

Swissmedic working group with patient and consumer organisations: Terms of Reference

1. Introduction

Swissmedic endeavours to become aware of the concerns of patients and consumers as a stakeholder group at an early stage and, by maintaining contact with their representatives, to learn as directly as possible about the experiences of users of therapeutic products.

To this end, Swissmedic set up a working group (WG) in May 2014, comprising representatives from patient and consumer organisations (PCOs) and Swissmedic experts. Initially conceived as a project, the WG was established as a permanent working group at the end of 2018 on completion of a four-year pilot phase.

2. Objectives

The WG will be a forum in which participants can share information and experience. The focus will be on the following objectives:

- To hear, take on board and, if appropriate, incorporate into Swissmedic's processes the experience of patients and consumers in connection with issues associated with medicinal products and medical devices.
- To enable Swissmedic to provide target group-appropriate information to improve patients' and consumers' knowledge of Swissmedic's tasks and competencies.
- To maintain a regular dialogue between patients/consumers and Swissmedic with the aim of becoming aware of the wishes and needs of this stakeholder group with respect to therapeutic products.

The topics are shown in the current work plan.

3. Composition

The WG is comprised of the following active members:

- Representatives from PCOs which fulfil the criteria listed in the nomination request. One active member and one deputy may be proposed for the WG by each organisation. Either the active member or the deputy member will attend meetings.
- Representation of Swissmedic
 - Management Services and International Affairs Sector: Represented by the Stakeholder Engagement Division (chairs the WG).
 - Authorisation Sector: Represented by the Regulatory Assessment and Regulatory Operations & Development Divisions.
 - Market Surveillance Sector: Represented by the Safety of Medicines and Medical Devices Regulation Divisions.
 - Additional employees are invited to meetings of the WG as required by the topic.

Swissmedic will publish on its website a list of all the organisations (name of the organisation, acronym) that are members of the WG.

To ensure that the WG functions effectively, the number of active members from the PCOs will be restricted to a maximum of 25. Swissmedic may select from the requests received if a large number of requests for membership are submitted, the aim being to achieve balanced representation with respect to the relevant therapeutic areas and regional representation. In case of doubt, a decision will be taken in favour of an umbrella organisation which represents PCOs.

Participation in the WG is voluntary. A member may leave the WG at any time.

Active members

The active member or their deputy ensures communication with the bodies in their organisation and informs the organisation about the activities of the WG.

Active membership of the WG includes an obligation to play an active role and to participate regularly in meetings. If an active member or their deputy have not taken part in three consecutive meetings, Swissmedic will assume that the respective organisation no longer wishes to be an active member and is making its place in the WG available to others. If Swissmedic is in contact with the organisation, Swissmedic will decide in conjunction with the respective organisation whether the latter will remain in the working group as a passive member or whether it will leave the working group. The WG will be informed accordingly.

Passive members

PCOs which, for lack of resources or for other reasons, cannot provide active members may participate as passive members. They will be informed about the outcomes of the WG on a regular basis.

Interested organisations may join the working group if they fulfil the criteria listed in the nomination request (see point 6: Other valid documents).

4. Nature and frequency of meetings

The working group will generally meet two to three times per year. The duration of the meeting will be determined by the items on the agenda, but should not exceed half a day. The meetings will be organised by Swissmedic and will generally take place on Swissmedic's premises in Bern or as hybrid meetings. In addition, topic-specific workshops, training sessions and project group meetings will be organised as necessary.

5. Principles of collaboration

a. Chair / SPoC

The WG will be chaired by the Stakeholder Engagement (SHE) Division. The Chairperson will endeavour to organise the working group's activities as efficiently as possible. The representatives from the PCOs will elect a Single Point of Contact (SPoC) for a period of three years. The first election will take place in 2024.

The Chairperson and SPoC will be jointly responsible for planning the working group's activities, including updating the work plan. Further responsibilities are allocated as follows:

- Chairperson
 - Chairing meetings
 - Annual review of potential conflicts of interest
 - Commitment to consensus decision-making
 - Establishing contact with the Federal Department of Home Affairs (FDHA) and other federal offices, the Federal Office of Public Health (FOPH) in particular, as required
 - Reporting on activities of the WG within Swissmedic

- SPoC
 - Reporting on activities of the WG
 - External representation of the WG
 - Establishing contact with other stakeholder groups in accordance with the work plan or as required

b. Meeting organisation and reporting

- The dates of all regular meetings in the next calendar year will be determined by the WG at the end of the previous year.
- Meetings will be chaired and held in German and/or French.
- The draft agenda will be sent to the members of the WG by SHE in consultation with the SPoC an appropriate length of time before the meeting.
- SHE will produce minutes of each meeting. This document will summarise the outcomes and main points of discussion of the WG. The draft will be sent to the participants after the meeting for comment. At the end of the commenting phase, the minutes will be published on the Swissmedic website in German and French.
- SHE will report periodically on the activities of the WG to the Swissmedic Management Board and Agency Council.
- Topic-specific discussions may be continued between meetings in conference calls or in writing as required.

c. Participation of experts

The WG may involve further experts, including those from participating PCOs and other stakeholder groups¹, for specific topics.

These experts may participate in meetings as guests after prior notification to SHE and in agreement with the Chairperson of the WG and the SPoC. Experts are usually contacted by the Chairperson or the SPoC of the WG.

d. Confidentiality

All information and documents of which participants become aware during meetings, with the exception of documents provided to the members of the WG subsequently (e.g. presentations, minutes), must be treated in confidence and may not be disclosed to third parties outside the group of participants (Swissmedic, PCOs present, guests if applicable) except with the consent of the other party. Consent is obtained via the respective SPoC or is agreed during the meeting and recorded in the minutes.

¹ Here “other stakeholder groups” refers in particular to organisations/initiatives mentioned in the work plan, further PCOs and Swiss federal authorities (e.g. FOPH, FSIO) (this list is not exhaustive).

e. Project groups

In order to deal with special topics, the WG may decide to set up a project group for a limited period of time. The project group will comprise members of the WG and further experts as required. It will report its outcomes to the WG. Termination of the project group's mandate will be decided by the WG.

f. Avoiding conflicts of interest

The patient/consumer organisations with which Swissmedic collaborates fulfil the criteria for participation stated in the nomination request (see point 6: Other valid documents).

- All members' conflicts of interest will be reviewed by the Chairperson every two years.
- Possible conflicts of interest with respect to specific topics must be declared at the start of a meeting by active members, their deputies and experts.
- Active and deputy members and experts taking part in meetings as guests represent the interests of the organisation which nominated them. The organisation will ensure that its representative in the WG has no direct interest in the therapeutic products industry which could affect their impartiality.

g. Interactions with other stakeholder groups

The WG will decide which documents may be exchanged with other stakeholder groups.

If the WG is represented at a national or international event by one of its members, the Chairperson and the SPoC of the working group must be informed in advance. The WG must be informed about the event at the next meeting.

Preference will be given to invitations to national or international events hosted by non-profit organisations. Invitations to events hosted by individual therapeutic products companies will be reviewed by the Chairperson and the SPoC of the WG and may be considered on a case-by-case basis.

If members of the WG take part in national or international events, and if they are not explicitly representing the working group at these events, their comments and the views they express will be those of the individual person or organisation and will not necessarily reflect the views of the working group.

6. Other valid documents

Nomination request V03