Ordinance on Licensing in the Medicinal Products Sector

(Medicinal Products Licensing Ordinance, MPLO)

of 14 November 2018 (Status as of 16 July 2019)

The Swiss Federal Council,
having regard to the Therapeutic Products Act of 15 December 2000[1] (TPA),
ordains:

Chapter 1 Subject Matter and Definitions

Art. 1 Object and definition of terms

1 This Ordinance regulates:

a. the manufacture of medicinal products;

b. wholesale trading in medicinal products;

c. the import, export and transit trade in medicinal products;

d. trading in medicinal products in foreign countries from Switzerland;

e. the extracting of blood for transfusions or for the manufacture of medicinal products together with other essential elements of transfusion safety in handling blood and labile blood products;

f. brokerage or agency activities in connection with medicinal products;

g. temporary licences to use medicinal products in accordance with Article 9*b* paragraph 1 TPA.

2 With the exception of Articles 27, 28 and 47, this Ordinance applies by analogy to the handling of transplant products as described in Article 2 paragraph 1 letter c of the Transplantation Ordinance of 16 March 2007[2].

3 Articles 29–38 do not apply to transplant products described in Article 2 paragraph 1 letter c number 2 of the Transplantation Ordinance of 16 March 2007.

AS **2018** 5029
1 SR **812.21**
2 SR **810.211**

Art. 2 Definitions

In this Ordinance:

a. *active pharmaceutical ingredients* means substances or mixtures to which the effect of a ready-to-use medicinal product is attributed and which are used in ready-to-use medicinal products;

b. *immunological medicinal products* means medicinal products administered to create active or passive immunity or help diagnose immunity status, in particular vaccines, toxins and sera, and medicinal products intended to identify or cause a particular acquired modification of the immune response to an allergising substance, such as allergens;

c. *ready-to-use medicinal product* means a medicinal product that has been released technically on the basis of the entire manufacturing process and is available in a form and presentation enabling it to be used as intended;

d. *blood* means human blood;

e. *labile blood products* means products that are extracted from donated blood, either directly or in one or a small number of manufacturing steps, and which quickly change without any external influence, in particular cell preparations and plasma;

f. *medicated feedingstuffs* means ready-to-use veterinary medicinal products comprising a mixture of premixed medicinal products and feedstuffs or drinking water;

g. *premixed medicinal products* means veterinary medicinal products, comprising active ingredients and excipients intended for mixing with animal feedstuffs or drinking water or for direct administration to a category of animals;

h. *batch* means a homogeneous and defined quantity of raw materials, medicinal products or packaging material prepared in one manufacturing operation or in a series of manufacturing operations;

i. *system to ensure the pharmaceutical quality of medicinal products* means the whole range of measures taken to ensure that medicinal products have the necessary quality for their intended use;

j. *medical personnel* means doctors, dentists, veterinary surgeons and pharmacists;

k. *facilities* means individual parts or groups of buildings or systems, in one or more locations, and vehicles and other resources involved in the manufacturing, testing, import and export of medicinal products, in wholesale trading or trading abroad with medicinal products, or in brokerage or agency activities related to medicinal products;

l. *wholesale trade* means all activities relating to the paid or unpaid transferring or provision of medicinal products – from acquisition, stockage, storage, offering and advertising to the supply of medicinal products – to per-

sons authorised to trade in them, process them, dispense them or use them in a professional capacity;

m. *import* means all the activities listed under letter l relating to the transport of medicinal products into Switzerland;

n. *export* means all the activities listed under letter l relating to the transport of medicinal products out of Switzerland;

o. *technical release* means the decision taken on completion of manufacture or of a step in the manufacturing process confirming that the batch in question conforms to the requirements of internal or external clients in terms of composition, manufacturing procedure, specifications and quality and was manufactured in compliance with the rules of Good Manufacturing Practice (GMP[3]) as shown in Annex 1 or 2.

Chapter 2 Establishment Licences

Section 1 Manufacturing Licence

Art. 3 Conditions for granting a licence

[1] Any person applying to the Swiss Agency for Therapeutic Products (Swissmedic) for a manufacturing licence must prove that:

a. a system to ensure the pharmaceutical quality of medicinal products is in operation and that the company management and staff in the individual departments concerned take an active part in such a system;

b. each department has a sufficient number of qualified and competent staff members to enable it to achieve its quality targets;

c. a Responsible Person as described in Articles 5 and 6 is available;

d. the facilities are organised in an appropriate way;

e. the facilities are designed, structured, maintained and modernised regularly to guarantee the safe manufacture of medicinal products and the premises and equipment that can influence the quality of the medicinal products are qualified for their purpose;

f. a documentation system is available to provide the working instructions, process descriptions and protocols of the relevant manufacturing procedures;

g. the manufacturing, testing and cleaning procedures are validated;

h. quality control is separate from manufacture;

i. the obligations described in Articles 4 and 7 and in relation to the manufacture of labile blood products and the obligations in Articles 28–38 are met.

3 Footnote not relevant to the English text.

2 The work of all persons occupying key positions in the company must be set out in job descriptions and their hierarchical positions set out in organisational charts.

3 Swissmedic may specify further technical requirements and details.

Art. 4 Responsibility and Good Manufacturing Practice

1 Holders of a licence under Article 3 are responsible for the processing and working procedures they carry out.

2 Medicinal product manufacture must be carried out in accordance with the rules of Good Manufacturing Practice described in Annex 1 or 2.

3 In the manufacture of complementary medicinal products, the GMP rules must be followed by analogy and the specific regulations for the therapies concerned which are laid down in the pharmacopoeias recognised by Swissmedic must be adhered to.

Art. 5 Technical supervision of the facilities

1 The Responsible Person is responsible for the direct technical supervision of the facilities and in particular ensures that the medicinal products are handled appropriately.

2 They are responsible for the quality of the manufactured medicinal products and ensure that the legal provisions applicable to therapeutic products are observed.

3 They are authorised to issue instructions within their sphere of activity.

4 They and the company management jointly ensure their deputisation by adequately qualified specialists.

5 If the facilities cease operations, or if operations can be expected to cease imminently, the Responsible Person must report this situation to Swissmedic without delay.

6 They may not sit on one of the facilities' supervisory committees and must decide on the release or rejection of batches independently of the company's management. Swissmedic may grant a licence to small facilities without such segregation if they cannot implement the segregation because of their size.

7 If the size and nature of the facilities permit this activity to be performed on a part-time basis, responsibilities must be set out in writing and the minimum number of hours during which the person must be present in the facility must be determined.

Art. 6 Individual requirements that the Responsible Person must fulfil

1 The Responsible Person must have the necessary technical knowledge and be trustworthy. They must also fulfil the following professional requirements:

a. for the manufacture of ready-to-use medicinal products or intermediate products, the Responsible Person must be a qualified pharmacist with professional experience;

b. for the manufacture of labile blood products or immunological medicinal products the Responsible Person must have a university degree in medicine or a life science and have the necessary professional experience.

c. for the manufacture of active pharmaceutical ingredients or medicated feedingstuffs, the Responsible Person must have a university degree in a life science and the necessary professional experience;

d. for the manufacture of radiopharmaceuticals, the Responsible Person must have a certificate issued by the European Association of Nuclear Medicine for Radiopharmacy and have the necessary experience.

