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Switzerland

Ordinance **812.212.1**
on establishment licences (ELO)

of 17 October 2001 (Status of 28 decembre 2001)

The Swiss Federal Council,
having regard to Art. 4 para. 2; Art. 5 para. 2; Art. 7 para. 2; Art. 18 para. 3 a, para. 5; Art. 20 para. 2 and 3; Art. 29 para. 2; Art. 35 para. 2; Art. 37 para. 3; Art. 38 paragraphs 2 and 3; Art. 40 para. 2 b; Art. 41, Art. 60 and Art. 82 para. 2 of the Law on Therapeutic Products (LTP) dated 15 December 2000[1] (HMG)
and implementing the Federal Law on Technical Barriers to Trade dated 6 October 1995[2],
hereby decrees:

Chapter 1: Object and definition of terms

Art. 1 Object

This ordinance regulates:

a. the manufacture of medicinal products;
b. wholesale trade with medicinal products;
c. the import, export and transit trade in medicinal products;
d. trading of 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.

Art. 2 Definition of terms

The following definitions shall apply in the present ordinance:

a. *Premixed medicinal products:* 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;
b. *Facility:* individual parts or groups of buildings or plant, located on one or more sites, including vehicles and other equipment, which are involved in the manufacture, testing or wholesale distribution of medicinal products;
c. *Batch:* a homogeneous and defined quantity of raw materials, medicinal products or packaging material prepared in one manufacture operation or in one series of manufacture operations;

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2 SR **946.51**

d. *Medicated feedstuffs:* ready-to-use veterinary medicinal products comprising a mixture of premixed medicinal products and feedstuffs or drinking water;

e. *Wholesale trade:* the distribution of medicinal products to people who are entitled to trade in them, process them, sell them retail, or use them in a professional capacity;

f. *Immunological medicinal products:* medicinal products administered to create active or passive immunity or help diagnose immunity status, in particular vaccines, toxins and serums;

g. *Labile blood products:* products that are extracted from donated blood, either directly or in one or few manufacturing steps, and which quickly change without any external influence (e.g. cell preparations and plasma);

h. *Medical personnel:* doctors, dentists, veterinary surgeons, and pharmacists;

i. *active (pharmaceutical) ingredient:* substance or mixture to which the effect of a ready-to-use medicinal product is attributed and which are used as such;

j. *System to ensure the pharmaceutical quality of medicinal products:* the whole range of measures taken to ensure that medicinal products have the necessary quality for their intended use;

k. *Wholesale distribution:* the acquisition, importing, exporting, stocking, storage, offering, advertising, the paid or unpaid transferring or provision of medicinal products, including their delivery, but not including their retail sale.

Chapter 2: Authorization for operating facilities

Section 1: Manufacturing authorization

Art. 3 Conditions for granting an authorization

1 Anyone applying for a manufacturing authorization 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 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 facilities have a Responsible Person as described in Art. 5;

d. the facilities are organized in an appropriate way;

e. the facilities are designed, structured, maintained and modernized regularly to guarantee the safe manufacture of medicinal products and that the premises and equipment that can influence the quality of the medicinal products are approved;

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

g. Manufacturing, testing and cleaning procedures are validated;

h. quality control is separate from manufacture;

i. due diligence as described in Art. 4 is exercised. For the manufacture of labile blood products due diligence must be exercised as described in Arts. 16–26.

2 The work of all persons occupying key positions in the company must be laid out in job descriptions and their positions in the hierarchy shown in organization charts.

3 The Swiss Agency for Therapeutic Products (Agency) may specify further technical requirements and details.

Art. 4 Due diligence

1 The holder of an authorization under Art. 3 bears responsibility for the processing and working procedures he carries out.

2 Medicinal product manufacture must be carried out in accordance with the rules of good manufacturing practice (GMP) under Annexe 1.

3 In the manufacture of complementary medicinal products, the rules of good manufacturing practice (GMP) must be followed by analogy and the specific regulations for the therapies concerned which are laid down in the pharmacopoeias recognized by the agency must be adhered to.

Art. 5 Responsible Person

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. He is responsible for the quality of the medicinal products produced and must ensure that they correspond to the specifications in force and are produced in accordance with the rules of good manufacturing practice (GMP). He is authorized to issue instructions within his sphere of activity.

