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

of 15 December 2000 (Status as of 1 January 2022)

The Federal Assembly of the Swiss Confederation,

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

decrees:

Chapter 1 General Provisions

Art. 1 Purpose

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

[2] It shall furthermore:

a. protect the consumers of therapeutic products against fraud;

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

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

[3] In the implementation of this Act, in particular in the enactment of the regulations and in the application to an individual case, it 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

1 SR **101**

2 BBl **1999** 3453

Art. 2 Scope

[1] This Act applies to:

a.[3] the handling of medicinal products and medical devices (therapeutic products);

b. narcotics as defined in the Narcotics Act of 3 October 1951[4], insofar as they are used as therapeutic products;

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

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

[3] 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.[5]

Art. 2*a*[6] Devitalised human tissue or cells

[1] 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.

[2] It may make subject to specific requirements of this Act and of the Transplantation Act of 8 October 2004[7] 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.

[3] 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

[1] 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.

3 Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS **2020** 2961; BBl **2019** 1).
4 SR **812.121**
5 Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS **2020** 2961; BBl **2019** 1).
6 Inserted by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS **2020** 2961; BBl **2019** 1).
7 SR **810.21**

[2] 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.[8]

Art. 4 Definitions

[1] 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[bis].[9] *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[ter].[10] *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[quater].[11] *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[quinquies].[12] *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[sexies].[13] *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;

8 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).
9 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).
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asepties.[14] *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;

aocties.[15] *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;

anovies.[16] *Biosimilar product* means a biological medicinal product sufficiently similar to a reference preparation authorised by the Agency and that refers to its documentation;

adecies.[17] *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.[18] *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;

14 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).
15 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).
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18 Amended by No I of the FA of 22 March 2019, in force since 26 May 2021 (AS **2020** 2961; BBl **2019** 1).

e.[19] *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^{bis}.[20] *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.[21] *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.[22] *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.[23] *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 2bis, an internal radiopharmaceutical establishment is also deemed to be a hospital pharmacy;

k.[24] *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.

[2] The Federal Council may, by ordinance, distinguish between the terms used in this Act as well as those used in paragraph 1, define them in greater detail, and may

19 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).
20 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).
21 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).
22 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).
23 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).
24 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).