Conduct of inspections of establishments manufacturing or distributing medicinal products or collecting blood

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Index

1. Purpose and scope

The purpose of this document is to provide guidance on the conduct of inspection of an establishment collecting blood, manufacturing or distributing medicinal products and holding or seeking an establishment licence referred to in Articles 5 (manufacture), 18 (import, export, foreign trade, brokers/agents), 28 (wholesale trade) and 34 (blood and blood products) of the Swiss Federal Act on Medicinal Products and Medical Devices (TPA; SR 812.21). The Directive shall harmonise inspection procedures, frequency of inspections and follow-up procedures thus ensuring a consistent approach to assessment and decision-making by the competent Swiss inspectorates and Swissmedic as the competent Establishment authority. It is issued on the basis of Article 63 MPLO (SR 812.212.1).

Swissmedic may issue, in co-operation with the Inspectorates' Coordinating Committee (ICC), additional procedures, giving more detailed guidance on the principles regulated in this document.

2. Basics

- This Directive is based on European Union "Compilation of Union Procedures on Inspections and Exchanges of Information" and on relevant PIC/S documents and has been adapted to the Swiss circumstances.
- This Directive is issued on the basis of Article 63 MPLO.

3. Definitions and abbreviations

The definition of terms in the TPA, in the MPLO and in the detailed guidelines listed in the Annexes of the MPLO (throughout this document jointly referred to as **Good Practices**, **GMP/GDP**) are applicable to this document. In addition, the following definitions apply:

MPLO	Medicinal Products Licensing Ordinance (SR 812.212.1).
Inspection	Spot check on-site assessment of the compliance with the legal requirements, which are valid in Switzerland according to TPA and MPLO (including the detailed guidelines, which are listed in the Annexes of the MPLO), performed by officials of the competent Swiss inspectorates.
Inspection report	Report prepared by the official representing the competent inspection authority documenting the assessment of a company's compliance with the valid legal requirements. Further information on inspection reports is given in the specific chapter later in this document.
Inspectorate's proposal	Recommendation of the inspectorate conducting an inspection to Swissmedic as the competent authority for granting establishment licences and issuing certificates. The proposal states, whether an establishment complies with the Swiss requirements for having an establishment licence or not. The statement is based on the inspection itself and on a company's corrective action plan resulting from an inspection.
TPA	Therapeutic Products Act (SR 812.21).

QC Laboratory inspections	On-site assessment of the adherence to Good Quality Control Laboratory Practice is normally part of a Good Manufacturing Practice (GMP) Inspection. Contract QC Laboratories authorised according to Article 5 TPA are also subject to these inspections. Laboratory Inspection for compliance with GLP Principles is not part of this document.
Distant Assessment	Assessment of the compliance of a company to a given standard performed on the basis of documents/photos/interviews but without being on site, thus representing an alternative to inspection in special situations.

4. Responsibility

This document is binding for inspectorates acting under Article 60 TPA.

5. Description

5.1 General considerations on inspections

1. The primary role of the inspector is the protection of public health in accordance with Swiss provisions.

2. The inspector shall ensure that establishments comply with the principles and guidelines of Good Practice, the approval requirements and the applicable legal obligations. The possibility of a specialist participating in the inspection should be taken into consideration.

3. The main task of the inspector is to determine whether the various elements of the quality assurance system are effective and suitable for achieving compliance with Good Practice guidelines. For inspections of marketing authorisation holders, it is useful to determine whether the medicinal products comply with the quality-relevant part of the authorisation documents approved by Swissmedic and thus with the provisions under which the product was authorised by Swissmedic. The inspector also checks whether the licence corresponds with the activities currently carried out by the company. The inspector should note in the inspection report any activities whose fulfilment cannot be checked because they have not been undertaken in the past twelve months and address this issue in the authorisation application to Swissmedic (art. 42 para. 2 MPLO). The inspector should also ensure that any unlawful situations are identified (e.g. the undertaking of non-authorised activities that must be authorised; the placing on the market of non-authorised medicinal products that must be authorised, or the manufacture or placing on the market of counterfeit medicinal products).

