1 Introduction

In 2010 Swissmedic introduced the electronic application submission format eCTD for authorisation applications. In the preceding project Swissmedic successfully sought the cooperation of the pharmaceutical industry in developing the technical and procedural requirements. This industry involvement was a major factor in ensuring the practicability of the resulting solution and a high level of acceptance.
Following its introduction, Swissmedic continued to refine the eCTD solution on an ongoing basis, and collaboration with the pharmaceutical industry continued in the form of regular meetings. This resulted in the 'Round Table eCTD', which today is still an important tool in the process of developing electronic submission formats.

2 Purpose of the Round Table

The Round Table eCTD is 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 about eCTD and other electronic technologies for submitting authorisation applications (e.g. eDok, eGov portal).
- The industry's proposals will be heard by Swissmedic and, if appropriate, may lead to process-related or technical modifications.
- Swissmedic will provide information on planned system- and process-related modifications and obtain feedback from the pharmaceutical industry. The industry may comment on the usability and feasibility of applications.
- Discussions will take place on a technical and procedural level and relate to practical use. This committee will not discuss strategic questions.
- The pharmaceutical industry participants will support the opinion-forming process in the regulated sector and express their opinions at the Round Table meetings. Relevant information from the Round Table meetings will be passed on to the regulated sector in a suitable form.
- The Round Table eCTD will underpin the quality and stability of new solutions relating to application submission.

3 Participants

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

3.1 Representation of the pharmaceutical industry

The delegation comprises up to 12 representatives of the pharmaceutical industry who are familiar with the technology and processes associated with application submission, and eCTD in particular, as a result of their day-to-day work and experience.
The associations will agree among themselves on their representatives at the Round Table eCTD. It will be the responsibility of the industry delegation to ensure that the various areas of the sector regulated by Swissmedic are represented appropriately.
The names and affiliation of the representatives will be published on the Swissmedic website.

3.2 Representation of Swissmedic

Swissmedic will be represented by members of the Operational Support Services Department and by specialists, typically from the IT organisation.

4 Nature and frequency of meetings

The Round Table eCTD will generally convene once a year for a meeting lasting several hours. If there are no current topics for discussion, the Round Table may be cancelled.
The meetings will be organised by Swissmedic and will generally take place on Swissmedic's premises. The date of the next meeting will be agreed bilaterally between the Single Points of Contact in the industry delegation and at Swissmedic. The date will be announced at least two months in advance.

5 Principles of collaboration

5.1 Chairing the Round Table

The Round Table eCTD will be chaired by the Head of the Operational Support Services Department.

5.2 Single Points of Contact

- **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 in 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 by the Swissmedic SPoC in agreement with the Head of the Infrastructure 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 Swissmedic Management Board**
  The Head of the Infrastructure division will report periodically to the Swissmedic Management Board on the outcomes of the Round Table eCTD.

5.4 Participation of experts

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