2 If a person can prove sufficient knowledge and experience, Swissmedic may also recognise other professional qualifications for this job.

3 Swissmedic may specify further details to Article 5 and this Article, in particular the minimum number of hours during which the Responsible Person must be present in the facility and the requirements that they must fulfil in terms of training and experience.

Art. 7 Technical release

1 The Responsible Person decides on the technical release of a product batch.

2 They issue a batch certificate confirming that the batch in question conforms to the requirements of internal or external clients in terms of composition, manufacturing procedure, specifications and quality and was manufactured in compliance with the GMP rules in accordance with Annex 1 or 2.

Art. 8 Cantonal manufacturing licence

1 Hospital pharmacists and persons in possession of a cantonal licence in accordance with Article 30 TPA who prepare medicinal products in accordance with Article 9 paragraph 2 letters a–c^{bis} or paragraph 2bis TPA must carry out a risk assessment in accordance with Annex 3. This provision does not apply to the cases set out in paragraph 6 below.

2 The conduct of these risk assessments should be documented. This documentation should be presented to the cantonal supervisory authority on request.

3 If the risk assessment produces a value below the threshold specified in Annex 3, a cantonal manufacturing licence is required instead of a licence issued by Swissmedic.

4 The licence is granted if it can be ensured that the rules of Good Manufacturing Practice for small quantities of medicinal products in accordance with Annex 2 are observed.

5 The cantons regulate the other conditions for the granting of the licence in accordance with paragraph 3 and periodically carry out facility checks.

6 Any person who manufactures radiopharmaceuticals requires a licence granted by Swissmedic.

Art. 9*a* Surveys of medicinal products prepared in accordance with Article 9 paragraph 2 letters a–c^{bis} TPA

The cantons may conduct surveys among manufacturers concerning the medicinal products prepared in accordance with Article 9 paragraph 2 letters a–c^{bis} and paragraph 2bis TPA. The manufacturers are obliged to provide the necessary information to the cantons on request.

Art. 10 Cantonally authorised medicinal products

The preparation of medicinal products in accordance with Article 9 paragraph 2 letter f TPA is exempt from licensing by Swissmedic.

Section 2
Licence for the Import, Wholesale Trade and Export of Medicinal Products

Art. 11 General preconditions

1 Any person applying for a licence to import medicinal products must prove that:

a. a system to ensure the pharmaceutical quality of medicinal products is in operation and that the company management and staff in the individual departments concerned take an active part in such a system;

b. each department has a sufficient number of qualified and competent staff members to enable it to achieve its quality targets;

c. the tasks of all persons occupying key positions in the company are set out in job descriptions and their hierarchical positions are set out in organisational charts;

d. a Responsible Person in accordance with Articles 17 and 18 is available;

e. the facilities are organised in an appropriate way;

f. the facilities are designed, structured, maintained and modernised regularly to guarantee the safe import of medicinal products;

g. a documentation system is available that comprises the working instructions, process descriptions and protocols of the relevant import procedures;

h. the requirements and obligations of Articles 15 and 16 are fulfilled;

i. the manufacturer of the medicinal products to be imported has a manufacturing licence issued by a country whose GMP control system is considered by Swissmedic to be equivalent, or which states that the medicinal products are manufactured in compliance with the GMP rules valid in Switzerland.

2 Any person who applies for a licence to trade wholesale in medicinal products or a licence to export medicinal products must fulfil the requirements stated in paragraph 1 letters a–h; letters f and g apply by analogy.

3 Swissmedic may specify further technical requirements and details.

Art. 12 Additional preconditions

[1] Any person who applies for a licence to trade wholesale in medicinal products or a licence to import ready-to-use medicinal products, and who in addition wishes to release ready-to-use medicinal products onto the market in their capacity as holder of the marketing authorisation must fulfil the requirements stated in Article 11 and also ensure that:

a. an analysis sample sufficient for two complete release analyses is kept of each batch of a medicinal product released onto the market;

b. an inspection sample is available for each batch of a medicinal product;

c. general and batch-specific documentation of the manufacture of a medicinal product, including documentation of its technical release and testing, is available;

d. a person is appointed for pharmacovigilance who has the appropriate specialist knowledge and is in charge of reporting adverse drug reactions in accordance with Articles 61 and 65 of the Therapeutic Products Ordinance of 21 September 2018[4] (TPO);

e. the requirements described in Article 13 have been fulfilled.

[2] The person described in paragraph 1 letter d need not be on the staff of the company; however, their responsibilities must in all cases be described in writing.

[3] Any person who applies for a licence to trade wholesale in medicinal products or a licence to import or export medicinal products and who in addition, and in their capacity as customer, wishes to have medicinal products manufactured or tested by a third party, must fulfil the requirements described in Article 11 and also ensure that:

a. the contractor has the information and qualifications necessary to manufacture the medicinal product lawfully;

b. each batch of a medicinal product fulfils the requirements established for composition, manufacturing procedure, specifications and quality and is manufactured in conformity with the GMP rules;

c. general and batch-specific documentation on the manufacture of a medicinal product, including documentation of its technical release and testing, is available.

[4] Swissmedic may specify further technical requirements and details.

Art. 13 Market release

[1] The Responsible Person employed by the holder of the marketing authorisation decides on the market release of a batch before it is placed on the market.

4 SR **812.212.21**

2 They check whether:

a. a valid batch certificate issued by the manufacturer is available and whether the batch was manufactured in conformity with the GMP rules described in Annex 1;

b. the batch in question fulfils the requirements of the authorisation;

c. the conditions described in Articles 11 and 12 have been fulfilled; and

d. the entire supply chain is in conformity with the authorisation and the GDP[5] rules described in Annex 4.

3 Swissmedic may specify additional checks.

4 The Responsible Person confirms that the checks described in paragraphs 2 and 3 have been performed.

Art. 14 Reanalysis

If ready-to-use medicinal products are manufactured in a State with which Switzerland has not signed an agreement on the mutual recognition of the GMP control procedures and there are justified doubts about the safety or quality of the batches to be imported, Swissmedic may order that each batch undergo reanalysis in Switzerland.

Art. 15 Responsibility and Good Distribution Practice

1 Holders of a licence under Article 11 bear responsibility for the activities they carry out.

2 The import, export and wholesale trading of ready-to-use medicinal products must conform to the GDP rules described in Annex 4. These rules also apply by analogy to veterinary medicinal products and non-ready-to-use medicinal products.

Art. 16 Mandatory documentation

Licence holders must keep the following documents in particular in order to ensure traceability:

a. the name of the medicinal product;

b. the transaction date;

c. the quantity;

d. the batch number;

e. the expiry date;

f. the name and address of the supplier and the customer.

5 Footnote not relevant to the English text.

Art. 17 Technical supervision of the facilities

[1] The Responsible Person is responsible for the direct technical supervision of the facilities and in particular ensures that the medicinal products are handled appropriately.

