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

of 15 December 2000 (Status as of 26 May 2021)

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*The Federal Assembly of the Swiss Confederation,*  
based on Articles 95 paragraph 1 and 118 paragraph 2 of the Federal Constitution<sup>1</sup>,  
and having considered the Federal Council Dispatch dated 1 March 1999<sup>2</sup>,  
*decrees:*

### **Chapter 1    General Provisions**

#### **Art. 1            Purpose**

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> In the implementation of this Act, in particular in the enactment of the regulations and in the application to an individual case, it must be ensured 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

<sup>1</sup> SR 101

<sup>2</sup> BBl 1999 3453

**Art. 2** Scope

<sup>1</sup> This Act applies to:

- a.<sup>3</sup> the handling of medicinal products and medical devices (therapeutic products);
- b. narcotics as defined in the Narcotics Act of 3 October 1951<sup>4</sup>, 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.

<sup>2</sup> 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.

<sup>3</sup> It may make subject to this Act certain products without an intended medical purpose which are comparable to medical devices in terms of functioning and risks profile.<sup>5</sup>

**Art. 2a<sup>6</sup>** Devitalised human tissue or cells

<sup>1</sup> For therapeutic products which contain or consist of devitalised human tissues or cells, or derivatives thereof, the Federal Council shall specify requirements for the donation, removal, testing and devitalisation of these tissues or cells.

<sup>2</sup> It may make subject to specific requirements of this Act and of the Transplantation Act of 8 October 2004<sup>7</sup> products which contain or consist of devitalised human tissues or cells, or derivatives thereof, and are not therapeutic products, but function as therapeutic products. In addition, it may also specify requirements for the donation, removal, testing and devitalisation of such tissues or cells, or derivatives thereof.

<sup>3</sup> Human tissue or human cells may only be removed or used for the manufacture of products as specified in paragraphs 1 and 2 if consent has been obtained for removal. For this tissue and these cells, neither financial gain nor any other advantage may be offered, granted, demanded or accepted.

**Art. 3** Due diligence

<sup>1</sup> 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.

<sup>3</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>4</sup> SR 812.121

<sup>5</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>6</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>7</sup> SR 810.21

<sup>2</sup> The state of the art in science and technology must be considered for complementary medicines without indications, including the principles of the corresponding therapy approach.<sup>8</sup>

#### Art. 4 Definitions

<sup>1</sup> In this Act:

- a. *Medicinal products* means products of chemical or biological origin which are intended or claimed to have 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;
- a<sup>bis</sup>.<sup>9</sup> *Medicinal products with indications* means medicinal products with an officially authorised indication in a specific field of application which are intended for use in accordance with the rules of the medical and pharmaceutical sciences;
- a<sup>ter</sup>.<sup>10</sup> *Complementary medicines with indications* means medicinal products with an officially authorised indication in a specific field of application which are manufactured according to the manufacturing regulations for complementary therapies such as homeopathy, anthroposophic medicine or traditional Asian medicine and whose field of application is determined according to the principles of the corresponding therapy approach;
- a<sup>quater</sup>.<sup>11</sup> *Complementary medicines without indications* means complementary medicines without an officially authorised indication in a specific field of application which are intended for use in individual therapies;
- a<sup>quinquies</sup>.<sup>12</sup> *Herbal medicines* means medicinal products with an authorised indication which exclusively contain one or more herbal substances or herbal preparations and which are not classified as complementary medicines;
- a<sup>sexies</sup>.<sup>13</sup> *Original preparation* means a medicinal product that is authorised by the Swiss Agency for Therapeutic Products (Agency) as the first with a specific active substance, including all dosage forms authorised at the same time or later;

<sup>8</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>9</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>10</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>11</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>12</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>13</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

- <sup>a</sup>septies.<sup>14</sup> *Generic medicinal product* means a medicinal product authorised by the Agency which is essentially the same as an original preparation and which is interchangeable with the original preparation due to its identical active substances and its dosage form and dosage;
- <sup>a</sup>octies.<sup>15</sup> *Reference preparation* means a biological medicinal product that is used in the authorisation documentation for a biosimilar product as a reference for the comparability of its pharmaceutical quality, efficacy and safety;
- <sup>a</sup>novies.<sup>16</sup> *Biosimilar product* means a biological medicinal product sufficiently similar to a reference preparation authorised by the Agency and that refers to its documentation;
- <sup>a</sup>decies.<sup>17</sup> *Important medicinal products intended to treat rare diseases (orphan drugs)* means medicinal products for human use for which it has been proven that:
1. they are indicated for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating disease affecting no more than five in ten thousand people in Switzerland when the application was submitted, or
  2. they or their active substances are granted the status of Important medicinal products intended to treat rare diseases by another country with an equivalent system of medicinal product control within the meaning of Article 13;
- b.<sup>18</sup> *Medical devices* means products, including instruments, apparatus, equipment, in vitro diagnostics, software, implants, reagents, materials and other goods or substances which are intended or claimed to have 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;

<sup>14</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>15</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>16</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>17</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>18</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

- e.<sup>19</sup> *Distribution* means the transfer or release, either free of charge or in return for payment, but not the dispensing, of a therapeutic product and includes the activities of brokers and agents;
- 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;
- f<sup>bis</sup>.<sup>20</sup> *Prescription* means the recorded decision of a qualified medical professional issued in accordance with Article 26 paragraph 2 to a specific person, granting that person a right of access to medical services such as care services, medication, analyses or medical devices;
- g. *Pharmacopoeia (Pharmacopoeia Europaea and Pharmacopoeia Helvetica)* means a collection of regulations on the quality of medicinal products, excipients and certain medical devices;
- h.<sup>21</sup> *New active substance* means an active substance which is authorised for the first time in Switzerland pursuant to an ordinary procedure under Article 11. Active substances previously only authorised in medicinal products for human use shall be considered new active substances if they are used in products for veterinary use, and vice versa;
- i.<sup>22</sup> *Public pharmacy* means a pharmacy licensed by the canton, run by a pharmacist, which guarantees regular opening hours and offers direct access to the public;
- j.<sup>23</sup> *Hospital pharmacy* means a pharmacy in a hospital establishment which is run by a pharmacist and offers, in particular, pharmaceutical services to the customers of the hospital; for the preparation of radiopharmaceuticals in accordance with Article 9 paragraph 2 letter a and paragraph 2<sup>bis</sup>, an internal radiopharmaceutical establishment is also deemed to be a hospital pharmacy;
- k.<sup>24</sup> *Pro-pharmacy* means the cantonally approved dispensing of medicinal products in a doctor's practice or an outpatient healthcare service whose pharmacy is under the professional responsibility of a doctor with a professional licence.

<sup>2</sup>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

<sup>19</sup> Amended by Annex No 2 of the FD of 29 Sept. 2017 (Medicrime Convention), in force since 1 Jan. 2019 (AS 2018 4771; BBl 2017 3135).

<sup>20</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>21</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>22</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>23</sup> Inserted by No I of the FA of 18 March 2016 (AS 2017 2745, 2018 3575; BBl 2013 1). Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>24</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

provide for exceptions based upon new findings in science and technology as well as on international developments.

<sup>3</sup> It may, for the area of medical devices, by ordinance, specify different definitions for the terms listed in paragraph 1, provided that this serves the purpose of international harmonisation.<sup>25</sup>

## **Chapter 2 Medicinal Products**

### **Section 1 Manufacture**

#### **Art. 5 Mandatory licence**

<sup>1</sup> A licence from the Agency shall be required by those who:<sup>26</sup>

- a. manufacture medicinal products;
- b. add medicinal products to animal feed.

<sup>2</sup> The Federal Council regulates exemptions from the licence requirement. In particular, it may:

- a.<sup>27</sup> make the manufacture of medicinal products under Article 9 paragraph 2 letters a–bis 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.

<sup>3</sup> It may provide for a licence requirement in accordance with the corresponding internationally recognised requirements for the manufacture of certain categories of pharmaceutical excipients which present an increased risk to patients.<sup>28</sup>

#### **Art. 6 Conditions**

<sup>1</sup> The licence shall be issued if:

- a. the necessary technical and operational conditions are fulfilled;
- b. an appropriate system of quality assurance exists.

<sup>2</sup> The competent authority shall verify by inspection that the conditions are fulfilled.

<sup>25</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>26</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>27</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>28</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

**Art. 7** Manufacturing standards

<sup>1</sup> The manufacture of medicinal products and pharmaceutical excipients whose manufacture requires a licence must conform to the recognised rules of good manufacturing practice.<sup>29</sup>

<sup>2</sup> 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. 7a<sup>30</sup>** Public pharmacies and hospital pharmacies

Public pharmacies and public hospitals must hold a manufacturing licence that covers the following:

- a. public pharmacies: a licence authorising at least the manufacture of medicinal products in accordance with Article 9 paragraph 2 letter a;
- b. hospital pharmacies: a licence authorising at least the manufacture of medicinal products in accordance with Article 9 paragraph 2.

**Section 2****Principle for Placing Products on the Market and Authorisation Procedure****Art. 8<sup>31</sup>** Principle for placing products on the market

Medicinal products and excipients placed on the market must meet the requirements of the Pharmacopoeia or other pharmacopoeias recognised by the Agency provided that such requirements exist.

**Art. 9** Marketing authorisation

<sup>1</sup> 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; the foregoing is without prejudice to international agreements on the recognition of marketing authorisations.

<sup>2</sup> The following shall be exempt from authorisation:

- a.<sup>32</sup> 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 licence, and for a given person or

<sup>29</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>30</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>31</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>32</sup> 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).

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.<sup>33</sup> 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 (official formula);
- c.<sup>34</sup> 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<sup>bis</sup>.<sup>35</sup> 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 hospital'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.<sup>36</sup> medicinal products that were authorised in a canton on 1 January 2002 and which were still on the market when the Amendment of 18 March 2016 came into force; they must be labelled accordingly and may only be placed on the market in the canton concerned and only supplied by persons entitled to supply medicinal products under this Act.

<sup>2bis</sup> An establishment with a manufacturing licence may be commissioned to manufacture medicinal products (contract manufacture) in accordance with paragraph 2 a–c<sup>bis</sup>.<sup>37</sup>

<sup>2ter</sup> Companies holding a manufacturing licence issued by the Agency may manufacture a complementary medicine for which no alternative and equivalent medicinal product is demonstrably available or authorised, even without a contract manufactur-

<sup>33</sup> 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).

<sup>34</sup> 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).

<sup>35</sup> 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).

<sup>36</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2018 (AS 2017 2745; BBl 2013 1).

<sup>37</sup> Inserted by No 1 of the FA of 13 June 2008 (AS 2008 4873, 2010 4027; BBl 2007 2393). Amended by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).



ing order in accordance with paragraph 2<sup>bis</sup>, and market them to companies which are authorised to manufacture these products in accordance with paragraph 2 letters a, b and c. A company may not manufacture more than 100 packages of such a medicinal product with a maximum total of 3,000 daily doses; in the case of homeopathic and anthroposophic medicinal products, this restriction applies to each dilution individually.<sup>38</sup>

<sup>2</sup><sup>quater</sup> The Federal Council shall lay down the qualitative and quantitative criteria for the medicinal products manufactured in accordance with paragraphs 2 letters a–c<sup>bis</sup> and 2<sup>bis</sup>, and the qualitative criteria for the medicinal products manufactured in accordance with paragraph 2<sup>ter</sup>.<sup>39</sup>

<sup>3</sup> 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.

<sup>4</sup> ...<sup>40</sup>

#### **Art. 9a<sup>41</sup>** Temporary authorisation

<sup>1</sup> The Agency may, in accordance with a simplified procedure under Article 14 paragraph 1, temporarily authorise medicinal products for life-threatening or debilitating diseases if:

- a. they are compatible with the protection of health;
- b. their use is expected to have a major therapeutic benefit; and
- c. no authorised, alternative or equivalent medicinal product is available in Switzerland.

<sup>2</sup> The Agency shall determine the evidence to be submitted for the evaluation of an application pursuant to paragraph 1.

