.

[5] The Federal Council shall regulate the details. In particular, it may grant exemptions from the obligation to record in the case of autologous blood donations.

Art. 40 Obligation to archive

[1] The information recorded under Article 39 and all important documents must be archived for 20 years.

[2] The Federal Council shall regulate the details. In particular, it may:

a. make provision for the transfer to the Agency, or the archiving, of the records referred to in Article 39 and any important documents, should the establishment cease its activity prior to the expiry of the archiving period;

b. grant exemptions from the obligation to archive in the case of autologous transfusions.

Art. 41 Further regulations

The Federal Council may prescribe additional safety precautions; in particular it may determine that the procedures for the removal or the inactivation of possible pathogens may only be applied after the Agency has given authorisation.

Section 7 Special Provisions on Veterinary Medicinal Products

Art. 42 Prescription and dispensing

[1] A medicinal product may only be prescribed or supplied for an animal if the prescriber knows the animal or livestock.

[2] If the medicinal product is intended for production animals, the prescriber must also know the state of health of the animal.

[3] The Federal Council may prohibit the prescription and dispensing of medicinal products prepared according to a magistral formula (Art. 9 para. 2 let. a) for production animals.

Art. 43 Obligation to keep a record

Any person who imports or exports, distributes or dispenses veterinary medicinal products or administers or allows them to be administered to production animals must keep a record of incomings and outgoings of such medicinal products and archive the supporting documents.

Art. 44 Standardisation and coordination of enforcement

The Federal Council may impose measures for enforcement on the cantons and oblige them to inform the competent federal office of the enforcement measures taken and the test results.

Chapter 3 Medical Devices

Art. 45 Requirements

[1] A medical device used in accordance with its intended use must not endanger the health of the user, the consumer, the patient or a third party. Claims for its performance or effectiveness must be provable.

[2] Any person placing a medical device on the market must be able to prove that the device satisfies the fundamental requirements.

[3] The Federal Council shall lay down the requirements that medical devices must satisfy. In particular it shall lay down:

a. the fundamental requirements;

b. the rules of their classification;

c. the languages used for the product information.

[4] The Agency shall designate the technical standards which are appropriate for fulfilling the fundamental requirements. It shall designate, as far as possible, the internationally harmonised standards. Any deviations must be approved by the competent authority[18].

[5] The Federal Council shall lay down the requirements for medical devices intended for use in clinical trials.

18 Currently: State Secretariat for Economic Affairs.

Art. 46 Procedures for assessing conformity

[1] Any person placing a medical device on the market must be able to prove that it has been submitted to the prescribed procedures for assessing conformity.

[2] The Federal Council shall regulate the prescribed procedures for assessing conformity. In particular it shall lay down:

a. the types of procedures;

b. the medical devices for which an authority for assessing conformity must be enlisted;

c. the documents required and the length of time for which they should be archived.

[3] It may:

a. require proof or a certificate of conformity for medical devices manufactured or reconditioned in the same establishment where they are to be used;

b. require human clinical trials for certain medical devices, which will form an integral part of the proof of conformity.

Art. 47 Further regulations concerning the placing on the market

[1] Any person placing medical devices on the market must introduce and maintain a product-tracking system allowing for the collection and analysis of experiences with the devices, and to ensure that such acquired insights are taken into account during the manufacture and further development of the devices.

[2] The Federal Council may:

a. make provision for mandatory notification for the placing of certain medical devices on the market;

b. make provision for a licence for the placing of certain medical devices on the market, in particular for in vitro diagnostics.

Art. 48 Dispensing and use

[1] For the protection of health, the Federal Council may, for certain medical devices:

a. make provision that they can only be dispensed on a medical prescription;

b. lay down the necessary technical and operational conditions or a mandatory notification for their dispensing and use;

c. attach to the dispensing of products the condition that the devices concerned must be traceable between their manufacture and their use and vice versa.

Art. 49 Obligation of maintenance

[1] Any person who uses a medical device commercially or who uses it on a third party shall be obliged to take all the necessary measures for the maintenance of such device to ensure the continued performance and the safety of the medical device.

[2] The Federal Council may:

a. specify the type of maintenance required for certain medical devices or certain classes of medical devices;

b. regulate the procedure for proving that the obligation of maintenance and the relative requirements have been fulfilled;

c. make the maintenance dependent upon the technical conditions.