4. Inspectors should strive to create a positive atmosphere during the inspection.

5. An inspector should be aware of his influence on the decision making processes. The inspector should answer questions but avoid entering the role of a consultant.

6. The task of an inspector is not limited to the disclosure of faults, deficiencies and discrepancies. The inspector should connect an observation with an explanation of the relevant Good Practice requirements.

7. Different types of inspection may be carried out according to the activities of the company and the specific remit.

   Conduct of inspections may vary according to their objectives and may focus for example on the general level of GMP/GDP, or on the manufacture and/or distribution of a specific medicinal product or on a specific manufacturing and/or distribution process.

   General GMP/GDP inspections (also termed basic, regular, periodic, planned routine inspections, including the first inspection) are designed to assess the whole, or part of, a GMP/GDP system and are carried out before an establishment licence as per Articles 5, 18, 28 and 34 TPA is issued or extended, and periodically thereafter as required. This kind of inspection may also be necessary in connection with significant changes to premises, equipment, facilities, etc. and/or if there is a history of deficiencies. Swissmedic can issue inspection orders for this purpose.

   A general GMP/GDP inspection will normally, in order to assess compliance with the terms and conditions of the establishment licence, include examination of the following subjects:

   Good Manufacturing Practice (GMP) inspection:
   - Quality management
     (e.g. quality assurance principles, product quality reviews, change and deviation management, regulatory compliance)
   - Personnel and tasks of the responsible person(s)
     (incl. e.g. responsibilities, training, hygiene, direct supervision by Responsible Person)
   - Premises and equipment (incl. e.g. maintenance, monitoring, qualification aspects)
   - Documentation
     (incl. e.g. release and control of documents, data integrity)
   - Production
     (incl. e.g. manufacturing formulae / specifications, instructions and records, qualification, validation)
   - Quality control
     (incl. e.g. sampling, testing, validation, handling of out-of-specification results, ongoing stability programmes)
   - Outsourced activities
     (incl. e.g. definition of responsibilities, competence of contract giver, qualification of suppliers, service providers and contract manufacturers)
   - Batch release procedure (technical release(s))
   - Storage, transports
   - Complaints and recall procedures
   - Self inspections

   Good Distribution Practice (GDP) inspection:
   - Quality management
     (e.g. quality assurance principles)
   - Personnel
     (incl. e.g. responsibilities, training, hygiene)
   - Documentation
     (incl. e.g. release and control of documents)
   - Premises and equipment used for storage and delivery (incl. e.g. maintenance, monitoring of storage and delivery conditions, calibration of monitoring devices)
   - Operation (incl. e.g. Qualification of suppliers and customers)

- Storage, transports
- Documentation of distribution for the purpose of traceability (incl. e.g. documentation of incoming and outgoing goods)
- Definition of mutual responsibilities for distribution in the contractual relationship (incl. e.g. logistical activities such as storage and transport)
- Only for marketing authorisation holders: Regulatory compliance (incl. e.g. market release) and the role of the responsible person(s) (incl. e.g. definition of responsibilities and assessment of contract acceptor if contract manufacture takes place)
- Complaints and recall procedure, pharmacovigilance
- Returns
- Self inspections

Re-inspections (also termed follow-up or reassessment inspections) may be indicated to monitor the corrective actions required during the previous inspection.

Product- or process-related inspections (also termed special or problem oriented inspections), may be indicated to assess the adherence of the establishment to the marketing authorisation dossier (e.g. pre-/post-approval-inspections) or to investigate a specific problem on-site (e.g. for-cause-inspections based on complaints, quality defects or doubts related to the compliance of a company with the legal requirements). Such inspections may concern a specific product or a group of products as well as one or more processing procedures.