#### **Art. 9b<sup>42</sup>** Temporary authorisation for use and limited placing on the market

<sup>1</sup> The Agency may temporarily authorise the use of medicinal products referred to in Article 9 paragraph 2 letter d on certain persons or on certain categories of persons outside clinical trials.

<sup>2</sup> It may also authorise the temporary or quantitative marketing of a medicinal product to bridge the temporary unavailability of an identical medicinal product authorised in Switzerland, provided that:

<sup>38</sup> Inserted by No I of the FA of 13 June 2008 (AS **2008** 4873, **2010** 4027; BBl **2007** 2393). Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS **2017** 2745, **2018** 3575; BBl **2013** 1).

<sup>39</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS **2017** 2745, **2018** 3575; BBl **2013** 1).

<sup>40</sup> Repealed by No I of the FA of 18 March 2016, with effect from 1 Jan. 2019 (AS **2017** 2745, **2018** 3575; BBl **2013** 1).

<sup>41</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS **2017** 2745, **2018** 3575; BBl **2013** 1).

<sup>42</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS **2017** 2745, **2018** 3575; BBl **2013** 1).

- a. the medicinal product is authorised in another country that has equivalent medicinal product control; and
- b. no essentially identical medicinal product is authorised and available in Switzerland.

**Art. 10** Conditions for granting a marketing authorisation

<sup>1</sup> Any person applying for a marketing authorisation must:<sup>43</sup>

- a.<sup>44</sup> prove that the medicinal products with indications or procedures are of high quality and are safe and effective;
- a<sup>bis</sup>.<sup>45</sup> in the case of complementary medicines without indication, at any time on the basis of documentation:
  1. prove that they are of high quality, and
  2. credibly demonstrate that the medicinal product in question does not pose a risk to the safety of consumers;
- 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.

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

**Art. 11**<sup>46</sup> Application for a marketing authorisation

<sup>1</sup> The application for a marketing authorisation must contain all of the essential data and documents for its assessment, in particular:

- a. the name of the medicinal product;
- b. the name of the manufacturer and the distributor;
- c. the manufacturing process, the composition, the quality and the stability of the medicinal product.

<sup>2</sup> The application for a marketing authorisation for the following medicinal products must include the information and documents listed below:

- a. Medicinal products with indication:
  1. the results of physical, chemical, pharmaceutical and biological or microbiological tests,

<sup>43</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>44</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>45</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>46</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

2. the results of pharmacological and toxicological tests and clinical trials, including all results from trials in specific population groups,
  3. the therapeutic effects and the undesirable effects,
  4. the labelling, the information supplied about the medicinal product, and the dispensing method and method of administration,
  5. an assessment of the risks and, if necessary, a plan for their systematic recording, investigation and prevention (pharmacovigilance plan),
  6. the paediatric investigation plan referred to in Article 54a;
- b. Medicinal products for animals raised for food production:
1. the information and documents referred to in letter a,
  2. the detection of residues,
  3. the withdrawal periods.

<sup>3</sup> In addition to the information and documents referred to in paragraph 1, the application for the authorisation of the processes indicated in Article 9 paragraph 3 must include those referred to in paragraph 2 letter a.

<sup>4</sup> The Agency shall describe the information and the documents referred to in paragraphs 1–3 in greater detail.

<sup>5</sup> The Federal Council shall stipulate:

- a. the requirements for organising, carrying out and recording the pharmacological and toxicological tests referred to in paragraph 2 letter a number 2 and the control procedure, taking into account internationally recognised guidelines and standards;
- b. the languages to be used for labelling and information leaflets.

**Art. 11a<sup>47</sup>** Document protection in general

The documents relating to a medicinal product containing at least one new active substance and authorised in accordance with Article 11 shall be protected for a period of ten years.

**Art. 11b<sup>48</sup>** Document protection in special cases

<sup>1</sup> If a medicinal product is submitted with one or more known active substances, the corresponding documentation on new indications, modes of administration, dosage forms or dosages, or on its application to a new target animal species shall be protected for a period of three years.

<sup>2</sup> For a new indication, this period of protection shall be set by the Agency, on request, at 10 years if it is expected to bring a significant clinical benefit in comparison with existing therapies and if it is backed up by extensive clinical trials.

<sup>47</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>48</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>3</sup> On request, the Agency shall grant a ten-year document protection for a medicinal product specifically and exclusively for paediatric use in accordance with the paediatric investigation plan, provided that no document protection exists for another medicinal product authorised by the Agency with the same active substance for the same specific paediatric use.

<sup>4</sup> In the case of an important orphan medicinal product, the Agency shall, on request, grant document protection for a period of fifteen years.

<sup>5</sup> The Federal Council shall regulate the details.

#### **Art. 12<sup>49</sup>** Authorisation of essentially similar medicinal products

<sup>1</sup> The application for a marketing authorisation for a medicinal product which is essentially the same as a medicinal product whose documents are protected in accordance with Articles 11a or 11b may be based on the results of the pharmacological, toxicological and clinical tests if:

- a. the holder of the marketing authorisation for the medicinal product with document protection provides written permission; or
- b. the protection period for the relevant documents has expired.

<sup>2</sup> If the holder of the marketing authorisation does not agree, the granting of a marketing authorisation for an essentially identical medicinal product shall be permissible at the earliest on the first day after expiry of the period of protection for the medicinal product with document protection. A corresponding application for marketing authorisation may be submitted at the earliest two years before the end of the term of protection.

#### **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

<sup>1</sup> 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 substances;
- abis,<sup>50</sup> medicinal products whose active substances are used in a medicinal product which, when the application was submitted, has been authorised as a medicinal product for at least 10 years in at least one EU or EFTA country

<sup>49</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>50</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

and which is comparable in terms of indications, dosage and method of administration;

- a<sup>ter</sup>.<sup>51</sup> non-prescription medicinal products with indications which, when the application was submitted, have been proven to have been used medically for at least 30 years, and for at least 15 years in EU and EFTA countries;
- a<sup>quater</sup>.<sup>52</sup> medicinal products which, when the application was submitted, have been authorised as medicinal products for at least 15 years in a canton;
- b.<sup>53</sup> complementary medicines;
- c.<sup>54</sup> ...
- c<sup>bis</sup>.<sup>55</sup> herbal medicines;
- d.<sup>56</sup> 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 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.

<sup>2</sup> 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.

<sup>3</sup> ...<sup>57</sup>

<sup>51</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>52</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>53</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>54</sup> Repealed by No I of the FA of 18 March 2016, with effect from 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>55</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>56</sup> Amended by No I of the FA of 13 June 2008, in force since 1 Oct. 2010 (AS 2008 4873, 2010 4027; BBl 2007 2393).

<sup>57</sup> Repealed by No II of the FA of 19 Dec. 2008, with effect from 1 July 2009 (AS 2009 2615; BBl 2008 303).

**Art. 14a<sup>58</sup>** Application for a marketing authorisation under the simplified authorisation procedure

<sup>1</sup> Applications for a marketing authorisation under the simplified authorisation procedure must contain the following data and documents for the following medicinal products:

- a. Medicinal products referred to in Article 14 paragraph 1 letter a<sup>bis</sup>:
  1. the data and documents referred to in Article 11 paragraphs 1 and 2 letter a numbers 1–4; the data referred to in Article 11 paragraph 2 letter a number 2 may be replaced by a compilation of equivalent scientific evidence,
  2. proof of the marketing authorisations of the foreign comparator product;
- b. Medicinal products referred to in Article 14 paragraph 1 letter a<sup>ter</sup>:
  1. the data and documents referred to in Article 11 paragraphs 1 and 2 letter a numbers 1, 3 and 4,
  2. an assessment of the risks,
  3. proof of 30 or 15 years of medical use;
- c. Medicinal products referred to in Article 14 paragraph 1 letter a<sup>quater</sup>:
  1. the data and documents referred to in Article 11 paragraphs 1 and 2 letter a numbers 1, 3 and 4,
  2. an assessment of the risks,
  3. the cantonal marketing authorisation;
- d. Medicinal products referred to in Article 14 paragraph 1 letter b: the data and documents referred to in Article 11 paragraphs 1 and 2 letter a; the data referred to in Article 11 paragraph 2 letter a number 2 may be replaced by equivalent data in accordance with specific therapy approaches, in particular by bibliographical evidence of efficacy and safety, or by evidence of use;
- e. Medicinal products referred to in Article 14 paragraph 1 letter c<sup>bis</sup>: the data and documents referred to in Article 11 paragraphs 1 and 2 letter a; the data referred to in Article 11 paragraph 2 letter a number 2 may be replaced by bibliographical evidence of efficacy and safety, or by evidence of use.

<sup>2</sup> Throughout the period of marketing authorisation of medicinal products referred to in paragraph 1 letter a, the following information on the foreign comparator product shall be submitted to the Agency without being requested:

- a. all internationally recorded safety signals;
- b. all interim reports and final results of the foreign regulatory authority.

<sup>58</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

**Art. 15<sup>59</sup>** Marketing authorisation on the basis of a notification

<sup>1</sup> The following may be placed on the market following notification to the Agency:

- a. complementary medicines without indications, the active substances of which are included in lists for specific therapy approaches;
- b. other medicinal products or groups of medicinal products for which, due to their low risk potential, a simplified marketing authorisation proves to be disproportionate.

<sup>2</sup> The Agency shall draw up the lists referred to in paragraph 1 letter a. It shall determine the medicinal products or groups of medicinal products referred to in paragraph 1 letter b and regulate the notification procedure.

**Art. 16** Authorisation decision and period of the marketing authorisation<sup>60</sup>

<sup>1</sup> The Agency shall grant a marketing authorisation if the conditions are fulfilled. It may attach conditions and requirements to the authorisation.

<sup>2</sup> The marketing authorisation is issued for the first time for a period of five years. The Agency shall order a shorter period of authorisation if:

- a. the authorisations are limited in accordance with Article 9a; or
- b. this is necessary for the protection of health.<sup>61</sup>

<sup>3</sup> The authorisation of medicinal products on the basis of a notification shall be valid for an unlimited period.<sup>62</sup>

<sup>4</sup> ...<sup>63</sup>

**Art. 16a<sup>64</sup>** Revocation and transfer of the authorisation<sup>65</sup>

<sup>1</sup> 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.

<sup>2</sup> The Federal Council may provide for exceptions from paragraph 1.

<sup>59</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>60</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>61</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>62</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>63</sup> Repealed by No I of the FA of 18 March 2016, with effect from 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>64</sup> 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).

<sup>65</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>3</sup> It may provide that, in the case of medicinal products for severe illnesses, injuries or disabilities or of medicinal products with a paediatric indication or for paediatric use, the authorisation is revoked before the period referred to in paragraph 1 has expired. It decides the duration of such periods and lays down the criteria for revocation.<sup>66</sup>

<sup>4</sup> If the holder of the marketing authorisation intends to cease marketing a medicinal product authorised for a paediatric indication or for paediatric use for which they have obtained protection under Article 11*b* paragraphs 3 and 4 of this Act or under Article 140*n* or 140*t* of the Patents Act of 25 June 1954<sup>67</sup>, they shall publish that intention in an appropriate form.<sup>68</sup>

<sup>5</sup> The holder of the marketing authorisation must state in the publication that they will transfer the authorisation documentation to third parties so they can obtain their own authorisation.<sup>69</sup>

#### **Art. 16*b***<sup>70</sup>      Renewal of the marketing authorisation

<sup>1</sup> A marketing authorisation shall be renewed upon application if the authorisation requirements continue to be met.

<sup>2</sup> As a rule, renewed authorisations are valid for an unlimited period. The Agency may, however, limit them, in particular authorisations in accordance with Article 16 paragraph 2 letters a and b.

#### **Art. 16*c***<sup>71</sup>      Review of the marketing authorisation

The Agency may review the authorisation at any time; it may adapt or revoke the authorisation in the light of changing circumstances.

#### **Art. 17**            Official batch release

<sup>1</sup> 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; the foregoing is without prejudice to international agreements on batch release recognition.

<sup>2</sup> 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.

<sup>66</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>67</sup> SR 232.14

<sup>68</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>69</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>70</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>71</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).