[2] They ensure that the import, export and wholesale trading in medicinal products are in conformity with the GDP rules described in Annex 4 and ensure that the legal provisions applicable to therapeutic products are observed.

[3] They are authorised to issue instructions within their sphere of activity.

[4] They and the company management jointly ensure their deputisation by adequately qualified specialists.

[5] If the facilities cease operations, or if operations can be expected to cease imminently, they must report this situation to Swissmedic without delay.

[6] They may not sit on one of the facilities' supervisory committees and must decide on the release or rejection of batches independently of the company's management. Swissmedic can grant a licence to small facilities without such segregation if they cannot implement the segregation because of their size.

[7] If the size and nature of the facilities permit this activity to be performed on a part-time basis, responsibilities must be specified in writing and the minimum number of hours during which the person must be present in the facility must be determined.

Art. 18 Individual requirements that the Responsible Person must fulfil

[1] The Responsible Person must have the necessary training, technical knowledge and experience, and be trustworthy.

[2] To obtain a licence in accordance with Article 12 paragraphs 1 and 3, the Responsible Person must also fulfil the following requirements and tasks:[6]

a. The Responsible Person must possess a degree in pharmacology and the necessary experience in the manufacture of ready-to-use medicinal products. If the person can prove sufficient knowledge and experience in the medicinal products sector, Swissmedic may also recognise other professional qualifications for this job.

b. In granting market release, the Responsible Person ensures that each batch is not placed on the Swiss market until all the applicable conditions of Articles 11–13 have been fulfilled and the entire supply chain is in conformity with the authorisation and the GDP rules.

[3] Swissmedic may specify further details to Article 17 and this Article, in particular the minimum number of hours during which the Responsible Person must be present in the facility and the requirements that they must fulfil in terms of training and experience.

6 Correction of 28 May 2019 (AS **2019** 1605).

Art. 19 Import of non-authorised medicinal products for clinical trials

[1] The import of medicinal products for use in a clinical trial in accordance with the protocol for that trial requires a licence issued by Swissmedic. This licence also covers the individual import of immunological medicinal products and of blood and blood products.

[2] A licence is not required if the importing person or institution already holds a licence as described in Article 11.

Art. 20 Exemption from mandatory licensing

[1] Doctors and veterinary surgeons who practise their profession on both sides of the border in accordance with current international agreements may import and export ready-to-use medicinal products in small quantities without a licence insofar as this is indispensable for practising their profession.

[2–4] …[7]

Section 3 Licence for Trading in Foreign Countries

Art. 21 Preconditions

[1] Any person applying for a licence to trade in foreign countries must prove that:

a. the facilities operate a system to ensure the pharmaceutical quality of medicinal products and that the company management and staff in the individual departments concerned take an active part in this system;

b. a Responsible Person in accordance with Article 23 is available;

c. the facilities are organised in an appropriate way;

d. a documentation system is available that comprises the working instructions, process descriptions and protocols of the relevant procedures involved in the activities;

e. due diligence is exercised as described in Article 22.

[2] Swissmedic may specify further technical requirements and details.

[3] The licence does not entitle the holder to issue manufacturing orders.

Art. 22 Due diligence

[1] Holders of a licence under Article 21 are responsible for the correct conduct of trade with medicinal products and the traceability of the buying and selling of medicinal products.

[2] They ensure that supplier and customer are authorised to carry out the work procedures that they perform. They must be able to prove this.

7 Comes into force on 1 January 2020.

3 They obtain in particular the documents showing the quality of the medicinal product and those showing at least the transaction date, quantity, batch number, expiry date and exact name of the medicinal product and the name and address of the supplier and customer, and keep these documents.

4 They ensure, including during transport, that the necessary storage conditions remain within the limits determined by the manufacturer or stated on the packaging. They must be able to prove this in writing.

5 They must provide the customer on each delivery with details of the original manufacturer and the original batch number of the merchandise delivered.

6 They must forward to the customer or the supplier all information provided by any supplier or customer that pertains to the quality and safety of the medicinal product or is relevant for the authorities.

7 They must operate an effective procedure for the batch recall of medicinal products.

Art. 23 Technical supervision and Responsible Person

1 Responsible Persons carry out the direct technical supervision of the facilities and, in particular, ensure orderly trading in medicinal products.

2 They are authorised to issue instructions within their sphere of activity.

3 They ensure their deputisation by adequately qualified specialists.

4 If the facilities cease operations, or if operations can be expected to cease imminently, they must report this situation to Swissmedic without delay.

5 They must have the necessary training, expertise and experience, and be trustworthy.

6 They decide independently of the company's management and may not sit on any of the facilities' supervisory committees. Swissmedic may grant a licence to small facilities without such segregation if they cannot implement the segregation because of their size.

7 If the size and nature of the facilities permit this activity to be performed on a part-time basis, responsibilities must be specified in writing and the minimum number of hours that the Responsible Person must be present in the facility must be determined.

8 Swissmedic may specify further details, in particular the minimum number of hours that the Responsible Person must be present in the facility and the requirements that they must fulfil in terms of training and experience.

Section 4
Licence to perform Brokerage or Agency Activities

Art. 24 Preconditions

1 Any person applying for a licence to perform brokerage or agency activities must prove that:

a. the facilities operate a functioning quality assurance system and that the company management and staff in the individual departments concerned take an active part in this system;

b. a Responsible Person in accordance with Article 26 is available;

c. the facilities are organised in an appropriate way;

d. a documentation system is available that comprises the working instructions, process descriptions and protocols of the relevant procedures;

e. due diligence is exercised as described in Article 25.

2 Swissmedic may specify further technical requirements and details.

3 The licence does not entitle the holder to issue manufacturing orders.

Art. 25 Due diligence

1 Holders of a licence in accordance with Article 24 must ensure that the supplier and the customer are authorised to carry out the work processes that they perform. They must be able to prove this.

2 They must ensure that the medicinal products have not originated from illegal trading and are not intended for unlawful purposes.

3 They must forward to the customer or the supplier all information provided by any supplier or customer regarding the quality and safety of the medicinal product or that is relevant for the authorities, in particular information about medicinal product recalls.

4 The agents must additionally retain copies of the paperwork documenting the business transaction.

Art. 26 Technical supervision and Responsible Person

1 Responsible Persons carry out the direct technical supervision of the facilities and in particular ensure compliance with due diligence within the facilities.

2 They are authorised to issue instructions within their sphere of activity.

3 They ensure their deputisation by adequately qualified specialists.

4 If the facility ceases operations, or if operations can be expected to cease imminently, they must report this situation to Swissmedic without delay.

5 They must have the necessary training, expertise and experience, and be trustworthy.

6 They decide independently of the company's management and may not sit on any of the facilities' supervisory committees. Swissmedic may grant a licence to small facilities without such segregation if they cannot implement the segregation because of their size.

7 If the size and nature of the facilities permit this activity to be performed on a part-time basis, responsibilities must be specified in writing and the minimum number of hours during which the Responsible Person must be present in the facility must be determined.