8. The wide diversity of facilities (both in terms of physical lay-out and management structure) together with the variety of products and production processes as well as analytical methods and distribution processes means that judgment by inspectors on-site of the degree of compliance with GMP/GDP is essential.

9. A consistent approach to evaluation of the compliance with GMP/GDP standards of companies is essential.

10. Inspections may disturb the normal work patterns within a company. Therefore, inspectors should take care not to put the product at risk, and should carry out their work in a careful and planned way.

11. Inspectors will, while conducting the inspection, have access to confidential information and should handle it with integrity and great care, as all persons responsible for the execution of the TPA are obliged to maintain professional secrecy according to Article 61 TPA.

5.2 Planning

12. Planning of inspections: The competent inspectorate according to Article 60 TPA should plan the succession of inspections in advance and elaborate a programme. This programme should ensure that the relevant establishments and their sites are inspected in a risk-based manner and that the scheduled frequency of inspection of individual establishments can be adhered to as planned. The competent inspectorate employs a systematic approach to the risk-based planning and conduct of inspections. Sufficient resources must be determined and made available to ensure that the designated programme of inspections can be carried out in an appropriate manner. If a large company has multiple buildings and/or sites, dividing the inspection of the establishment into several partial inspections may be considered.

5.3 Inspection frequency

13. If the inspection is not triggered by an inspection order from Swissmedic in connection with an application for renewal or change of an establishment licence, the inspection dates are fixed by the competent inspectorates, based on a risk assessment. In this scenario, general GMP/GDP inspections should be carried out at the following intervals:

Activity	*Inspection frequency*
Collection of blood and manufacture of labile blood products	2 years
Manufacture of active pharmaceutical ingredients or dosage forms (including contract production, contract packaging and contract testing)	2 years
Import, including the authorisation for market release	2 years
Wholesale trading, including the authorisation for market release	2 years
Manufacture of medicated feedstuffs* *excluding livestock holders who add pre-mixed medicinal products to feedstuffs for their own livestock in amounts covering a maximum need for one day; these do not fall under the scope of this document	3 years
Collection of blood for autologous transfusion or the manufacture of labile blood products for autologous transfusion	3 years
Import, excluding the authorisation for market release* *with or without the placing of production orders	4 years
Wholesale trading, excluding the authorisation for market release* *with or without the placing of production orders	4 years
Export* *with or without the placing of production orders	4 years
Trading abroad	4 years
Brokers or agents	4 years

As for the individual risk assessment, which is the basis for planning the frequency and duration of general GMP/GDP inspections, it should be stressed that the activities of the individual companies (products and dosage forms manufactured and/or distributed, units and substances handled and personnel, premises and equipment involved in the manufacture) and its past record of GMP/GDP compliance should be taken into consideration. In planning for inspections, the competent inspectorates use appropriate risk management tools in order to prioritise the inspection frequency, the scope and the selection of sites or activities and then take these into account accordingly in the inspection plan. International requirements (e.g. PIC/S PI 037) describe a procedure for considering both intrinsic and compliance-related risks.

The intervals shown above are valid for companies with acceptable GMP/GDP compliance. An extension of the inspection interval for establishments having a good record of GMP/GDP compliance as well as for smaller and less complex establishments may be considered on the basis of a risk evaluation. Nevertheless, the interval between inspections should not be more than one year longer than indicated in the table above, as lack of continuity may give rise to less meticulous compliance with current Good Practices or allow significant deficiencies to develop. In such cases, the companies in question should preferably be inspected less intensively (i.e. shorter) and not less frequently.

For companies showing difficulties in complying with the requirements, a shortening of the inspection interval and/or a prolongation of the duration of an inspection should be considered.

Large companies may be inspected in several partial inspections (e.g. site-specific), subject to a full general GMP/GDP inspection at least every five years.

5.4 Preparation/announcement

14. Preparation of inspections: prior to conducting an inspection the inspector(s) should familiarise themselves with the company to be inspected.