<sup>3</sup> 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

<sup>1</sup> A licence granted by the Agency is required by any person who professionally:

- 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;
- d. acts from Switzerland as a broker or agent for medicinal products.<sup>72</sup>

<sup>2</sup> The Federal Council shall specify the requirements for activities under paragraph 1.<sup>73</sup>

<sup>3</sup> It may issue exemptions from the requirement of licence for:

- a. medical professionals who work across borders;
- b. international organisations.

<sup>4</sup> Goods stored in a customs warehouse or a bonded warehouse shall be considered to be imported.<sup>74</sup>

<sup>5</sup> The Federal Council may issue special regulations for goods in transit.

<sup>6</sup> 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

<sup>1</sup> The licence shall be issued if:

- a. the necessary technical and operational conditions are fulfilled;
- b. an appropriate system of quality assurance exists.

<sup>2</sup> 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

<sup>72</sup> Amended by Annex No 2 of the FD of 29 Sept. 2017 (Medicrime Convention), in force since 1 Jan. 2019 (AS **2018** 4771; BBl **2017** 3135).

<sup>73</sup> Amended by Annex No 2 of the FD of 29 Sept. 2017 (Medicrime Convention), in force since 1 Jan. 2019 (AS **2018** 4771; BBl **2017** 3135).

<sup>74</sup> Inserted by Annex No 17 of the Customs Act of 18 March 2005, in force since 1 May 2007 (AS **2007** 1411; BBl **2004** 567).

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.

<sup>3</sup> The competent authority shall verify by inspection that the conditions are fulfilled.

#### **Art. 20** Special provisions for imports

<sup>1</sup> Medicinal products which have been authorised, or which are not subject to authorisation, may be imported.

<sup>2</sup> 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.

<sup>2bis</sup> It may allow unauthorised, ready-to-use, non-prescription medicinal products for which no alternative and equivalent medicinal product has been authorised to be imported in small quantities in accordance with Article 25 paragraph 1 letters b and c within the limits of their dispensing authority.<sup>75</sup>

<sup>3</sup> 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.

<sup>4</sup> 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

<sup>1</sup> The export of medicinal products and their foreign trade from Switzerland shall be prohibited if:

- a. they are prohibited in the target country;
- b.<sup>76</sup> circumstances suggest that they are intended for illegal purposes; or
- c.<sup>77</sup> it is deemed that they are intended for capital punishment.

<sup>1bis</sup> The Federal Council shall regulate the requirements for the export and foreign trade of medicinal products which could be used for capital punishment. It shall take account of the EU provisions.<sup>78</sup>

<sup>75</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>76</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>77</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>78</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>2</sup> 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.

<sup>3</sup> The Agency shall draw up a list of medicinal products for which export shall be restricted or prohibited.

<sup>4</sup> 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

<sup>1</sup> 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.

<sup>2</sup> 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, Dispensing and Application<sup>79</sup>**

**Art. 23** Categories of medicinal products

<sup>1</sup> Medicinal products shall be classified into categories according to whether or not they are subject to prescription.

<sup>2</sup> A category of over-the-counter medicinal products shall be created for which neither medical and pharmaceutical nor professional customer advice is required. Articles 24–27 and 30 do not apply to this category.<sup>80</sup>

<sup>3</sup> The Federal Council shall lay down the classification criteria.<sup>81</sup>

**Art. 23a<sup>82</sup>** Allocation of the medicinal products to the individual categories

<sup>1</sup> The Agency shall categorise each medicinal product for which it has granted a marketing authorisation in accordance with the criteria laid down by the Federal Council. It shall take into account the professional competence of the professional groups entitled to dispense medicinal products.

<sup>2</sup> It shall review the categorisation of medicinal products periodically or at the request of the holder of the marketing authorisation and adapt it to the state of the art in science and technology.

<sup>79</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>80</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>81</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>82</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

**Art. 24** Dispensing of medicinal products subject to prescription

<sup>1</sup> The following persons shall be entitled to dispense prescription-only medicinal products:

- a.<sup>83</sup> pharmacists, on presentation of a doctor's prescription. They may dispense medicinal products without a doctor's prescription if they have direct contact with the person concerned, if they document the product dispensed, and if:
  - 1. the medicinal products and indications have been designated by the Federal Council, or
  - 2. the case is justified and exceptional;
- b.<sup>84</sup> all other medical professionals in accordance with the provisions on pro-pharmacy and taking account of Article 1 paragraph 3 letter c;
- c. all duly trained professionals, under the supervision of a person specified in letters a and b.

<sup>1bis</sup> The Federal Council shall determine the form and the scope of the documentation obligation pursuant to paragraph 1 letter a.<sup>85</sup>

<sup>2</sup> 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.

<sup>3</sup> The cantons may license the persons referred to in Article 25 paragraph 1 letter c, to use certain prescription-only medicinal products.

**Art. 25** Dispensing of non-prescription medicinal products

<sup>1</sup> The following shall be entitled to dispense non-prescription medicinal products:

- a. persons entitled to dispense prescription medicinal products;
- b.<sup>86</sup> druggist holding a federal diploma;
- 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.

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

<sup>3</sup> The Agency shall determine the medicinal products which may be dispensed by the persons referred to in paragraph 1 letter c.<sup>87</sup>

<sup>83</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>84</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>85</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>86</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

4 ...<sup>88</sup>

<sup>5</sup> 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, dispensing and application<sup>89</sup>

<sup>1</sup> The recognised rules of pharmaceutical and medical sciences must be respected when prescribing, dispensing and using medicinal products, and the principles of the corresponding therapy approach must be respected when prescribing, dispensing and using complementary medicines without indications. The Federal Council may specify these rules in more detail.<sup>90</sup>

<sup>2</sup> A medicinal product may only be prescribed if the state of health of the consumer or patient is known.

<sup>2bis</sup> The following principles and minimum requirements must be observed for the prescription of medicinal products:

- a. The prescription meets the minimal requirements set by the Federal Council following consultations with the medical professions concerned.
- b. The prescription shall become the property of the person for whom it was issued. The person should remain free to decide whether to receive the prescribed product or to obtain a second opinion and to determine with which authorised provider they want to redeem the prescription. In the case of electronic prescriptions, the choice of provider should not be restricted by technical obstacles.<sup>91</sup>

<sup>3</sup> The prescriber shall not influence patients in the choice of the person who supplies them with the medicinal products if he or she derives a material benefit from doing so. The Federal Council may provide for exceptions.<sup>92</sup>

<sup>4</sup> Before a prescription-only medicinal product for human use is dispensed, a person authorised to prescribe and dispense the product must in principle issue a prescription to the patient. The patient may decline to accept the prescription.<sup>93</sup>

<sup>87</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>88</sup> Repealed by No I of the FA of 18 March 2016, with effect from 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>89</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>90</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>91</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019, let. a in force since 1 Jan. 2020 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>92</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>93</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

**Art. 27** Mail-order trade

<sup>1</sup> In principle, mail-order trade in medicinal products is prohibited.

<sup>2</sup> 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.

<sup>3</sup> The Federal Council shall regulate the details.

<sup>4</sup> The cantons shall issue the authorisation.

**Art. 28** Licence for wholesale trade

<sup>1</sup> Any person engaged in the wholesale trade of medicinal products must possess a licence issued by the Agency.

<sup>2</sup> The licence shall be issued if:

- a. the necessary technical and operational conditions are fulfilled;
- b. an appropriate system of quality assurance exists.

<sup>3</sup> The licence shall also be issued if the applicant already possesses a manufacturing or import licence for medicinal products.

<sup>4</sup> The competent authority shall verify by inspection that the conditions are fulfilled.

**Art. 29<sup>94</sup>** Wholesale standards

<sup>1</sup> Any person engaged in the wholesale trade of medicinal products must respect the recognised principles of good distribution practice.

<sup>2</sup> The Federal Council shall specify the recognised principles of good distribution practice. In doing so, it shall take account of internationally recognised guidelines and standards.

**Art. 30<sup>95</sup>** Dispensing licence

<sup>1</sup> Any person dispensing medicinal products must possess a cantonal licence.

<sup>2</sup> The licence shall be issued when the required specialist conditions are met and there is a quality assurance system in place which is appropriate for the type and size of the establishment.

<sup>94</sup> Amended by Annex No 2 of the FD of 29 Sept. 2017 (Medicrime Convention), in force since 1 Jan. 2019 (AS **2018** 4771; BBl **2017** 3135).

<sup>95</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2020 (AS **2017** 2745, **2018** 3575; BBl **2013** 1).

<sup>3</sup> The cantons may issue further requirements. They regulate the mandatory licensing process and carry out periodical inspections of retail establishments and practices.

## Section 5 Advertising and Price Comparisons

### Art. 31 Principle

<sup>1</sup> 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.

<sup>2</sup> The Federal Council shall lay down the conditions for the publication of price comparisons for prescription medicinal products.

<sup>3</sup> 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

<sup>1</sup> 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.<sup>96</sup> if it is for medicinal products which may not be placed on the market nationally or cantonally.

<sup>2</sup> 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<sup>97</sup>;
- 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.

<sup>96</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>97</sup> SR 812.121

**Art. 33**<sup>98</sup>**Section 6 Special Provisions on Blood and Blood Products****Art. 34** Operating licence

<sup>1</sup> 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.

<sup>2</sup> The licence shall be issued if:

- a. the necessary technical and operational conditions are fulfilled;
- b. an appropriate system of quality assurance exists.

<sup>3</sup> The Agency shall verify by inspection that the licensing conditions are fulfilled.

<sup>4</sup> 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

<sup>1</sup> 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.

<sup>2</sup> 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

<sup>1</sup> The holder of the licence referred to in Article 34 paragraph 1 must verify that the donor is fit to give blood.

<sup>2</sup> Persons excluded from donating blood shall be those:

- a. whose health could suffer from the extraction of blood;
- b. whose blood may transmit pathogens.

<sup>3</sup> 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

<sup>1</sup> Any operations relating to blood and labile blood products, in particular the extraction, manufacture, processing, storage and the placing on the market, must be con-

<sup>98</sup> Repealed by No I of the FA of 18 March 2016, with effect from 1 Jan. 2020 (AS 2017 2745, 2019 1393; BBl 2013 1).



ducted in accordance with the principles of quality management and the recognised principles of good manufacturing practice in the handling of blood and blood products.

<sup>2</sup> Blood and labile blood products as well as associated blood samples must be labelled such that they can be unambiguously identified at any time.

<sup>3</sup> 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

<sup>1</sup> Donated blood must be tested for the presence or signs of pathogens and examinations must be carried out in order to guarantee compatibility.

<sup>2</sup> 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.

<sup>3</sup> It may grant exemptions to the obligation to test in the case of autologous transfusions.

**Art. 39**            Obligation to record

<sup>1</sup> 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;

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> 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

<sup>1</sup> The information recorded under Article 39 and all important documents must be archived for 30 years.<sup>99</sup>

<sup>2</sup> 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

<sup>1</sup> A medicinal product may only be prescribed or supplied for an animal if the prescriber knows the animal or livestock.

<sup>2</sup> If the medicinal product is intended for production animals, the prescriber must also know the state of health of the animal.

<sup>3</sup> The Federal Council may prohibit the prescription and dispensing of medicinal products or the application of medicinal products that need no authorisation in accordance with Article 9 paragraph 2 for production animals. It may also restrict the prescription, dispensing or application of these products.<sup>100</sup>

**Art. 42a**<sup>101</sup> Measures to reduce antimicrobial resistance

<sup>1</sup> The Federal Council may provide for measures to reduce antimicrobial resistance, in particular:

- a. measures to reduce antibiotic consumption and promote animal health;

<sup>99</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>100</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>101</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

- b. requirements for the training and further education of veterinarians and live-stock holders.

<sup>2</sup> It may also restrict or prohibit the use of certain antibiotic agents in veterinary medicine in accordance with foreign regulations if this appears necessary for the effective treatment of patients.

**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

<sup>1</sup> 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. The intended performance must be demonstrated.<sup>102</sup>

<sup>2</sup> Any person placing a medical device on the market must be able to prove that the device satisfies the fundamental requirements.

<sup>3</sup> The Federal Council shall lay down the requirements that medical devices must satisfy. In particular it shall lay down:

- a<sup>103</sup>. the fundamental safety and performance requirements;
- b. the rules of their classification;
- c. the languages used for the product information;
- d.<sup>104</sup> the product labelling.