Art. 50 Import and export

[1] If required for the protection of health, the Federal Council may restrict or prohibit the import or export of certain medical devices.

[2] If another State requires export certificates and attestations for the import of medical devices, the Agency may issue such documents to the exporters.

Art. 51 Advertising

The Federal Council may, in order to protect health and prevent fraud, restrict or prohibit the advertising of certain medical devices and enact regulations concerning cross-border advertising.

Chapter 4: Common Provisions on Medicinal Products and Medical Devices

Section 1 Pharmacopoeia

Art. 52

[1] The Agency shall publish the Pharmacopoeia.

[2] It shall involve the interested parties in the drafting of the Pharmacopoeia. In particular, it shall call upon experts and working groups.

[3] It shall participate in the development of the European Pharmacopoeia (Pharmacopoeia Europaea) in accordance with international conventions and transpose it into federal law. It may enact additional regulations valid for Switzerland (Pharmacopoeia Helvetica).

[4] The Pharmacopoeia shall be published separately from the Official Compilation of Federal Legislation. The Federal Council shall regulate the details of publication and in particular shall stipulate the languages in which it shall be published.

Section 2 Clinical Trials

Art. 53[19] Principle

For clinical trials of therapeutic products in humans, the Human Research Act of 30 September 2011[20] applies in addition to the provisions of this Act.

Art. 54[21] Mandatory authorisation

[1] Clinical trials of therapeutic products require authorisation from the Agency in advance.

[2] Exempted from mandatory authorisation are clinical trials involving:

a. authorised medicinal products administered in accordance with the approved conditions of use;

b. compliant medical devices applied in accordance with the intended use specified in the conformity assessment.

[3] The Federal Council may:

a. for other trials, grant an exemption from mandatory authorisation or specify mandatory notification;

b. for clinical trials of veterinary therapeutic products, specify mandatory authorisation or notification.

[4] As part of the authorisation procedure, the Agency shall verify whether:

a. the medicinal products meet the requirements of Good Manufacturing Practice and of medicinal product safety; or whether

b. the medical devices meet the requirements specified in Article 45, the product risks are duly considered in the clinical trial, and the product data is in line with current scientific knowledge and correctly indicated in the protocol.

[5] It may at any time carry out an inspection to determine whether the conduct of the clinical trial meets the requirements specified in this Act and in the Human Research Act of 30 September 2011[22].

[6] The Federal Council shall issue regulations concerning the procedure. It may specify mandatory authorisation for changes to clinical trials.

[7] It may specify notification or information requirements, in particular with regard to:

a. the completion or discontinuation of a clinical trial;

19 Amended by Annex No 6 of the Human Research Act of 30 Sept. 2011, in force since 1 Jan. 2014 (AS **2013** 3215; BBl **2009** 8045).
20 SR **810.30**
21 Amended by Annex No 6 of the Human Research Act of 30 Sept. 2011, in force since 1 Jan. 2014 (AS **2013** 3215; BBl **2009** 8045).
22 SR **810.30**

b. adverse events observed in connection with a clinical trial;

c. the occurrence of circumstances during the conduct of a clinical trial which could affect the safety or health of the participants.

[8] In issuing regulations in accordance with paragraphs 4 and 5, the Federal Council shall have regard to recognised international regulations.

Art. 55–57[23]

Section 3 Market Surveillance and Inspection Procedures

Art. 58 Official market surveillance

[1] The Agency and the cantons shall monitor, within the limits of their powers, whether the manufacture, distribution, dispensing and presentation of therapeutic products are in accordance with this Act. They shall verify by periodic inspection that the conditions for the licences are still fulfilled.

[2] The Agency shall verify the therapeutic products placed on the market. It shall verify that the medicinal products conform to the marketing authorisation and that the medical devices satisfy the legal requirements.

[3] The Agency shall be responsible for monitoring the safety of therapeutic products. To this effect, it shall in particular collect the notifications referred to in Article 59, evaluate them, and take the necessary administrative measures.

[4] The Agency and the cantons may, free of charge, take samples, request essential information and documents, and ask for any help necessary for this purpose.

