# 1 Introduction

Swissmedic and the pharmaceutical industry are keen to engage in an exchange during regular meetings on topics relating to the regulation of medicinal products. The meetings are intended to enable the parties to make their concerns heard in order to respond promptly and appropriately to regulatory and technical signals, as necessary. There are cases in which Swissmedic needs to discuss changes in the regulation of medicinal products with representatives of the pharmaceutical industry before the changes are made, so that practical aspects of operational implementation can be properly taken into account and communicated appropriately to the target audience.
It is against this background that Swissmedic has established the Round Table on Regulatory Affairs (referred to below as the "Round Table"). The Round Table comprises representatives of the pharmaceutical industry and its associations plus senior representatives of the Authorisation division at Swissmedic. Over the years, the direct exchange between Swissmedic and the pharmaceutical industry has proved to be a productive way of promoting mutual understanding of the parties' concerns as well as for planning and implementing regulatory, process-related and technical changes in an efficient manner.

# 2 Purpose of the Round Table

The Round Table will be a forum in which participants can share information and experience. The following aims in particular will be pursued:

- An exchange of information and opinions between Swissmedic and the pharmaceutical industry on regulatory, process-related and technical topics regarding the authorisation of medicinal products.
- The industry's concerns will be heard by Swissmedic and, if appropriate, may lead to regulatory, process-related or technical modifications.
- Provision of preliminary information to the pharmaceutical industry on technical, process-related and regulatory changes planned by Swissmedic. An opportunity for industry stakeholders to comment on the practicability and operational feasibility of planned changes.
- The Round Table will help to improve the quality and stability of therapeutic products regulation.

Its mission is therefore distinct from that of the Pharma Policy Committee (PPG) which is concerned with more strategic issues.

# 3 Participants

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

## 3.1 Representation of the pharmaceutical industriy

A maximum of 12 representatives of the pharmaceutical industry are permitted to be present. Participants must be familiar with the operational issues in the pharmaceutical industry on the basis of their day-to-day work or many years of experience. They will also need to have in-depth knowledge of the legislation, the political environment and the working methods of Swissmedic.
The number of representatives and their affiliation to the industry associations should ensure balanced representation of the interests of the pharmaceutical industry. The associations will agree among themselves on their representatives at the Round Table. The names and affiliation of the representatives will be published on the Swissmedic website.

## 3.2 Representation of Swissmedic

Swissmedic will be represented by senior staff members of the Authorisation division. Specialists from other departments will be involved in specific topics on a case-by-case basis.



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# 4 Nature and frequency of meetings

The Round Table will generally convene two to three times per year for a half-day meeting. 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 Authorisation division.

## 5.2 Single Points of Contact in the pharmaceutical industry and at Swissmedic

- **Pharmaceutical industry**
  The representatives of the pharmaceutical industry and associations will designate a Single Point of Contact (SPoC) who will liaise with the Swissmedic SPoC and the representatives of the pharmaceutical industry 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 in the pharmaceutical industry.

## 5.3 Organisation and reporting

- **Agenda**
  Prior to the Round Table, the SPoC in the pharmaceutical industry 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 Head of the Authorisation division 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 in the pharmaceutical industry 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, and sent to the pharmaceutical industry SPoC for distribution to the association representatives.
- **Reporting to the Management Board**
  The Head of the Authorisation division will periodically report to the Swissmedic Management Board and Agency Council regarding the outcomes of the Round Table.

## 5.4 Participation of experts

The Round Table may call on experts for special topics. These may participate in the Round Table as guests.



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