<sup>4</sup> The Agency shall, in consultation with the State Secretariat for Economic Affairs, designate technical standards and common specifications which are appropriate for giving concrete form to the fundamental requirements. It shall designate, as far as possible, internationally harmonised standards. It shall publish in the Federal Ga-

<sup>102</sup> Second sentence amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>103</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>104</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

zette the titles of the designated technical standards and common specifications, also indicating the references or where they may be obtained.<sup>105</sup>

<sup>5</sup> The Federal Council shall lay down the requirements for medical devices intended for use in clinical trials.

<sup>6</sup> It may provide for the relaxation of requirements for medical devices produced and used only within health institutions.<sup>106</sup>

<sup>7</sup> It may provide for the permissibility of reprocessing and further use of single-use devices. It shall specify the relevant conditions.<sup>107</sup>

#### **Art. 46** Procedures for assessing conformity

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> It may:

- a. require clinical trials for certain medical devices, which will form an integral part of the proof of conformity;
- b. permit exemptions from the conformity assessment for certain medical devices or medical device groups.<sup>108</sup>

#### **Art. 47**<sup>109</sup> Registration and device identification

<sup>1</sup> The manufacturer must register medical devices in the information system specified in Article 62c or in the European database on medical devices (Eudamed). It must also ensure that a unique device identifier is assigned to the medical device.

<sup>2</sup> The Federal Council shall define the modalities for registration and for device identification. It may provide for exemptions from the obligations specified in paragraph 1.

<sup>105</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>106</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>107</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>108</sup> Amended by No I of the FA of 22 March 2019, in force since 1 Aug. 2020 (AS 2020 2961; BBl 2019 1).

<sup>109</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>3</sup> It may regulate the obligations incumbent on the other economic operators concerned and on health institutions in connection with registration and device identification. It may, in particular, provide for an obligation to record and store the unique device identifiers of the devices acquired or supplied in certain categories.

<sup>4</sup> The following are deemed to be economic operators:

- a. the manufacturers;
- b. the persons authorised to represent manufacturers with headquarters abroad (authorised representatives);
- c. the importers;
- d. the distributors;
- e. the natural and legal persons who combine medical devices in order to place them on the market in the form of a system or a procedure pack;
- f. the natural and legal persons who sterilise devices as specified in letter e before they are placed on the market.

**Art. 47a<sup>110</sup>** Documentation requirements

<sup>1</sup> The manufacturer must produce technical documentation.

<sup>2</sup> The technical documentation must be such as to permit an assessment of the conformity of the medical device with the requirements of this Act. In particular, it shall also contain information and data on post-market surveillance.

<sup>3</sup> The manufacturer must keep the technical documentation up to date.

<sup>4</sup> The Federal Council shall specify for what medical devices what data and information must be included in the technical documentation, and how this documentation must be made available.

**Art. 47b<sup>111</sup>** Quality management

<sup>1</sup> The manufacturer must establish and maintain a quality management system which is appropriate to the risk class and type of medical device and ensures compliance with the requirements of this Act.

<sup>2</sup> The quality management system shall include, in particular, a risk management system and a post-market surveillance system.

**Art. 47c<sup>112</sup>** Disclosure requirements

<sup>1</sup> The economic operators shall disclose to the competent authority, on request:

<sup>110</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBI 2019 1).

<sup>111</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBI 2019 1).

<sup>112</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBI 2019 1).

- a. all economic operators from whom they have acquired a medical device;
- b. all economic operators to whom they have supplied a medical device;
- c. all health institutions or health professionals to whom they have supplied a medical device.

<sup>2</sup> The Federal Council shall specify for how long the information has to be kept.

**Art. 47d<sup>113</sup>** Financial coverage and liability

<sup>1</sup> The manufacturer or the authorised representative must have sufficient financial coverage to compensate for damage caused by defective medical devices.

<sup>2</sup> The authorised representative shall be jointly and severally liable with the manufacturer vis-à-vis the injured party.

**Art. 47e<sup>114</sup>** Additional obligations

<sup>1</sup> The Federal Council may:

- a. make provision for mandatory notification for the placing on the market of certain medical devices;
- b. make provision for mandatory licensing for the placing on the market of certain medical devices, in particular for in vitro diagnostics;
- c. make provision for an obligation for economic operators and conformity assessment bodies to use Eudamed or the information system specified in Article 62c.

<sup>2</sup> It shall regulate:

- a. the additional obligations of economic operators and health institutions, in particular concerning the registration of the manufacturers and the information to be provided in connection with implantable medical devices;
- b. the requirements for the manufacturers' and authorised representatives' persons responsible for regulatory compliance, and their other obligations.

**Art. 48** Dispensing and use

<sup>1</sup> 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.

<sup>113</sup> Inserted by No 1 of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>114</sup> Inserted by No 1 of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>2</sup> Article 26 applies by analogy to medical devices.<sup>115</sup>

**Art. 49** Obligation of maintenance

<sup>1</sup> 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.

<sup>2</sup> 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

<sup>1</sup> If required for the protection of health, the Federal Council may restrict or prohibit the import or export of certain medical devices.

<sup>2</sup> If another state requests export certificates and attestations for medical devices which are to be imported, the Agency may, on request, issue these documents to the manufacturer or to the authorised representative with a registered office in Switzerland.<sup>116</sup>

<sup>3</sup> Anyone exporting a medical device to a state with which Switzerland has concluded an agreement under international law for the mutual recognition of conformity assessments and procedures for medical devices must be able to demonstrate that the fundamental requirements referred to in Article 45 paragraph 2 are fulfilled.<sup>117</sup>

**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.

<sup>115</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>116</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>117</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

## Chapter 4 Common Provisions on Medicinal Products and Medical Devices

### Section 1 Pharmacopoeia

#### Art. 52

<sup>1</sup> The Agency shall publish the Pharmacopoeia.

<sup>2</sup> It shall involve the interested parties in the drafting of the Pharmacopoeia. In particular, it shall call upon experts and working groups.

<sup>3</sup> 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).

<sup>4</sup> 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<sup>118</sup> Principle

For clinical trials of therapeutic products in humans, the Human Research Act of 30 September 2011<sup>119</sup> applies in addition to the provisions of this Act.

#### Art. 54<sup>120</sup> Mandatory authorisation

<sup>1</sup> Clinical trials of therapeutic products require authorisation from the Agency in advance.

<sup>2</sup> Exempted from mandatory authorisation are clinical trials involving authorised medicinal products used in accordance with the product information.<sup>121</sup>

<sup>3</sup> 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;

<sup>118</sup> 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).

<sup>119</sup> SR 810.30

<sup>120</sup> 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).

<sup>121</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).



c.<sup>122</sup> make modifications to clinical trials subject to mandatory authorisation.

<sup>4</sup> As part of the authorisation procedure, the Agency shall verify:

- a. in the case of medicinal products, whether they comply with the rules of Good Manufacturing Practice and of medicinal product safety;
- b. in the case of medical devices, whether:
  1. the medical devices meet the requirements specified in Article 45, insofar as compliance with these requirements is not the subject of the clinical trial,
  2. the risks associated with a medical device are duly considered in the clinical trial,
  3. the information on the medical device is in line with current scientific knowledge and is correctly indicated in the protocol.<sup>123</sup>

<sup>5</sup> ...<sup>124</sup>

<sup>6</sup> The Federal Council shall regulate the authorisation procedure. It may define the required form of the application and stipulate that the submission of applications, correspondence and the publication of decisions must be effected electronically.<sup>125</sup>

<sup>7</sup> ...<sup>126</sup>

<sup>8</sup> In issuing regulations in accordance with paragraphs 3 and 6, the Federal Council shall have regard to the recognised international regulations.<sup>127</sup>

#### **Art. 54a**<sup>128</sup> Paediatric investigation plan

<sup>1</sup> For each medicinal product, a paediatric investigation plan shall be drawn up with a view to its marketing authorisation which sets out the requirements for the development of the medicinal product in paediatrics and which must be submitted to the Agency.

<sup>2</sup> The Federal Council shall regulate:

- a. the procedure;
- b. the requirements for the paediatric investigation plan in accordance with the EU provisions.

<sup>122</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>123</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>124</sup> Repealed by No I of the FA of 22 March 2019, with effect from 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>125</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>126</sup> Repealed by No I of the FA of 22 March 2019, with effect from 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>127</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>128</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>3</sup> It may waive the obligation to prepare a paediatric investigation plan, in particular for medicinal products for the treatment of diseases that occur only in adults. It may provide for a paediatric investigation plan assessed by a foreign authority to be taken into account.

**Art. 54b**<sup>129</sup> Supervision

<sup>1</sup> The Agency 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<sup>130</sup>.

<sup>2</sup> The Federal Council may, having regard to recognised international regulations, specify notification and information requirements, concerning in particular:

- a. the completion or discontinuation of a clinical trial;
- b. adverse events observed in connection with a clinical trial;
- c. incidents occurring during the conduct of a clinical trial which may affect the safety or health of the participants or call into question the acquisition of reliable and robust data.

<sup>3</sup> It shall regulate the notification procedure and the exchange of information. It may stipulate that notification and the exchange of information must be effected electronically.

**Section 2a Integrity and Transparency**<sup>131</sup>

**Art. 55**<sup>132</sup> Integrity

<sup>1</sup> Persons who prescribe, dispense, use or purchase for this purpose prescription medicinal products, and organisations employing such persons shall not claim, be promised or accept any undue advantage for themselves or for the benefit of a third party. Similarly, it is forbidden to offer, promise or grant an undue advantage to any such person or organisation for their benefit or for the benefit of a third party.

<sup>2</sup> The following are not regarded as undue advantages:

- a. advantages of modest value which are of relevance to medical or pharmaceutical practice;
- b. support for research, education and training, provided that certain criteria are met;

<sup>129</sup> Inserted by No 1 of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>130</sup> SR 810.30

<sup>131</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2020 (AS 2017 2745, 2019 1393; BBl 2013 1).

<sup>132</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2020 (AS 2017 2745, 2019 1393; BBl 2013 1).

- c. compensation for equivalent services in return, in particular for those provided in connection with orders and deliveries of therapeutic products;
- d. price discounts or refunds granted on medical purchases, provided they have no influence on the choice of treatment.

<sup>3</sup> The Federal Council shall regulate the details. It may extend the applicability of paragraphs 1 and 2 to other categories of therapeutic products.

**Art. 56**<sup>133</sup> Duty of transparency

<sup>1</sup> All discounts and rebates granted on purchases of medicinal products shall be shown on the receipts and invoices and in the accounts of both the selling and the purchasing persons and organisations and shall be disclosed to the competent authorities on request.

<sup>2</sup> The Federal Council shall regulate the details.

<sup>3</sup> It may provide for exceptions to the requirement laid down in paragraph 1 in the case of therapeutic products with a low risk potential.

**Art. 57**<sup>134</sup>

### **Section 3 Market Surveillance and Inspection Procedures**

**Art. 58** Official market surveillance

<sup>1</sup> The Agency and the other authorities entrusted with the enforcement of this Act shall monitor, within the limits of their powers, whether the manufacture, distribution, dispensing and maintenance of, and claims relating to therapeutic products are lawful. For this purpose, they may carry out announced and unannounced inspections.<sup>135</sup>

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> The Agency and the other authorities entrusted with the implementation of this Act may take samples, request essential information and documents, and ask for any

<sup>133</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2020 (AS 2017 2745, 2019 1393; BBl 2013 1).

<sup>134</sup> 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).