The preparation of an inspection may include:

- Examination of the current version of the site master file (if requested).
- A review of the products or type of products manufactured and/or distributed by the company.
- A review of the reports of previous inspections.
- Inspection orders.
- A review of the follow-up actions (if any) arising from previous inspections.
- Familiarisation with the relevant aspects of the establishment licence.
- A review of any information on product recalls and quality deficiencies or other observations since the last inspection.
- A review of the analysis of any samples analysed by an official laboratory of the competent authority since the previous inspection, where applicable.
- A review of any special standards or guidelines associated with the site to be inspected.
- Spot checking of relevant parts of the registration file of one or more selected products to be examined during the inspection (for marketing authorisation holders).
- Notifications of changes and related documents.
- Other documents, requested previously to the inspection.

An aide-memoire may be used or specifically prepared for the inspection to be performed. The aide memoire helps to avoid missing important aspects of the inspection.

It is recommended that inspectors prepare an inspection plan which may include:

- The objectives and the scope of the inspection, in the light of previous inspections.
- Identification of the Responsible Person (bearing the overall technical responsibility) and of other people who are directly responsible for quality assurance, production, quality control, release, distribution and, if applicable, pharmacovigilance activities.
- Identification of the inspection team members and their respective roles, if more than one inspector is going to conduct the inspection.
- The date and place, where the inspection is to be conducted - identification of the organisational units to be inspected.
- Samples (if any) to be taken.
- The schedule for the final meeting.
- Timetable for the next steps.

The main areas and the depth of the inspection of issues are selected on the basis of a risk assessment.

15. Announcement of inspection: The competent inspectorate has the right to inspect at any time (including during shift work). Normally, prior announcement of inspection is given. By informing in advance the day/days for the inspection to take place and the length of time the inspector expects to be at the premises, the objectives of the inspection will be known to the company and the relevant personnel and documentation can more easily be made available. Non-announced inspections may show a less palliated picture and should be especially considered, if there are any doubts that announced inspections show a representative picture.

5.5 Performance

16. Opening Meeting: The inspector should normally meet the management and the key personnel of the company to introduce himself and any accompanying official(s) or specialist(s) and to discuss his inspection plan (of course subject to unannounced modifications).

    During the opening meeting the inspector should:
    - state the purpose and scope of the inspection, this may include an information on the legal basis for the inspection;
    - review the management structure of the company (organisation chart);
    - identify some of the documentation which may be required during the inspection.

    During the opening meeting the inspector can expect the company to:
    - describe the Quality Management System - explain the company's quality policy;
    - explain significant changes in facilities, equipment, products and personnel since the last inspection;
    - mention planned changes;
    - explain how deficiencies have been resolved if this information has not already been forwarded to the competent inspectorate;
    - designate the people to accompany the inspector during the inspection;
    - allocate a room for the inspector if needed (with desk and seating).

    Immediate inspection after arrival on site may be of value in some cases.

17. Inspection of the plant facilities: A rapid plant tour is often useful for familiarisation with the site and any major changes. This can be followed by a detailed plant tour to determine whether the facilities and equipment are of suitable layout and design and whether the way in which they are used suits the intended operations.

    For *manufacturers*, the inspector normally follows the logical flow of the starting materials, goods inwards warehouse, through the production areas, quality control areas to the warehouse for released finished goods, taking into account the detailed guidelines of Good Manufacturing Practice (GMP).

    In *establishments that collect blood or manufacture blood products,* the inspector normally follows the flow of the donor and the products through the donation and production areas, ending at the distribution or supply of the products, taking into account the detailed specific guidelines related to the blood collection and manufacture of blood products.

    For *distributors*, the inspector normally follows the logical flow of the incoming goods, through storage in the warehouse and shipment, taking into account the detailed guidelines of Good Distribution Practice (GDP) and due diligence obligations. Special attention should be given to separated and clearly labelled areas for returned and rejected goods.

