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Change history

Version	Valid and binding as of:	Description, comments (by author)	Author's initials
1.2	03.05.2022	Document newly created due to changes in the organisational structure	bra
1.1	01.01.2021	Document newly created due to changes in the organisational structure	bra

1 Introduction

Swissmedic has committed itself to engage with stakeholders in the medtech industry in regular meetings on topics relating to the medical devices regulations. The meetings are intended to enable the parties to exchange information and raise issues in order to respond promptly and appropriately, as necessary, to regulatory or technical developments.

It is against this background that Swissmedic established the Round Table on Medical Technology (RTMT) in May 2019. Direct exchange with association representatives has since proven to be effective and should be continued. This promotes mutual understanding of the parties' demands and concerns and ensures efficient planning and implementation of regulatory, process-related and technical changes.

Due to the new regulations for medical devices and in vitro diagnostic medical devices (entry into force 2021 and 2022, respectively), the content and the group of those concerned and stakeholder groups interested in exchange in the area of medical devices have changed. This change is taken into account in these updated Terms of Reference.

2 Purpose of the Round Table

The RTMT will be a forum in which stakeholders can share information and experience. In general, it will be possible to address only those topics related to the implementing powers of Swissmedic in the area of medical devices and in vitro diagnostic medical devices. The following objectives in particular will be pursued in the RTMT:

- The implementation of medical device and in vitro diagnostic medical device regulations in Switzerland is improved and strengthened through the RTMT.

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- An exchange of information and opinions takes place between Swissmedic and stakeholders on regulatory, process-related and technical topics.
- Stakeholders receive information on relevant developments or changes to implementation and have the opportunity to check their practicability and operational feasibility.
- The RTMT serves as a disseminator for providing information on new and upcoming technical, procedural and regulatory changes.
- Individual members can be specifically involved as necessary to support the implementation of the new or revised provisions of the medical devices regulations (e.g. support group for new database or participation in usability tests).

3 Stakeholder groups

Based on the stakeholder map defined by Swissmedic (national collaboration), the Round Table on Medical Technology comprises representatives from the medical technology industry and healthcare institutions, professionals and Swissmedic representatives..

3.1 Representation of stakeholder groups

Importance is attached to balanced representation of the stakeholder groups in the composition of the Round Table. Interested associations/organisations can apply to participate in the RTMT using the application for nomination form.

The Round Table is limited to 12 associations/organisations, each of which is represented in principle by one representative (or their deputy). In justified exceptional cases, a second representative may participate on request. Statements and positions of the representatives constitute the opinion of the association/organisation and its members.

If more than 12 associations/organisations are interested in participating in the RTMT, associations/organisations that broadly gather and provide coordinated representation of the concerns of the stakeholder group to Swissmedic based on their network and that if necessary can ensure the necessary exchange of information with several associations are given priority.

Only persons who, on the basis of their day-to-day work and many years of experience, are familiar with concerns of the stakeholder group may be nominated as a representative or deputy representative of an association/organisation. They will also need to have in-depth knowledge of therapeutic products legislation and the implementation tasks performed by Swissmedic. The names and association affiliation of the representatives are published on the Swissmedic website.

3.2 Representation of Swissmedic

Swissmedic will be represented by the management of the Medical Devices sector.

4 Nature and frequency of meetings

The RTMT will be held two to three times per year. The meetings will be organised by Swissmedic and will take place on Swissmedic's premises.
Details of the next meeting will be put forward at meetings of the RTMT and subsequently agreed after the meeting by Swissmedic. Swissmedic can call ad-hoc meetings or subgroups on specific topics.

5 Principles of collaboration

5.1 Chairing the Round Table

Swissmedic's Head of Sector Market Surveillance or a deputy nominated by them will chair the RTMT.

5.2 Single Points of Contact

- **Stakeholder groups**

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The association representatives for their part will designate a Single Point of Contact (SPoC) who will liaise with Swissmedic and the association representatives regarding organisational matters related to the Round Table. The tasks of the SPoC shall in particular include the consolidation of the stakeholder groups' proposals for the Round Table agenda and the production of the preparatory documentation in accordance with the agenda.

- **Swissmedic**
  Swissmedic will designate a 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 stakeholder groups.

5.3 Organisation

- **Agenda**
  Prior to the RTMT, the stakeholder groups; SPoC will collect and consolidate the items proposed by and questions from the participating associations. Proposed topics, including planned input (presentations) will be made available in good time to Swissmedic's SPoC. Swissmedic will draw up a proposed agenda and generally send this out to participants together with the preparatory documents one week before the Round Table takes place.
- **Minutes**
  The draft minutes – consolidated internally by Swissmedic – will be sent to the SPoC of the stakeholders so that any additional material can be added. Once the stakeholders' SPoC has reported back to Swissmedic, the minutes will be finalised, taking the additional material into account, and sent to the stakeholders' SPoC for distribution to the association/organisation representatives.

5.4 Transparency

The following information will be published on Swissmedic's website:

- The associations/organisations participating in the RTMT and the names of the representatives and deputies,
- the agenda,
- the minutes.

5.5 Participation of experts

Specialists may be called on for special topics. These may participate in the RTMT as guests by invitation.

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