8 Swissmedic may specify further details, in particular the minimum number of hours during which the Responsible Person must be present in the facility and the requirements that they must fulfil in terms of training and experience.

Section 5 Special Provisions for Blood and Blood Products

Art. 27 Conditions for granting a licence for the collection of blood

1 Any person applying for a licence to collect blood for transfusion or the manufacture of medicinal products in accordance with Article 34 TPA must prove that:

a. the conditions described in Article 3 have been fulfilled;

b. the Responsible Person fulfils the conditions of Articles 5 and 6 and has a university degree in medicine or a life science and the scientific and medical experience needed to collect blood;

c. blood is collected in compliance with the GMP rules described in Annex 1;

d. due diligence is exercised as described in Articles 28–38.

2 Swissmedic may specify further technical requirements and details.

Art. 28 Responsible Person for haemovigilance

1 The holder of a licence for activities with blood or labile blood products must appoint a person responsible for haemovigilance.

2 The Responsible Person must be a doctor and have the appropriate technical knowledge.

3 This person has an obligation to report adverse drug reactions in accordance with Articles 61 and 65 TPO[8].

4 Swissmedic may also recognise persons with other professional qualifications as Responsible Persons, provided they possess sufficient knowledge and experience.

5 While Responsible Persons do not need to be employees of the company, their responsibilities must in all cases be defined in writing.

8 SR **812.212.21**

Art. 29 Donor suitability

[1] The suitability of blood donors must be evaluated by a qualified physician with experience in transfusion medicine or by a person trained in this assessment who is working under the supervision of a qualified physician.

[2] The donors must be provided with comprehensive information about donating blood and the risks of infection with major pathogens must be explained before the blood donation so that they can decide not to donate blood if the blood they donate could represent a risk of infection for third parties.

[3] Otherwise, the information provided in the context of a donation is guided by Annex 5 number 3.

[4] Persons in the following categories are not permitted to donate blood:

a. those who have been diagnosed with HIV;

b. those who are suffering from AIDS or who have symptoms indicative of an AIDS-related illness;

c. those whose behaviour carries the risk of infection with HIV;

d. intimate partners of persons described under letters a–c;

e. those who carry a specific risk of prion infection;

f. those who have received transplant material of animal origin.

[5] Otherwise, donor suitability is evaluated in accordance with Annex 5 number 1.

Art. 30 Compulsory testing

[1] A sample of every collected blood donation used for transfusion or to manufacture labile blood products must be tested in accordance with the testing requirements listed in Annex 5 number 2.

[2] The tests must be performed using appropriate methods or procedures that are validated in accordance with the state-of-the-art scientific and technical knowledge and are suitable for testing donated blood and plasma.

[3] Before blood or erythrocyte preparations are transfused, their compatibility with the recipient's blood must be established using appropriate methods.

Art. 31 Appropriate tests and test procedures

[1] If the tests are carried out abroad, it must be proven that they comply with the state-of-the-art scientific and technological knowledge.

[2] Swissmedic may specify technical requirements and particulars in relation to the tests and test procedures.

[3] When tests are being carried out on blood or labile blood products intended for transfusion or to manufacture medicinal products, the rules of good practice must be

adhered to in accordance with Annex 1 of the Ordinance of 29 April 2015[9] on Microbiological Laboratories.

Art. 32 Procedure in the event of a positive test result

[1] If the test is repeatedly reactive, the blood donation may not be used for transfusion or to manufacture blood products.

[2] If further confirmation tests on blood intended for autologous transfusion give a negative result or if the results of tests carried out in accordance with Annex 5, number 2.2 letter d deviate from the norm, the treating physician decides whether to carry out the transfusion.

Art. 33 Donor counselling

[1] The donor may only be informed of a positive test result if the test has been confirmed using an appropriate method.

[2] Where a donor is informed of a positive test result, they must also be offered counselling and assistance.

[3] The donor may refuse to be informed of a test result.

Art. 34 Labelling

[1] Blood and labile blood products and the corresponding blood samples must be labelled in accordance with the rules of GMP and good practice in accordance with Annex 1 of the Ordinance of 29 April 2015[10] on Microbiological Laboratories.

[2] In the case of autologous transfusion, the label must also bear the name of the donor and the label must be signed by the autologous donor immediately before blood collection.

[3] Autologous donations must be kept separate from homologous donations.

Art. 35 Records and traceability

[1] Holders of a licence for handling blood and labile blood products must maintain records of all safety-relevant activities, in particular in relation to the collection of blood, and the manufacture, release, distribution, destruction and recall of blood or labile blood products.

[2] They must ensure that blood or labile blood products can be traced back to the donor. For this purpose, each blood donation must be given a donor number that makes it possible at any time to clearly identify the donation, the donor's medical history, every blood product made from his donation and all documents related to these products.

9 SR **818.101.32**
10 SR **818.101.32**

3 Whenever blood is donated, the following information must be recorded in detail:

a. the date and identification of the donation and the donor;

b. information on the decision on donor suitability and, if relevant, the reason for excluding a donor;

c. the test results and their interpretation.

4 Each protocol must be signed by a person who is authorised to do so by the quality management system.

Art. 36 Archiving and transmitting data

1 If the holder of a licence to handle blood and labile blood products ceases this activity prior to expiry of the archiving obligation in accordance with Article 40 TPA, the archives must be handed over to Swissmedic, or to the Blood Transfusion Service of the Swiss Red Cross if it is one of its establishments.

2 Swissmedic or the Blood Transfusion Service of the Swiss Red Cross destroys the archives on expiry of the archiving obligation.

Art. 37 Protective measures

1 Holders of a licence to handle blood or labile blood products must immediately take the necessary protective measures if they notice that:

a. at the time of donation the donor did not fulfil the criteria required to be considered a suitable donor;

b. the tests for transmittable diseases have not been carried out in accordance with the regulations;

c. the donor has undergone seroconversion or has contracted a blood-borne infection;

d. the recipient of a donation develops a post-transfusion infection which could be traced back to the donor;

e. serious defects in relation to the GMP rules described in Annex 1 have occurred during the blood collection process or the manufacturing of labile blood products.

2 The measures that will be taken if the situations described in paragraph 1 letters b–e occur must be reported to Swissmedic.

3 Measures taken in the event of occurrences described in paragraph 1 letters c and d may involve investigations into previous donations or other donors.

4 Institutions which use blood and labile blood products in patients must inform the manufacturers on request of the relevant information about use of the labile blood product and about the conclusion of the tracing procedure if investigations as described in paragraph 3 are carried out.

Art. 38 Additional safety measures

[1] Blood and labile blood products may only be used for homologous transfusions if the leucocytes have been depleted in a validated state-of-the-art scientific or technical procedure.

[2] Plasma may only be used for homologous transfusions if, in addition to the safety measure described in paragraph 1 and the tests described in Article 30:

a. it has been stored for four months and on expiry of the deadline a new test on the donor produced a negative result; or

b. it has undergone a procedure to inactivate or eliminate viruses.

[3] Platelet concentrates may only be used in Switzerland if appropriate measures are taken to mitigate the risk of bacterial contamination.

