

Terms of Reference Round Table Innovation (RTI)

1. Introduction

The development of innovative technologies in the therapeutic products sector is closely linked to the rapid advances being made in digital technology. New forms of evidence generation (patient-reported outcomes, real-world data and real-world evidence) are becoming increasingly common in clinical research. Major advances in diagnostic technology are driving forward personalised medicine ("precision medicine"), particularly in oncology. Apps and wearables are gradually becoming the new standard. Demarcation is becoming an ever more important issue owing to the growing difficulty of drawing boundaries between the various product categories (medical devices, medicinal products, food products and cosmetics). It is almost impossible to categorise new product types and combinations using the current definitions. The growing number of complex products and new technologies is constantly creating fresh challenges for Swissmedic and its stakeholders.

In an effort to recognise and address these challenges at an early stage, Swissmedic is establishing a **Round Table Innovation** (hereafter RTI) as a forum for multi-stakeholder dialogue. Innovative topics that look set to become important for Swissmedic and its stakeholders over the next few years will be defined, either in connection with Swissmedic's horizon scanning activities or at stakeholder groups' suggestion.

These innovative topics will typically affect several Swissmedic divisions and several stakeholder groups.

These Terms of Reference (hereafter ToR) set out the goals of the RTI, define the scope and nature of collaboration and describe the working methods.

2. Goals

The RTI will be a forum in which all participants can share information and experience. It will endeavour to commence dialogue on innovation-related topics in the therapeutic products sector with the relevant stakeholder groups at an early stage so that innovative, state-of-the-art approaches can be translated from theory into practice as quickly as possible for the benefit of the people affected.

The primary goals of the RTI are:

- To conduct an open and constructive dialogue with all affected stakeholder groups;
- To consider all relevant perspectives when assessing an innovative topic;
- To discuss and define the specific short-, medium- and longer-term impact of a particular innovative topic on Swissmedic;
- To make proposals and recommendations concerning measures that would enable Swissmedic to prepare for the impact of the innovation in question (along the regulatory requirements, skills and processes and systems axes).

3. Scope of collaboration

The RTI will address innovative developments and new technologies in the therapeutic products sector where these are relevant to the production, authorisation and market surveillance of

therapeutic products. By doing so it will deal with innovation-related topics that affect medicinal products and medical devices.

The RTI will not provide scientific advice, nor will it address product-specific issues.

The horizon scanning process has given Swissmedic a resource capable of recognising and addressing new and innovative developments and trends at an early stage. Swissmedic will use it as a basis for preparing and defining issues to be addressed by the RTI.

Stakeholders will also be welcome to propose topics for discussion. Such proposals can be submitted to Networking (networking@swissmedic.ch) accompanied by the following information:

- Description of the topic or innovation and background information on it
- Explanation of why the issue is relevant
- Outline of the questions to be discussed

Networking will review the proposal and respond to it within two (2) weeks. Networking will maintain a list of potential topics that will be prioritised by topicality and importance.

4. Form and nature of collaboration

What form will the RTI take?

The RTI will take the form of a meeting and will be organised and run by Communication and Networking at Swissmedic. Meetings will generally take place at Swissmedic's premises at Hallerstrasse 7 in Bern.

There will normally be only one IRT per innovation issue. However, an additional IRT can be held after a certain period of time if the dynamic nature of a particular issue makes further discussion necessary.

How often will the RTI take place?

The RTI will generally take place two to three times a year and last half a day. Meetings can be extended to a full day if necessary.

How will the RTI be constituted?

The RTI will not have fixed members and its composition will therefore change. In principle, participants can be drawn from any stakeholder group (see stakeholder map in Annex 1). In accordance with Swissmedic's stakeholder engagement principles, collaboration will involve associations, organisations and/or formalised groupings, but not companies or individuals.

How will participants be selected?

Participation will be by invitation of Swissmedic. Each association or organisation that receives an invitation will be able to nominate a maximum of two representatives. The speakers who will give input presentations will be invited additionally/separately.

When selecting associations and organisations to invite, Swissmedic will be guided primarily by the principle of equal treatment for all stakeholder groups and aim to ensure that the composition of the RTI is as balanced as possible. Furthermore, when making its selection, Swissmedic will take account of the extent to which the issue to be discussed affects particular associations or organisations and the competencies or expertise that these organisations have in this area. To ensure that the RTI functions effectively, participant numbers will be restricted to a maximum of 25 per round table.

What kind of structure could an RTI meeting follow?

As a rule, the issue to be discussed will be introduced in one or two concise input presentations, which should also take account of any divergence in the viewpoints of individual stakeholder groups. The input presentation will include regulatory questions and what is expected of Swissmedic in terms of support for the innovative development or approach in question.

There will then be a facilitated discussion on the issue to which all participants can contribute equally (main part of the RTI). Outcomes and possible next steps will be summarised at the end of the RTI. An agenda template is attached as Annex 2.

5. Principles of collaboration

In line with its established values of

- integrity,
- quality,
- transparency,
- commitment and
- respect

Swissmedic's stakeholder engagement will be a dialogue among equals. Collaboration will be based on mutual respect and appreciation of the other party's position and will thus build up a relationship of trust.

6. Organisation of the RTI

a. Chairing the RTI

Swissmedic will chair and facilitate the RTI.

