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Switzerland has long been recognised as a centre of scientific excellence, and in the field of Advanced Therapy Medicinal Products (ATMPs), it is quickly becoming a regulatory trailblazer. In this in-depth conversation, Julia Djonova, Head of ATMPs at Swissmedic, shares how the agency is positioning itself at the forefront of global innovation through flexible regulatory frameworks, strategic early engagement, and a steadfast commitment to scientific integrity.

What professional path led you to take charge of Advanced Therapy Medicinal Products (ATMPs) regulation at Swissmedic?

I trained as a medical doctor in cardiology before pursuing a doctorate in the same field at the University of Bern. This was followed by academic and research roles at the Universities of Lausanne and Fribourg, where I was also involved in medical education. My regulatory career began at the Federal Office of Public Health (FOPH), where I conducted inspections in areas such as transplantation and blood products, and contributed to establishing Switzerland's national haemovigilance system.

In 2002, I joined Swissmedic following its creation through the merger of the Intercantonal Office for the Control of Medicines with the FOPH's Therapeutic Products Division. I initially worked as a clinical assessor while continuing my engagement in transplantation oversight. The introduction of

the Swiss Transplantation Act in 2007 marked a significant milestone: it prompted the formation of a specialised regulatory group to evaluate emerging therapies derived from cells and tissues that did not fall under traditional transplant definitions. These products required a novel regulatory approach, and I have been involved from the outset in building the frameworks and expertise necessary to support their evaluation.

How did Switzerland's early legislation anticipate the European ATMP framework, and what changes has this brought to the regulatory landscape?

Prior to the Transplantation Act's implementation in 2007, Switzerland operated under a fragmented cantonal system, which created inconsistencies in transplantation practices across the country. The Act provided a unified national framework, harmonising ethical standards, consent protocols, and clinical procedures, and crucially, it laid the legal foundation for regulating a new class of therapies based on manipulated human cells and tissues.

Because the Swiss legislation came into force ahead of the European Union's 2008 Regulation on ATMPs, we introduced the designation "standardised transplants" to describe manipulated cell- and tissue-based therapies processed under defined protocols.

The legislative shift introduced a requirement for marketing authorisation, even for products already applied to patients but for which the safety and the benefit have not been verified until that moment. In response, Swissmedic established a dedicated team to assess the quality, safety, and efficacy of these therapies. What began as a group of just three individuals has now grown to 26 specialists, reflecting the increasing scientific complexity, innovation pace, and strategic regulatory importance of ATMPs within the Swiss healthcare system.

Although currently in Switzerland the terminology "ATMP" is used in daily practice, this Swiss-specific term "standardised transplants" will be replaced with the new Therapeutic Products Act which is currently under revision. By specifying definitions and criteria in its national legislation, Switzerland will ensure maximum harmonization within the international regulatory framework. The modification of the legislation aims to improve the regulatory environment, support the ATMP development and ensuring Switzerland remains an attractive site for innovation.

What distinguishes the structure and mission of Swissmedic's ATMP division?

From its inception, Swissmedic’s ATMP division was designed to reflect the unique specificity of advanced therapies. While classified in principle as medicinal, these products involve living cells and tissues or viral vectors and are highly complex because of variability, manufacturing challenges, quality controls and specific criteria for efficacy/safety and therefore require a tailored level of scrutiny. Departing from the agency’s conventional process-based model, which separates quality, clinical, and regulatory assessments, the ATMP group was conceived as an integrated, multidisciplinary unit.

This structure, uniting experts from regulatory, preclinical, clinical, quality, and inspection domains, fosters close daily collaboration and allows for collective benefit-risk evaluations, an approach particularly valuable in situations where data may be incomplete or highly specialised. As the scientific landscape has evolved, with increasingly sophisticated technologies such as tissue engineering, stem cell technologies, gene editing technologies and the development of novel viral vector systems in order to treat complex, life-threatening rare and ultrarare indications, the division has expanded accordingly. The ATMP Division continues to adapt in response to innovation in manufacturing methods, scientific tools, and therapeutic mechanisms, ensuring that Swissmedic remains equipped to meet the demands of this rapidly advancing field.

How does Swissmedic ensure it builds and maintains the advanced scientific expertise needed to evaluate such a diverse and rapidly evolving class of therapies?

Regulating ATMPs in a constantly evolving landscape requires more than structural adaptation; it demands sustained, deliberate investment in people. Swissmedic approaches this by recruiting experts with strong scientific foundations in fields such as gene therapy, molecular biology, and biochemistry, selected with exceptional care due to the specialised nature of the work. These professionals are continuously trained to ensure they remain fully aligned with the latest developments. The sheer diversity and complexity of ATMPs necessitate that assessors maintain cutting-edge knowledge, which is supported not only through formal training programmes but also through daily interdisciplinary collaboration across clinical, quality, regulatory, and inspection functions. For example, inspectors often gain early insight during manufacturing site visits and feed that perspective directly into the regulatory review process, enriching the overall evaluation through real-time knowledge exchange.

