Work plan
Swissmedic working group with patient and consumer organisations 2021–2024

1. Scheduled meetings for 2021–2024

The working group holds two or three half-day meetings a year. Additional half-day meetings or workshops can be organised if required.

2. Introduction

2.1 Background

Swissmedic started its partnership with patient and consumer organisations in early 2014 in a bid to identify this stakeholder group's needs and concerns at an early stage and as a way of obtaining – at first hand wherever possible – information on their experience of using therapeutic products through contact with representative organisations.
To this end, Swissmedic set up a working group in May 2014, comprising representatives from patient and consumer organisations and members of Swissmedic. The principles underlying the partnership were laid out in a set of rules (as published on the Swissmedic website at: https://www.swissmedic.ch/swissmedic/en/home/about-us/nationale-zusammenarbeit/collaboration-with-patient-and-consumer-organisations.html).
The working group was set up with the aim of offering all stakeholders a forum for sharing information and experiences.

The working group's Terms of Reference defined the following goals for the partnership with patients and consumer organisations:

- To hear, take on board and, if appropriate, incorporate into Swissmedic's processes the experiences of patients and consumers in connection with relevant issues associated with medicinal products and medical devices. Swissmedic uses the working group as a platform for feedback.
- To enable Swissmedic to provide target group-appropriate information to improve patients' and consumers' knowledge of the Agency's tasks and competencies.

The working group's four-year pilot phase ended in December 2018. In line with Swissmedic's strategy for 2019 – 2022 (https://www.swissmedic.ch/swissmedic/en/home/about-us/swissmedic--swiss-agency-for-therapeutic-products/strategy.html), the working group became an official standing group in January 2019. In all, the group met 25 times in the period from May 2014 to the end of 2020. As of January 2021, the working group consists of 17 active member organisations, each of which nominates one member and one deputy member.

3. Strategic focus areas of work planning for 2021 – 2024

The working group's aim is to further promote the **involvement** of representatives of patient and consumer organisations in defined areas of Swissmedic's activities. The pilot project "Assessing patient information for the authorisation of certain human medicinal products with new active substances (NA NAS HMP)", which was expanded during 2020 to include indication extensions and variations to medicinal product information, will be fully implemented (see point 5.1). Once Swissmedic has published the first "Public Summary SwissPARs", active involvement in the continuation of activities to provide layperson-friendly summaries of the results will resume (see point 5.2). The authorisation processes in which involvement might be possible will generally be discussed with the representatives of the patient and consumer organisations, taking account of the framework conditions governing cooperation with patient and consumer organisations already in place at partner authorities (see point 6.3).

A further strategic goal is **partnership** with the Swiss branch of the European Patients' Academy on Therapeutic Innovation (EUPATI) and other organisations and initiatives in Switzerland working on patient and consumer organisation involvement or participation and which are tackling issues compatible with those dealt with by the working group. Examples of such organisations include the Council for International Organizations of Medical Sciences (CIOMS) working group "Patient involvement in the development and safe use of medicines" and the "Involving patients and their families" initiative launched by the Swiss Academy of Medical Sciences (SAMS). The aim of so doing is to avoid duplication and to use resources and capacity as efficiently as possible. An ancillary aim of partnership with other organisations and initiatives is to raise the group's **visibility** and increase **awareness** of it.

The individual strategic issues and measures that have been defined are listed below, divided into the categories:

- Information, communication and cooperation
- Involvement in defined areas of Swissmedic's activities
- Regulatory focal issues/workshop topics
- Administrative activities.

Top-priority issues are marked ++.

4. Information, communication and cooperation

1	Issue ++
	Cooperation and dialogue with EUPATI Switzerland
	Measures
	• Share information and review possible support for EUPATI Switzerland activities • Hold shared training sessions on regulatory issues for patient representatives outside the regular meetings of the Swissmedic working group

2	Issue ++
	Seek out cooperation with organisations and initiatives (e.g. CIOMS, SAMS, Swiss Group for Clinical Cancer Research (SAKK)) and federal authorities (e.g. FOPH, FSIO) in Switzerland that are working on patient and consumer organisation involvement.
	Measures
	• Explore the possibility of dialogue with the CIOMS working group • Invite a guest representative from the FOPH/FSIO for certain issues

3	Issue ++
	Early access to innovative medicinal products
	Measure
	• Provide current information on COVID-19 treatments, diagnostics and vaccines and on authorisation and market surveillance processes • Introduce Project Orbis, in which Swissmedic has been an official participant since March 2021 • Provide transparent information on possible adverse effects • Open-label extension studies • Doctor importing non-authorised medicinal products to treat a particular patient (Art. 49 para. 2 MPLO) • “Temporary licence to use medicinal products in accordance with Art. 9b para. 1 TPA” (compassionate use; Art. 52–55 MPLO) • Invite a guest representative from the FOPH: ways of speeding up market access; possibly a representative from the FSIO for the list of medical supplies and devices

4	Issue +
	Swissmedic communications on therapeutic product safety intended for patients, consumers and their organisations as a stakeholder group
	Measures
	• Obtain input from patient/consumer views using selected test examples • Develop a process based on the results of the test examples • Maintain Direct Healthcare Professional Communications (DHPC) distribution list including important communications from abroad

5	Issue +
	Safety of therapeutic products notifications from other countries
	Measures
	• Swissmedic will also provide information on relevant undesirable effects that have occurred abroad and have been communicated via international networks, amongst other channels.