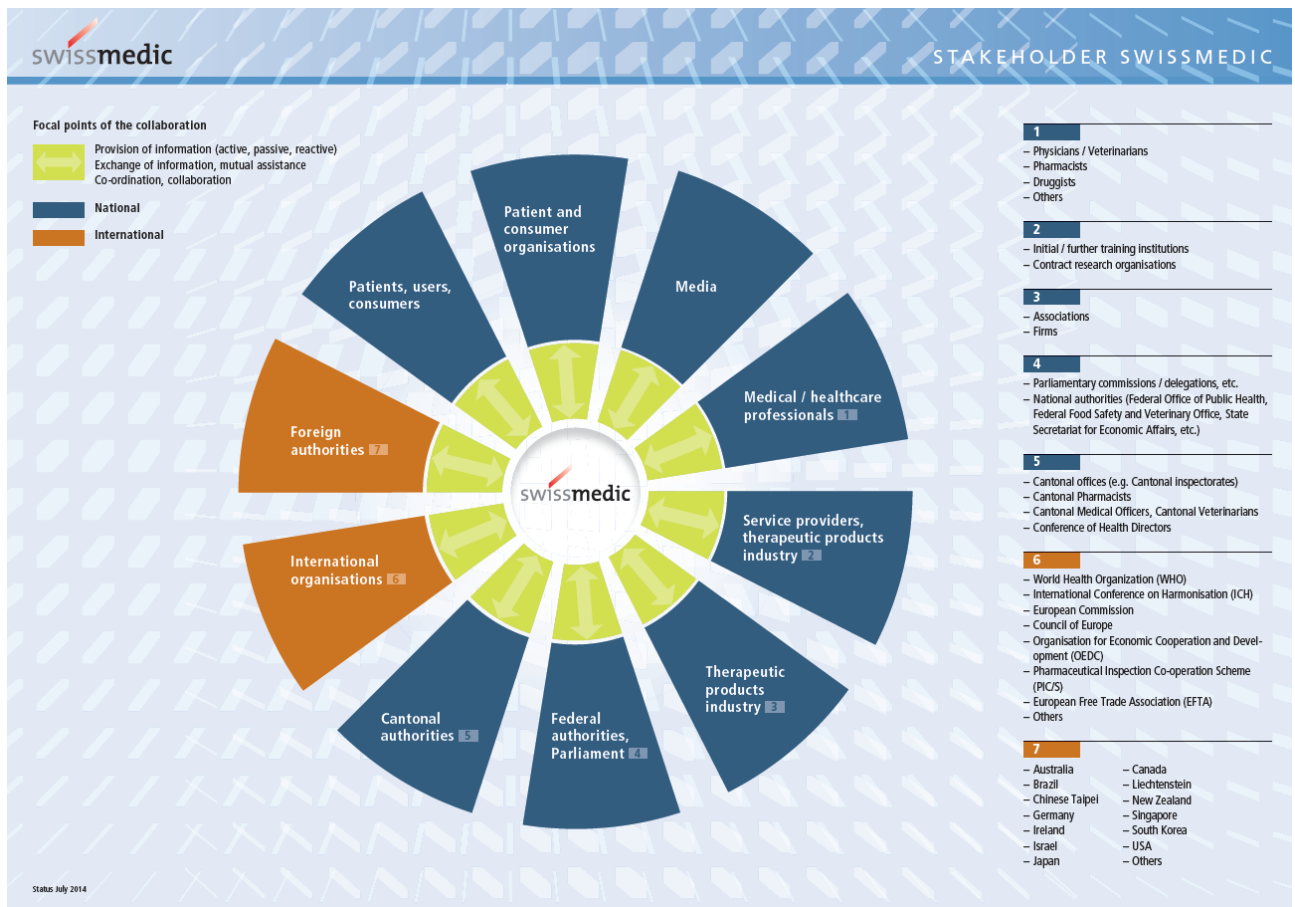
b. Meeting organisation and reporting

- The two or three meetings will generally be spread evenly throughout the year, and dates will take account of the summer holiday period in July and August.
- Doodle polls will be held to organise the actual dates with affected or interested stakeholder groups.
- Meetings will normally be held in German and/or French. If there are good reasons for doing so, meetings may also take place in English if non-Swiss guests are attending. Meeting summaries and other working documents will be written in German and French. Italian and/or English translations can be organised if needed.
- Swissmedic will send the agenda to all participants no later than two (2) weeks before the meeting date.
- Swissmedic will produce minutes of each meeting. These minutes will summarise the key discussion points and outcomes of the RTI without recording any participant's actual statements and opinions. Draft copies of the minutes will be sent to participants for comment no later than three (3) weeks after the meeting. The minutes will be published on Swissmedic's website once the period for submitting comments – generally no more than two weeks – has ended.

c. Avoiding conflicts of interest

All participants represent the interests of the association or organisation that has nominated them.

7. Annex 1



8. Annex 2

Agenda template

Swissmedic Round Table Innovation (RTI)

Subject: XXX

Day XX Month Year, XX a.m./p.m., Swissmedic, Bern

Max. 15 min	Welcome and introduction of participants XXX Introduction: Goals and background XXX
Max. 30 min	Input presentation 1 and questions XXX
Max. 30 min	Input presentation 2 and questions XXX
15 min	Break
75 min	Facilitated discussion XXX/everyone Question 1, question 2, ... Challenge 1, challenge 2,
15 min	Summary and next steps XXX
3 hrs	End of RTI