For companies releasing products for the market (e.g. *marketing authorisation holders*), special attention should be given to the status of stored products (i.e. quarantine area for incoming non-released goods, clear identification of released goods and separated and clearly labelled areas for returned and rejected goods, taking into account the detailed requirements of the MPLO and of the guidelines of GDP.

Sometimes it is appropriate to concentrate effort in one department of the company if there are special problems or requirements, e.g. a department only producing sterile dosage forms or non-sterile dosage forms. Relevant service areas should be included, e.g. water, steam and ventilation/dust extraction systems and engineering support.

Taking pictures may be supportive.

The inspector normally discusses observations as they arise during the inspection with the key personnel, supervisors and operators in order to establish facts, indicate areas of concern and to assess the knowledge and competence of this personnel.

18. Review of documentation: The whole system of documentation, based on specifications, manufacturing formulae and processing and packaging instructions, procedures and records covering the different production, quality control and distribution operations should be checked by examining particular examples both during use and after compilation into complete batch or distribution records.

19. Outsourced activities: operations contracted out and the responsibilities of the different parties should be clearly identified. The contract between the contract giver and the contract acceptor should be examined for compliance with the detailed guidelines of GMP/GDP.

20. Complaints, product recall, pharmacovigilance, returns: The system for recording and reviewing complaints as well as the system for recalling batches of medicinal products from within and outside Switzerland should be examined during the inspection, including certain system elements of pharmacovigilance and the handling of returns.

    The complaints file should be examined. Defect reports and recalls should be discussed.

21. Self-Inspection: the system for performing self-inspections in the company should be examined. Reports themselves should normally not be read by the inspector.

5.6 Final meeting

22. When the inspection has been completed, the inspector should summarise his general impression and the findings in the final meeting with representatives of the company. This normally includes the Responsible Person, key personnel, and some or all of the senior management, if these are different from the key personnel.

23. The final meeting is a significant part of the inspection. The deficiencies observed during the inspection should be explained.

24. All noted deficiencies should be reported at this meeting, giving the company also a chance to correct misinterpretations. Furthermore the company can initiate the necessary corrective actions and other measures at the earliest possible date, as well as the definition of further steps. The presence or absence of critical deficiencies should be mentioned, although the classification of deficiencies – if this occurred during the inspection – is provisional and may

change, when the inspector reviews and references the assessed data for the inspection report. It should also be noted, that the final judgment on the status of compliance with the relevant GMP/GDP guidelines may depend on the company's corrective and preventive action plan (CAPA plan). It is therefore not documented in the inspection report, but results in the inspectorate's proposal to Swissmedic's licensing Division.

25. Immediate actions and sampling: If necessary, the inspection can initiate administrative measures immediately and/or collect samples during the inspection and forward these to an accredited laboratory for analysis (preferably to the Swissmedic OMCL). The inspectorate informs Swissmedic if a sample is analysed by a different laboratory.

5.7 Records

26. Inspection reports should be based on records taken during the inspection (i.e. notes, pictures etc.). The records should be kept until the assessment of the corrective and preventive action plan proposed by the company arising from the corresponding inspection has been accepted by the competent inspectorate or has been concluded.

5.8 Inspection report

27. An inspection report should contain the general information on the company (especially on the extent of activities and operations), describe the scope of the inspection, the inspection itself, and observations arising from the inspection. All deviations are listed, including those that were corrected during the inspection, in which case a corresponding note can be entered in the report. Deficiencies should be referenced and classified into the following categories. Risk management principles are applied during the classification, taking account of the product and/or process:

Critical deficiency

- A deficiency which has produced, or leads to a significant risk of producing or distributing, either a product which is harmful to the human or veterinary patient or a product which could result in a harmful residue in a food-producing animal.
- A deficiency involving a suspicion that the manufacturer or distributor may be involved in fraudulent activities, misrepresentation of facts or the counterfeiting of products or data.
- A combination of several "major" deficiencies, none of which on their own may be critical, but which may together represent a critical deficiency or indicate a failure of the quality systems, which should be explained and reported as such in the inspection report.