<sup>135</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

help necessary for this purpose. Neither the samples nor any other kind of help will be compensated for.<sup>136</sup>

<sup>5</sup> In the course of their monitoring services, the cantons shall notify the Agency or the Federal Office of Public Health (FOPH) in accordance with their respective responsibilities of any events, findings or complaints. The Agency or the FOPH 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.<sup>137</sup>

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

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> Any person who professionally dispenses therapeutic products or administers them to humans or animals or who is entitled to do so as medical personnel must notify the Agency of any serious and previously unknown adverse effects and incidents, observations of other serious and previously unknown facts or quality defects that are of significance for drug safety.<sup>138</sup>

<sup>3bis</sup> Any person who manufactures or places on the market therapeutic products must report to the Agency any suspicion of illegal trading in therapeutic products by third parties that come to its knowledge in connection with its activities, its products or their components.<sup>139</sup>

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

<sup>5</sup> The notifications referred to in paragraphs 1–3 shall be made in accordance with the recognised rules of good vigilance practice.<sup>140</sup>

<sup>6</sup> The Federal Council shall define the recognised rules of good vigilance practice. It shall take into account internationally recognised guidelines and standards.<sup>141</sup>

<sup>136</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>137</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>138</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>139</sup> Inserted by Annex No 2 of the FD of 29 Sept. 2017 (Medicrime Convention), in force since 1 Jan. 2019 (AS 2018 4771; BBl 2017 3135).

<sup>140</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>7</sup> Employees of persons and organisations who manufacture, distribute, prescribe or dispense therapeutic products are entitled to notify the competent authorities of observations that indicate a violation of the provisions of this Act.<sup>142</sup>

**Art. 60** Competence for conducting inspections

<sup>1</sup> The Agency is responsible for inspections carried out in Switzerland subject to the reservations of Articles 30 and 34 paragraph 4.

<sup>2</sup> 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.

<sup>3</sup> 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.

<sup>4</sup> It may involve the cantonal inspectorates in, or ask them to carry out inspections within its area of competence.

<sup>5</sup> 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 Data Processing<sup>143</sup>

**Art. 61** Obligation of secrecy

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

**Art. 62** Data confidentiality

<sup>1</sup> 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.

<sup>2</sup> The Federal Council may determine the data which are disclosed by the competent authority.

<sup>141</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>142</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>143</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

**Art. 62a**<sup>144</sup> Processing of personal data

<sup>1</sup> Federal and cantonal authorities, regional centres and third parties entrusted with enforcement tasks may, to the extent necessary to fulfil their duties under this Act, process the following sensitive personal data:<sup>145</sup>

- a. data on health:
  - 1.<sup>146</sup> for official market surveillance,
  2. to exercise vigilance in connection with incoming notifications on adverse effects and events and on quality defects,
  3. to verify clinical trials on the basis of incoming notifications and inspections, or
  - 4.<sup>147</sup> in connection with applications for temporary authorisations as specified in Article 9b paragraph 1 and for exemptions for medical devices as specified in Article 46 paragraph 3 letter b;
- b. data on administrative or criminal prosecutions and sanctions:
  1. within the framework of procedures for granting establishment licences, or
  2. to assess whether an investigator is qualified for conducting clinical trials.

<sup>2</sup> Sensitive personal data pursuant to paragraph 1 letter a shall be made anonymous wherever possible.

<sup>3</sup> The Federal Council shall issue implementing provisions on:

- a. responsibility for data processing;
- b. the scope of access rights for retrieval procedures;
- c. the length of time the data is to be kept;
- d. the archiving and destruction of data;
- e. data security.

**Art. 62b**<sup>148</sup> Cooperation with the private sector

<sup>1</sup> The Agency and the Federal Customs Administration (FCA), after weighing up the interests, are entitled on a case-by-case basis to disclose confidential data collected in accordance with this Act to the holder of an operating licence or of a marketing authorisation for medicinal products or to any person who places a medical device

<sup>144</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745; 2018 3575; BBl 2013 1).

<sup>145</sup> Amended by No 1 of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>146</sup> Amended by No 1 of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>147</sup> Inserted by No 1 of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>148</sup> Inserted by Annex No 2 of the FD of 29 Sept. 2017 (Medicrime Convention), in force since 1 Jan. 2019 (AS 2018 4771; BBl 2017 3135).

on the market, including sensitive personal data in accordance with Article 3 letter c number 4 of the Federal Act of 19 June 1992<sup>149</sup> on Data Protection, provided this measure is regarded as necessary in order to uncover or combat suspected illegal trading in therapeutic products.

<sup>2</sup> Personal data relating to patients may not be disclosed.

**Art. 62**<sup>150</sup> Medical devices information system

<sup>1</sup> The Agency, to fulfil its tasks, shall operate a medical devices information system; this shall serve in particular to ensure the safety of medical devices, as well as vigilance and surveillance.

<sup>2</sup> The information system shall contain data as specified in Article 62a which is necessary for the surveillance of medical devices and the conduct of notification and authorisation procedures for clinical trials in accordance with this Act.

<sup>3</sup> The data referred to in paragraph 2 may be automatically aligned with Eudamed.

<sup>4</sup> Any data referred to in paragraph 2 which is not sensitive may be published with due protection of professional confidentiality and trade secrets.

<sup>5</sup> The Federal Council shall regulate:

- a. the structure and data catalogue;
- b. the access rights;
- c. the organisational and technical measures necessary to ensure data protection and data security;
- d. the storage period.

**Art. 63** Data disclosure between the enforcement authorities in Switzerland

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> It may make provision for the Agency to disclose data to other federal authorities if this is necessary for the enforcement of federal legislation relating to health.<sup>151</sup>

**Art. 64**<sup>152</sup> Conditions for the disclosure of data and information abroad

<sup>1</sup> The federal authorities responsible for the enforcement of this Act may disclose information which is not publicly accessible to the foreign authorities and institu-

<sup>149</sup> SR 235.1

<sup>150</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>151</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>152</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

tions responsible for the enforcement of therapeutic product regulations and to international organisations, provided that it is ensured that:

- a. the requesting body is bound by official secrecy and uses the information received exclusively in an administrative procedure in connection with the enforcement of therapeutic product regulations and does not pass it on to third parties;
- b. only information required for the enforcement of therapeutic product regulations is transmitted;
- c. no manufacturing or trade secrets are disclosed, unless the transmission of such information is required to avert an immediate and serious risk to human life or health.

<sup>2</sup> They may disclose personal data, including data on health and on administrative or criminal proceedings or sanctions, if legislation in the state concerned guarantees adequate protection of the privacy of the data subject. In the absence of such legislation, the data may only be disclosed if:

- a. sufficient safeguards, in particular contractual clauses, ensure an adequate level of protection;
- b. the data subject has consented in the specific case;
- c. serious risks to health can thereby be averted in the specific case;
- d. disclosure is required in the specific case in order to protect the life or the physical integrity of the data subject; or
- e. in the specific case, there is a possibility that illegal traffic or other serious violations of this Act may be revealed as a result.

<sup>3</sup> In particular, the following data may be disclosed:

- a. results of market surveillance;
- b. inspection reports;
- c. information on clinical trials;
- d. information from vigilance;
- e. information on authorisations;
- f. information on conformity assessment bodies.

<sup>4</sup> The Agency is entitled to disclose the following information to the World Health Organization via its Global Pharmacovigilance Database, in connection with notifications and registrations of adverse reactions to medicinal products:

- a. information which is not publicly accessible and personal data relating to health, together with the data subject's initials, sex and year of birth;
- b. a report on the adverse reactions.



**Art. 64a**<sup>153</sup> Cross-border inspections

<sup>1</sup> Competent foreign authorities shall, on notifying the Agency, be entitled to inspect Swiss establishments operating in the therapeutic products sector provided that:

- a. the inspection has the sole purpose of verifying compliance with regulations on therapeutic products;
- b. the results of the inspection are used solely in administrative proceedings in connection with the enforcement of regulations on therapeutic products;
- c. the establishment concerned consents to the inspection; and
- d. the foreign authority informs the Agency of the results by providing it with the inspection report in an official Swiss language or in English.

<sup>2</sup> The Agency may accompany the foreign authority during its inspection.

<sup>3</sup> It may in consultation with the competent authorities carry out inspections of establishments abroad that operate in the therapeutic products sector, if this is required to guarantee the protection of health. In addition, it may participate in inspections carried out by competent foreign authorities.<sup>154</sup>

**Section 4a**<sup>155</sup>**Information System on Antibiotics in Veterinary Medicine****Art. 64b** Processing of personal data

The competent federal and cantonal authorities are entitled to process personal data as part of the implementation of their duties under this Act with regard to measures to reduce antibiotic resistance in veterinary medicine.

**Art. 64c** Operation and purpose of the Antibiotics Information System

<sup>1</sup> The Federal Food Safety and Veterinary Office (FSVO) operates an information system to monitor antibiotic sales, antibiotic consumption and antibiotic resistance (Antibiotics Information System).

<sup>2</sup> The Antibiotics Information System is part of the joint central information system along the food chain of the Federal Office for Agriculture (FOAG) and the FSVO.

<sup>3</sup> The costs of setting up and operating the Antibiotics Information System are borne by the federal government.

<sup>153</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2018 (AS 2017 2745; BBl 2013 1).

<sup>154</sup> Second sentence inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>155</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

**Art. 64d** Content of the Antibiotics Information System

<sup>1</sup> The Antibiotics Information System contains personal data including:

- a. the quantity of medicinal products containing antimicrobial agents distributed to the persons entitled to dispense them;
- b. the data on prescription, dispensing and use of medicinal products containing antimicrobial agents in accordance with the instructions for use and the official prescription form;
- c. the name and address of the dispensing person or practice;
- d. the name of the livestock holder to whom the medicinal product is dispensed;
- e. the date of dispensing.

<sup>2</sup> The Antibiotics Information System obtains:

- a. data from other applications of the joint central information system along the food chain as referred to in Article 64c paragraph 2;
- b. personal data from the Register of Medical Professions in accordance with Articles 51–54 of the Medical Professions Act of 23 June 2006<sup>156</sup>.

**Art. 64e** Access to the Antibiotics Information System

<sup>1</sup> As part of their statutory duties, the following authorities may process data online in the Antibiotics Information System:

- a. the FSVO: to compile antibiotics sales and consumption statistics, to monitor the antibiotic resistance situation and to guarantee the enforcement of the legislation;
- b. the cantonal enforcement authorities: to fulfil their tasks in their respective areas of responsibility.

<sup>2</sup> In order to fulfil their statutory duties, the following authorities or persons may retrieve data online from the Antibiotics Information System:

- a. the FSVO and the cantonal enforcement authorities: distribution, prescription, dispensing and application data;
- b. the FSVO: distribution, prescription, dispensing and application data to fulfil the tasks assigned to it in accordance with the Agriculture Act of 29 April 1998<sup>157</sup>;
- c. livestock holders: data concerning themselves;
- d. veterinarians and other persons subject to the obligation to report under Article 64f letter h: data concerning them and data which they have reported.

<sup>156</sup> SR 811.11

<sup>157</sup> SR 910.1

**Art. 64<sup>f</sup>** Implementing provisions

The Federal Council regulates the following for the Antibiotics Information System:

- a. the structure and data catalogue, including the part used by the cantons;
- b. the responsibilities for data processing;
- c. the access rights under Article 64<sup>e</sup>, in particular their scope;
- d. the organisational and technical measures necessary to ensure data protection and data security;
- e. the cooperation procedure with the cantons;
- f. storage and destruction periods;
- g. archiving;
- h. the reporting obligations of persons who market, prescribe, dispense and use antibiotics; livestock holders are exempt from the obligation to report;
- i. obtaining data on the veterinary profession from the Register of Medical Professions in accordance with Articles 51–54 of the Medical Professions Act of 23 June 2006<sup>158</sup>.

**Art. 64<sup>g</sup>** Use of the Antibiotics Information System by the cantons

The cantons that use the Antibiotics Information System for their own enforcement purposes are obliged to issue equivalent data protection provisions for their own areas and to designate a body to monitor compliance with these provisions.

**Section 5 Fees and Supervision Fee<sup>159</sup>****Art. 65**

<sup>1</sup> 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.

<sup>2</sup> It shall levy a supervision fee on the marketing authorisation holders for the financing of costs it incurs in the field of medicinal products which are not covered by fees in accordance with paragraph 1 or by payments from the Confederation in accordance with Article 77 paragraph 2a.<sup>160</sup>

<sup>3</sup> The supervision fee shall be levied on the ex-factory price of the authorised ready-to-use medicinal products sold in Switzerland. The maximum fee is 1.5 per cent of

<sup>158</sup> SR **811.11**

<sup>159</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS **2017** 2745, **2018** 3575; BBl **2013** 1).