2 He is competent to decide whether or not to release a batch, independently of the company management.

3 He must have the necessary technical knowledge and be trustworthy. The Agency may demand a copy of the Responsible Person’s police record.

4 He must in particular fulfil the following professional requirements:

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

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

c. for the manufacture of active pharmaceutical ingredients or medicinal feedstuffs he must have a university degree in science and the necessary professional experience.

5 If a person can prove sufficient knowledge and experience, the Agency may also recognize other professional qualifications for this job.

6 Should the size and type of the facilities enable this job to be carried out part time, the responsibilities and the minimum number of working hours should be laid out in writing.

7 In the event that the Responsible Person must be replaced, this should be by sufficiently qualified specialists.

Art. 6 Cantonal authorization

Anyone manufacturing medicinal products according to a magistral formula, an officinal formula, or an own formula (Art. 9 para. 2 a, b and c LTP) requires a cantonal authorization rather than an authorization from the Agency.

Section 2: Authorization for the import, wholesale trade and export of medicinal products

Art. 7 Conditions for granting an authorization

1 Anyone applying for an authorization to import ready-to-use medicinal products must prove that:

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

b. each department has enough qualified and suitably trained staff to ensure the quality targets are achieved;

c. the work of all persons occupying key positions in the company is described in job descriptions and their hierarchical positions set out in organization charts;

d. the facilities have a Responsible Person as described in Art. 10;

e. the facilities are organized in an appropriate way;

f. the facilities are designed, structured, maintained and modernized regularly to guarantee the safe wholesale distribution of medicinal products;

g. a documentation system is available to provide the working instructions, procedure descriptions and protocols of the relevant wholesale distribution processes.;

h. due diligence is exercised as described in Art. 9;

i. the manufacturer of the ready-to-use medicinal products to be imported holds a manufacturing authorization granted by a State whose GMP control procedures are recognized by Switzerland or guarantees that the medicinal products have been produced in accordance with the rules of good manufacturing practice (GMP) in force in Switzerland.

2 Anyone who applies for an authorization to trade wholesale in medicinal products or an authorization to export ready-to-use medicinal products must fulfil the conditions laid out in para. 1 a–h.

3 Anyone who applies for an authorization to trade wholesale in medicinal products or an authorization to import ready-to-use medicinal products and who in addition wishes to release ready-to-use medicinal products onto the market, must also ensure that:

a. each batch of a medicinal product corresponds to the authorization with regard to the composition, manufacturing process, specifications and quality demands and that it is manufactured in accordance with the rules of good manufacturing practice (GMP);

b. the person who releases the medicinal products onto the market holds the qualifications described in Art. 10 para. 3 a;

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

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

e. general documentation and batch documents are available on the manufacture and testing of a medicinal product;

f. a person is appointed for pharmacovigilance who has the appropriate specialist knowledge and is in charge of reporting adverse side-effects of medicinal products in accordance with Arts. 35 and 39 of the ordinance dated 17 October 2001[3]. This person need not be on the staff of the company; however, his responsibilities must in all cases be described in writing.

4 The Agency may specify further technical requirements and details.

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Art. 8 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, the Agency can order that each batch undergo reanalysis in Switzerland.

Art. 9 Due diligence

1 The holder of an authorization in accordance with Art. 7 bears responsibility for all operations he carries out.

2 The medicinal products must be distributed in accordance with the rules of good distribution practice (GDP) mentioned in Annexe 2. These rules also apply by analogy to veterinary medicinal products and for non-ready-for-use medicinal products.

Art. 10 Responsible Person

1 The Responsible Person is responsible for the direct technical supervision of facilities and in particular ensures that the medicinal products are handled appropriately. He ensures that the medicinal products are distributed in accordance with the rules of good distribution practice (GDP). He is authorized to issue instructions within his sphere of activity.

2 He must have the necessary training, expertise and experience and must be trustworthy. The Agency may demand a copy of the Responsible Person's police record.

3 To obtain an authorization in accordance with Art. 7 para. 3 the Responsible Person must also fulfil the following requirements and tasks:

a. He must hold 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, the Agency may also recognize other professional qualifications for this job.
b. He is responsible for ensuring that the medicinal products released onto the market meet the specifications in force and are produced in accordance with good manufacturing practice (GMP).
c. He decides whether or not a batch is released, independently of the management.