[5] The cantons shall notify the Agency for any events, findings or complaints resulting from the application of paragraph 1. The Agency shall take the necessary administrative measures. The cantons may also take the necessary administrative measures in the case of a serious direct threat to health.

Art. 59 Mandatory notification, notification system and the right to notify

[1] Any person manufacturing or distributing ready-to-use therapeutic products must put in place a system of notification. He must notify the Agency of any adverse event or reaction which:

a. is or may be attributable to the therapeutic product itself, its use or to incorrect labelling or instructions;

b. may endanger or damage the health of the consumer, of the patient, of a third party or of the treated animals.

23 Repealed by Annex No 6 of the Human Research Act of 30 Sept. 2011, with effect from 1 Jan. 2014 (AS **2013** 3215; BBl **2009** 8045).

[2] Any person manufacturing or distributing therapeutic products must furthermore notify the Agency of any quality defects and any further findings and assessments which could influence the basis of evaluation.

[3] Any person professionally administering therapeutic products to humans or animals or dispensing such must also notify the Agency of any serious and previously unknown adverse events and reactions or quality defects.

[4] Consumers, patients and their organisations as well as interested third parties, may notify the Agency for adverse events and reactions with therapeutic products.

Art. 60 Competence for conducting inspections

[1] The Agency is responsible for inspections carried out in Switzerland subject to the reservations of Articles 30 and 34 paragraph 4.

[2] It is responsible for the inspections specified in Articles 6, 19 and 28 in the following sectors:

a. immunological medicinal products;

b. blood and blood products;

c. rarely used procedures which require very specific and specialised knowledge.

[3] It shall delegate the inspections referred to in Articles 6, 19 and 28 in all other sectors to the cantonal inspectorates insofar as they satisfy the requirements of federal legislation and international law applicable in Switzerland.

[4] It may involve the cantonal inspectorates in, or ask them to carry out inspections within its area of competence.

[5] The cantons may involve regional or other cantonal inspectorates or the Agency in, or ask them to carry out the inspections referred to in paragraph 3.

Section 4 Obligation of Secrecy and Disclosure of Data

Art. 61 Obligation of secrecy

Persons responsible for the execution of this Act are obliged to maintain professional secrecy.

Art. 62 Data confidentiality

[1] If there is an overriding legitimate interest in preserving the secrecy of the data collected in accordance with this Act, the competent authority must treat such data as confidential.

[2] The Federal Council may determine the data which are disclosed by the competent authority.

Art. 63 Data disclosure between the enforcement authorities in Switzerland

[1] The Federal and cantonal authorities responsible for enforcing this Act shall ensure mutual disclosure of the data insofar as this is necessary for enforcing this Act.

[2] The Federal Council may make provision for the disclosure of data to other authorities or organisations should this be necessary for the enforcement of this Act.

Art. 64 International administrative assistance

[1] The Federal authorities responsible for enforcing this Act may request information from the competent foreign authorities or international organisations.

[2] They shall be authorised to disclose non-confidential data collected in accordance with this Act to competent foreign authorities or international organisations.

[3] They shall be authorised to disclose confidential data collected in accordance with this Act to competent foreign authorities or international organisations insofar as this makes it possible to avoid serious health risks or to uncover illegal traffic or other serious violations of the present Act.

[4] They shall be authorised to disclose confidential data collected in accordance with this Act to competent foreign authorities, on request, on condition that:

a. the foreign authorities making the request guarantee confidentiality;

b. the foreign authorities making the request use the data exclusively within the scope of an administrative procedure for the execution of provisions relating to therapeutic products;

c. only data necessary for the execution of the provisions relating to therapeutic products are disclosed;

d. no manufacturing or trade secrets are revealed unless the disclosure of such information is essential for averting dangers directly threatening to health.

[5] The Federal Council may conclude international agreements on the disclosure of confidential data to foreign authorities or to international organisations insofar as this is necessary for the enforcement of this Act.

[6] The provisions on international mutual assistance in criminal matters are reserved.