Beyond internal collaboration, Swissmedic benefits from strong academic and international engagement. One team member holds a part-time teaching position at a Swiss university,

maintaining close ties to research while supporting knowledge transfer in both directions. Through its Innovation Office, Swissmedic also engages actively with start-ups and research institutions, ensuring early awareness of emerging technologies. On the global stage, the agency plays an influential role in multilateral regulatory dialogue, contributing to international working groups and discussions on still-evolving topics such as decentralised manufacturing and personalised medicine. This collaborative posture proved particularly valuable during the COVID-19 pandemic, when Swissmedic contributed to global efforts in determining appropriate regulatory standards for variant-adapted mRNA vaccines, helping to strike the right balance between safety, immunogenicity, and scientific feasibility in the absence of precedent.

How does Swissmedic approach the classification of novel therapies like CAR-T, particularly when legal and scientific frameworks overlap or remain ambiguous?

Classifying novel therapies is often a complex task, particularly as innovation outpaces legislation and regulatory frameworks evolve in parallel. While CAR-T therapies are clearly recognised as ATMPs due to their genetic modification and associated risk profile, their underlying biological mechanisms resemble transplant procedures originating from blood cells and historically fall under a different legal framework. In Switzerland, the classification process is currently shaped by two overlapping legal instruments: the Transplantation Act and Article 49 which transmits the competences of the Therapeutic Products Act and its ordinances.

However, as CAR-T therapies are derived from blood cells but involve genetic manipulation, they were in the past explicitly excluded from the scope of the Transplantation Act. With appropriate modifications of that Act, it was possible to align with the international regulation, to classify them as ATMPs and subject to rigorous evaluation to ensure their quality, safety, and efficacy. This is particularly crucial given the risk of serious side effects, such as the cytokine release syndrome or off-target effects.

While the status of CAR-T is now clearly defined, other innovative therapies occupy more ambiguous regulatory territory. Products such as exosomes, stromal vascular fractions, depending on their level of manipulation and intended use, often resist straightforward categorisation. In some cases, therapies initially developed for cosmetic applications fall within Swissmedic’s remit, further complicating regulatory decisions. These cases require careful regulatory and scientific review, close engagement with developers, and consideration of international regulatory consensus. Anticipated amendments to the Swiss therapeutic products legislation will help resolve

these ambiguities by formally recognising ATMPs as medicinal products, streamlining regulatory procedures, and easing compliance burdens. Furthermore, flexible ways are being sought to reduce the legislative gap in the practice for certain products, such as oligonucleotides. For instance, companies working with such products are currently navigating the regulatory process under dual establishment licences. However, an adapted procedure allows them to benefit from a single authorisation pathway, facilitating regulatory clarity and, as a priority, the companies' operational efficiency.

How does Swissmedic determine the treatment line placement for ATMPs, and to what extent does its approach align with international regulatory practice?

Determining the appropriate placement of ATMPs within the treatment paradigm involves careful consideration of both safety and efficacy, particularly given the complex risk/benefit profile associated with these products. Unlike the FOPH, Swissmedic does not factor in economic dimensions such as reimbursement, and its decisions are based strictly on the quality, preclinical and clinical data submitted by the applicant.

While Swissmedic often participates in reliance procedures and remains broadly aligned with international counterparts, its evaluations are conducted independently. When data from pivotal trials clearly support first-line use and demonstrate a favourable benefit-risk profile relative to standard therapies, approval may be granted.

However, where evidence is inconclusive or where safety concerns are significant and outweigh the benefit, Swissmedic may take a more conservative stance. Although the agency recognises the ethical imperative to expand access to advanced therapies for patients with limited alternatives, it remains committed to ensuring that any product entering the market delivers benefit compared to the potential risks and does not expose patients to unjustifiable harm. In practice, Swissmedic's decisions align closely with those of other agencies such as EMA (European Medicines Agency) or US FDA, with in general only minor divergences in indication language or application in exceptional cases.

How does Swissmedic manage early regulatory approvals for ATMPs that are still under clinical investigation, especially in cases of rare or high unmet medical need?

Given the urgency often associated with ATMPs – many of which target rare diseases or conditions lacking therapeutic alternatives – Swissmedic has adopted a regulatory approach that allows for early market access without compromising safety standards. In such cases, conventional timelines based on large-scale Phase III trials are frequently unworkable, as patient populations are limited and the medical need is immediate. Swissmedic can grant conditional approval when preliminary clinical data, although incomplete, suggest a favourable benefit-risk profile and when additional confirmatory data are expected in the near term.

