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Swissmedic is well-equipped to address the challenges in the ATMP field and is ready to help shape the future of drug regulation

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Raimund Bruhin discusses Swissmedic's participation in cross-border regulatory initiatives such as the Access Consortium and Orbis and its efforts to support the Global South in developing regulatory standards. Bruhin also addresses the regulatory challenges posed by new technologies, such as Advanced Therapy Medicinal Products (ATMP), and Swissmedic's strategic objectives, especially in digital transformation and further international cooperation.

Can you give us an overview of your role and Swissmedic's specific responsibilities?

Swissmedic is the national regulatory authority for therapeutic products in Switzerland, with the legal mandate of ensuring the quality, safety, and efficacy of medicines, vaccines, and medical devices. Unlike some other regulatory bodies, Swissmedic's mandate does not include procurement, pricing, or reimbursement for medicines, nor the antibiotic strategy; these fall under the responsibility of the Federal Office of Public Health (FOPH). Swissmedic's core responsibilities lie in the authorisation, licensing, and surveillance of medicines, as well as the market surveillance of medical devices. Additionally, Swissmedic enforces criminal law in the therapeutic products sector, representing cases in court up to the federal level and implementing criminal measures within this sector.

The pandemic placed significant demands on actors across the pharmaceutical value chain, including regulatory authorities. What lessons have you drawn from this challenging time that continue to impact Swissmedic's work today?

The pandemic was a formative period that reinforced the importance of swift and effective communication—both nationally and internationally—and demonstrated that international collaboration, particularly in times of crisis, brings substantial added value. An example of this is our close cooperation with the International Coalition of Medicines Regulatory Authorities (ICMRA).

Second, the crisis taught us organisational flexibility and regulatory agility, serving as essential preparation for new challenges. We introduced the Rolling Submission process, which, while resource-intensive, allowed us to maintain focus, prioritise, and optimise processes during crises. This measure enabled us to be among the first three countries worldwide to authorise mRNA vaccines.

Third, we established internal task forces and optimised our crisis management to direct resources toward managing the pandemic while continuing our daily operations without disruption. These challenging times demanded extraordinary dedication and teamwork from our employees, who tackled daily challenges while finding creative solutions to increase efficiency and maintain high-quality work. Both individuals and the organisation exceeded expectations.

According to a recent survey, Swissmedic's approval timelines lag behind those of the EMA or FDA. What factors contributed to this delay, and are there already measures in place to speed up the process?

Primarily, it is important to understand that various publications comparing international approval timelines for innovative medicines use different data foundations. These differences stem from distinct inclusion criteria, which can heavily influence the results. When comparing Swissmedic's approval times with those of the EMA or FDA, a degree of caution is therefore advisable. On the international level, the CIRS study serves as the primary reference for comparing regulatory authorities. This study, which analysed the approval timelines for all new active substances at Swissmedic, EMA, and FDA, demonstrates that Swissmedic performs well by comparison. For standard procedures, the average approval time at Swissmedic was 441 days, compared to 453 days at EMA. These results show that we are even slightly faster than EMA; however, FDA remains ahead with an average of just 333 days.

It’s important to recognise that the overall timeline measured combines Swissmedic’s processing time with the so-called “company time,” the period companies require to respond to questions. According to the “stop the clock” principle, we always account for these exchange phases, as they often lead to delays. A long approval timeline, therefore, does not automatically mean that a regulatory authority is inefficient. It is equally possible that delays on the company’s side prolong the approval process. Swissmedic is not in a position to make process times transparent for individual cases..

Together with the industry, Swissmedic is conducting a second major study to measure process performance. The higher level of detail in this analysis helps us better understand stakeholder expectations and preferences, identify process weaknesses, and make targeted improvements. We are continuously optimising our processes to remain competitive and ensure Swiss patients have rapid access to important therapies. Feedback and comparative studies like this ensure that our processes and capacities are consistently aligned with the needs of the industry and patients.

Some stakeholders have noted that, while Swissmedic’s overall approval processes are efficient, discussions regarding product labeling often take more time. Is this still a challenge, or have improvements been made?