Art. 64*a*[24] Cross-border controls

[1] Competent foreign authorities shall, on notifying the Agency, be entitled to control Swiss establishments operating in the therapeutic product sector provided:

a. the control has the sole purpose of verifying compliance with the regulations on therapeutic products;

b. the result of the control is used solely in administrative proceedings in connection with the enforcement of regulations on therapeutic products;

24 Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2018 (AS **2017** 2745; BBl **2013** 1).

c. the establishment concerned consents to the control; and

d. the foreign authority informs the Agency of the result by providing it with the inspection report in an official Swiss language or in English.

2 The Agency may accompany the foreign authority during the control.

3 It may in consultation with the competent authorities carry out controls of establishments abroad that operate in the therapeutic product sector if this is required to guarantee the protection of health.

Section 5 Fees

Art. 65

1 The Agency and other authorities entrusted with enforcing this Act shall levy fees for the licences, controls and the services that they provide. Furthermore, the Agency may levy fees for the receipt of notifications.

2 The Agency may levy a fee for monitoring the trade of ready-to-use medicinal products sold in Switzerland.

3 The Federal Council may authorise the Agency to levy an annual fee for maintaining licences.

4 The Agency shall fix the scale of the fees referred to in paragraphs 2 and 3 such that they also cover the costs of developing quality standards, monitoring the market, informing the public and taking measures against abusive or incorrect use.

5 It shall set the scale of fees such that it fulfils the service mandate relating to the coverage of costs.

6 The Federal Council may, under the service mandate, request that the Agency relinquish all or part of the fees for certain licences, provisions of service or controls.

Section 6 Administrative Measures

Art. 66 In general

1 The Agency may take all administrative measures necessary to enforce this Act.

2 In particular it may:

a. raise objections and set an appropriate time period for restoring the state of law;

b. suspend or revoke licences and marketing authorisations;

c. close down establishments;

d. seize, hold in official storage or destroy therapeutic products which endanger health or which do not conform to the regulations of this Act;

e. prohibit the distribution, dispensing, import, export and foreign trade from Switzerland of therapeutic products, order their immediate recall from the market, or order the publication of recommendations of conduct to prevent damage;

f. seize, hold in official storage, destroy or prohibit the use of illegal advertising media, and publish the prohibition at the expense of the responsible parties;

g. temporarily or permanently prohibit the advertising of a specific therapeutic product in the event of serious or repeated infringements of the provisions of this Act, and publish the prohibition at the expense of the responsible parties.

3 Within the limits of their competence, the cantons shall take the administrative measures necessary to enforce this Act in accordance with paragraph 2.

4 The customs authorities shall be entitled, if they suspect an infringement of the provisions of this Act, to hold back shipments of therapeutic products at the border or in a customs warehouse and to call upon the enforcement authorities. The latter shall make any further enquiries and take the necessary measures.

Art. 67 Informing the general public

1 The Agency shall ensure that the public is informed of occurrences specifically relating to therapeutic products which endanger health, and shall issue appropriate recommendations. It shall publish information of general interest about the therapeutic products sector, in particular regarding authorisation and revocation decisions as well as about amendments to professional and patient information concerning medicinal products.

2 The competent Federal offices may inform the public on the correct use of therapeutic products for the purpose of protecting health and combating the abuse of such products.

Art. 67*a*[25] Provision of information about the use of medicinal products in certain population groups

1 In order to improve safety in the use of medicinal products in paediatrics, the Federal Council may allow for the collection, harmonisation, evaluation and publication of data relating to the prescription, supply and use of medicinal products.

2 The Confederation may arrange for a database to be established and operated by third parties for this purpose. This database may not contain personal data.

3 The Federal Council:

a. shall specify the basic requirements for the content, operation and quality of the database fest and regulate the conditions for the access to and use of the data;

25 Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2018 (AS **2017** 2745; BBl **2013** 1).

b. determines the entity responsible for managing the database and may authorise the same to gather information in anonymised form from medical professionals.

4 The operators in accordance with paragraph 2 shall guarantee the interoperability of this database with the register in accordance with Article 67.

5 The Federal Council may extend the activities under paragraphs 1 and 2 to include further specific population groups. It may provide for the establishment of advisory committees or the consultation of experts.

Chapter 5 Swiss Agency for Therapeutic Products

Section 1 Legal Form and Position

Art. 68

1 The Confederation shall run the Agency with the cooperation of the cantons.

2 The Agency is an institution under public law with its own legal personality.

3 It is autonomous in its organisation and management; it may use its funding as it sees fit and shall keep its own accounts.