<sup>160</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS **2017** 2745, **2018** 3575; BBl **2013** 1).

the ex-factory price. The income from the fee may not exceed a total of 1 per cent of the proceeds from all medicinal products sold in the respective levy year.<sup>161</sup>

<sup>4</sup> The Federal Council shall regulate the details of the supervision fee, in particular the fee rate applicable to the individual price categories.<sup>162</sup>

<sup>5</sup> The Agency Council shall set its fees in accordance with paragraph 1 in the Agency's Fees Ordinance. The Fees Ordinance shall be submitted to the Federal Council for approval.<sup>163</sup>

<sup>6</sup> The Federal Council may, under the strategic objectives, request that the Agency relinquish all or part of the fees for certain licences, provisions of service or controls.<sup>164</sup>

## Section 6 Administrative Measures

### Art. 66 In general

<sup>1</sup> The Agency and the other authorities entrusted with the enforcement of this Act may within their jurisdiction take all administrative measures necessary to enforce this Act.<sup>165</sup>

<sup>2</sup> In particular they may:<sup>166</sup>

- 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;

<sup>161</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>162</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>163</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>164</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>165</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>166</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

- 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.

<sup>3</sup> They may order therapeutic products from a person under a fictitious name if:

- a. they suspect that the person is manufacturing, importing or exporting therapeutic products illegally or placing them on the market illegally; and
- b. previous enquiries have been unsuccessful or further enquiries would otherwise be futile or would be disproportionately difficult.<sup>167</sup>

<sup>4</sup> The customs authorities shall be entitled to hold back shipments of therapeutic products at the border, in a free port or in a customs warehouse if they suspect that the recipient or sender in Switzerland is in breach of the provisions governing the import, manufacture, placing on the market or export of therapeutic products with the contents of the shipment.<sup>168</sup>

<sup>5</sup> They may call in the enforcement authorities. The latter shall make any further enquiries and take the necessary measures. In particular, they may ask postal service providers for the name and address of the holder of a post office box. In this case, the providers are obliged to provide information.<sup>169</sup>

<sup>6</sup> The enforcement authorities shall inform the persons concerned at the latest after the completion of the procedure of:

- a. the order under a fictitious name;
- b. the request for information and the reason for it.<sup>170</sup>

#### **Art. 67** Informing the general public

<sup>1</sup> 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 findings within the framework of market surveillance.<sup>171</sup>

<sup>1bis</sup> The professional information contains all the active substances and excipients of a medicinal product.<sup>172</sup>

<sup>167</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>168</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>169</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>170</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>171</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>172</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>2</sup> 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.

<sup>3</sup> The marketing authorisation holders, representatives of the interested medical professions, persons with independent dispensing rights in accordance with Article 25 and patients or their associations shall jointly maintain an institution in the form of a foundation which operates an electronic register with the legally prescribed information on medicinal products in the human and veterinary fields.<sup>173</sup>

<sup>4</sup> The institution shall publish in the electronic register referred to in paragraph 3 in a suitable and structured form the full and up-to-date information on medicinal products of the marketing authorisation holders at their expense. A simple register with the full and up-to-date information on medicinal products shall be publicly accessible and free of charge for all.<sup>174</sup>

<sup>5</sup> The marketing authorisation holders shall provide the institution with the legally prescribed information on the medicinal products in the form intended for this purpose. If the marketing authorisation holders fail to comply with this obligation, the institution shall structure the information at their expense.<sup>175</sup>

<sup>6</sup> The institution shall establish, with the involvement of the institution and the persons with independent dispensing rights in accordance with Article 25, the requirements as to the scope and structure of the data referred to in paragraph 4 and their supply in accordance with paragraph 5. It shall, as far as possible, take into account the relevant international standards.<sup>176</sup>

<sup>7</sup> The competent federal authorities may make further officially published information accessible via the register service.<sup>177</sup>

<sup>8</sup> If the institution does not fulfil its task, the Agency shall publish the legally prescribed information on medicinal products at the expense of the marketing authorisation holders in the form of an electronic register. The Agency may delegate the creation and operation of the register to third parties.<sup>178</sup>

<sup>9</sup> As soon as it has received an application for marketing authorisation for a medicinal product, the Agency shall publish the indication, the active substances in the medicinal product and the name and address of the applicant, provided the publication does not conflict with any interests of secrecy worth protecting.<sup>179</sup>

<sup>173</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>174</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>175</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>176</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>177</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>178</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>179</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

**Art. 67a**<sup>180</sup> Provision of information about the use of medicinal products in certain population groups

<sup>1</sup> 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.

<sup>2</sup> 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.

<sup>3</sup> The Federal Council:

- a. shall specify the basic requirements for the content, operation and quality of the database and regulate the conditions for the access to and use of the data;
- b. determines the entity responsible for managing the database and may authorise the same to gather information in anonymised form from medical professionals.

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

<sup>5</sup> 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.

**Art. 67b**<sup>181</sup> Publication of clinical trial results

<sup>1</sup> The Federal Council may, taking into account internationally recognised regulations, provide that the results of clinical trials carried out with a view to developing a medicinal product for human use shall be published after the authorisation decision.

<sup>2</sup> For this purpose, the Confederation may operate a database or have it operated by third parties. This database may not contain any data that would allow any reference to persons participating in clinical trials.

<sup>3</sup> The Federal Council:

- a. designates the authority responsible for maintaining the database;
- b. specifies the duties and procedure with regard to publication;
- c. determines the content and form of the results to be published;
- d. determines the requirements for the content and operation of the database;
- e. regulates the access to and use of the data.

<sup>180</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2018 (AS 2017 2745; BBl 2013 1).

<sup>181</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

## Chapter 5 Swiss Agency for Therapeutic Products

### Section 1 Legal Form and Position

#### Art. 68

- <sup>1</sup> The Confederation shall run the Agency with the cooperation of the cantons.
- <sup>2</sup> The Agency is an institution under public law with its own legal personality.
- <sup>3</sup> It is autonomous in its organisation and management; it may use its funding as it sees fit and shall keep its own accounts.
- <sup>4</sup> It may call upon private individuals to perform certain tasks.
- <sup>5</sup> It may appoint advisory committees and experts.

### Section 2 Tasks and Strategic Objectives<sup>182</sup>

#### Art. 69 Tasks

- <sup>1</sup> The Agency shall accomplish the tasks assigned to it under this Act and other federal acts.<sup>183</sup>
  - <sup>1bis</sup> The Federal Council may, against payment, delegate other tasks to the Agency which are closely related to the tasks assigned to it by law and which do not impair its performance.<sup>184</sup>
- <sup>2</sup> The Agency may, in return for payment, provide services to other authorities and international organisations within the scope of its tasks under this Act, provided that such services do not jeopardise the independence of the Agency.<sup>185</sup>
- <sup>3</sup> The Federal Council may ask the Agency to participate in the drafting of legislation in the therapeutic products sector.
- <sup>4</sup> The Agency is the national central and contact point pursuant to Articles 17 paragraph 3 and 22 paragraph 2 of the Council of Europe Convention of 28 October 2011<sup>186</sup> on the counterfeiting of medical products and similar crimes involving threats to public health. It shall maintain contacts with the designated contact points in other countries.<sup>187</sup>

<sup>182</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS **2017** 2745, **2018** 3575; BBl **2013** 1).

<sup>183</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS **2017** 2745, **2018** 3575; BBl **2013** 1).

<sup>184</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS **2017** 2745, **2018** 3575; BBl **2013** 1).

<sup>185</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS **2017** 2745, **2018** 3575; BBl **2013** 1).

<sup>186</sup> SR **0.812.41**

<sup>187</sup> Inserted by Annex No 2 of the FD of 29 Sept. 2017 (Medicrime Convention), in force since 1 Jan. 2019 (AS **2018** 4771; BBl **2017** 3135).



**Art. 70**<sup>188</sup> Strategic objectives

<sup>1</sup> The Federal Council shall approve the Agency's strategic objectives for a period of four years at the recommendation of the Agency Council.

<sup>2</sup> Adjustments which become necessary on the basis of the annual review by the Agency Council shall be submitted to the Federal Council for review.

**Section 3 Governing Bodies and Responsibilities****Art. 71**<sup>189</sup> Governing bodies

<sup>1</sup> The governing bodies of the Agency are:

- a. the Agency Council;
- b. the Management Board;
- c. the auditor.

<sup>2</sup> No person may belong to more than one of these bodies.

<sup>3</sup> The Federal Council may remove one or more members of the Agency Council for good cause.

**Art. 71a**<sup>190</sup> Disclosure of the vested interests of the members of the Agency Council

<sup>1</sup> The members of the Agency Council shall disclose their vested interests to the Federal Council prior to their election.

<sup>2</sup> Any person who refuses to disclose their vested interests shall not be eligible for election as a member.

<sup>3</sup> The members of the Agency Council shall immediately notify the Federal Department of Home Affairs of any change in their vested interests during their term of office.

<sup>4</sup> The Agency shall update the register and publish the vested interests.

<sup>5</sup> Professional secrecy within the meaning of the Criminal Code<sup>191</sup> shall remain reserved.

<sup>6</sup> A member of the Agency Council may be removed if they have not fully disclosed their vested interests at the time of the election or if they have not reported changes in their vested interests during their term of office, and if they fail to do so even after being requested to do so by the Federal Office of Home Affairs.

<sup>188</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>189</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>190</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>191</sup> SR 311.0

**Art. 72**<sup>192</sup> Composition and election of the Agency Council

<sup>1</sup> The Agency Council shall comprise a maximum of seven members.

<sup>2</sup> On the basis of a profile of requirements, the Federal Council shall elect the members of the Agency Council and appoint one of these members as chairperson. The cantons have the right to propose three members.

<sup>3</sup> The election shall be for a term of four years. Re-election is possible for two further terms of office.

**Art. 72a**<sup>193</sup> Function and duties of the Agency Council

<sup>1</sup> The Agency Council is the strategic body of the Agency and safeguards its interests. It has the following duties:

- a. It draws up the Agency's strategic objectives, submits them to the Federal Council for approval and reviews them annually.
- b. It submits an annual report to the Federal Council on the achievement of the strategic objectives. It submits to the Federal Council the report of the Swiss Federal Audit Office on an audit of the Agency as part of financial supervision.
- c. It proposes to the Federal Council the amount of compensation to be paid by the Confederation for services rendered pursuant to Article 69.
- d. It issues the regulations of the organisation of the Agency.
- e. It issues its own rules of procedure and shall in particular lay down the rules on recusal.
- f. It prepares and approves a business report for each financial year and submits it to the Federal Council for approval. At the same time, it submits a request to the Federal Council for discharge and for the appropriation of any profit. It publishes the business report after approval.
- g. It decides on the establishment, amendment and termination of the employment relationship with the executive director. The establishment and termination of the employment relationship require the approval of the Federal Council.
- h. It decides on the establishment, amendment and termination of the employment relationship of the other members of the Management Board at the request of the executive director.
- i. It fulfils other duties in the therapeutic products sector which the Federal Council assigns to it.
- j. It supervises the Management Board and ensures that the internal control system and risk management are appropriate for the Agency.

<sup>192</sup> Amended by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>193</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

- k. It enacts the provisions referred to in Article 82 paragraph 2.
- l. It approves the business plan and the budget.
- m. It concludes the affiliation agreement with the Federal Pension Fund (PUBLICA) and submits it to the Federal Council for approval.
- n. It regulates the composition, election procedure and organisation of the joint body for the pension fund.
- o. It issues regulatory provisions which guarantee the independence of the experts appointed by the Agency.

<sup>2</sup> The members of the Agency Council shall fulfil their duties and obligations with all due care and shall safeguard the interests of the Agency in good faith. The Agency Council shall take organisational precautions to safeguard the interests of the Agency and to prevent conflicts of interest.

**Art. 73<sup>194</sup>** Management Board

<sup>1</sup> The Management Board is the operative body of the Agency. It is headed by an executive director.