[4] Unused autologous donations must not be used for homologous transfusions or to manufacture blood products.

Chapter 3 Licensing Procedure

Art. 39 Granting the licence

[1] The licence is granted if:

a. the application is complete;

b. the applicant fulfils all relevant conditions at all facilities for the activities applied for.

[2] Swissmedic shall suspend the substantive assessment of the application if criminal proceedings are pending against a Responsible Person in accordance with Articles 5, 6, 17, 18, 23 or 26, as a result of which Swissmedic concludes that the conditions for adequate technical supervision are no longer fulfilled.

[3] If a Responsible Person is under investigation for infringing the TPA or the Narcotics Act of 3 October 1951[11] in criminal proceedings, Swissmedic may suspend the corresponding licence.

[4] It may demand an extract from the criminal records relating to the Responsible Person's.

[5] The applicant is granted a single licence for all activities in the application in accordance with the TPA and this Ordinance.

Art. 40 Content of the licence

The licence specifies the name of the Responsible Person, the licensed activities and the site of the facilities. It may not be transferred to other persons or to other sites.

11 SR **812.121**

Art. 41 Amendments

[1] Holders of a licence must apply to Swissmedic with the necessary documentation for any amendments to the content of the licence.

[2] They must report the essential details of all major changes to facilities, equipment or procedures used in the manufacture, testing or import and export of medicinal products, for wholesale trading or in trading abroad with medicinal products or for brokerage or agency activities in connection with medicinal products and which could influence quality.

[3] Swissmedic shall respond to applications under paragraph 1 and make any objections to amendments as in paragraph 2 within a period of 30 days.

Art. 42 Periodic review

[1] Fulfilment of all the conditions for retaining the licence is reviewed periodically by inspection.

[2] If the conditions are no longer fulfilled or if their fulfilment cannot be examined, specifically because the licensed activities have not been performed for more than twelve months, Swissmedic may revoke the licence either wholly or in part.

Art. 43 Detailed specifications

Swissmedic may specify the terms of the licensing procedure in greater detail.

Chapter 4
Special Provisions for Import, Export, Transit and Trading Abroad

Art. 44 Import of individual batches of immunological medicinal products that are authorised or not subject to authorisation or of blood and blood products

[1] Any person who imports the following medicinal products that are authorised or not subject to authorisation or blood and blood products into Switzerland requires a licence for each shipment:

a. immunological medicinal products;

b. blood and blood products.

[2] A licence is not required for the import of individual batches of:

a. allergens;

b. blood that is authorised or not subject to authorisation and blood products of this kind if these medicinal products:

1. are imported in medical emergencies or for autologous transfusion,

2. are not intended for use in humans, or

3. have an official batch release from one of the control authorities belonging to the Official Control Authority Batch Release Network (OCABR Network);

c. immunological medicinal products that are authorised or not subject to authorisation provided an official batch release from one of the control authorities belonging to the OCABR Network is available for the batch to be imported.

3 In the interest of protecting health, Swissmedic may impose temporary or permanent mandatory licensing on the import of individual batches of immunological medicinal products or of blood and blood products that are authorised or not subject to authorisation even if an official batch release as described in paragraph 2 letter b number 3 is available.

Art. 45 Conditions for granting a licence

Any person applying for a licence in accordance with Article 44 paragraph 1 must prove that:

a. they have a licence to import medicinal products;

b. if these are ready-to-use medicinal products destined for the Swiss market, they have the corresponding authorisation;

c. they ensure the safe and lawful import of the medicinal products and accept responsibility for this;

d. the manufacturing and import of the medicinal products and wholesale trading in medicinal products are in conformity with the GMP rules described in Annex 1 and the GDP rules described in Annex 4;

e. in the case of blood and blood products for use in humans, in addition to letters a–d:
   1. no pathogens or indication of the presence of pathogens can be detected,
   2. each individual blood donation is analysed using tests that correspond to state-of-the-art scientific and technical knowledge,
   3. blood and plasma are only imported unmixed, unless Swissmedic has exceptionally granted a licence to import mixed products,
   4. the requirements in accordance with Article 27 paragraph 1 letter c and Articles 34, 35 and 37 are adhered to.

Art. 46 Procedure

1 The application for a licence to import individual batches must be submitted to Swissmedic together with the necessary documentation.

2 The licence is valid for one month.

3 The applicant must ensure that the licence is presented to the customs office at the time when the medicinal products are imported.

4 On customs clearance, the customs office shall discharge the licence and forward it to Swissmedic.

5 In the absence of a licence to import individual batches in accordance with Article 44 paragraph 1, medicinal products are refused entry at the border and reported to Swissmedic.

Art. 47 Individual batch import of immunological medicinal products for veterinary use

1 The application to import individual batches of immunological medicinal products for veterinary use must be submitted to the Federal Food Safety and Veterinary Office in accordance with Article 46 paragraph 1. A licence is not required to import individual batches of allergens.

2 The applicant must ensure that the licence is presented to the customs office at the time when the medicinal products are imported.

3 On customs clearance, the customs office discharges the licence and forwards it to the Institute for Virology and Immunology of the Federal Food Safety and Veterinary Office.

Art. 48 Import of non-authorised ready-to-use medicinal products by individuals

Individuals may import ready-to-use medicinal products that are not authorised in Switzerland in quantities needed for their personal use. This does not apply to:

a. medicinal products which contain genetically modified organisms,

b. immunological medicinal products for use in livestock;

c. vaccines, toxins and sera for veterinary usage;

d. transplant products within the meaning of the Transplantation Ordinance of 16 March 2007[12] which have been genetically modified.

Art. 49 Import of non-authorised ready-to-use medicinal products by professionals

1 A medical professional who has a cantonal dispensing licence may import small quantities of a ready-to-use human medicinal product that is not authorised in Switzerland provided:

a. the medicinal product is intended for a specific patient or for emergencies;

b. the medicinal product has been authorised by a country with a comparable regulatory system; and

c. for the medicinal product concerned:

1. no alternatively usable medicinal product is authorised in Switzerland,

12 SR **810.211**

2. an alternatively usable medicinal product is authorised in Switzerland, but is not available on the Swiss market, or
3. it is not appropriate to switch the medication to a medicinal product authorised and available in Switzerland.

2 Treating physicians with a cantonal professional licence may import small quantities of ready-to-use human medicinal products that are not authorised in Switzerland if:

a. they have performed a risk analysis to confirm the appropriateness of the usage and notified the competent cantonal authorities of their conclusions before the medicinal products are imported; and
b. the medicinal product:
   1. fulfils the conditions described in paragraph 1 letters a and c, and
   2. has been authorised by a country with a comparable regulatory system for use in a clinical trial.

3 Pharmacists with pharmaceutical responsibility in a hospital pharmacy may import small quantities of ready-to-use human medicinal products to supply their own customers if the conditions in paragraph 1 letters b and c or the conditions in paragraph 1 letter c and 2 letters a and b are fulfilled.