Major deficiency

- A deficiency which is non-critical

and

- which has produced, or may produce, a product which does not comply with its marketing authorisation or the authorisation of the clinical trial, the product specifications or pharmacopoeia requirements

or

- which allows, or may allow, a product to be distributed that does not comply with the relevant requirements

or

- which does not ensure effective implementation of the necessary GMP/GDP control systems

or
- which indicates a major deviation from Good Practices or other relevant requirements

or
- which indicates a major deviation from the terms of the establishment licence

or
- which indicates a failure to carry out satisfactory procedures for technical release or market release, or a failure of the authorised person to fulfil their duties

or
- a combination of several “other” deficiencies, none of which on their own may be major, but which may together represent a major deficiency and should be explained and reported as such.

Other deficiency
- A deficiency which cannot be classified as either critical or major, but which indicates a departure from Good Practices or other relevant requirements.

A deficiency may be “other” either because it is judged as minor, or because there is insufficient information to classify it as major or critical.

The repeated observance of deviations that were already criticised in previous inspections indicates that the company has not implemented the actions proposed after the previous inspection or has not implemented appropriate measures on time so as to avoid a repetition of corresponding deviations. This usually leads to a stricter classification of the deficiencies.

28. If a deficiency cannot be classified with sufficient clarity, the guidance document PIC/S PI 040 can be consulted for the purpose of classification.

29. If deficiencies could affect patient safety, further measures should be reviewed without delay and, if necessary, initiated before a final inspection report is produced.

30. The report should also contain a summary, where critical deficiencies are mentioned. Administrative measures, which already have been or which may be initiated, should also be mentioned. The original of the report is forwarded to the company in which the inspection took place. Swissmedic receives a copy. The report is distributed to other authorities in accordance with the written provisions of the inspectorate's quality management system. The information should be treated in confidence (Art. 61-63 TPA).

31. Swissmedic may issue further guidance on the issue of inspection reports as well as on the referencing and classification of deficiencies.

5.9 Corrective and preventive action plan

32. When the inspection report is sent to the company, the latter is asked to draft a written reply in the form of a corrective and preventive action plan (CAPA plan) within a period specified by the inspectorate. Normally, this period should not exceed 4 working weeks. In its reply, the company must include a timetable and the planned actions for the permanent correction of the deficiencies described in the report. This letter should be signed by the Responsible Person and, ideally, by a person listed as an authorised signatory (e.g. in the commercial register) for the company. After receiving and evaluating the submitted corrective and preventive action plan, the competent inspectorate prepares an application to the Swissmedic department responsible for establishment licences.

33. The inspectorate can request additional documents/information or improvements to the CAPA plan. An inspection is formally concluded when the inspectorate has concluded the evaluation of the CAPA plan (incl. additional documents/information), provided the inspection result does not justify a premature conclusion of the inspection process. The need for an early re-inspection to check the implementation of corrective actions or other actions should be considered by the competent inspectorate.

34. The action taken by Swissmedic will consider the inspector's proposal and depend upon the nature and the extent of non-compliance.

5.10 Distant assessment

35. In case of situation where inspections cannot be carried out on site, e.g. because of unacceptable risks to the inspectors (for political, health, safety or other reasons), a risk-based decision may be taken whether to postpone an inspection or to perform a "distant assessment", taking into account the date of the last inspection. A distant assessment should not replace an on-site inspection more than once.

36. A distant assessment may be performed based on a documented interview with the company and/or by reviewing relevant documentation that has been requested from the company. The process of a distant assessment, starting from the initiation of the inspection procedure up to the closure of the inspection procedure, is in principle not different from an on-site-inspection, with the exception that the inspectors are not physically on site and therefore a plant tour is not possible. Alternative approaches using e.g. photographs or videos taken by the company for illustration purpose only, may be helpful. The review of carefully selected relevant documentation should be deep enough to evaluate the GMP/GDP compliance of the relevant site or activity, also taking into consideration the GMP/GDP compliance history of the company.