<sup>2</sup> The Management Board has the following duties:

- a. to conduct business;
- b. to issue administrative orders as provided for in the regulations of the organisation;
- c. to prepare the basis for the decisions of the Agency Council and report to it regularly and without delay in the event of special incidents;
- d. to represent the Agency in contacts with the outside world;
- e. to issue the business plan and the budget and submit the same to the Agency Council for approval;
- f. to decide on establishment, amendment and termination of the employment relationship of Agency staff; the foregoing is without prejudice to Article 72a paragraph 1 letter h;
- g. to carry out the tasks not assigned to any other Agency body.

**Art. 74<sup>195</sup>** Review body

<sup>1</sup> The Federal Council appoints the review body for a period of four years. It may be re-appointed for a further term of office.

<sup>2</sup> The provisions of the Swiss Code of Obligations<sup>196</sup> concerning the review body of companies limited by shares apply by analogy to the auditor.

<sup>194</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>195</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>196</sup> SR 220

<sup>3</sup> The review body shall conduct a statutory audit and submit comprehensive reports to the Federal Council and the Agency Council on the results of their audit.

<sup>4</sup> The Federal Council may ask the review body to clarify certain matters.

<sup>5</sup> It may remove the review body.

## Section 4 Staff

**Art. 75** Compensation of the Agency Council and employment conditions<sup>197</sup>

<sup>1</sup> The Agency shall employ its staff under public law. In justified cases, contracts may be concluded in accordance with the Code of Obligations<sup>198</sup>.

<sup>2</sup> The Agency Council issues the Agency's staff regulations subject to approval by the Federal Council.<sup>199</sup>

<sup>3</sup> With regard to the salaries of the members of the Management Board and other persons 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 Federal Personnel Act of 24 March 2000<sup>200</sup> apply by analogy.<sup>201</sup>

<sup>4</sup> The Federal Council shall determine the compensation of the members of the Agency Council. Article 6a paragraphs 1–5 of the Federal Personnel Act apply to the remuneration of the members of the Agency Council and to the other contractual conditions agreed with these persons.<sup>202</sup>

**Art. 75a**<sup>203</sup> Obligation to notify, right to report and protection

<sup>1</sup> Employees shall notify the prosecution authorities, their superiors, the Agency Council or the Swiss Federal Audit Office of any felony or misdemeanour which they have discovered or has been reported to them in the course of their official duties.

<sup>2</sup> The obligations to notify arising from other federal acts are reserved.

<sup>3</sup> The obligation to notify does not apply to persons entitled to refuse to testify or give evidence under Articles 113 paragraph 1, 168 and 169 of the Criminal Procedure Code<sup>204</sup>.

<sup>197</sup> Amended by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>198</sup> SR 220

<sup>199</sup> Amended by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>200</sup> SR 172.220.1

<sup>201</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>202</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>203</sup> Inserted by Annex No 2 of the FD of 29 Sept. 2017 (Medicrime Convention), in force since 1 Jan. 2019 (AS 2018 4771; BBl 2017 3135).

<sup>204</sup> SR 312.0

<sup>4</sup> Employees are entitled to report to their superiors, the Agency Council or the Swiss Federal Audit Office any other irregularities discovered or reported to them in the course of their official duties.

<sup>5</sup> Any person who has submitted a notification or a report in good faith or who has testified as a witness may not be disadvantaged in their professional status as a consequence.

**Art. 75b<sup>205</sup>** Data processing

<sup>1</sup> The Agency shall process, on paper and in one or more information systems, employee data for the fulfilment of its tasks in accordance with this Act, in particular for:

- a. determining personnel requirements;
- b. meeting personnel requirements through staff recruitment;
- c. wage and salary accounting, preparation of personnel records, social insurance notifications;
- d. development and long-term retention of staff;
- e. maintenance and improvement of staff qualifications;
- f. planning, management and control through data analysis, benchmarking, reporting and planning of measures.

<sup>2</sup> It may process the following personnel data necessary for the fulfilment of its tasks as specified in paragraph 1, including sensitive personal data:

- a. personal details;
- b. information on the health situation in relation to fitness for work;
- c. information on performance and potential, and on personal and professional development;
- d. data required for participation in the enforcement of social insurance law;
- e. procedural documents and decisions by authorities relating to work.

<sup>3</sup> It shall be responsible for data protection and security.

<sup>4</sup> It may pass on data to third parties if a legal basis for this exists, or if written consent has been given by the data subject.

<sup>5</sup> It shall issue implementing provisions on:

- a. the architecture, organisation and operation of the information systems;
- b. the processing of data, in particular the collection, storage, archiving and destruction thereof;
- c. data processing permissions;
- d. data categories in accordance with paragraph 2;

<sup>205</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBI 2019 1).

e. data protection and security.

<sup>6</sup> It may provide for the disclosure of non-sensitive data through retrieval procedures. It shall issue implementing provisions for this purpose.

**Art. 76<sup>206</sup>** Pension fund

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

## **Section 5 Budget and Annual Report<sup>207</sup>**

**Art. 77<sup>208</sup>** Financial resources

<sup>1</sup> The Confederation and the cantons may allocate an interest-free endowment fund to the Agency.

<sup>2</sup> The Agency shall finance its expenditure, in particular, from:

- a.<sup>209</sup> federal remuneration for tasks referred to in Article 69 paragraph 1, where these are not covered by charges and fees;
- b. charges and fees referred to in Article 65;
- c. charges for services provided to other authorities and international organisations referred to in Article 69 paragraph 2.

<sup>2bis</sup> The following tasks and activities of the Agency shall be fully financed from federal remuneration:

- a. legislation;
- b. enforcement of criminal provisions;
- c. surveillance of medical devices.<sup>210</sup>

<sup>3</sup> The task-specific use of the funds referred to in paragraph 2 letters a and b and the adjustments to be made in the event of over- or underfinancing of the tasks and activities referred to in paragraph <sup>2bis</sup> shall be determined within the framework of the approval of strategic objectives.<sup>211</sup>

<sup>4</sup> The fines and income from sanctions shall go to the Confederation.

<sup>206</sup> Amended by Annex No 3 of the FA of 14 Dec. 2012, in force since 1 July 2013 (AS 2013 1493; BBl 2011 6703).

<sup>207</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>208</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>209</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>210</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>211</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

**Art. 78**<sup>212</sup> Accounting

<sup>1</sup> The financial statements of the Agency shall present its financial position and performance in accordance with the actual circumstances.

<sup>2</sup> The accounting follows the general principles of materiality, completeness, comprehensibility, consistency and gross presentation, and is based on generally accepted standards.

<sup>3</sup> The accounting and valuation rules derived from the accounting principles must be disclosed in the annex.

<sup>4</sup> The Federal Council may issue accounting regulations for the Agency.

**Art. 78a**<sup>213</sup> Annual report

<sup>1</sup> The annual report contains the annual accounts, the confirmation of audit of the annual accounts and the financial report.

<sup>2</sup> The annual accounts consist of the balance sheet, the income statement and the annex.

<sup>3</sup> The annual accounts shall be audited by the auditor.

**Art. 79**<sup>214</sup> Reserves

<sup>1</sup> If reserves are formed, they shall serve to finance future investments by the Agency and cover any losses.

<sup>2</sup> Should the reserves exceed the amount of an annual budget, the charges and fees shall be reduced.

**Art. 79a**<sup>215</sup> Treasury

<sup>1</sup> At the request of the Agency, the Federal Finance Administration may manage its liquid assets as part of its central treasury.

<sup>2</sup> The Federal Finance Administration may grant the Agency loans at market interest rates to ensure that it is able to pay.

<sup>3</sup> The Federal Finance Administration and the Agency shall agree on the details of this cooperation.

<sup>212</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>213</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>214</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>215</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

**Art. 80<sup>216</sup>** Liability

<sup>1</sup> The responsibilities of the Agency, its governing bodies, staff and agents are governed, subject to paragraph 2, by the Government Liability Act of 14 March 1958<sup>217</sup>.

<sup>2</sup> The Agency and its agents shall be liable only if:

- a. they breach important official obligations;
- b. damage is not attributable to a breach of duty by an agent.

**Art. 81** Tax exemption

<sup>1</sup> The Agency shall be exempt from all federal, cantonal and communal taxes.

<sup>2</sup> This shall be without prejudice to the federal law governing:

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

**Section 6<sup>218</sup> Independence and Oversight****Art. 81a**

<sup>1</sup> The Agency shall conduct its supervisory activities autonomously and independently.

<sup>2</sup> It is subject to the supervision of the Federal Council.

<sup>3</sup> The Federal Council shall carry out its supervisory and control functions in particular by:

- a. electing and removing the members and the president of the Agency Council;
- b. approving the establishment and termination of the employment relationship with the director;
- c. electing and removing the auditor;
- d. approving the Agency's staff and Fees Ordinance and affiliation agreement with PUBLICA (the federal pension fund);
- e. approving the annual report and the decision on the appropriation of any profit;
- f. approving the strategic objectives and the annual review of the achievement of the strategic objectives;

<sup>216</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>217</sup> SR 170.32

<sup>218</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).



g. granting discharge to the Agency Council.

<sup>4</sup> The Federal Council may inspect the business records of the Agency in order to check whether the strategic objectives have been achieved and, for this purpose, obtain information on its business activities at any time.

<sup>5</sup> The statutory powers of the Swiss Federal Audit Office remain reserved.

## Chapter 6 Enforcement

### Art. 82 Federal government

<sup>1</sup> The Federal Council and the Agency shall enforce this Act insofar as the Act states that the Confederation is competent to do so. The Agency is the enforcement authority for products specified in Article 2a. The FOPH is responsible for the enforcement of Chapter 4 Section 2a. The Federal Council may delegate certain of the Agency's or the FOPH's tasks to other authorities.<sup>219</sup>

<sup>2</sup> 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.

<sup>3</sup> Insofar as certain delegated acts and implementing acts of the European Commission in the area of medical devices concern technical or administrative details that are regulated on an ongoing basis and generally amended at short notice, the Federal Council may determine that the relevant acts in the version binding for EU member states are also to be applicable in Switzerland.<sup>220</sup>

### Art. 82a<sup>221</sup> International cooperation

<sup>1</sup> The federal authorities responsible for the enforcement of this Act shall cooperate with foreign authorities and international organisations.

<sup>2</sup> The Federal Council may conclude treaties under international law concerning:

- a. the exchange of information with foreign authorities or international organisations and Switzerland's involvement in international information systems to ensure the safety of therapeutic products;
- b. the disclosure of personal data, including data on health and on administrative or criminal proceedings or sanctions, to foreign authorities or international organisations, insofar as this is necessary for the enforcement of this Act.

<sup>219</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>220</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>221</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

**Art. 83** Cantons

<sup>1</sup> 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.

<sup>2</sup> The cantons shall notify the Agency of their legislation concerning therapeutic products.

**Chapter 7 Administrative Procedure and Rights of Appeal****Art. 84** ...<sup>222</sup>

<sup>1</sup> Unless this Act provides otherwise, the administrative procedure and rights of appeal are regulated by the Federal Act of 20 December 1968<sup>223</sup> on Administrative Procedure and by the Federal Administrative Court Act of 17 June 2005<sup>224</sup>, and the Federal Supreme Court Act of 17 June 2005<sup>225,226</sup>

<sup>1bis</sup> In administrative proceedings involving the Agency, the consent of assessors and scientific advisors is required before their names may be disclosed to the parties.<sup>227</sup>

<sup>2</sup> 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.<sup>228</sup>

<sup>3</sup> 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<sup>229</sup> (Art. 89 para. 2 let. a of the Federal Supreme Court Act of 17 June 2005).<sup>230</sup>

**Art. 85**<sup>231</sup>

<sup>222</sup> 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).

<sup>223</sup> SR **172.021**

<sup>224</sup> SR **173.32**

<sup>225</sup> SR **173.110**

<sup>226</sup> 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).

<sup>227</sup> Inserted by No 1 of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS **2017** 2745, **2018** 3575; BBl **2013** 1).

<sup>228</sup> 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).

<sup>229</sup> SR **810.30**

<sup>230</sup> 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).

<sup>231</sup> 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).