4 Medical professionals as described in Article 25 paragraph 1 letters b and c TPA who have a cantonal professional licence may import small quantities of non-prescription ready-to-use human medicinal products that are not authorised in Switzerland under the terms of their dispensing licence provided the conditions in paragraph 1 are fulfilled.

5 Prior to import, importing persons must check in each case whether the relevant requirements in paragraphs 1–4 are met and ensure that the medicinal products are transported in conformity with the GDP rules described in Annex 4.

6 They must keep a record of the check described in paragraph 5 and of the time when the check was carried out and the import took place, and the nature, number and intended use of the imported human medicinal products.

7 The import of medicinal products for animals by medical professionals is subject to Article 7 of the Veterinary Medicinal Products Ordinance of 18 August 2004[13]

Art. 50 Medicinal products that can be used for capital punishment

1 Any person who exports medicinal products that can be used for capital punishment requires a licence from Swissmedic for each transaction.

2 Any person who trades abroad in such medicinal products requires a licence from Swissmedic for each transaction.

3 A licence as described in paragraphs 1 and 2 may be granted provided the applicant:

13 SR **812.212.27**

a. confirms to Swissmedic that, following investigations, there is no evidence that the medicinal products in question will be used for capital punishment; and

b. submits a declaration by the customer stating that the medicinal products will not be used by the customer or by third parties for capital punishment.

4 Swissmedic publishes a list of medicinal products that can be used for capital punishment It takes into account valid EU law, in particular the delegated acts and implementing acts adopted by the European Commission on the basis of Council Regulation (EC) No. 1236/2005[14].

Art. 51 Transit

The transit of medicinal products which are dangerous to health is not permitted.

Chapter 5
Temporary licences to use medicinal products in accordance with Art. 9*b* para. 1 TPA

Art. 52 Preconditions

1 A temporary licence to use medicinal products in accordance with Article 9*b* paragraph 1 TPA may be granted to the sponsor of a clinical trial approved in Switzerland if the sponsor:

a. confirms that the medicinal product is identical to the medicinal product used in at least one clinical trial approved in Switzerland;

b. justifies every deviation from the most recently approved protocol and specifies the conditions under which the medicinal product will be used;

c. justifies the non-inclusion of patients in the clinical trial;

d. states the reasons why use is likely to be of major therapeutic benefit;

e. proves that there is no alternative and equivalent medicinal product authorised in Switzerland;

f. proposes and justifies a period of validity for the licence;

g. states and justifies the treatment centres and the proposed number of patients;

h. submits a draft of the information provided for patients; and

i. has obtained a preliminary opinion on letters b–h from the Ethics Committee which approved the reference trial or, in the case of a multicentre clinical trial, from the lead Ethics Committee.

14 Council Regulation (EC) No 1236/2005 of 27 June 2005 concerning trade in certain goods which could be used for capital punishment, torture or other cruel, inhuman or degrading treatment or punishment; OJ L 200 of 30.07.2005 p. 1.

2 If the application concerns the use of a medicinal product which has been tested in patients with good results in a clinical trial, it must be used in accordance with the protocol for that clinical trial. The conditions set out in paragraph 1 letters a and d–i must be fulfilled.

3 This licence also covers the import of the medicinal products concerned, including the individual import of immunological medicinal products, blood and blood products.

Art. 53 Procedure for granting and extending a licence

1 The application is submitted to Swissmedic with the documents listed in Annex 6.

2 Swissmedic may request additional information.

3 It informs the Ethics Committee about its decision and, where appropriate, any subsequent decisions.

Art. 54 Preconditions

1 The sponsor notifies Swissmedic of all major changes affecting the medicinal product or its usage by analogy with Article 34 paragraph 3 of the Ordinance of 20 September 2013[15] on Clinical Trials.

2 The sponsor notifies Swissmedic of all adverse reactions and events in accordance with Article 59 TPA.

3 The sponsor sends Swissmedic a safety report once a year.

Art. 55 Withdrawal of the licence

1 Swissmedic may withdraw the licence in the interest of protecting patients' health.

2 The announcement of a final Swissmedic decision rejecting the application for a licence to place the medicinal product on the market leads to withdrawal of the licence.

3 If Swissmedic authorises the marketing of the medicinal product, the temporary licence to use the product ends when the medicinal product is actually supplied. The sponsor informs Swissmedic of the time at which the medicinal product is actually supplied.

15 SR **810.305**

Chapter 6 Implementation
Section 1 Inspections

Art. 56 Requirements pertaining to inspectorates

Inspectorates that conduct inspections by virtue of this Ordinance must have a quality management system that complies with internationally recognised standards and must be accredited.

Art. 57 Requirements pertaining to inspectors

[1] Inspectors must have an appropriate university degree in the relevant field or a comparable qualification, together with experience and regular training.

[2] They must be independent of the companies that they are in charge of inspecting. If this is not the case, they must recuse themselves.

Article 58 Recognition of inspectorates

[1] Swissmedic checks and supervises whether the cantonal inspectorates mandated to carry out inspections in accordance with Article 60 TPA fulfil the requirements described in Articles 56 and 57.

[2] It recognises the inspectorates that fulfil these requirements.

Art. 59 Cantonal obligation to notify

The cantons must notify Swissmedic of any changes within their inspectorates.

Art. 60 Ordering and conduct of inspections

[1] The competent authority may at any time order inspections in Switzerland or carry them out themselves whenever they consider this necessary.

[2] Swissmedic may inspect manufacturers of medicinal product abroad and facilities abroad that engage in wholesale trading in medicinal products, at the importing company's expense. It informs this company in advance.

[3] In those States with which Switzerland has signed an agreement for the mutual recognition of GMP systems, Swissmedic only carries out inspections in justified exceptional cases and after consultation with the competent healthcare authorities in that State.

Art. 61 Issuing certificates

At the request of facilities inspected in Switzerland or abroad in accordance with Article 60, Swissmedic may confirm by means of a certificate that the facilities are in conformity with the standards of good practice recognised in Switzerland.

Art. 62 Powers of the inspectors

The inspectors may:

a. demand a current description of the facilities in the form of a Site Master File from the company to be inspected;

b. enter any part of a company's facilities with or without prior notification and, if required, take photographs;

c. make copies of documents, including data saved on electronic data storage media or in part of a computer system;

d. take samples of medicinal products, raw materials, intermediate products, packaging material or materials used in the manufacturing process; and

e. take all necessary immediate measures.

Art. 63 Guidelines on the Swiss inspection system

After consultation with the inspectors appointed by the cantons, Swissmedic issues guidelines to guarantee uniform inspection procedures throughout Switzerland.

Section 2
Collaboration between Swissmedic and Other Authorities

Art. 64 Collaboration between Swissmedic and the cantons

[1] Swissmedic and the cantonal authorities collaborate in their control work and may in particular exchange confidential information.

[2] They notify each other about:

a. the granting, amendment, suspension or withdrawal of a licence;

b. measures taken;

c. inspections.

[3] The cantonal authorities provide Swissmedic with any information brought to their attention that indicates quality or safety defects.

[4] Swissmedic may assist the cantonal inspectorates in training their inspectors.

