Federal Law
on Medicinal Products and Medical Devices
(Law on Therapeutic Products – LTP)

dated 15 December 2000 (updated on 1 May 2007)

The Federal Assembly of the Swiss Confederation,
in accordance with Articles 95, paragraph 1 and 118, paragraph 2 of the Federal Constitution,
after consultation of the draft legislation of the Federal Council dated 1 March 1999
decrees:

Chapter 1 General provisions

Art. 1 Purpose

1 The purpose of this law 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-organized supply of therapeutic products, together with the necessary technical information and advice, is available throughout the country.

3 In the implementation of this law, 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.

Art. 2 Scope

1 This law shall apply to:

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

b. narcotics in the sense of the Law on Narcotics of 3 October 1951, 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 law.

Art. 3 Duty of 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 Under the present law, the following definitions shall apply:

a. Medicinal products: 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 shall also be considered as medicinal products.

b. Medical devices: 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: 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: the distribution and supply of therapeutic products;

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

f. Supply: 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, as well as for use on a third party or on animals;

g. Pharmacopoeia (Pharmacopoeia Europaea and Pharmacopoeia Helvetica):

a collection of regulations on the quality of medicinal products, excipients and certain medical devices.

2 The Federal Council may, by decree, distinguish between the terms used in this law 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 Requirement of authorization

1 An authorization from the Swiss Agency for Therapeutic Products (Agency) shall be required by those who:

a. manufacture medicinal products;

b. add medicinal products into animal feed.

2 The Federal Council may allow special dispensation for the requirement of authorization. In particular, it may:

a. make the manufacture of therapeutic products, produced according to a magistral formula, an officinal formula, or an own formula, conforming to the Pharmacopoeia or to any other Agency-recognized pharmacopoeia or formularies subject to a cantonal authorization or mandatory notification (art. 9, par. 2, subpar. a, b and c, art. 14, par. 1, subpar. c);

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

Art. 6 Conditions

1 The authorization 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 therapeutic products must conform to the recognized principles of good manufacturing practice.

2 The Federal Council shall specify the recognized principles of good manufacturing practice. In doing so, it shall take account of internationally recognized guidelines and standards.

Section 2

Principle for placing products on the market and authorization 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 Authorization for placing products on the market

1 Ready-to-use medicinal products and veterinary medicinal products intended for the manufacture of medicinal foodstuffs (premixed medicinal products) may only be placed on the market if authorized by the Agency. This shall be subject to international agreements on the recognition of marketing authorizations.

2 The following shall be exempt from authorization:

a. 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 authorization, and for to a given person or group of persons or for a given animal or livestock (magistral formula);

b. medicinal products prepared in small quantities by a public pharmacy, a hospital pharmacy, a chemist's shop or by another establishment holding a manufacturing authorization, conforming to a special monograph of the Pharmacopoeia or another pharmacopoeia or a formulary recognized by the Agency, and which are supplied to their own customers (officinal formula);

c. medicinal products prepared in small quantities by a public pharmacy, a hospital pharmacy, a chemist's shop or by another establishment holding a manufacturing authorization, according to an own formula and within the limits of the right to supply of the person responsible for the manufacture in accordance with Article 25, and which are destined for supply to their own customers. The holder of the formula may appoint another establishment holding a manufacturing authorization to prepare the medicinal products for supply to their own customers;

d. medicinal products intended for clinical trials;

e. medicinal products which cannot be standardized.

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

4 The Agency may authorize, for a limited period, the distribution or supply of unauthorized medicinal products to treat life-threatening diseases if such an authorization 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 the granting of a marketing authorization

1 Any person requesting a marketing authorization 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 or registered office, or a subsidiary, in Switzerland.

2 The Agency shall verify that the conditions attached to the marketing authorization are fulfilled. To this effect, it may carry out product-specific inspections.