4 It may call upon private individuals to perform certain tasks.

5 It may appoint advisory committees and experts.

Section 2 Duties and Service Mandate

Art. 69 Duties

1 The Agency shall accomplish such duties:

a. as are assigned to it by law;

b. as the Federal Council assigns to it under its service mandate.

2 It may, in return for payment, provide services for authorities or private individuals.

3 The Federal Council may ask the Agency to participate in the drafting of legislation in the therapeutic products sector.

Art. 70 Service mandate and service agreement

1 The Federal Council shall assign a service mandate to the Agency.

2 Each year, the competent government department shall conclude with the Agency a service agreement within the framework of its service mandate.

Section 3 Governing Bodies and Responsibilities

Art. 71 Governing bodies

[1] The governing bodies of the Agency are:

a. the Agency Council, comprising a maximum of seven members;

b. the executive director;

c. the review body.

[2] The Federal Council shall appoint the members of the Agency Council and its president. The cantons shall have the right to propose the appointment of a maximum of three members. With regard to the fees paid to the members of the Agency Council and the other contractual conditions agreed with these persons, Article 6a paragraphs 1–5 of the Swiss Law on Civil Servants dated 24 March 2000[26] shall apply by analogy.[27]

[3] The Federal Council shall appoint the executive director after consultation with the Agency Council and shall appoint the auditors.

Art. 72 Agency Council

The Agency Council shall:

a. bring the interests of the Agency in the drafting of the service mandate and the service agreement before the Federal Council and the competent department;

b. approve the management plan and the budget, taking into account the service mandate and the service agreement.

c. monitor the fulfilment of the service mandate and the service agreement.

d. propose to the Federal Council the amount of compensation to be paid by the Confederation to the Agency for its services in the public interest.

e. approve the regulations for the organisation of the Agency.

f. establish the ordinance of fees for the services of the Agency.

g. approve the business report and the annual accounts.

h. select the other members of the management at the request of the executive director.

i. approve the reports intended for the clients commissioning them.

j. fulfil other duties which the Federal Council assigns to it.

26 SR **172.220.1**

27 Third sentence added by No I 4 of the FA of 20 June 2003 on the Remuneration and Other Contractual Conditions of Senior Staff and Management Officers of Federal Enterprises and Institutions, in force since 1 Feb. 2004 (AS **2004** 297; BBl **2002** 7496 7514).

Art. 73 Executive director

The executive director shall:

a. preside over the management;

b. run the Agency together with the management according to the principles of delegation and defined objectives;

c. be responsible for the management before the Agency Council;

d. represent the Agency in contacts with the outside world.

Art. 74 Review body

The review body shall report to the Federal Council and the Agency Council. To this end it shall verify:

a. the bookkeeping;

b. the report on the compliance with the service mandate and the service agreement;

c. the smooth running of the planning, control, directing and reporting systems within the Agency.

Section 4 Staff

Art. 75 Employment conditions

[1] The Agency shall employ its staff under public law. In justified cases, contracts may be concluded in accordance with the Code of Obligations[28].

[2] The Federal Council shall enact the necessary provisions. In doing so, it shall take into account the autonomy which the Agency requires to perform its duties. With regard to the salaries of the executive members of the management and the other members of the staff who are remunerated in a comparable way, and with regard to the other contractual conditions agreed with these persons, Article 6*a* paragraphs 1–5 of the Swiss Law on Civil Servants dated 24 March 2000[29] shall apply by analogy.[30]

Art. 76[31] Pension fund

The staff of the Agency are insured by the Federal Pension Fund.

28 SR **220**
29 SR **172.220.1**
30 Third sentence added by No I 4 of the FA of 20 June 2003 on the Remuneration and Other Contractual Conditions of Senior Staff and Management Officers of Federal Enterprises and Institutions, in force since 1 Feb. 2004 (AS **2004** 297; BBl **2002** 7496 7514).
31 Amended by Annex No 3 of the FA of 14 Dec. 2012, in force since 1 July 2013 (AS **2013** 1493; BBl **2011** 6703).

Section 5 Budget

Art. 77 Financial resources

[1] The Confederation and the cantons may allocate an endowment fund to the Agency.