4 Should the size and type of the facilities enable this job to be carried out part time, the responsibilities and the minimum number of working hours should be laid out in writing.

5 In the event that the Responsible Person must be replaced, this should be by sufficiently qualified specialists.

Art. 11 Derogation from the obligation to obtain an authorization

Doctors and veterinary surgeons who carry out 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 insofar as this is indispensable for the practising of their profession.

Section 3: Authorization to trade in foreign countries

Art. 12 Conditions for granting an authorization

1 Anyone applying for authorization to trade in foreign countries must prove that:

a. the facilities operate a functioning system to ensure the pharmaceutical quality of medicinal products and that the management and staff in the individual sectors concerned take an active part in this system;
b. the facilities have a Responsible Person as described in Art. 14;
c. the facilities are organized in an appropriate way;
d. a documentation system is available to provide the working instructions, procedure descriptions and protocols of the relevant distribution processes;
e. due diligence is exercised as described in Art. 13.

2 The Agency may specify further technical requirements and details.

Art. 13 Due diligence

1 The holder of an authorization in accordance with Art. 12 is responsible for the safe conduct of trade with medicinal products and the traceability of the buying and selling of medicinal products.

2 He must in particular keep documents showing at least the date, quantity, batch number and exact description of the medicinal products together with the name and address of the supplier and customer.

3 He must forward to the supplier or the customer all information provided by any supplier or customer regarding quality or relevant for the authorities.

4 He must inform the customer in all cases of the original manufacturer and the original batch number of the merchandise delivered.

5 He must operate an effective procedure for the batch recall of medicinal products.

Art. 14 Responsible Person

1 The Responsible Person is responsible for the direct technical supervision of the facilities and in particular ensures safe trading with medicinal products. He shall be authorized to issue instructions within his sphere of activity.

2 He must have the necessary training, technical knowledge and experience and be trustworthy. The Agency may demand a copy of the Responsible Person’s police record.

3 Should the size and type of the facilities enable this job to be carried out part time, the responsibilities and the minimum number of working hours should be laid out in writing.

4 In the event that the Responsible Person must be replaced, this should be by sufficiently qualified specialists.

Section 4: Special provisions for blood and blood products

Art. 15 Conditions for granting an authorization for the collection of blood.

1 Anyone applying for an authorization to collect blood for transfusion or the manufacture of medicinal products in accordance with Art. 34 LTP must prove that:

a. the conditions described in Art. 3 have been fulfilled;
b. the Responsible Person fulfils the requirements laid out in Art. 5 para. 1 to 3 and holds a university degree in medicine or science and also has the necessary medical and scientific experience for the collection of blood;
c. the collection of blood is carried out in accordance with the rules of good manufacturing practice (GMP) as described in Annexe 1;
d. the rules of due diligence as described in the following articles are observed.

2 The Agency may specify further technical requirements and details.

Art. 16 Haemovigilance

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

2 The Responsible Person for haemovigilance must have the relevant specialized knowledge and is responsible for reporting any undesirable effects of medicinal products in accordance with Arts. 32 and 37 of the Medical Devices Ordinance dated 17 October 2001[4].

3 It is not mandatory that he is an employee of the company; however, his responsibilities must be defined in writing.

Art. 17 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 abstain from donating blood if they cannot exclude all likelihood of harboring infection

3 Persons in the following categories should not donate blood:

a. those who have been diagnosed with HIV;
b. those who are suffering from AIDS- or who have symptoms that suggest an AIDS-related illness;
c. those whose behaviour carries the risk of infection with HIV;
d. the sexual partners of those described in a, b, and c above;
e. those who carry a specific risk of prion infection;
f. those who have had a xenotransplant and contact persons in accordance with Art. 28*e* of the ordinance dated 26 June 1996[5] on the control of transplants .

4 The evaluation for donor suitability shall be in accordance with Annexe 3.

Art. 18 Compulsory test

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

2 A mixed or unmixed sample from each blood donation intended for transfusion or manufacture of labile blood products must also be tested for hepatitis C (HCV) using an appropriate gene amplification technique which has been validated according to state-of-the-art scientific and technical knowledge.