37. The result of the assessment should be documented in an inspection report, equivalent to a normal inspection report. In the report, it should be stated that the inspection was performed as a distant assessment.

38. For new sites/companies involved in manufacturing or distributing with storage that have never been inspected before, a distant assessment is normally not allowed. However, if a relevant benefit for the general public can be assumed, an exception can be granted by Swissmedic and a distant assessment conducted in order to evaluate if the site could be authorised without a prior on-site inspection. An on-site inspection should be conducted as soon as circumstances permit. If after starting the distant assessment proves not adequate to perform a proper evaluation, the inspector may decide to stop the procedure. If the outcome of the distant assessment does not permit the granting of the GMP/GDP certificate, the assessment should be deferred until an on-site inspection is possible.

39. If an inspection is performed as a distant assessment, this has to be indicated on the inspectorate's proposal. If a GMP/GDP certificate is issued on the basis of the distant assessment this will be mentioned on the certificate.

40. It is important to highlight that manufacturers and distributors must continue to comply with the relevant legal provisions and Good Practice requirements. Inspections (including distant assessments) may be launched at any time and, in case of non-compliance, appropriate regulatory actions will be triggered.

5.11 Compliance management

41. If necessary, as part of the inspection process the competent inspectorate can also employ appropriate procedures for improving the compliance of an establishment that repeatedly shows only marginally acceptable compliance or that inadequately rectifies the observed deficiencies. These procedures include measures such as re-inspections, the shortening of the inspection interval, the requesting of interim reports on deficiency correction and of appropriate evidence on the implementation of corrective actions, etc. These measures form part of the ordinary inspection process. If they are not sufficient, the competent inspectorate decides whether the situation will lead to a negative authorisation application to Swissmedic and whether corresponding administrative measures are needed, or whether the compliance is just adequate but Swissmedic should nevertheless be asked to initiated appropriate compliance management measures. In this case Swissmedic initiates a compliance management process and reviews appropriate measures designed to ensure that the compliance will be improved within a reasonable period of time so that administrative measures for suspending or withdrawing the authorisation are not needed.

5.12 Quality management of the inspector's activity

42. Swissmedic is responsible for the Swiss Inspection System in the context of Article 60 TPA and in this connection decides whether to approve Swiss GMP/GDP inspectorates according to Article 58 MPLO. In order to be approved, an inspectorate has to fulfil the requirements given in Articles 56 and 57 MPLO. Article 56 MPLO requires inspectorates to have a quality management system and to be accredited. The quality management system should take into account the principles described in document PI 002 Quality system requirements for pharmaceutical inspectorates, issued by PIC/S (Pharmaceutical inspection convention and pharmaceutical inspection co-operation scheme) and assure the performance of inspections in compliance with this directive. The relevant accreditation standard in this context is ISO 17020. Article 57 MPLO requires inspectors to be qualified and independent. The fulfilment of this requirement is a pre-requisite to receive an accreditation according to ISO 17020. Therefore Swissmedic considers inspectorates as approved when they are accredited according to ISO 17020.

43. In order to ensure a consistent approach on different occasions and between different approved inspectorates Swissmedic organises, performs or monitors activities contributing to a harmonised performance of inspections performed by Swissmedic itself or by another inspectorate acting under Swissmedic's responsibility. These activities may include:
    - Regular meetings with representatives of the competent inspectorates (Inspectorates' Coordinating Committee, ICC).
    - Joint trainings with the different competent inspectorates.
    - Joint inspections of different Swiss and/or foreign inspectorates.
    - The accompaniment of inspections.

6. Changes to the previous version

- Chap. 3: Definition of distant assessment
- Chap. 5.10: New chapter related to Distant Assessment