swissmedic

Information sheet

General procedure for foreign governmental inspections in Switzerland

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1 Definition

The instructions hereafter describe the general procedure to be followed for the request of an authorization for foreign governmental inspections related to therapeutic products in Switzerland.

Due to a change in Swiss Law in accordance with the Federal Council's decision of 5th April 2017, the new Article 64a of the revised Therapeutic Products Act (revTPA) specifies the new requirements for foreign governmental inspections related to therapeutic products in Switzerland. The inspecting authority will be required as of 1st January 2018 to submit a **notification** to Swissmedic **at latest 30 days** prior to the planned beginning of the inspection. An authorization as requested according to the old procedure, in no longer required.

Thus, starting 1st January 2018, an inspection in Switzerland by a foreign authority is only allowed if the inspecting authority has

a. received prior agreement of the company to be inspected on dates, scope, inspectors and extent of the inspection, and
b. submitted a notification by e-mail to Swissmedic at latest 30 days prior to the planned beginning of the inspection including the relevant information, and
c. accepted to deliver a copy of the inspection report within 10 days after issuing the report (in English, French, Italian or German).

This change will apply to inspections in the following fields:

- Good Manufacturing Practice (GMP) inspections related to medicinal products, including blood, blood products and immunological products (e.g. vaccines, sera)
- Good Manufacturing Practice (GMP) inspections related to transplant products and autologous transplants
- Good Clinical Practice (GCP) inspections with medicinal products and transplant products
- Pharmacovigilance inspections
- Inspections in the field of medical devices

The notification must contain the following information:

- The name, full address (incl. e-mail) and phone number of the notifying authority
- The name and address of the company and the sites in Switzerland to be inspected
- The planned inspection date/s as agreed with the company prior to the submission of the notification
- Contacts/responsabilities at the company/sites: name, phone, e-mail
- Following information on the intent and scope of the inspection:

- For Good Manufacturing Practice (GMP) inspections:
  e.g.: product specific pre-approval inspection, post-marketing adverse drug experience inspection, manufacturing, packaging
- For Good Clinical Practice (GCP) inspections:
  e.g.: identification of the clinical study/studies to be inspected, name of the investigational medicinal product(s), type of inspection (i.e. for-cause or routine), inspection focus
- For Good Pharmacovigilance (GVP) inspections:
  e.g.: Name of the related product(s), type of inspection (i.e. for-cause or routine), inspection focus
- For inspections related to medical devices:
  e.g.: name of the product/s or family of products, type of inspection (i.e. for-cause or routine), inspection focus

A template form for the notification is available on Swissmedic's website. Swissmedic will confirm receipt of the notification and will decide on a case-by-case basis if the inspection will be accompanied by its representatives.

2 Contacts at Swissmedic:

In case of *Good Manufacturing Practice (GMP)* inspections related to *medicinal products*, including blood, blood products and immunological products (e.g. vaccines, sera), as well as transplant products/transplants, please send the documents to:

Swissmedic, Swiss Agency for Therapeutic Products
Authorisations, Certificates and Licences
3012 Bern / Switzerland
E-mail: inspectorates@swissmedic.ch

In case of *Good Clinical Practice (GCP)* inspections related to human medicinal products as well as in case of *pharmacovigilance* inspections, please send the documents to:

Swissmedic, Swiss Agency for Therapeutic Products
GCP/GVP Inspectorate
3012 Bern / Switzerland
E-mail: ct.medicinalproducts@swissmedic.ch

In case of inspections related to *medical devices* intended for human use please send the documents to:

Swissmedic, Swiss Agency for Therapeutic Products
Medical Devices Division
3012 Bern / Switzerland
E-mail: medical.devices@swissmedic.ch

3 Changes to the previous version

- New layout