4 SR **812.212.21**
5 SR **818.111.3**

3 Required testing includes determinations of

a. HIV 1 and 2 antibodies (anti-HIV 1+2);
b. Hepatitis B surface antigens;
c. Hepatitis C antibodies (anti-HCV);
d. Treponema pallidum antibodies;
e. Alanine aminotransferase (ALAT).

4 The ABO blood group and the Rhesus D antigen expression must be determined for each blood donation.

5 An unmixed sample of plasma intended for fractionation must be tested for the prescence of HIV 1+2, HBV and HCV. Testing according to paragraph 3, a to c must be performed for this purpose. Paragraph 4 does not apply to plasma which is intended for fractionating.

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

7 Tests should only be conducted in laboratories which hold an authorization to do so from the Agency.

Art. 19 Appropriate tests and procedures

1 Only tests that have been approved as appropriate by the Agency may be used to analyse donated blood and plasma.

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

3 The Agency can specify technical requirements and particulars in relation to the tests and test procedures.

4 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 Annexe 1 of the ordinance dated 26 June 1996[6] on microbiological and serological laboratories.

Art. 20 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 Art. 18, para. 3 d and e deviate from the norm, the patient's physician should decide whether to carry out the transfusion.

Art. 21 Donor councelling

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

2 If a donor is informed of a positive test result, this must be in conjunction with the offer of counselling and assistance.

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

6 SR **818.123.1**

Art. 22 Labelling

1 Blood and labile blood products and the corresponding blood samples must be labelled in accordance with the rules of good manufacturing practice (GMP) and good practice described in Annexe 1 of the ordinance dated 26 June 1996[7] on microbiological and serological 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. 23 Records and traceability

1 The holder of an authorization for handling blood and labile blood products must maintain records of all activities of importance for safety, in particular in relation to to the collection of blood, the manufacturing, release, distribution, destruction and recall of blood or labile blood products.

2 He 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 unequivocally identify the donation, the donor's medical history, every blood product made from his donation and all documents related to these products.

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

a. 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. Test results and the interpretation of such results.

4 Each record must be signed by an authorized person.

Art. 24 Archiving and transmitting data

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

Art. 25 Protective measures

1 The holder of an authorization to handle blood or labile blood products must immediately take the necessary protective measures if he notices that:

a. at the time of donation the donor did not fulfil the criteria required to be considered as 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 can be traced back to the donor;

e. serious defects, in relation to good manufacturing practice (GMP), have occurred during the blood collection process or the manufacturing of labile blood products.

2 All measures taken in the event of occurrences as described in para. 1 b to e must be reported to the Agency.

7 SR **818.123.1**

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

Art. 26 Additional safety measures

1 Blood and labile blood products may only be used for homologous transfusions if the leucocytes have been reduced in a validated state-of-the-art scientific or technical procedure (leucocyte depletion).

2 Plasma may only be used for homologous transfusions if, in addition to leucocyte depletion and the tests described in Art. 18:

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

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

c. it is used for transfusion in a person who has already been given other labile blood products manufactured from the same blood donation (matched transfusion).

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

Chapter 3: Authorization procedure

Art. 27 Granting the authorization

1 The authorization is granted if:

a. the application is complete;

b. the applicant fulfils all relevant conditions for the activities in the application.

2 The applicant is granted a single authorization for all activities in the application in accordance with the LTP and the present ordinance.

Art. 28 Content and duration of the authorization

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

2 It is granted for a maximum of five years and may be renewed on request.

Art. 29 Renewal of the authorization

1 The application to renew an authorization must be submitted to the Agency with the necessary documentation at least six months before expiry of the authorization.

2 The authorization is renewed if the conditions for granting an authorization are still fulfilled.

3 The renewal of an authorization may be preceded by an inspection.

Art. 30 Amendments

1 The holder of an authorization must apply to the Agency with the necessary documentation for any amendments to the content of the authorization.

2 He must announce all essential changes to facilities, equipment, or procedures used in the manufacturing, testing and wholesale distribution of medicinal products and which can influence the quality, and must provide all necessary information about this.

3 The Agency will pronounce on applications under para. 1 and make any objections to changes as in para. 2 within a period of 30 days.

