NEWS FROM swissmedic

INVOLVING PATIENTS AND CONSUMERS IN SWISSMEDIC'S REGULATORY PROCESSES: FROM INFORMATION SHARING TO PARTICIPATION

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The COVID-19 pandemic has highlighted the value of public engagement as a way of building confidence in innovative treatments, diagnostics, and vaccines for coronavirus-induced disease that have been brought to market readiness within a very short space of time. Developing public trust and engagement extends beyond providing transparent research results and evidence-based information to creating a framework for a dialogue that includes patients' perspectives. Whereas frameworks exist in the US, the UK, the Netherlands, and Germany, systematic patient involvement in Switzerland's healthcare system is still taking root. Even though Swiss policymakers acknowledge the importance of stakeholder involvement in healthcare, tangible, overarching forms and systems of participation are only gradually being rolled out. Swissmedic, the Swiss Agency for Therapeutic Products, is also tackling the issue of how to integrate patients and the public into its regulatory processes. As it responds to this issue, Swissmedic aims to not only adopt current approaches but also actively create solutions that give patients a voice and incorporate their experiences and concerns into regulatory processes wherever possible.

A Google search for "patient and public involvement" or "patient engagement" results in over six million hits. This demonstrates that a widespread effort exists to involve patients and the public in the entire development and life cycle of therapeutic products. During the research and development stages, patient involvement can promote projects that are geared to patients' needs. Involving patients in the approval process can help regulatory decision makers address any stakeholder needs that have remained unmet. Moreover, the market surveillance process benefits from user engagement: when product users identify warning signals early on, regulatory authorities can quickly initiate safety measures.

SWISSMEDIC'S APPROACH TO PATIENT ENGAGEMENT

Regulatory authorities in different countries take different approaches to patient and public involvement. Whereas US patients or their representatives have seats on decision-making bodies at the Food and Drug Administration (**FDA**), other regulatory authorities involve patients in decision-making through patient interest groups or they consult patients during their decision-making processes. Compared to other countries, Switzerland is still in the early stages of finding tangible solutions that transform passive recipients and users of therapeutic products into active, well-informed participants.

As Switzerland's regulatory authority for therapeutic products, Swissmedic considers collaboration with all national and international stakeholders to be an essential part of fulfilling its legal mandate and reaching the defined objectives set out in its strategic goals. As the users and beneficiaries of safe therapeutic products, patients are considered important stakeholders in Swissmedic's national network. Swissmedic's cooperation with patients is rooted in the concepts of information exchange and active involvement in specific areas of its activities.

PARTNERING WITH PATIENTS: ONGOING AND FUTURE PROJECTS

Early in 2014, Swissmedic launched a pilot partnership project that established a regular dialogue with patient and consumer organisations in order to more effectively take into account the needs and concerns of this stakeholder group and to obtain timely information on patients' experiences with therapeutic products. The newly formed Swissmedic Patient and Consumer Organisations Working Group met three to four times a year to discuss a range of key regulatory topics, such as the authorisation requirements and process for biosimilars, the legal basis for and relevant characteristics of patient information leaflets, and various aspects of the – at that time the new version (from 1 January 2014) – Human Research Act, including stakeholders' initial experience with its implementation.

In 2016, the project's pilot phase was extended for an additional two years based on the results of a survey of the working group and members' willingness to continue actively participating in the working group. The survey indicated that the project's goal of exchanging information had been achieved. However, the involvement of patient representatives in defined areas of Swissmedic's activities still fell short of expectations. After everyone involved in the working group unanimously agreed that it had made a valuable contribution to participation processes in the regulatory environment, Swissmedic decided to continue this forum for exchanging information and experience beyond its four-year pilot phase. Between May 2014 and the end of 2020, the working group met a total of 25 times. It continues to meet regularly and currently includes 18 active member organisations.

In the upcoming years, Swissmedic will focus on the challenge of identifying in which regulatory processes patient and consumer participation is feasible and worth pursuing. To actively address this issue, Swissmedic launched a pilot project in July 2018 to incorporate patients' perspectives into the process of reviewing patient information leaflets. By the end of that year, the project's first candidate for a patient review had already been identified. In 2020, the pilot project was expanded to include additional indications and variations. The project is currently being fully implemented, giving all applicants an opportunity to involve patient organisations in the review of their patient information leaflets within Swissmedic's assessment process.

In addition, Swissmedic will relaunch a project in which patient representatives have the opportunity to review summaries of Swiss Public Assessment Reports (**SwissPARs**) that should be easily understood by laypeople (these Public Summary SwissPARs are available on Swissmedic's website).

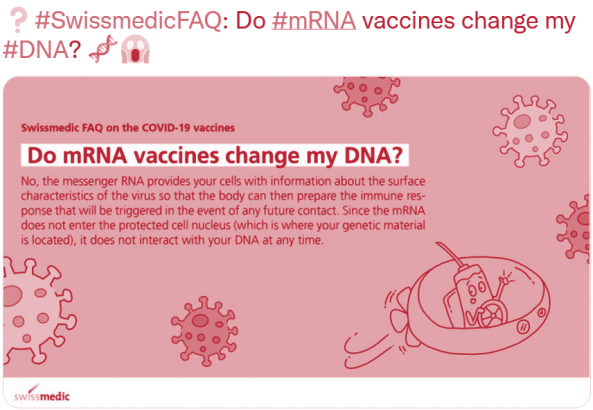
PARTNERING WITH LIKE-MINDED ORGANISATIONS AND INITIATIVES

Two of the aims stated in the updated ~~2021–2024~~ work plan of Swissmedic's Patient and Consumer Organisations Working Group are to raise awareness of the group and increase its visibility. An additional goal is to partner with organisations and initiatives that are working on participation projects in Switzerland in areas aligned with the working group's activities. Swissmedic's partners include organisations such as the European Patients' Academy on Therapeutic Innovation Switzerland (**EUPATI CH**), the Patient Involvement in Development and Safe Uses of Medicines working group from the Council for International Organizations of Medical Sciences (**CIOMS**), and the Patient Advisory Board of the Swiss Group for Clinical Cancer Research (**SAKK**), an organisation that seeks to gather the experience and concerns of cancer patients and their families and more effectively channel them into research. These partnerships help to avoid duplication and to use existing resources and capacities as efficiently as possible.

Like our partner authorities, Swissmedic supports patient engagement activities of international forums. For example, it contributed to the Reflection Paper on Patient-Focused Drug Development issued by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (**ICH**). This reflection paper identifies key areas in which incorporating the patient's perspective could improve the quality, safety, and efficiency of medicinal product development and thus inform regulatory decision-making.

INFORMING AND ENGAGING THE PUBLIC THROUGH SOCIAL MEDIA

In response to social media's growing influence on public opinion, Swissmedic established its social media presence in May 2020, which it continues to develop and expand. Swissmedic's social media platforms have become important sources of information for the public, especially during the COVID-19 pandemic. In the future, these media channels will include even more images, infographics, and videos and will be more interactive. This will allow Swissmedic's social media platforms to be more than just another broadcasting opportunity – they can become key tools for fostering a dialogue with the public and patients.



A FRAMEWORK FOR THE FUTURE

Patient and public involvement in healthcare is increasingly being accepted as stakeholders' right to contribute to decision-making processes. For in the end, patients are the beneficiaries of healthcare and are therefore important stakeholders in the regulatory process. Plenty of work awaits Swissmedic in the next few years as it continues to put into place its framework for partnering with patients and the public and incorporate their perspectives into its processes. Swissmedic is convinced that this work will lead to greater benefits for patients and the public.