Art. 11 Application for a marketing authorization

1 The application for a marketing authorization 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 undesirable effects;

f. the labelling, the medical information, the method of supply 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 recognized international guidelines and standards, the requirements for organizing, carrying out and recording the pharmacological and toxicological tests referred to in paragraph 1g, and shall adopt provisions for the control procedure;

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

3 The Agency shall define in more 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 authorization for a medicinal product which is essentially the same as an already authorized 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 authorized 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 authorized in foreign countries

If a medicinal product or procedure is already authorized 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 procedures for marketing authorization

1 The Agency shall make provision for simplified procedures for the authorization 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 shall apply in the case of:

a. medicinal products in which the active agents are known;

b. medicinal products of complementary medicine;

c. medicinal products prepared for stocks by a public pharmacy, a chemist's shop or by another establishment holding a manufacturing authorization, according to an own formula (over-the-counter medicine), conforming to the Pharmacopoeia or another pharmacopoeia, or a formula recognized by the Agency, and which are supplied to their own customers;

d. medicinal products prepared by a hospital pharmacy for the needs of the hospital;

e. medicinal products prepared by the army and used in the context of a coordinated 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 authorization procedure in the case of an application from another person responsible for the placing on the market of a medicinal product which is already authorized in Switzerland and which is imported from a country with an equivalent authorization system:

a. if the medicinal product satisfies the same requirements as the medicinal product already authorized 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 authorized medicinal products that he distributes shall fulfil the same requirements of safety and quality as those of the first applicant.

3 A medicinal product may not be authorized within the meaning of paragraph 2 for as long as the authorized medicinal product of the first applicant (original preparation) is protected by a patent.

The Federal Council shall regulate the procedure for claiming such patent protection. Intellectual property rights shall be reserved.

Art. 15 Mandatory notification

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

Art. 16 Granting of a marketing authorization

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

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

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

4 Upon request, it shall renew the authorization if the conditions are still fulfilled.

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 authorization must be obtained from the Agency for each batch before distribution. This shall be subject to international agreements on the recognition of batch releases.

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

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 Requirement of authorization

1 An authorization 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 supply;

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

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

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

3 It may issue exemptions from the requirement of authorization for:

a. medical professionals who work across borders;

b. international organizations.

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

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 having an authorization to export.

Art. 19 Conditions for authorization

1 The authorization shall be issued if:

a. the necessary technical and operational conditions are fulfilled;

b. an appropriate system of quality assurance exists.

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

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

Art. 20 Special provisions for imports

1 Medicinal products which are authorized for placing on the market, or which are not subject to such an authorization, may be imported.

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

a. private individuals for their personal use;

b. medical professionals.

3 It may:

a. stipulate that the authorization to import certain medicinal products requiring a specific control for the protection of health is 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 an illegal purpose or an abusive use.

4 The Agency shall draw up a list of medicinal products for which the import 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 destination country;

b. circumstances suggest that they could be intended for an illegal purpose.

2 The Federal Council may stipulate that in particular cases the export of medicinal products which are not authorized in Switzerland or in the country of destination 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 destination 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 prepackaged 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 provide proof that the principles of good clinical trial practice were observed.

Section 4 Distribution, prescription and supply

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 medicinal products on free sale shall be created. Articles 24 to 27 and 30 do not apply to this category.

3 The Federal Council shall lay down the criteria of classification. The Agency shall categorize each medicinal product for which it has assigned a marketing authorization.

Art. 24 Supply of medicinal products subject to prescription

1 The following shall be entitled to supply medicinal products subject to prescription:

a. pharmacists, upon 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 Medicinal foods for animals which are subject to a prescription may also, with a prescription from a veterinary surgeon, be supplied by persons licensed to add medicinal products to animal foodstuffs.

3 The cantons may authorize the persons referred to in Article 25 paragraph 1c, to handle certain medicinal products subject to prescription.

Art. 25 Supply of medicinal products not subject to prescription

1 The following shall be entitled to supply medicinal products not subject to prescription:

a. persons entitled to supply medicinal products subject to prescription;

b. chemist's shop assistants holding a federal diploma, within the limits of their right to supply medicinal products;

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

d. all duly trained professionals, under the supervision of persons referred to in paragraphs 1a and b.

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

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

4 The cantons may grant to chemist's shop assistants holding a federal diploma the right to supply all medicinal products not subject to prescription insofar as the supply of medicinal products of this type is not guaranteed over the whole of the cantonal territory. The Federal Council shall determine the conditions to which this rule is accorded.

5 Subject to the provisions of paragraphs 2 and 3, the cantons may grant to persons holding a qualification recognized by the canton the right to supply 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 supply

1 The recognized rules of pharmaceutical and medical sciences must be respected during the prescription and supply of 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 An authorization may be issued, however, under the following conditions:

a. the medicinal product supplied on a doctor’s prescription;

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 authorization.