Art. 31 Terms

The Agency can specify the terms of the authorization procedure.

Chapter 4: Special regulations for import and transit

Art. 32 Authorization for importing individual batches

1 Anyone who imports immunological medicinal products or blood and blood products into Switzerland requires an authorization for each batch imported.

2 No authorization is required for importing individual batches of blood or blood products in medical emergencies or for autologous transfusions.

Art. 33 Conditions for granting an authorization

Anyone applying for an authorization in accordance with Art. 32 para. 1 must prove that:

a. he holds an authorization to import ready-to-use medicinal products or, in the case of importing non-ready-to-use medicinal products, an authorization for wholesale trade in medicinal products;
b. the medicinal products, insofar as they are ready to use, have been authorized in his name;
c. he bears the responsibility for the reliable and conform wholesale trade in medicinal products;
d. the medicinal products have been manufactured and distributed in accordance with the recognized rules of good manufacturing practice (GMP) and good distribution practice (GDP);
e. in the case of blood and blood products for use on human beings:
    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 the Agency has exceptionally granted an authorization to import mixed products;
    4. the requirements in accordance with Art. 15 para. 1 c and Arts. 22, 23 and 25 are adhered to.

Art. 34 Procedure

1 The application for an authorization to import individual batches must be submitted to the Agency together with the necessary documentation.

2 The authorization is valid for one month.

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

4 On customs clearance, the customs office will dischrge the authorization and forward it to the Agency.

5 In the absence of an authorization for importing individual batches in accordance with Art. 32 para. 1 medicinal products will be refused entry at the border and reported to the Agency.

Art. 35 Individual batch import of immunological medicinal products for veterinary usage

1 The application to import individual batches of immunological medicinal products for veterinary usage must be submitted to the Federal Veterinary Office in accordance with Art. 34 para. 1.

2 The customs office transmits the authorization to the Federal Veterinary Office border service which checks the authorization and forwards it to the Federal Veterinary Office.

Art. 36 Importing non-authorized ready-to-use medicinal products

1 Individuals may import ready-to-use medicinal products which are not authorized in Switzerland in quantities needed for their own use. This does not apply to medicinal products which contain genetically modified organisms or to immunological medicinal products for veterinary usage.

2 Medical professionals may import small quantities of ready-to-use medicinal products which are not authorized in Switzerland, insofar as such medicinal products are intended for treating a particular patient and they hold a relevant authorization from the Agency for importing individual batches. The terms of Art. 32 para. 1 remain reserved.

3 If the import described in para. 2 above is for immunological medicinal products for veterinary usage, the Federal Veterinary Office is responsible for issuing authorizations.

Art. 37 Transit

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

Chapter 5: Implementation

Section 1: Inspections

Art. 38 Demands on the Inspectorate

The Inspectorates, which conduct inspections by virtue of the present ordinance, must be accredited and have a quality assurance system which complies to international standards.

Art. 39 Demands on inspectors

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

2 The inspectors must be independent of the companies they are in charge of inspecting. If this is not the case they must abstain.

Art. 40 Delegation of inspections

1 The Agency controls and supervises whether the cantonal inspectorates mandated to carry out inspections fulfil the requirements described in Arts. 38 and 39.

2 It recognizes the inspectorates which fulfil these requirements.

Art. 41 Cantonal obligation to notify

The cantons must notify the Agency of any changes within their inspectorates.

Art. 42 Ordering inspections and conducting inspections abroad

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

2 The Agency may inspect manufacturers of medicinal products located abroad at the expense of the importer; however, the latter must be notified of this beforehand.

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

Art. 43 Powers of the inspectors

The inspectors can:

a. demand 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, insofar as this is 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.

Art. 44 Guidelines on the Swiss inspection system

After consultation with the cantons, the Agency issues guidelines to guarantee uniform inspection procedures throughout Switzerland.

Section 2: Collaboration between the Agency and other authorities

Art. 45 Collaboration between the Agency and the cantons

1 The Agency and the cantonal authorities collaborate in their control work and can in particular exchange confidential information.

2 They notify each other about:

a. the granting, amendment, suspension, or withdrawal of an authorization;

b. measures taken;

c. inspections.

3 The cantonal authorities provide the Agency with any information brought to their attention which indicates quality or safety defects.