## Chapter 8 Criminal Provisions

### Art. 86<sup>232</sup> Felonies and misdemeanours

<sup>1</sup> A custodial sentence not exceeding three years or a monetary penalty shall be imposed on any person who wilfully:

- a. manufactures, places on the market, uses, prescribes, imports or exports, or trades in a foreign country medicinal products without the required marketing authorisation or licence, or contrary to the due diligence requirements stipulated in Articles 3, 7, 21, 22, 26, 29 and 42;
- b. uses antibiotic substances contrary to the restrictions or prohibitions laid down in Article 42a paragraph 2;
- c. violates, when handling blood or blood products, the provisions on the fitness of the donor to give blood, on the obligation to test, on the obligation to record or archive or due diligence requirements in accordance with Article 37, or fails to take the necessary protections and safeguards;
- d.<sup>233</sup> places on the market, exports or uses medical devices which do not satisfy the requirements of this Act, or uses medical devices without the necessary technical or operational requirements being fulfilled;
- e. violates the due diligence requirement pursuant to Article 48 or the obligation to maintain medical devices;
- f. performs a clinical trial on a human being which does not satisfy the requirements of this Act, or allows the same to be performed;
- g. unlawfully copies, falsifies or incorrectly names medicinal products or medical devices, or places on the market, uses, imports or exports, or trades in a foreign country, unlawfully copied, falsified or incorrectly named medicinal products or medical devices;
- h. violates a prohibition under Article 55.
- i.<sup>234</sup> places on the market products which do not meet the requirements specified by the Federal Council in accordance with Article 2a;
- j.<sup>235</sup> offers, grants, demands or accepts a financial gain or other advantage for human tissue or human cells or uses such tissues or cells for the manufacture of products as specified in Article 2a;
- k.<sup>236</sup> removes or uses human tissue or human cells for the manufacture of products as specified in Article 2a in the absence of consent for removal.

<sup>232</sup> Amended by No I of the FA of 18 March 2016 with the exception of paragraph 1 letter h in force since 1 Jan. 2020 (AS 2017 2745, 2018 3575, 2019 1393; BBl 2013 1).

<sup>233</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>234</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>235</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>2</sup> A custodial sentence not exceeding ten years, which may be combined with a monetary penalty, or a monetary penalty shall be imposed on any person who, in the cases referred to in paragraph 1 letters a–g and i–k:<sup>237</sup>

- a. knows or must assume that the violation specifically endangers human health;
- b. achieves a high turnover or makes substantial profits through commercial activity.

<sup>3</sup> Any person acting as a member of a gang involved in the illicit trade in therapeutic products in the cases referred to in paragraph 1 letters a, c, d, f, g and i–k shall be liable to a custodial sentence not exceeding ten years, which may be combined with a monetary penalty, or to a monetary penalty.<sup>238</sup>

<sup>4</sup> If the person concerned acts through negligence, he or she shall be liable to a monetary penalty. In minor cases, a fine may be imposed.<sup>239</sup>

#### **Art. 87** Other offences<sup>240</sup>

<sup>1</sup> A fine not exceeding 50,000 Swiss francs shall be imposed on any person who wilfully:<sup>241</sup>

- 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.<sup>242</sup> violates an obligation under this Act to notify, register or disclose;
- 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<sup>243</sup>;
- f.<sup>244</sup> commits an offence referred to in Article 86 paragraph 1 letters a–g where the therapeutic product is intended exclusively for personal use or involves

<sup>236</sup> Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>237</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>238</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>239</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>240</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>241</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>242</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>243</sup> SR 311.0

<sup>244</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

an over-the-counter medicinal product or a Class I medical device in accordance with Annex IX to Directive 93/42/EEC<sup>245</sup> concerning medical devices;

g.<sup>246</sup> fails to comply with a ruling against him or her which refers to the penalties provided for in this article;

h.<sup>247</sup> infringes the obligation of transparency laid down in Article 56.

<sup>2</sup> If the person concerned acts in a professional capacity in the cases referred to in paragraph 1 letter a, b, e or f, he or she shall be liable to a monetary penalty.<sup>248</sup>

<sup>3</sup> If the person concerned acts through negligence, the penalty shall be a fine not exceeding 20,000 Swiss francs.<sup>249</sup>

<sup>4</sup> Attempts and aiding and abetting are also offences.

<sup>5</sup> The right to prosecute contraventions and execute the penalties for contraventions are subject to a time limit of five years.

<sup>6</sup> 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<sup>250</sup> 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.

#### **Art. 89**<sup>251</sup> Offences committed within a company

<sup>1</sup> If a fine not exceeding 20,000 Swiss francs may be imposed and if the investigation of persons suspected of an offence under Article 6 of the Federal Act of 22 March 1974<sup>252</sup> on Administrative Criminal Law (ACLA) would result in *investigative* measures which would be disproportionate to the penalty imposed, the company (Art. 7 ACLA) may be ordered to pay the fine instead of prosecuting such persons.

<sup>2</sup> Articles 6 and 7 of the ACLA apply to criminal proceedings carried out by cantonal authorities.

<sup>245</sup> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169 of 12.7.1993, p. 1; last amended by Directive 2007/47/EC, OJ L 247 of 21.9.2007, p. 21.

<sup>246</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>247</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>248</sup> Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS 2020 2961; BBl 2019 1).

<sup>249</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>250</sup> SR 946.51

<sup>251</sup> Amended by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1).

<sup>252</sup> SR 313.0

**Art. 90**<sup>253</sup> Prosecution

<sup>1</sup> Prosecutions conducted at federal level shall be conducted by the Agency and by the FOPH in accordance with the ACLA<sup>254</sup>. If the import, transit and export of therapeutic products also involves a violation of the Customs Act of 18 March 2005<sup>255</sup> or the Value Added Tax Act of 12 June 2009<sup>256</sup>, the Federal Customs Administration shall prosecute and judge the offences.

<sup>2</sup> If two or more federal authorities are competent to prosecute under this or another federal act, they may agree to bring the prosecution under one authority, provided the facts of the case are the same or are closely related.

<sup>3</sup> Criminal proceedings in the sphere of enforcement of the cantons fall within their jurisdiction. The Agency may exercise the rights of a private claimant in the proceedings. The cantonal prosecutor shall inform the Agency of the initiation of preliminary proceedings.

**Art. 90a**<sup>257</sup> Covert surveillance measures

<sup>1</sup> The Agency or the FCA may order covert surveillance measures pursuant to Articles 282 and 283 or 298a–298d CrimPC<sup>258</sup>.

<sup>2</sup> Where a measure under paragraph 1 lasts for more than 30 days, approval is required from the director of the ordering authority.

<sup>3</sup> At the latest following conclusion of the investigation, the ordering authority shall notify the person concerned of the reason, form and duration of the covert surveillance.

<sup>4</sup> Where covert surveillance measures pursuant to Articles 269–281 or 284–298 CrimPC are considered necessary, the Agency or the FCA shall notify the Office of the Attorney General of Switzerland (OAG) immediately.

<sup>5</sup> In cases under paragraph 4, the Agency or the FCA with the agreement of the OAG shall apply to the compulsory measures court. If the court approves the measures, the OAG shall take over the proceedings in accordance with the CrimPC.

**Art. 90b**<sup>259</sup> Offences committed abroad and complex proceedings

Where proceedings conducted by the Agency or the FCA relate primarily to offences committed abroad or if the proceedings prove to be so complex or time-consuming that they cannot be concluded at all or within a reasonable time using the resources available to the Agency or the FCA, the Agency or the FCA may request

<sup>253</sup> Amended by Annex No 2 of the FD of 29 Sept. 2017 (Medicrime Convention), in force since 1 Jan. 2019 (AS **2018** 4771; BBl **2017** 3135).

<sup>254</sup> SR **313.0**

<sup>255</sup> SR **631.0**

<sup>256</sup> SR **641.20**

<sup>257</sup> Inserted by Annex No 2 of the FD of 29 Sept. 2017 (Medicrime Convention), in force since 1 Jan. 2019 (AS **2018** 4771; BBl **2017** 3135).

<sup>258</sup> SR **312.0**

<sup>259</sup> Inserted by Annex No 2 of the FD of 29 Sept. 2017 (Medicrime Convention), in force since 1 Jan. 2019 (AS **2018** 4771; BBl **2017** 3135).

the OAG to take over the proceedings. The OAG shall conduct the proceedings in accordance with the CrimPC<sup>260</sup>.

**Art. 90c**<sup>261</sup> Involvement of third parties

The Agency and the FOPH may instruct independent specialists to secure, save, analyse and retain data seized in the course of administrative criminal proceedings. When acting on behalf of the Agency or the FOPH, such specialists shall be subject to the obligations that apply to employees of the Agency or the Federal Administration. The compensation paid to the specialists is deemed to be cash outlays in terms of Article 94 paragraph 1 ACLA<sup>262</sup>.

## **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

<sup>1</sup> 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.

<sup>2</sup> 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

<sup>1</sup> The Federal Council shall appoint the first executive director of the Agency on the proposal of the Federal Department of Home Affairs.

<sup>2</sup> 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.

<sup>3</sup> The contract service conditions of the staff transferred to the Agency from the FOPH<sup>263</sup> 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.

<sup>260</sup> SR 312.0

<sup>261</sup> Inserted by Annex No 2 of the FD of 29 Sept. 2017 (Medicrime Convention), in force since 1 Jan. 2019 (AS 2018 4771; BBl 2017 3135).

<sup>262</sup> SR 313.0

<sup>263</sup> Name in accordance with No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1). The change has been made throughout the text.

**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 FOPH.

**Art. 94** Pending procedures

<sup>1</sup> Procedures which on the commencement of this Act are pending before the FOPH, the FSVO<sup>264</sup>, 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.

<sup>2</sup> Procedural acts carried out by authorities deemed competent before the commencement of this Act shall remain valid unless they contradict the material provisions of this Act.

**Art. 95** Transitional provisions

<sup>1</sup> Registrations of medicinal products carried out by the FOPH, the FSVO and by the Intercantonal Office for the Control of Medicinal Products remain valid for up to five years after the commencement of this Act.

<sup>2</sup> Cantonal authorisations for medicinal products are valid until 31 December 2017; medicinal products may be authorised by the Agency within two years of the expiry of the transitional period.<sup>265</sup> The foregoing is without prejudice to:

- 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.

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> Authorisations issued by the Confederation and by the cantons in accordance with the former Act are valid until the expiry of their validity period or for a maximum of five years from the commencement date of this Act.

<sup>6</sup> 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

<sup>264</sup> Name in accordance with No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS 2017 2745, 2018 3575; BBl 2013 1). The change has been made throughout the text.

<sup>265</sup> Amended by No I of the FA of 21 June 2013, in force since 1 Jan. 2014 (AS 2013 4137; BBl 2013 3281 3289).



the commencement of this Act. The Federal Council may, however, issue exemptions for persons who can prove that they have sufficient education and training.

<sup>7</sup> The administrative measures taken by the Agency and referred to in Article 66 are reserved.

**Art. 95a**<sup>266</sup> 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 start from the date on which this amendment comes into force.

**Art. 95b**<sup>267</sup> Transitional provisions to the amendment of 18 March 2016

As long as there is no full list in accordance with Article 67 paragraphs 3 and 4, the Agency shall publish the information on medicinal products in the form of an electronic directory at the expense of the marketing authorisation holders. It may delegate the establishment and operation of the directory to third parties.

## Section 2 Referendum and Commencement

**Art. 96**

<sup>1</sup> This Act is subject to an optional referendum.

<sup>2</sup> The Federal Council shall determine the commencement date.

Commencement date:<sup>268</sup> 1 January 2002  
Art. 71 and 72: 1 October 2001

<sup>266</sup> 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).

<sup>267</sup> Inserted by No I of the FA of 18 March 2016, in force since 1 Jan. 2019 (AS **2017** 2745, **2018** 3575; BBl **2013** 1).

<sup>268</sup> FCD of 28 Sept. 2001.

*Annex***Repeal and Amendment of Current Legislation**

I

The Pharmacopoeia Law of 6 October 1989<sup>269</sup> is repealed.

II

The following enactments are amended as follows:

...<sup>270</sup>

<sup>269</sup> [AS 1990 570]

<sup>270</sup> The amendments may be consulted under AS 2001 2790.