Accelerating the speed of the labeling phase is a strategic goal for Swissmedic. In September 2024, we implemented measures to streamline this phase. One significant change that is about to take effect is that Swissmedic will reduce its review time for labeling verification rounds from 90 to 45 days, expediting the completion of procedures. Additionally, we simplified the coordination process between Swissmedic and applicants, encouraging more flexible dialogue. Applicants can also contribute to time savings by reducing their response times. Overall, we are doing everything possible to speed up our processes so that Swissmedic can make medicines available to patients as quickly as possible. We expect these measures to significantly shorten the labelling phase and improve our overall efficiency.

What can you tell us about Swissmedic’s participation in the Access Consortium? How does this initiative affect Swissmedic and the companies that rely on Switzerland as their primary approval market?

The Access Consortium, founded in 2007, has developed into a significant international collaboration, bringing together regulatory authorities from Switzerland, Canada, Australia, Singapore, and the United Kingdom to accelerate the approval of medicines across multiple continents.

Initially, establishing a common foundation was challenging due to differing regulatory processes and requirements in the participating countries. However, sufficient harmonisation has been achieved over time, and since 2018, notable progress has been made by including new active substances alongside generics, resulting in a substantial increase in approvals.

A standout feature of this collaboration is true work-sharing, where partner authorities assess specific modules of the scientific documentation. This sharing of work enables shorter processing times and minimises the submission gap, leading to quick and efficient approvals. The scientific exchange within the Access Consortium, including joint pipeline meetings, allows us to continually expand our expertise. Additionally, the newly introduced “Promise” pathway offers companies an optimised, faster approval pathway within the consortium.

For companies choosing Switzerland as their primary approval market, the Access Consortium offers considerable time savings and enhanced flexibility by providing access to a broad market of over 150 million potential patients. This close international cooperation enables the rapid, targeted approval of medicines while fostering knowledge exchange and technological innovation.

Could you elaborate on the international collaborations that Swissmedic maintains and how they strengthen Switzerland’s position in the global healthcare and pharmaceutical sectors?

Recently, we co-hosted the ICMRA ‘Rare’ Symposium on Orphan Diseases in Lugano with the EMA and FDA. This gathering brought together experts from around the world to discuss and reassess the definition and regulation of orphan drugs. A key topic was distinguishing between truly rare diseases and so-called “orphan-like” diseases, which may require new criteria to update regulations in this area. ICMRA would be well-suited to address this, as it is widely recognised that such topics can only be effectively tackled through international collaboration.

Our participation in the EMA’s Open Initiative during the pandemic was also highly significant. This project enables regulatory authorities to attend meetings of the Committee for Medicinal Products for Human Use (CHMP). During the COVID-19 pandemic, this was crucial, as the exchange on

vaccine evaluation and adverse drug monitoring became central to our work. At Swissmedic, we emphasise, “We are not an island,” and international dialogue is essential for effectively managing global health crises.

Through initiatives like ICMRA, we stay up to date with developments and can contribute our regulatory expertise at the global level. This allows us to help shape new standards and procedures that influence the global pharmaceutical market. In the area of rare diseases, in particular, we have seen that global collaboration is essential to meet patient needs.

In the area of drug crime and misuse, international cooperation is equally indispensable. Criminal networks dealing in illegal drugs are not limited by borders, so Swissmedic works with partner authorities abroad to ensure the safety and integrity of the pharmaceutical market.

Other supranational organisations in which we actively participate include the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the International Pharmaceutical Regulators Programme (IPRP), and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme). We are also increasingly involved in the medical device sector, including the International Medical Device Regulators Forum (IMDRF).

All these collaborations give us access to global networks and allow us to help shape standards and regulatory frameworks for innovations and new technologies worldwide, which in turn benefits Switzerland’s therapeutic product industry.

What is the Orbis Initiative and how does it strengthen Switzerland’s position in the global pharmaceutical sector?

Through the Orbis Initiative, we work closely with the FDA, engaging in scientific exchange to conduct parallel approvals of cancer drugs, significantly reducing approval times. While resource-intensive, this initiative shortens the submission gap and brings substantial benefits to patients by granting faster access to life-saving therapies.

Our participation in international initiatives like Orbis enhances Switzerland’s global influence by providing rapid access to innovative treatments.

Swissmedic also shares its expertise with regulatory authorities in developing countries and has launched the Marketing Authorization for Global Health Products (MAGHP)

procedure for this purpose. What global role does Swissmedic play today?

