

## Rules of the ICC

### Purpose

A permanent Inspectorates' Steering Group called the Inspectorates' Coordinating Committee" (ICC) has been set up by Swissmedic to which it is attached. This annex defines the ICC meeting rules.

### Scope of the ICC

In order to protect human and animal health and to guarantee that only high quality, safe and effective therapeutic products are placed on the market as defined in article 1 of the Therapeutic Products Act and in order to assure the acceptance of the Swiss Medicines Inspectorate by foreign governmental bodies, the ICC has been established. The ICC shall reach this goal by harmonizing the execution of inspections by the regional and the specialized Swissmedic divisions and by common guidance on technical aspects. International standards are duly taken in account.

### Tasks

The ICC examines:

- Any question relating to the application of the Good Manufacturing Practice (GMP), the Good Distribution Practice (GDP) or the recommendations on the preparation, use and quality assurance of blood components (MPLO attachments 1, 2, 3, 4 and 5) in its responsibility as defined by Article 60 of the TPA which are brought up by its Chairperson - either on his initiative or at the request of a member of the ICC;
- Any other question in the field of proprietary medicinal products brought up by its Chairperson- either on his initiative or at the request of a member of the ICC;
- Questions of training of inspectors;
- All questions of quality and harmonization of inspections.

Swissmedic shall consult the ICC when preparing directives in its field defined by Article 60 of the TPA.

### Representatives (Members) / Presence

The members of the ICC are listed in chapter 5.4 of the guideline I-SMI.RL.02. In case of absence, members have to arrange deputies to attend; they may point out another ICC member for representation. The chairperson can invite Swiss and foreign observers and experts if deemed helpful. If a representative suggests inviting an observer or expert, the Chairperson should send out an invitation.

### Decision procedures

Before its implementation, guidelines and technical interpretations related to GMP or GDP matters are to be consulted among the ICC members.

Decisions are taken by consensus and are binding for all concerned inspectorates. When consensus cannot be reached, the chair of ICC will make the decision.

These decisions, guidelines and technical interpretations should be made available to the stakeholders of Swissmedic and / or of the regional inspectorates. If appropriate internal documents can also be issued that will not be public.

### **Meeting procedures**

The chairperson shall invite the ICC regularly, normally for 4 meetings per year. If deemed necessary ad-hoc meetings or quick circular inquiries may be organized.

English language or an official Swiss language should be spoken in the ICC. Short minutes will be written in English by the secretary of the ICC and shall contain all decisions taken during the meeting. Swissmedic is responsible for the administration and minutes. The Committee shall adopt its rules of procedure if deemed necessary.