Round Table on GMP/GDP – Terms of Reference

1 Introduction

Swissmedic and the pharmaceutical industry associations are keen to engage in an exchange during regular meetings on topics relating to GMP/GDP. The meetings are intended to enable the parties to make their concerns heard and to promote mutual understanding of the parties' concerns in order to respond promptly and appropriately as necessary and to plan and implement regulatory, process-related and technical changes relating to GMP/GDP and establishment licensing in an efficient manner.
It is against this background that Swissmedic has established the Round Table on GMP/GDP (referred to below as the "Round Table"). The Round Table comprises representatives of the pharmaceutical industry associations plus senior representatives of the Inspectorates and Licences Department at Swissmedic and representatives of the regional inspectorates.

2 Purpose of the Round Table

The Round Table will be a forum in which participants can share information and experience at a technical level. It will be possible to address only those topics which fall within the mandate of Swissmedic.
The following aims in particular will be pursued:

- An exchange of information and opinions between Swissmedic and representatives of the pharmaceutical industry associations on topics relating to GMP/GDP.
- The industry's concerns will be heard by Swissmedic and, if appropriate, may lead to modifications.
- Provision of preliminary information to the pharmaceutical industry on changes planned by Swissmedic. An opportunity for industry stakeholders to comment on the practicability and operational feasibility of planned changes.

3 Participants

The Round Table comprises representatives of the pharmaceutical industry associations and Swissmedic.

3.1 Representation of the pharmaceutical industry associations

In order to ensure the efficiency of the Round Table, the number of participants will be limited to 15 representatives of associations, who are familiar with operational issues in the pharmaceutical industry on the basis of their day-to-day work or many years of experience. They are also required to have in-depth knowledge of GMP/GDP.

Each association may nominate its own representative and a deputy. The number of participants in the Round Table is usually limited to one representative per association. Three associations representing a broader spectrum of members may register two participants if necessary. There are plans to publish a list of the pharmaceutical industry associations participating in the Round Table on the Swissmedic website.

3.2 Representation of Swissmedic
Swissmedic will be represented by members of the Inspectorates and Licences Department and by representatives of the regional inspectorates. Specialists from other departments will be involved in specific topics on a case-by-case basis.

4 Nature and frequency of meetings
The Round Table will generally convene two to three times per year for a half-day meeting if there is a need and sufficient interest. The meetings will be organised by Swissmedic and will generally take place on Swissmedic's premises.
Details of the next meeting will be put forward at meetings of the Round Table and agreed definitively after the meeting.

5 Principles of collaboration

5.1 Chairing the Round Table
The Round Table will be chaired by the Head of the Inspectorates and Licences Department.

5.2 Single Points of Contact in the pharmaceutical industry associations and at Swissmedic
- **Pharmaceutical industry associations**
  The participating pharmaceutical industry associations will designate a Single Point of Contact (SPoC) who will liaise with the Swissmedic SPoC and all the other pharmaceutical industry associations for all matters related to the Round Table. The tasks of the SPoC shall in particular include the consolidation of the pharmaceutical industry's proposals for the Round Table agenda and the production of the preparatory documentation in accordance with the agenda.
- **Swissmedic**
  Swissmedic will designate an SPoC who will be responsible for the timely production of the agenda, the provision of the preparatory documentation and communication with the SPoC of the pharmaceutical industry associations.

5.3 Organisation and reporting
- **Agenda**
  Prior to the Round Table, the SPoC for the pharmaceutical industry associations will collect and consolidate the items proposed by the participating industry associations. The proposed topics will then be passed on to the Swissmedic SPoC and included in the draft agenda for the meeting. The final agenda will be produced in agreement with the management of the Inspectorates and Licences Department and generally sent to participants one week before the Round Table takes place.
- **Minutes**
  The draft minutes – consolidated internally by Swissmedic – will be sent to the SPoC for the pharmaceutical industry associations so that any additional material can be added. Once the industry SPoC has reported back to Swissmedic, the minutes will be finalised, taking the additional material into account, sent to the SPoC for the pharmaceutical industry associations for distribution to the association representatives and published on the website.

5.4 Participation of experts
The Round Table may call on experts for special topics. These may participate in the Round Table as guests. The Round Table may contact other stakeholder groups, such as experts from the health service, as needed.