Swissmedic has established itself as a leading international regulatory authority, deeply embedded in the global networks mentioned. A key component of our global role in supporting the Global South in developing regulatory standards is the MAGHP procedure. This initiative allows us to share our expertise and knowledge with regulatory authorities in low- and middle-income countries, as well as with the WHO. We invite these authorities to participate in the assessment of medicines, especially those targeting diseases that disproportionately affect the Global South. The goal is to promote international standards and support these countries in building their own regulatory capacities.

Since 2014, we have been active in this area on behalf of the Federal Council, working closely with WHO to improve access to essential medicines. We are also supporting the development of an African Medicines Agency (AMA), similar to the EMA, for African countries. This commitment helps African and Asian countries establish a robust regulatory system, allowing them to meet high international standards, ensuring safety and quality in the therapeutic products market.

Thus, Swissmedic is not only a national player but also plays a prominent role in the global health landscape by promoting knowledge exchange, best practices, and improving access to essential medicines internationally.

What does it mean for Swissmedic to be one of the first three WHO-listed regulatory authorities in the world?

This recognition has primarily resulted in greater global visibility for Swissmedic within the health sector, due to WHO’s extensive publication of this achievement. This acknowledgment has further solidified Swissmedic’s position as a globally respected authority.

Since this recognition is still recent, it is too early to discuss long-term effects. However, it’s likely that Swissmedic will increasingly serve as a reference for other countries. In collaboration with WHO, we offer a training program to help other regulatory authorities build and enhance their competencies, and interest in these trainings may continue to grow. Additionally, we have received requests from partner authorities seeking our support in their own WHO listing assessments, which further strengthens our expertise and international network.

We anticipate that Swissmedic’s decisions will increasingly serve as a basis for decision-making by other regulatory bodies, the WHO Prequalification Program, and procurement agencies. This

recognition from WHO is not only an endorsement of our past work but also an incentive to expand our role as a leading international regulatory authority and actively contribute to improving global health.

The new generation of innovative medicines, such as cell and gene therapies, are posing challenges for regulators around the world. What role does your department for Advanced Therapy Medicinal Products (ATMP) play in this area?

The development of innovative therapies, particularly in the field of ATMP, presents exciting new challenges for Swissmedic. To meet these demands, we have established a specialised department that allows us to quickly and safely approve these advanced medicinal products, as well as continuously refine our expertise and processes in this highly innovative field.

Swissmedic is prepared to support cutting-edge technologies and expedite the approval of these products. This initiative sends a strong signal to the industry: we have the competencies needed to regulate and promptly approve these novel therapies, and we are committed to taking a leading role in this area. This includes cell and gene therapies, CAR-T cell therapies, mRNA-based vaccines, and tissue engineering.

In summary, Swissmedic is well-equipped to address the challenges in the ATMP field and is ready to help shape the future of drug regulation.

What strategic goals do you have for the coming years, and what developments should we watch for in Swissmedic?

Swissmedic has ambitious goals for the years ahead. Our overarching objective is to remain “Fit for Mission,” meaning we must continue to fulfil our legal mandates despite rapid technological advancements. At the same time, we aim to be “Fit for Future” by promoting innovative regulatory approaches, especially in the ATMP sector. We want to strengthen our skills and knowledge and shape global regulatory frameworks for the benefit of our patients and stakeholders in Switzerland.

Swissmedic is driving its digital transformation forward. Our goal is to soon adopt state-of-the-art digital technology and become a data-centric authority. For example, in August 2024, we successfully introduced a new cloud-based medical device database. This is one step toward becoming one of the top five digitally advanced regulatory authorities. This modernisation is

essential not only for interoperability with other regulatory authorities but also for effective collaboration with the industry.

Another key aspect of our strategy is promoting global harmonisation and cooperation, particularly in the pharmaceutical and medical technology sectors. We are actively committed to international collaboration and work closely with other regulatory authorities to shape evidence-based future approvals. This includes contributing to global policy development, especially regarding innovative technologies such as artificial intelligence applications in the pharmaceutical and manufacturing processes.

To summarise, our strategic goals for 2023 to 2026 focus on protecting human and animal health through high-quality, safe, and effective therapeutic products. We strive to be perceived as a trustworthy authority by the public while supporting the development of novel therapies to accelerate access to innovative treatments. With these objectives in mind, we are working to shape the regulatory framework of the future and sustainably improve healthcare.

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