Art. 65 Collaboration with the customs authorities

[1] Customs clearance for imports, exports and goods in transit is governed by customs legislation.

[2] The customs authorities provide Swissmedic with information on the import, export and transit of medicinal products.

[3] Swissmedic may require the customs authorities to detain medicinal products for further inspection and take samples.

Section 3 Data protection and Informing the General Public

Art. 66 Processing personal data

The organs responsible for enforcement are authorised to process the personal data that they require for performing all the tasks assigned to them by this Ordinance. These data include:

a. health data recorded in connection with the official market surveillance of blood and blood products (Art. 39, 58 and 59 TPA);

b. data on administrative and criminal proceedings and sanctions that are relevant to the assessment of licence applications, specifically in assessing whether a Responsible Person is appropriate for this task.

Art. 67 Operating information systems

[1] Swissmedic is responsible for the secure operation of its information systems and the lawfulness of its data processing.

[2] It issues a processing policy for each information system. In this policy, it establishes the technical and organisational measures used to ensure the security and protection of the processed data.

[3] If it transfers activities to third parties, it ensures compliance with data security requirements by means of a contract.

Art. 68 Access rights

[1] Employees of Swissmedic have online access to the information systems to the extent necessary for them to perform their tasks.

[2] Access to the information systems may be logged. Such logs are kept for no longer than two years.

Art. 69 Archiving and deletion of data

Swissmedic retains personal data in its information systems for no longer than ten years. The data are deleted as soon as they are no longer required to perform a task.

Art. 70 Informing the public about licences

Swissmedic regularly publishes lists with the information specified in Annex 7.

Chapter 7 Final Provisions

Art. 71 Amendments to the annexes

[1] The Federal Department of Home Affairs may adapt the annexes to this Ordinance to take account of international or technical developments.

2 Amendments that could constitute technical barriers to trade are made in agreement with the Federal Department of Economic Affairs, Education and Research.

Art. 72 Repeal and amendment of other legislation

The repeal and amendment of other legislation are covered in Annex 8.

Art. 73 Transitional provisions

1 Licences granted under the previous law retain their validity no longer than the date on which they expire. The application to renew a licence must be submitted spontaneously to Swissmedic with the necessary documentation at least six months before expiry of the licence. Amendments to such licences must be requested as part of a renewal application.

2 Applications for brokerage and agency licences must be submitted to Swissmedic no later than 30 June 2019. Activities may be continued until Swissmedic reaches a decision.

3 Applications for licences that were submitted before 1 January 2019 will be assessed and granted in accordance with previous law.

Art. 74 Commencement

1 This Ordinance comes into force on 1 January 2019 subject to paragraph 2.

2 Article 20 paragraphs 2–4 come into force on 1 January 2020.

Annex 1[16]
(Art. 4 para. 2, 7 para. 2, 13 para. 2 let. a, 27 para. 1 let. c, 37 para. 1 let. e, 45 let. d)

International rules of Good Manufacturing Practice

1. The following guidelines apply as rules of Good Manufacturing Practice (GMP):
   a. Commission Directive 2003/94/EC of 8 October 2003[17] laying down the principles and guidelines of Good Manufacturing Practice in respect of medicinal products for human use and investigational medicinal products for human use;
   b. Commission Directive 91/412/EEC of 23 July 1991[18] laying down the principles and guidelines of Good Manufacturing Practice for veterinary medicinal products;
   c. Guide to Good Manufacturing Practice for medicinal products for human use and medicinal products for veterinary use of the European Commission (EudraLex, Volume 4)[19];
   d. Principles and Guidelines for Good Manufacturing Practice in accordance with the Convention for the mutual recognition of inspections in respect of the manufacture of pharmaceutical products of 8 October 1970[20].
2. *Special provisions for medicated feedingstuffs:* Council Directive 90/167/EEC of 26 March 1990[21] laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community.
3. *Special provisions for blood and blood products:* The Guidelines for Good Practice described in the annex to Recommendation R (95) 15 of the Council of Europe of 12 October 1995[22] on the preparation, use and quality assurance of blood components.

16 Revised in accordance with the correction of 16 July 2019 (AS **2019** 2195).
17 OJ L 262 of 14.10.2003, p. 22.
18 OJ L 228 of 17.8.1991, p. 70.
19 The text of the guidelines can be obtained from the Swiss Association for Standardisation, Sulzerallee 70, 8404 Winterthur; www.snv.ch, or downloaded from https://ec.europa.eu/health/documents/eudralex/vol-4_en.
20 SR **0.812.101** The text of these principles and guidelines can be obtained from the PIC/S-Secretariat, case postale 5695, CH-1211 Geneva 11, or downloaded from www.picscheme.org.
21 OJ L 92 of 7.4.1990, p. 42.
22 The text of this recommendation can be obtained from the Council of Europe, F-67075 Strasbourg (www.coe.int) or downloaded from www.edqm.eu/en/blood-transfusion-guide.

Annex 2[23]
(Art. 4 para. 2, 8 para. 4)

Rules of Good Manufacturing Practice for medicinal products in small quantities

The provisions of Chapters 20.1 and 20.2 of the Pharmacopoea Helvetica[24] (Ph. Helv.) apply as rules of Good Manufacturing Practice for small quantities of medicinal products.

23 Revised in accordance with the correction of 16 July 2019 (AS **2019** 2195).
24 The Pharmacopoea Helvetica is published by Swissmedic and can be obtained from FOBL, Distribution of Federal Publications, 3003 Bern, www.bundespublikationen.admin.ch, at the conditions shown in FeeO-FedPubs (SR **172.041.11**).

Annex 3
(Art. 8 para. 1–3)

Risk assessment for the preparation of medicinal products specified in Article 9 paragraph 2 letters a–c^{bis} TPA

1 Calculation of the risk factor

The risk factor should always be calculated for a particular medicinal product. If the multiplication of the factors in number 2 produces a figure below 100, a cantonal manufacturing licence is required instead of a Swissmedic licence.

2 Criteria

		Factor
1. Administration route:		
a.	parenteral administration	5
b.	ophthalmological administration in surgery or for traumatic injuries	4
c.	inhaled administration	4
d.	enteral or topical administration with requirements for sterility	4
e.	enteral administration	3
f.	ophthalmological administration in the uninjured eye	1
g.	topical administration	1
2. Annual production quantity:		
a.	liquid dosage forms in standard pack units or application units in litres	
1.	more than 2,000	5
2.	1000–2000	4
3.	500–999	3
4.	100-499	2
5.	less than 100	1
b.	solid dosage forms, number of units	
1.	more than 120,000	5
2.	60,000–120,000	4
3.	30,000–59,999	3
4.	6,000–29,999	2
5.	less than 6000	1
c.	semi-solid dosage forms (suppositories), number of units	
1.	more than 40,000	5

		Factor
	2. 20,000–40,000	4
	3. 10,000–19,999	3
	4. 2000-9999	2
	5. less than 2000	1
d.	semi-solid dosage forms (ointments, creams, etc.) in grams	
	1. more than 200,000	5
	2. 100,000–200,000	4
	3. 50,000–99,999	3
	4. 10,000–49,999	2
	5. less than 10,000	1
e.	eye drops in litres	
	1. more than 200	5
	2. 100-200	4
	3. 50-99	3
	4. 10-49	2
	5. less than 10	1
3. Inherent risks of the active ingredient:		
a.	high risk	5
b.	medium risk	3
c.	low risk	1

The following criteria at least are assessed in classifying the risk of an active ingredient: carcinogenicity, mutagenicity, environmental toxicity, allergy risk, therapeutic range, dosage unit, stability (light, oxygen, temperature, pH changes), pharmaceutical quality, pharmacopoeial conformity.