[2] The Agency Council may determine a rate of return on the endowment fund.

[3] The Agency shall finance its expenditure, in particular:

a. from the remuneration for the tasks which are assigned to it under the service mandate;

b. from the fees it collects;

c. from the remuneration for providing services of public interest;

d. from the revenue on services provided to authorities and private individuals.

Art. 78 Accounting system

The budget and accounts of the Agency shall be independent of those of the Confederation.

Art. 79 Profit and loss

[1] If the Agency realises a profit, it shall use it to build appropriate reserves.

[2] The reserves shall serve to finance future investments by the Agency and cover any future losses. Should the reserves exceed a reasonable amount, the fees shall be reduced.

[3] Any losses shall be deferred to the following year. If necessary, the Agency shall increase the fees.

Art. 80 Liability

The Agency shall be liable for its commitments. In all other respects, Article 19 of the Government Liability Act of 14 March 1958[32] applies.

Art. 81 Tax exemption

[1] The Agency shall be exempt from all federal, cantonal and communal taxes.

[2] This shall be without prejudice to the federal law governing:

a. value added tax on remunerations;

b. withholding tax and stamp duties.

32 SR **170.32**

Chapter 6 Enforcement

Art. 82 Federal government

[1] The Federal Council and the Agency shall enforce this Act insofar as the Act states that the Confederation is competent to do so. The Federal Council may delegate certain of the Agency's duties to other authorities.

[2] The Federal Council shall enact the implementing provisions unless this Act states that the Agency is competent to do so, or when it has not allocated the enactment of provisions of a technical nature or of minor importance to the Agency.

Art. 83 Cantons

[1] The cantons shall carry out the enforcement tasks:

a. that are assigned to them by this Act;

b. that are not expressly assigned to the Confederation.

[2] The cantons shall notify the Agency of their legislation concerning therapeutic products.

Chapter 7 Administrative Procedure and Rights of Appeal

Art. 84 …[33]

[1] Unless this Act provides otherwise, the administrative procedure and rights of appeal are regulated by the Federal Act of 20 December 1968[34] on Administrative Procedure and by the Federal Administrative Court Act of 17 June 2005[35], and the Federal Supreme Court Act of 17 June 2005[36].[37]

[2] The Agency is entitled to exercise the rights of appeal under cantonal and federal law against rulings of the cantonal authorities and the Federal Administrative Court in application of this Act and its implementing provisions.[38]

33 Repealed by Annex No 89 of the Federal Administrative Court Act of 17 June 2005, with effect from 1 Jan. 2007 (AS **2006** 2197 1069; BBl **2001** 4202).
34 SR **172.021**
35 SR **173.32**
36 SR **173.110**
37 Amended by Annex No 89 of the Federal Administrative Court Act of 17 June 2005, in force since 1 Jan. 2007 (AS **2006** 2197 1069; BBl **2001** 4202).
38 Amended by No 1 12 of the Federal Assembly O of 20 Dec. 2006 on the Amendment of Legislation in accordance with the provisions of the Federal Supreme Court Act and the Federal Administrative Court Act, in force since 1 Jan. 2007 (AS **2006** 5599; BBl **2006** 7759).

[3] It is also entitled to appeal against decisions made by the highest cantonal authorities in application of the Human Research Act of 30 September 2011[39] (Art. 89 para. 2 let. a of the Federal Supreme Court Act of 17 June 2005[40]).[41]

Art. 85[42]

Chapter 8 Criminal Provisions[43]

Art. 86 Misdemeanours

[1] Unless an offence carrying a more severe penalty under the Criminal Code[44] or the Narcotics Act of 3 October 1951[45], has been committed, any person who wilfully endangers human health by:

a. neglecting his duty to exercise diligence in dealing with therapeutic products;

b. manufacturing, placing on the market, prescribing, importing or exporting, or trading in a foreign country, medicinal products without authorisation nor licence or while infringing other provisions of this Act;

c. dispensing medicinal products without authorisation;

d. violating, when handling blood or blood products, the provisions on the fitness of the donor to give blood, on the obligation to test or on the obligation to record or archive;

e. placing on the market medical devices which do not satisfy the requirements of this Act;

f. neglecting the obligation to maintain medical devices;

g. performing, or allowing to be performed, a clinical trial on a human being which does not satisfy the requirements of this Act.

shall be liable to a term of imprisonment or to a fine not exceeding 200,000 francs

[2] If the person concerned acts in his professional capacity, he or she shall be liable to a term of imprisonment not exceeding five years and to a fine not exceeding 500,000 francs.