Art. 28 Authorization for wholesale trade

1 Any person engaged in the wholesale trade of medicinal products must possess an authorization issued by the Agency.

2 The authorization shall be issued if:

a. the necessary technical and operational conditions are fulfilled;

b. an appropriate system of quality assurance exists.

3 The authorization 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 Requirements for wholesale trade

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

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

Art. 30 Authorization for retail trade

1 Any person supplying medicinal products in a pharmacy, a chemist's shop or another retail trade establishment, must possess a cantonal authorization.

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

Section 5 Advertising and price comparisons

Art. 31 Principle

1 In principle, it shall be lawful to:

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

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

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 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 unlawful for medicinal products:

a. which may only be supplied on a prescription;

b. which contain narcotic or psychotropic substances as referred to in the Law on Narcotics of 3 October 1951;

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

d. that 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 supply medicinal products or to the organizations which employ them.

2 It shall be prohibited for persons who prescribe or supply medicinal products as well as for the organizations who 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 for blood and blood products

Art. 34 Operating authorization

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

2 The authorization 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 conditions for authorization are fulfilled.

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

Art. 35 Authorization 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 considered 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 authorization 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 because of the extraction of blood;

b. whose blood may transmit pathogenic agents.

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 executed in accordance with the principles of quality management and the recognized 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 recognized principles of good manufacturing practice. In doing so, it shall take account of internationally recognized guidelines and standards.

Art. 38 Obligation to test

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

2 The Federal Council shall specify:

a. for which pathogenic agents 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 carry 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 transfusions to the same person.

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;
b. 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 transfusions to the same person.

Art. 40 Obligation to archive

1 The recorded information referred to in 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 transfusions to the same person.

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 authorization.

Section 7 Special provisions for veterinary medicinal products

Art. 42 Prescription and supply

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 working animals, the prescriber must also know the state of health of the animal.

3 The Federal Council may prohibit the prescription and supply for working animals of medicinal products prepared according to a magistral formula (Article 9 paragraph 2a).

Art. 43 Obligation to keep a register

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

Art. 44 Standardization and coordination of the enforcement

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

Chapter 3 Medical Devices

Art. 45 Requirements

1 A medical device used in accordance with the use for which it is intended shall 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 harmonized standards. Any deviations must be approved by the competent authority.

5 The Federal Council shall lay down the requirements for medical devices intended for use in experiments.

Art. 46 Procedure for the assessment of 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 the assessment of conformity.

2 The Federal Council shall regulate the prescribed procedures for the assessment of conformity. In particular it shall lay down:

a. the types of procedures;

b. the medical devices for which an authority for the assessment of conformity has to 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 products, and to ensure that such acquired insights are taken into account during the manufacture and further development of the products.

2 The Federal Council may:

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

b. make provision for a marketing authorization for certain medical devices, in particular for in vitro diagnostics.

Art. 48 Supply and use

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

a. make provision that they can only be supplied with a medical prescription;

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

c. attach to the supply of products the condition that the products 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, the continued performance and the safety of the medical device.

2 The Federal Council may:

a. specify the type of maintenance 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 for medicinal products and medical devices

Section 1 Pharmacopoeia

Art. 52

1 The Agency shall enact 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 Collection of Federal Laws. 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 Principle

1 All human clinical trials of therapeutic products must be carried out in accordance with the recognized principles of good clinical practice.

2 The Federal Council shall specify the recognized principles of good clinical practice. In particular, it shall lay down the obligations to which the investigator and the sponsor are subject and shall adopt provisions concerning the control procedure.

In doing so, it shall take account of internationally recognized guidelines and standards.

Art. 54 Conditions and mandatory notification

1 For the execution of clinical trials, the following requirements in particular must be fulfilled:

a. the trial subjects have explicitly given their free consent in writing, or testified in writing, having being informed in particular on:
   1. the nature and purpose of the trial;
   2. all of the processes and investigations connected with the trial;
   3. the existence of other treatments;
   4. the anticipated risks, discomforts and benefits;
   5. their rights to compensation in the case of harm attributable to the trial;
   6. their right to withdraw their consent at any time without impairment to their therapeutic care;
b. the trial subjects are guaranteed full and complete compensation for injuries suffered in the course of the trial;
c. the competent ethics committee endorses the trial.

