

# **Work plan 2025 – 2028 Swissmedic working group with patient and consumer organisations**

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## **1. Introduction**

Swissmedic launched the patient and consumer organisations working group (WG PCO) in 2014.

By working with patient and consumer organisations, Swissmedic can take a differentiated approach to the needs of these central stakeholder groups and tailor communication more effectively to their concerns. At the same time, Swissmedic promotes understanding of its role as a therapeutic products agency, and supports the common interest in patient safety – as set out in its strategic objectives for 2023-2026:

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During working group meetings, Swissmedic informs the PCO members about new and modified processes in the life cycle of therapeutic products, and is available at all times to address their concerns and desired subjects for discussion.

The key focus areas and corresponding measures for 2025 – 2028 are listed below, subdivided into the marked categories of "Information provision" (IP), "Involvement" (I) and "Cooperation" (C).

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<sup>1</sup> Strategic objectives 2023-2026 of the Swiss Agency for Therapeutic Products (Swissmedic) of 16 September 2022, approved by the Federal Council on 9 December 2022

## 2. Key areas

### 2.1 Involvement of PCOs in processes concerned with the life cycle management of therapeutic products.

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. Swissmedic has managed to accumulate relevant initial experience over the past few years. Based on our findings and the experience of Swissmedic's partner authorities, the aim in the years 2025 – 2028 is to optimise existing processes and facilitate the involvement of PCOs in further processes.

1 Involvement of PCOs in the processes associated with the life cycle management of medicinal products.		
	Measures	
	<ul style="list-style-type: none"> <li>Present Swissmedic processes in life cycle management</li> </ul>	IP
	<ul style="list-style-type: none"> <li>Present the partner authorities' framework conditions for involvement in the authorisation processes (including FDA, EMA, Health Canada and MHRA)</li> </ul>	IP
	<ul style="list-style-type: none"> <li>Review the process of "Involvement of patient organisations in the assessment of patient information" with the aim of simplifying the process</li> </ul>	I
	<ul style="list-style-type: none"> <li>Set up a pilot project to obtain input from PCO representatives concerning "Summary reports on authorisation"</li> </ul>	I
	<ul style="list-style-type: none"> <li>Set up a pilot project for the participation of patient representatives in meetings of the Human Medicines Expert Committee (HMEC)                             <ul style="list-style-type: none"> <li>After the end of the HMEC pilot phase: Evaluation and, if applicable, implementation</li> </ul> </li> </ul>	I
	<ul style="list-style-type: none"> <li>Conduct events similar to the FDA's "Patient Listening Sessions" (incl. the drafting of a written summary for the attention of the Swissmedic assessors)</li> </ul>	I
	<ul style="list-style-type: none"> <li>Discuss other possible processes for the involvement of PCOs throughout the life cycle, similar to partner authorities</li> </ul>	C
	<ul style="list-style-type: none"> <li>Produce training materials on individual Swissmedic processes in life cycle management</li> </ul>	C

2 Innovation (new technologies, therapeutic approaches, etc.)		
	Measures	
	<ul style="list-style-type: none"> <li>Provide information on the restructuring of the Innovation Office                             <ul style="list-style-type: none"> <li>Involve PCO representatives where applicable</li> </ul> </li> </ul>	IP
	<ul style="list-style-type: none"> <li>Participation of PCO representatives at the Swissmedic Roundtable Innovation</li> </ul>	C
	<ul style="list-style-type: none"> <li>Involve the working group in drawing up new guidelines (including ICH), e.g.:                             <ul style="list-style-type: none"> <li>Actively forward public consultations</li> <li>Invite representatives to stakeholder meetings</li> <li>Organise a meeting with participating experts</li> </ul> </li> </ul>	C

3 Clinical trials		
Measures		
	• Open-label extension studies	IP
	• Moderate a discussion on the relevance of involving patient representatives in defining endpoints for pivotal studies, including combined studies <sup>2</sup>	C

4 Drug safety communications		
Measures		
	• Add interested working group members to Swissmedic's e-mail lists (Direct Healthcare Professional Communications [DHPC] / drug safety communications)	IP
	• Obtain input from patient/consumer views using selected test examples of DHPCs	I
	• Set up a process for involving PCOs in drafting DHPCs	I
	• Produce training materials for the reporting of adverse drug reactions (ADRs)	C

5 Medical devices		
Measures		
	• Collect information from the regulatory environment	IP
	• Collect information on enforcement (e.g. hospital inspections or targeted campaigns)	IP
	• Collect information on products without an intended medical purpose	IP
	• Discuss the possibility of involving PCOs in processes associated with the enforcement of medical devices regulation	C

## 2.2 Contact with stakeholders and working group representatives

A further strategic goal is partnership with the Swiss branch of EUPATI and other organisations and initiatives in Switzerland working on the involvement and participation of PCOs that are tackling issues compatible with those addressed by the WG. Cooperation can help avoid duplication of effort, use resources and capacity as efficiently as possible, and raise the profile of the WG.

6 Cooperation with various national and international organisations / initiatives and federal authorities in Switzerland working on the involvement and participation of PCOs		
Measures		
	• Information concerning ongoing projects of the International Council for Harmonisation (ICH) that are relevant to PCOs, including the E22 Expert Working Group "General Considerations for Patient Preference Studies"	IP
	• Sharing with organisations / initiatives that deal with the involvement of PCOs (e.g. Swiss Clinical Trial Organisation (SCTO), SAMS, SAKK, SNSF...)	C
	• Invite a EUPATI representative to be a permanent guest at the PCO meetings	C
	• Invite a guest representative from the federal authorities (e.g. FOPH, FSIO) for certain issues	C

<sup>2</sup> [Combined studies](https://www.swissmedic.ch) (swissmedic.ch)

7 Visibility and awareness of the working group		
	Measures	
	<ul style="list-style-type: none"> <li>Provide information/give a presentation on the working group at (national and international) events and conferences</li> </ul>	C
	<ul style="list-style-type: none"> <li>Develop information material that can be used to present the working group</li> </ul>	C

### 2.3 Administrative activities

The administrative activities listed below were already part of the Work Plan 2021 – 2024 and will be continued as such. These measures are not categorised, and Swissmedic's Stakeholder Engagement Division is responsible for their implementation.

8 Administrative activities		
	Measures	
	<ul style="list-style-type: none"> <li>Maintain an updated list of all working group members at organisation level</li> </ul>	/
	<ul style="list-style-type: none"> <li>List of members: Insert a link to the organisation's web page, where its goals, mission and vision are published</li> </ul>	/
	<ul style="list-style-type: none"> <li>If required: Update the publications on the Swissmedic website</li> </ul>	/
	<ul style="list-style-type: none"> <li>Ensure public transparency on member organisations' vested interests</li> </ul>	/
	<ul style="list-style-type: none"> <li>Members of the working group take part in the customer survey</li> </ul>	/
	<ul style="list-style-type: none"> <li>Regular updating of information material that can be used to present the working group</li> </ul>	/