Ordinance on Licensing in the Medicinal Products Sector

(Medicinal Products Licensing Ordinance, MPLO)

of 14 November 2018 (Status as of 28 January 2022)

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.