2 The Federal Council shall specify the conditions under which the consent of trial subjects should be obtained.

3 The Agency must be notified of clinical trials before they are carried out. The Federal Council shall define the mandatory notification. In particular, it may:

a. exempt certain trials or trials on certain therapeutic products from the mandatory notification;
b. subject clinical trials on veterinary therapeutic products on animals to the mandatory notification;

4 The Agency may prohibit a trial or attach conditions and requirements to its execution if the requirements set down by this law are not fulfilled. The Agency may carry out an inspection at any time in order to control the execution of a clinical trial.

5 The Federal Council may replace the mandatory notification by an mandatory authorization for certain clinical trials such as trials on gene therapy or the trials carried out on the trial subjects referred to in Article 55 and which do not bring them direct benefits.

6 The Agency must be notified of the interruption or the completion of a clinical trial.

7 The Federal Council may issue regulations concerning the publication of the notified and authorized clinical trials as well as their interruption or their completion.

Art. 55 Clinical trials on minors, persons under judicial disability or persons incapable of judgement

1 Clinical trials on minors, persons under judicial disability or persons incapable of judgement may only be carried out if:

a. trials on persons of adult age and who are capable of judgement would not produce comparable insights;
b. if the legal representatives of the trial subjects have given their informed consent;
c. if persons capable of judgment, but who are minors or persons under judicial disability, have given their consent;
d. if there is no indication to suggest that persons incapable of judgement would refuse to participate in the trials.

2 Exceptionally, clinical trials not bringing a direct benefit to the trial subjects may be carried out on minors, persons under judicial disability or persons incapable of judgement if, in addition to the conditions specified in paragraph 1:

a. the trials are expected to produce important knowledge concerning the status, illness or suffering of the trial subjects, and if this knowledge would bring long-term benefits for the trial subjects concerned or for persons of the same age group, or for persons suffering from the same illness or presenting the same characteristics;

b. the risks and the unpleasantness that the trial subjects must endure are minor.

Art. 56 Clinical trials in medical emergencies

In exceptional circumstances, clinical trials may be carried out in a medical emergency:

a. if a procedure, approved by the competent ethics committee, permits within a useful time period:

1. the obtaining of the consent of the legal representative of the minor or person under judicial disability;

2. the establishment of the willingness of the trial subjects, in particular in consultation with their relatives;

b. if there is no indication to suggest that the trial subjects would refuse to participate in the trial;

c. if the trials are expected to produce important knowledge concerning the status, illness or suffering of the trial subjects, and if this knowledge will bring long-term benefits for the trial subjects concerned or for persons suffering from the same illness or presenting the same characteristics;

d. if a doctor not participating in the trial provides the medical care for the trial subject and defends his or her interests.

Art. 57 Research ethics committees

1 The research ethics committees (ethics committees) shall guarantee the protection of the trial subjects in accordance with the recognized principles of good clinical practice. In particular, they shall assess the clinical trials from the ethical standpoint and verify their scientific quality taking into account the local conditions.

2 They must be independent and possess the necessary knowledge and experience to assess the trials submitted to them.

3 The Federal Council shall enact supplementary provisions concerning ethics committees. In particular, it shall determine the appointment procedure for their members, their composition, their tasks, their mode of operation, their financing and the supervision procedure.

4 The cantons shall appoint the ethics committees mentioned in Article 54 paragraph 1c, and shall supervise their activities.

5 The Agency shall publish a list of the ethics committees appointed by the cantons.

Section 3 Market supervision and inspection procedures

Art. 58 Official market supervision

1 The Agency and the cantons shall supervise, within the limits of their powers, that the manufacture, distribution, supply and presentation of therapeutic products are in accordance with the law. They shall verify by periodic inspection that the conditions for the authorization 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 authorization and that the medical devices satisfy the legal requirements.

3 The Agency shall be responsible for supervising 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 shall be obliged to notify the Agency for any undesirable effect or occurrence 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.

2 Any person manufacturing or distributing therapeutic products shall be furthermore obliged to notify the Agency for 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 supplying such shall also be obliged to notify the Agency for all serious and previously unknown undesirable effects and occurrences or quality defects.