39 SR **810.30**
40 SR **173.110**
41 Inserted by Annex No 6 of the Human Research Act of 30 Sept. 2011, in force since 1 Jan. 2014 (AS **2013** 3215; BBl **2009** 8045).
42 Repealed by Annex No 89 of the Federal Administrative Court Act of 17 June 2005, with effect from 1 Jan. 2007 (AS **2006** 2197 1069; BBl **2001** 4202).
43 From 1 Jan. 2007, the penalties and time limits are to be interpreted or recalculated in application of Art. 333 paras. 2–6 of the Criminal Code (SR **311.0**) in the version of the FA of 13 Dec. 2002 (AS **2006** 3459; BBl **1999** 1979).
44 SR **311.0**
45 SR **812.121**

[3] If the person concerned acts through negligence, he or she shall be liable to a term of imprisonment not exceeding six months or a fine of up to 100,000 francs.

Art. 87 Contraventions

[1] Any person who wilfully:

a. manufactures, places on the market, imports or exports, or trades in a foreign country, therapeutic products or excipients which do not conform to the requirements stated in the Pharmacopoeia;

b. contravenes the regulations on the advertising of medicinal products;

c. violates the obligation to notify;

d. violates the obligations to label, keep records, to archive or to cooperate;

e. violates the obligation of secrecy, unless there is a violation of Article 162, 320 or 321 of the Criminal Code[46];

f. commits the acts mentioned in Article 86 paragraph 1 but without endangering human health;

g. contravenes a implementing provision of this Act, the contravention of which is an offence, or fails to comply with a ruling against him which refers to the penalties provided for in this article.

shall be liable to a term of detention or to a fine not exceeding 50,000 francs

[2] If the person concerned acts in a professional capacity in the cases provided for by paragraphs 1a, b, e or f, the penalty shall be a term of imprisonment not exceeding six months and a fine not exceeding 100,000 francs.

[3] If the person concerned acts through negligence, the penalty shall be a fine not exceeding 10,000 Swiss francs.

[4] Attempts and aiding and abetting are also offences.

[5] The right to prosecute contraventions and execute the penalties for contraventions are subject to a time limit of five years.

[6] In particularly minor cases, prosecution and sentencing may be waived.

Art. 88 Application of other criminal provisions

The criminal provisions of the Federal Act of 6 October 1995[47] on Technical Barriers to Trade apply to forgeries, to false certificates, to obtaining a false certificate by fraudulent means, to the use of false or inaccurate attestations, to the unauthorised issuing of declarations of conformity, to the unauthorised attachment and use of marks of conformity, and to securing unlawful financial advantages under Articles 23 to 29 of the aforementioned Act.

46 SR **311.0**
47 SR **946.51**

Art. 89 Administrative Criminal Law

Articles 6 and 7 (offences committed within a company) of the Federal Act of 22 March 1974[48] on Administrative Criminal Law also apply to criminal proceedings carried out by cantonal authorities.

Art. 90 Prosecution

[1] Prosecutions that are to be conducted at federal level shall be conducted by the Agency in accordance with the Federal Act of 22 March 1974[49] on Administrative Criminal Law.

[2] Criminal proceedings in the sphere of enforcement of the cantons fall within their competence.

Chapter 9 Final Provisions

Section 1 Introductory and Transitional Provisions

Art. 91 Take-over of the Intercantonal Office for the Control of Medicinal Products by the Agency

[1] The Federal Council may require authorities which before the commencement of this Act were responsible for registering therapeutic products or for supervising the market to hand over their files to the Agency.

[2] Furthermore, the Federal Council shall conclude an agreement with the Intercantonal Union for the Control of Medicinal Products on the take-over of the Intercantonal Office for the Control of Medicinal Products by the Agency.

Art. 92 Transitional rules for staff

[1] The Federal Council shall appoint the first executive director of the Agency on the proposal of the Federal Department of Home Affairs.