6	Issue
	Visibility and awareness of the working group
	Measures
	• Provide information/give a presentation on the working group at (national and international) events and conferences • Develop a standard slide set to present the working group (in German, French and English) • Develop information material that can be used to present the working group

7	Issue
	Communication within the working group
	Measure
	• Provide timely feedback to the entire working group on involvement-related issues (see section 5) and collect input from the entire working group

8	Issue
	Onward dissemination of information by patient/consumer organisations
	Measures
	• Ensure onward dissemination of important information from Swissmedic, e.g. concerning drug safety, to affected patients/consumers • Discuss how/through what channels information can be disseminated onward and what information from group meetings can be passed on • Develop a procedure based on the outcome of the discussion

5. Involvement in defined areas of Swissmedic's activities

1	Issue ++
	Assessing patient information for the authorisation of certain human medicinal products with new active substances (NA NAS HMP), indication extensions or applications for variations in accordance with the process description
	Measures
	• Evaluate the pilot project that concluded on 31 December 2020 • Implement the pilot project, adapting the process description and, if necessary, the relevant forms. • Present the results at the Swissmedic regulatory round table • Publish on the Swissmedic website and on social media

2	Issue ++
	Public Summary SwissPAR: Involvement in lay person-friendly summaries of assessment results

	Measures
	• Feed patients'/consumers' perspectives into the review of the draft using existing published Public Summary SwissPARs • Obtain patients'/consumers' perspectives on existing SwissPAR summaries

3	Issue ++
	Reporting undesirable effects of therapeutic products
	Measures
	• Improve general awareness of reporting the undesirable effects of therapeutic products • Simplify the options available to patients and consumers for reporting (to Swissmedic) undesirable (side) effects and incidents involving therapeutic products, assessing the results of the CIOMS working group

4	Issue
	Innovation (new technologies, therapeutic approaches, etc.)
	Measure
	• Obtain patients'/consumers' perspective at scheduled Swissmedic innovation round tables

6. Regulatory focal issues/workshop topics

1	Issue ++
	Security of supply and shortages of therapeutic products
	Measures
	• Give a presentation on competencies and interfaces (FOPH, FONES, Swissmedic) • Hold first discussion on whether/how the working group could address this issue

2	Issue +
	Medical devices in Switzerland
	Measures
	• Regulation of medical devices in Switzerland after the conclusion of negotiations with the European Union • Effects of the revision of the Medical Devices and In Vitro Diagnostics Regulation • Clinical trials with medical devices

3	Issue +
	Clinical trials
	Measures
	• Discuss the possibility of involving patients in defining endpoints for pivotal trials, especially patient-reported outcomes (studies submitted to Swissmedic with applications for authorisation of a medicinal product)*

*The endpoints of clinical trials are defined by the trials' sponsors.

For this reason, a pharmaceutical industry representative should be invited along as a guest to talk about this issue, e.g. someone from Interpharma's Clinical Research Working Group.

4	Issue +
	Involving patient and consumer organisations in authorisation processes
	Measures
	• Give a presentation on partner authorities' framework conditions for involvement, including the US Food and Drug Administration (FDA), European Medicines Agency (EMA) and Health Canada • Discuss possible approaches for Swissmedic authorisation processes

5	Issue
	Temporary authorisation versus fast-track authorisation
	Measures
	• Give a presentation on the requirements for temporary authorisation and what this means in specific terms (benefits/possible disadvantages) • Analyse the application of the listed processes to orphan drugs and, if appropriate, define activities to speed up the authorisation of orphan drugs • Support efforts to establish information on and understanding of the concept of "temporary authorisation" among patients and consumers

6	Issue
	Authorisation of human medicinal products under Article 13 TPA (Article 16 to 20 TPO), possibly including changes in the simplified authorisation procedure (Article 14 TPA)
	Measures
	• Give a presentation on the changes valid from 1 January 2019 • Medicinal product information on authorisation by Swissmedic • Effects: faster accessibility for patients/possible risk

7	Issue
	Advertising
	Measures
	• Give a presentation on market monitoring activities for advertising • Marketing authorisation holder's advertising control responsibilities/obligations • Discuss the procedure followed if potentially non-permissible advertising is discovered

7. Administrative activities

1	Issue
	Updating the working group's Terms of Reference
	Measures
	• As needed, if the working group's Terms of Reference have to be revised because of new projects, for example • Publish updated version on the Swissmedic website

2	Issue
	Working group members
	Measures
	• Maintain a list of all working group members at organisation level

	• List of all members: Insert a link to the organisation's web page, where its goals, mission and vision are published • Update the publication on the Swissmedic website • Ensure public transparency on member organisations' vested interests

3	Issue
	Swissmedic stakeholder survey
	Measure
	• Members of the working group take part in the customer survey