4 Consumers, patients and their organizations as well as interested third parties, may notify the Agency for undesirable effects of, and occurrences with, therapeutic products.

Art. 60 Competence for conducting inspections

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

2 It shall be 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 specialized 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 law 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 responsibility.

5 The cantons may involve the 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 law are obliged to maintain professional secrecy.

Art. 62 Data confidentiality

1 Should a predominant legitimate interest exist for the observance of secrecy of the data collected in accordance with this law, the competent authority shall be held to 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 executing authorities in Switzerland

1 The Federal and Cantonal authorities responsible for the execution of this law shall ensure mutual disclosure of the data insofar as this is necessary for the execution of this law.

2 The Federal Council may make provision for the disclosure of data to other authorities or organizations should this be necessary for the execution of this law.

Art. 64 International assistance

1 The Federal authorities responsible for the execution of this law may request data from the competent foreign authorities or international organizations.

2 They shall be authorized to disclose to competent foreign authorities or international organizations non-confidential data collected in accordance with this law.

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

4 They shall be authorized to disclose to competent foreign authorities, upon request, confidential data collected in accordance with this law on condition that:

a. the foreign authorities making the request shall guarantee confidentiality;

b. the foreign authorities making the request shall 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 organizations insofar as this is necessary for the execution of this law.

6 The provisions for international judicial cooperation in penal matters shall be reserved.

Section 5 Charges

Art. 65

1 The Agency and other authorities entrusted with the execution of this law shall levy charges for the authorizations, controls and the services that they provide. Furthermore, the Agency may levy charges for the receipt of notifications.

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

3 The Federal Council may authorize the Agency to levy an annual charge for the maintenance of authorizations.

4 The Agency shall fix the scale of the charges 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 charges such that it fulfils the remit relating to the coverage of costs.

6 The Federal Council may, under the remit, request that the Agency renounces all or part of the charges for certain authorizations, provisions of service or controls.

Section 6 Administrative measures

Art. 66 General measures

1 The Agency may take all administrative measures necessary to execute this law.

2 In particular it may:

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

b. suspend or revoke authorizations;

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 law;

e. prohibit the distribution, supply, 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 law, 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 law in accordance with paragraph 2.

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

Art. 67 Public information

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

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

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 shall be a public law institution with its own legal personality.

3 It shall be autonomous in its organization 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 remit

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 remit.

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

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

Art. 70 Remit and service agreement

1 The Federal Council shall assign a remit to the Agency.

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

Section 3 Governing bodies and responsibilities

Art. 71 Governing bodies

1 The governing bodies of the Agency shall be:

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

b. the 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 2007 shall apply by analogy.

3 The Federal Council shall appoint the director after consultation with the Agency Council and shall appoint the review body.

Art. 72 Agency Council

The Agency Council shall:

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

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

c. monitor the execution of the remit 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 organization of the Agency.

f. establish the scale 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 director.

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

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

Art. 73 Director

The director shall:

a. preside over the management;

b. run the Agency together with the management according to the principles of the delegation and the 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 remit 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.

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 6a paragraphs 1-5 of the Swiss Law on Civil Servants dated 24 March 2007 shall apply by analogy.

Art. 76 Pension fund

1 The staff of the Agency are insured by the Federal pension fund.

2 The Agency may, with the consent of the Federal Council, manage its own pension fund or affiliate itself to other pension funds.

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 remit;
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 realizes 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 Liability Law of 14 March 1958 shall apply.

Art. 81 Tax exemption

1 The Agency shall be exempt from all Federal, cantonal and communal taxes.

2 Shall be reserved, the Federal Law governing:

a. value added tax on remunerations;
b. withholding tax and stamp duties.

Chapter 6 Enforcement

Art. 82 Confederation

1 The Federal Council and the Agency shall enforce this law whenever the Confederation states that it shall be competent to do so. The Federal Council may allocate certain of the Agency's duties to other authorities.

2 The Federal Council shall enact the provisions of execution whenever this law declares the Agency is not 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 execute the provisions:

a. that are entrusted to them by this law;
b. that are not expressly entrusted to the Confederation.