4. Manufacturing process:		
a.	aseptic manufacture	5
b.	manufacture with terminal sterilisation	4
c.	dissolving and mixing	3
d.	diluting	2
e.	filling of non-sterile dosage forms	1
5. Quantitative ratios: contract manufactured medicinal products – medicinal products manufactured for dispensing to own customers:		
a.	exclusively contract manufacture	5
b.	mainly contract manufacture (ratio: around 2:1)	4
c.	balanced (ratio: around 1:1)	3

		Factor
d.	mainly for own customers (ratio: around 1:2)	2
e.	exclusively for own customers	0.2

Annex 4[25]
(Art. 13 para. 2 let. d, 15 para. 2, 17 para. 2, 45 let. d)

International rules of Good Distribution Practice

The following guidelines apply as rules of Good Distribution Practice (GDP):

a. European Commission Guidelines of 5 November 2013[26] on Good Distribution Practice of medicinal products for human use;

b. *Special provisions for active pharmaceutical ingredients:* Guide to Good Manufacturing Practice for medicinal products for human use and medicinal products for veterinary use of the European Commission (EudraLex, Volume 4) Part II[27];

c. *Special provisions for medicated feedingstuffs:* Council Directive 90/167/EEC[28] laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community.

25 Revised in accordance with the correction of 16 July 2019 (AS **2019** 2195).
26 Communication of the European Commission, OJ C 343 of 23.11.2013, p. 1.
27 This text is only available in English. It can be found at: https://ec.europa.eu/health/documents/eudralex/vol-4_en
28 OJ L 92 of 7.4.1990, p. 42.

Annex 5
(Art. 29 para. 3 and 5, 30 para. 1, 32 para. 2)

Donor suitability, test procedures and information about donating blood

1 Evaluation of donor suitability

Recommendation R (95) of the Council of Europe of 12 October 1995[29] (incl. Appendices) on the Preparation, Use and Quality Assurance of Blood Components.

2 Test procedure requirements

2.1 An unmixed sample from each blood donation must be tested for HIV 1 and 2, the hepatitis B virus (HBV), the hepatitis C virus (HCV) and Treponema pallidum.

2.2 Testing must include the determination of:

a. HIV 1 and 2 antibodies (anti-HIV 1+2 antibodies);

b. hepatitis B virus surface antigen (HBsAg) or antibodies against the hepatitis B virus core antigen (anti-HBc antibodies);

c. hepatitis C antibodies (anti-HCV antibodies);

d. Treponema pallidum antibodies;

e. HI virus (HIV 1): using an appropriate nucleic acid amplification technique;

f. hepatitis B virus (HBV): using an appropriate nucleic acid amplification technique;

g. hepatitis C virus (HCV): using an appropriate nucleic acid amplification technique.

2.3 Testing of autologous blood donations need only comprise the tests listed in number 2.2 letters a–d.

2.4 For plasma intended for fractionation, at least the tests listed in number 2.2 letters a–c must be performed.

2.5 The ABO blood group and the Rhesus D antigen expression must be determined for each blood donation, except for plasma intended for fractionation.

2.6 Additional tests may be required for specific components, donors or epidemiological situations.

29 The text of this recommendation can be obtained from the Council of Europe, F-67075 Strasbourg (www.coe.int) or downloaded from www.edqm.eu/en/blood-transfusion-guide.

3 Regulations concerning information

3.1 The information that must be given to potential donors of blood and labile blood products is specified in Recommendation R (95) of the Council of Europe of 12 October 1995 (incl. Appendices) on the Preparation, Use and Quality Assurance of Blood Components.

3.2 The information that must be obtained from donors for every donation must contain the following details in particular:

a. the personal details of the donor that permit unique identification with no danger of a mix-up, and contact details (donor identification);

b. the donor's state of health and previous diseases, in particular the factors that can help to identify and exclude persons whose donation could pose a risk to themselves or a risk of transmitting a disease to others;

c. the donor's signature on the donor questionnaire;

d. the signature of the person specified in number 3.3.

3.3 The donor's state of health and previous diseases must be recorded by a qualified healthcare professional by means of a questionnaire and a personal interview.

3.4 In signing the questionnaire, the donor confirms that he or she:

a. has read and understood the information provided;

b. has had the opportunity to ask questions;

c. has received satisfactory answers to any questions asked;

d. having been informed about the process, has consented to the donation being continued;

e. in the case of an autologous blood donation, has been informed that the donated blood or blood components may not be sufficient for the planned transfusion; and

f. has provided all information to the best of their knowledge and in good faith.

Annex 6
(Art. 53 para. 1)

Documentation required for a temporary licence to use medicinal products in accordance with Article 9 *b* paragraph 1 TPA

1. Application for a temporary licence for use, including a reference to one or more clinical trials approved by the competent Ethics Committee and Swissmedic.
2. Description of the project, including justification of use outside the context of clinical trials, with a benefit-risk assessment for the patients and reference to the Investigator's Brochure (IB).
3. Updated reference IB, including risk assessment data.
4. Confirmation by the sponsor that the medicinal product is identical to the product used in the reference clinical trial.
5. Information provided to the patients, specifically concerning the special status of the medicinal product.
6. If relevant, decisions on compassionate use by the European Medicines Agency or by a country with a comparable regulatory system (Art. 13 TPA), including any conditions imposed and their justification.
7. Agreement between the sponsor and the treating physician defining their respective responsibilities.
8. Preliminary Ethics Committee decision.

Annex 7
(Art. 70)

Provision of information about licences to the public

The lists contain the following information:

a. name and address of the licence holder;
b. facility sites;
c. licensed activities;
d. date of last inspection;
e. list of inspected non-ready-to-use medicinal products (active ingredients);
f. status of GMP compliance;
g. GMP certificate number;
h. date of issue of the GMP certificate;
j. any comments.

Annex 8
(Art. 72)

Repeal and amendment of other legislation

I

The Medicinal Products Licensing Ordinance of 17 October 2001[30] is repealed.

II

The ordinances listed below are amended as follows:

… [31]

30 [AS **2001** 3399, **2004** 4037 No I 2, **2006** 2945, **2007** 1469 Annex 4 No 40 1847 Annex 3 No 2 1961 Annex 7 No 1 5651 No II 2, **2010** 4031, **2015** 1497 Art. 27 No 2 1901 No II, **2016** 1171 No I 3, **2017** 2785 5935 Annex No 2, **2018** 3577 Annex 6 No II 3]

31 The amendments can be consulted under AS **2018** 5029.