4 The Agency can assist the cantonal inspectorates in training their inspectors.

Art. 46 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 the Agency with information on the import, export and transit of medicinal products.

3 The Agency can require the customs authorities to detain medicinal products for further inspection and take samples.

Chapter 6: Final clauses

Art. 47 Amendments to the annexes

1 The Federal Department of the Interior can adapt the annexes to the present ordinance to take account of international or technical developments.

2 Amendments which could constitute technical barriers to trade are made in agreement with the Federal Department of Economic Affairs.

Art. 48 Transitory clauses

1 From the entry into force of the presence ordinance the Agency is responsible for any amendments to authorizations by the Federal authorities or the cantons, which are still in force by virtue of Art. 95 para. 5 LTP.

2 The Agency and the cantonal authorities settle the mutual transfer of documents arising from changes to previous spheres of responsibility.

3 Within three months of entry into force of the present ordinance the cantons appoint the inspectorates to which the Agency can delegate inspections.

4 Until such time that the Agency recognizes them officially, the inspectorates can continue their inspection activities..

5 The Agency can grant the inspectorates a deadline of a maximum of five years to comply with the requirements described in Arts. 38 and 39.

Art. 49 Entry into force

The present ordinance comes into force on 1 January 2002.

Annexe 1
(Art. 4 para. 2, Art. 15 para. 1.c)

International rules of good manufacturing practice (GMP)

1. The following guidelines are applicable as rules of good manufacturing practice (GMP):
   a. Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use [8];
   b. Commission Directive 91/412/EEC of 23 June 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products[9];
   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, edition 1999)[10];
   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[11].
2. *Special provisions for active pharmaceutical ingredients:* PIC/S GMP Guide on Active Pharmaceutical Ingredients (PIC/S Document PE 007-1 of 7 August 2001)[12];
3. *Special provisions for medicated feedingstuffs:* Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community [13].

8 OJ No. L 193 of 17.7.1991, p. 30. The directives quoted here can be obtained from Switec (Schweizerischen Informationszentrum für technische Regeln)Bürglistrasse 29, 8400 Winterthur or downloaded from http://europa.eu.int/eur-lex/en/index.html.
9 OJ No. L 228 of 17.8.1991, p. 70.
10 This guide can be obtained from Switec (Schweizerischen Informationszentrum für technische Regeln), Bürglistrasse 29, 8400 Winterthur bezogen or downloaded from http://europa.eu.int/eur-lex/en/index.html.
11 SR **0.812.101**. These guidelines can be obtained from the Secretariat of the Pharmaceutical Inspection Convention, c/o EFTA Secretariat, 9-11 rue de Varembé, 1202 Geneva or downloaded from www.picscheme.org.
12 The text of this guide can be obtained from the Secretariat of the Pharmaceutical Inspection Convention, c/o EFTA Secretariat, 9-11 rue de Varembé, 1202 Geneva or downloaded from www.picscheme.org.
13 OJ. No. L 092 of 7.4.1990, p. 42.

Annexe 2
(Art. 9 para. 2)

International rules of good distribution practice (GDP)

The following guidelines are applicable as rules of good distribution practice (GDP):

a. Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use [14];

b. Guidelines 94/C 63/03 for good distribution practice for medicinal products for human use[15];

c. *Special provisions for active pharmaceutical ingredients:* PIC/S GMP Guide on Active Pharmaceutical Ingredients (PIC/S Document PE 007-1 of 7. August 2001)[16];

d. *Special provisions for medicated feedingstuffs:* Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community [17].

14 OJ No. L 113 of 30.4.1992, p. 1.
15 OJ No. C 63 of 1.3.1994, p. 4.
16 This Guide can be obtained from the Secretariat of the Pharmaceutical Inspection Convention, c/o EFTA Secretariat, 9-11 rue de Varembé, 1202 Geneva or downloaded from www.picscheme.org.
17 OJ No. L 092 of 7.4.1990, p. 42.

Annexe 3
(Art. 17 para. 4)

Assessment of donor suitability

Recommendation of the Council of Europe dated 12 October 1995 (including Appendices)[18] for the manufacture, use and quality assurance of blood components.

18 The Recommendation can be obtained from the Council of Europe, F-67075 Strasbourg.