2 The cantons shall notify the Agency for their legislative acts concerning therapeutic products.

Chapter 7 Administrative procedure and legal protection

Art. 84

1 Unless this law provides for alternative provisions, the administrative procedure and legal protection shall be regulated by the Federal Law on Administrative Procedure dated 20 December 1968 and by the Federal Law on Administration of Justice dated 17 June 2005.

2 The Agency shall be entitled to use the rights provided under cantonal and federal law to appeal against the decisions issued by the cantonal authorities and the Federal Administrative Court in application of this law and its provisions of execution.

Art. 85 Committee of Appeal for Therapeutic Products

[1] It shall be permitted to appeal to the Committee of Appeal for Therapeutic Products against decisions of the Agency and other federal authorities which are issued on the basis of this law and its provisions of execution.

[2] The Federal Council shall nominate the members of the Committee of Appeal for Therapeutic Products. It shall ensure that it is appropriately composed of legal experts and medical specialists.

Chapter 8 Penal provisions

Art. 86 Offences

1 Provided that no offence carrying a heavier punishment has been committed within the terms of the penal code or the Law on Narcotics dated 3 October 1951, any person shall be punished by imprisonment or by a fine of up to 200,000 francs who intentionally 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 authorization or while infringing other provisions of this law;

c. supplying medicinal products without being authorized;

d. contravening, 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 law;

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 law.

2 If such person acts in his professional capacity, the punishment shall be imprisonment for up to five years and a fine of up to 500,000 Swiss francs.

3 If such person acts out of negligence, the punishment shall be imprisonment for up to six months or a fine of up to 100,000 Swiss francs.

Art. 87 Infringements

1 Any person shall be punished by arrest or a fine of up to 50,000 Swiss francs who intentionally:

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 appearing in the Pharmacopoeia;

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

c. contravenes the obligation to notify;

d. contravenes the obligation to label, to keep a register, to archive or to collaborate;

e. violates the obligation of secrecy, unless there is a violation of Article 162, 320 or 321 of the penal code;

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

g. contravenes a provision of execution of this law, the non-observance of which is punishable, or does not conform to a decision against him which carried the punishment provided for in the present article.

2 If the responsible person acts in his professional capacity in the cases provided for by paragraphs 1a, b, e or f, the penalty shall be imprisonment for up to six months and a fine of up to 100,000 francs.

3 If such person acts out of negligence, the penalty shall be a fine of up to 10,000 Swiss francs.

4 Attempting and aiding and abetting shall be punishable.

5 Infringement and penalties for infringement shall fall under the statute of limitations after a period of five years.

6 In particularly trivial cases, criminal prosecution and sentencing may be waived.

Art. 88 Application of other penal provisions

The penal provisions of the Federal Law on Technical Barriers to Trade dated 6 October 1995 shall be applicable to forgeries, to false certificates, to obtaining a false certificate by fraudulent means, to the use of false or inaccurate attestations, to the unauthorized issuing of declarations of conformity, to the unauthorized attachment and use of marks of conformity, as well as for unlawful use of financial benefits under Articles 23 to 29 of the aforementioned law.

Art. 89 Administrative penal law

Articles 6 and 7 (offences committed within a company) of the Federal Law on Administrative Criminal Law dated 22 March 1974 shall also apply to criminal proceedings carried out by cantonal authorities.Art. 90 Criminal proceedings

1 Criminal proceedings within the sphere of execution of the Confederation shall be rendered by the Agency in accordance with the provisions of the Federal Law on Administrative Law of 22 March 1974.

2 Criminal proceedings in the sphere of execution of the cantons falls 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 oblige the authorities which before the entry into force of this law were charged with registering therapeutic products or with 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 concerning the take-over of the Intercantonal Office for the Control of Medicinal Products by the Agency.

Art. 92 Transitional law concerning personnel

1 The Federal Council shall appoint the first director of the Agency upon 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 1h, 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.

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 Procedures pending

1 Procedures which on entry into force of the present law are pending before the Federal Office of Public Health, the Federal Veterinary Office, 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 regulations of this law and by the competent authorities designated by it.

2 Procedural actions taken by authorities deemed competent before the entry into force of this law shall remain valid unless they are in contradiction with the material provisions of this law.

Art. 95 Transitional provisions

1 Registrations of medicinal products carried out by the Federal Office of Public Health, by the Federal Veterinary Office and by the Intercantonal Office for the Control of Medicinal Products shall remain valid for up to five years after the entry into force of this law.