[2] The Federal Department of Home Affairs shall carry out the first appointment of the other members of the management. Their appointment shall be ratified by the Agency Council in accordance with Article 72 paragraph 1 letter h within 18 months of the Agency commencing its activity.

[3] The contract service conditions of the staff transferred to the Agency from the Federal Office of Public Health and the Intercantonal Office for the Control of Medicinal Products shall be subject to the conditions of employment of the Agency from the time it commences its activity.

48 SR **313.0**
49 SR **313.0**

Art. 93 Deficit of the Federal Pension Fund

At the time the Agency is set up, the Confederation shall take over the deficit of the Federal Pension Fund for the policyholders who are transferred from the Federal Office of Public Health to the Agency.

Art. 94 Pending procedures

[1] Procedures which on the commencement of this Act are pending before the Federal Office of Public Health, the Federal Food Safety and Veterinary Office[50], the Intercantonal Office for the Control of Medicinal Products, the organs of the Intercantonal Union for the Control of Medicinal Products as well as before the cantonal authorities of first instance shall be completed in accordance with the provisions of this Act and by the competent authorities designated by it.

[2] Procedural acts carried out by authorities deemed competent before the entry into force of this Act shall remain valid unless they contradict the material provisions of this Act.

Art. 95 Transitional provisions

[1] Registrations of medicinal products carried out by the Federal Office of Public Health, by the Federal Food Safety and Veterinary Office and by the Intercantonal Office for the Control of Medicinal Products shall remain valid for up to five years after the commencement of this Act.

[2] Cantonal authorisations for medicinal products shall be valid until 31 December 2017; medicinal products may be authorised by the Agency within two years of the expiry of the transitional period.[51] The following shall be reserved:

a. the revocation of an authorisation by the canton;

b. the replacement, on request, of a cantonal authorisation by a marketing authorisation issued by the Agency.

[3] Requests for a marketing authorisation for medicinal products for which no authorisation was previously required either under cantonal or Federal legislation, but which must be authorised under this Act must be submitted within one year of the commencement of this Act. Medicinal products may continue to be placed on the market until the Agency has reached a decision.

[4] In vitro diagnostics may be placed on the market in accordance with the former Act until 7 December 2003. Licences and registrations of in vitro diagnostics established in accordance with the former Act shall be valid until the expiration of their validity period or for a maximum of three years from the commencement of this Act.

50 The name of this administrative unit was changed on 1 Jan. 2014 in application of Art. 16 para. 3 of the Publications O of 17 Nov. 2004 (AS **2004** 4937). The change has been made throughout the text.

51 Amended by No I of the FA of 21 June 2013, in force since 1 Jan. 2014 (AS **2013** 4137; BBl **2013** 3281 3289).

[5] Authorisations issued by the Confederation and by the cantons in accordance with the former Act shall be valid until the expiration of their validity period or for a maximum of five years from the date of entry into force of the present Act.

[6] Persons who do not satisfy the provisions relating to the dispensing of medicinal products (Articles 24 and 25) must cease to dispense them within seven years from the commencement of this Act. The Federal Council may, however, issue exemptions for persons who can prove that they have sufficient education and training.

[7] The administrative measures taken by the Agency and referred to in Article 66 are reserved.

Art. 95*a*[52] Transitional provisions to the amendment of 13 June 2008

For medicinal products which are authorised when the amendment of 13 June 2008 comes into force, the periods mentioned under Article 16a paragraph 1 shall start from the date on which this amendment comes into force.

Section 2 Referendum and Commencement

Art. 96

[1] This Act is subject to an optional referendum.

[2] The Federal Council shall determine the commencement date.

Commencement date[53]: 1 January 2002
Art. 71 and 72: 1 October 2001

52 Inserted by No 1 of the FA of 13 June 2008, in force since 1 Oct. 2010 (AS **2008** 4873, **2010** 4027; BBl **2007** 2393).
53 Federal Council Decree of 28 Sept. 2001.

Annex

Repeal and Amendment of Current Legislation

I

The Pharmacopoeia Law of 6 October 1989[54] is repealed.

II

The following enactments are amended as follows:
…[55]

54 [AS **1990** 570]
55 The amendments may be consulted under AS **2001** 2790.