2 The cantonal authorizations of medicinal products shall be valid for seven years after the entry into force of the present law; medicinal products may be authorized by the Agency within two years of the expiration date of the transitional period. The following shall be reserved:

a. the revocation of an authorization by the canton;

b. the replacement, upon request, of a cantonal authorization by a marketing authorization issued by the Agency.

3 Requests for a marketing authorization for medicinal products for which no authorization was previously required either under cantonal or Federal law, but which must be authorized under the terms of the present law, must be submitted within one year of entry into force of this law. 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 law until 7 December 2003. Authorizations and registrations of in vitro diagnostics established in accordance with the former law shall be valid until the expiration of their validity period or for a maximum of three years from the date of the entry in force of the present law.

5 Authorizations issued by the Confederation and by the cantons in accordance with the former law 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 law.

6 Persons who do not satisfy the provisions relating to the supply of medicinal products (Articles 24 and 25) must cease to supply them within seven years from the date of entry into force of this law. 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 shall be reserved.

Section 2 Referendum and entry into force

Art. 96

1 This law shall be subject to the optional referendum.

2 The Federal Council shall determine the date of entry into force.

Date of entry into force: 1 January 2002

Articles 71 and 72:1 October 2001

Annexe

Abrogation and amendment of legal provisions heretofore in force

I

The Pharmacopoeia Law of 6 October 1989 shall be abrogated.

II

The following decrees shall be amended as follows:

1. 1. Federal Law on the Promotion of Physical Exercise and Sport dated 17 March 1972

Preamble

...

Art. 1 h

...

Vb. ...

Art. 11 b

...

Art. 11 c

...

Art. 11 d

...

Art. 11 e

...

Art. 11 f

...

2. 1. Federal Law on Radio and Television of 21 June 1991

Preamble

...

Art. 18 par.5 and 6

...

3. Law on Narcotics and Psychotropic Substances dated 3 October 1951

Preamble

...

Replacement of a term

In Article 1 paragraph 4, the term "Federal Office of Public Health" shall be replaced by "Swiss Agency for Therapeutic Products (Agency)", in Articles 3 paragraph 3, 5, 7, 9 paragraph 2a and 5, 16 paragraph 2, 17 paragraph 3, 32 and 33, the terms "Federal Office of Public Health" or "Office" are replaced by "Agency", with grammar adapted accordingly as necessary.

Art. 2 par. 1 bis

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Art. 4 par. 1

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Art. 17 par. 2

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Art. 31 par. 1

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4. Environmental Protection Law dated 7 October 1983

Preamble

...

Art. 44 par. 3

...

5. Federal Law on Foodstuffs dated 9 October 1992

Preamble
...
Art. 5, introductory sentence
...
Art. 8 par. 6
...
Art. 36 par. 5
...
6. 6. Law on Epidemic Diseases dated 18 December 1970
Preamble
...
Art. 5 par. 1 bis, 1 ter and 2
...
Art. 30 and 30a
Abrogated

Art. 35 par. 1 k and par. 2
k. Abrogated
...
Art. 38 a
Abrogated

7. 7. Federal Decree on the Control of Blood, Blood Products and Transplant Tissues dated 22 March 1996
Title
...
Preamble
...
Art. 1
...
Art. 2
Abrogated
Art. 3
...
Art. 3a
...
Art. 4
...
Chapter 2 (Art. 5 –16).
Abrogated

Art. 20 par. 3
...
Art. 21 par. 2
...
Art. 22 par. 1, first sentence
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Art. 23
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Art. 24
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Art. 25 par. 1, introductory sentence, and 2

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Art. 26
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Art. 28
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Art. 29
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Art. 32 par. 1 a and b
...
Art. 33 par. 1 a–d
a. ...
b. to d. Abrogated
Art. 36
Abrogated
Art. 37 par. 3
...
Annexe
Abrogated

8. Federal Law on Health Insurance dated 18 March 1994
Preamble
...
Art. 83 par. 2
...
Art. 92 d
...
9. Law on Epizootic Diseases dated 1 July 1996
Preamble
...
Art. 27 par. 1 and 3
1 Abrogated
3 ...
10. 10. Consumer Information Law dated 5 October 1990
Preamble
...
Art. 2 par. 5
...