This pathway is subject to strict conditions: the therapy must address a genuine unmet need, no comparable treatment should be available, and follow-up evidence must be delivered, typically within two years. Long-term safety monitoring is also a prerequisite, especially for gene therapies, where surveillance may extend for 15 to 20 years. Forthcoming revisions to the national therapeutic products legislation will reinforce these provisions by introducing more defined obligations around both safety and efficacy follow-up, ensuring that the flexibility of early access is matched by sustained regulatory oversight. This model reflects Swissmedic's continued commitment to enabling timely innovation while safeguarding public health through rigorous post-authorisation controls.

What ethical boundaries and considerations guide Swissmedic's evaluation of gene therapies and other advanced technologies?

While the scientific promise of ATMPs, such as gene therapies, is immense, it is accompanied by complex bioethical questions, particularly as these technologies become more prominent in clinical care. Swissmedic addresses such concerns by embedding ethical awareness within its scientific evaluation, especially when assessing novel modalities like CRISPR-Cas9, which hold the potential to transform previously untreatable diseases. The agency assesses whether the therapeutic benefit justifies the risk, particularly in light of limited long-term safety data. At the same time, Switzerland's legal framework sets clear ethical boundaries: the Constitution explicitly prohibits germline modifications, including interventions on embryos and reproductive cells, providing a firm line that cannot be crossed.

Although Swissmedic does not carry formal responsibility for ethical review, it collaborates closely with national ethics committees, which are tasked with evaluating the ethical dimensions of clinical trials and investigational products. This division of responsibilities ensures that products entering the market at a later stage are not only scientifically robust but also ethically permissible, allowing

Swissmedic to regulate in a manner that is both technically sound and socially responsible.

What role does Swissmedic play in ensuring the manufacturing quality of ATMPs within Switzerland's increasingly decentralised and complex production environment?

As Switzerland continues to establish itself as a leading centre for the production of complex biologics, Swissmedic plays a pivotal role in overseeing the quality of ATMPs through rigorous on-site inspections conducted by dedicated Good Manufacturing Practice (GMP) specialists. These inspections are applied uniformly, whether the products are manufactured at industrial scale or prepared in smaller, academic settings under hospital exemption schemes currently under discussion. Regardless of volume or context, the agency maintains that the quality of ATMPs must be fully assured for every patient. The complexity of these therapies, along with their sensitive manufacturing processes, demands strict adherence to GMP requirements, which are enforced without compromise.

At the same time, Swissmedic recognises the need for regulatory flexibility, particularly as decentralised manufacturing models evolve. The agency is actively engaged in international regulatory discussions, notably through the International Coalition of Medicines Regulatory Authorities (ICMRA), to refine global standards and clarify expectations for emerging manufacturing practices. To support innovation at an early stage, Swissmedic also offers Scientific Advice Meetings, helping developers understand regulatory expectations before GMP infrastructure is implemented. This proactive and collaborative approach ensures that quality is embedded from the outset, reinforcing Swissmedic's dual commitment to facilitating therapeutic innovation while safeguarding patient safety through uncompromising quality standards.

How is Swissmedic deepening early engagement with biotech developers, and what steps are being taken to streamline communication and regulatory readiness?

Early and sustained engagement with emerging biotechs is essential to Swissmedic's ability to anticipate and respond to innovation. Through the establishment of its Innovation Office, the agency has formalised its efforts to connect proactively with start-ups, academic researchers, and other stakeholders at the earliest stages of development. This comprises tailored advice on preclinical and quality data, clinical trial design, data requirements, etc. These interactions create a valuable two-way exchange: Swissmedic gains timely visibility into pioneering therapeutic

concepts, while innovators receive early guidance on regulatory and scientific expectations, well before development paths are locked in. An approval in Switzerland as an established authority can serve as a launchpad for other countries.

Although the process continues to evolve, and there is always scope for refinement, Swissmedic embraces this as part of a broader learning cycle. Regular feedback mechanisms, including stakeholder surveys, inform internal improvements and help align procedures with industry needs. Importantly, the agency has observed a marked increase in the number of companies actively seeking scientific advice meetings, reflecting a growing appreciation for early dialogue and its role in preventing misalignment or regulatory delays. Swissmedic remains strongly committed to fostering a transparent, collaborative environment in which scientific progress and regulatory clarity go hand in hand.

What strategic position does Swissmedic aim to hold within the global ATMP landscape, and how is the agency evolving to support that ambition?

Swissmedic aspires to be more than a regulatory gatekeeper, it aims to serve as an enabler of innovation and a strategic hub for the development and early authorisation of ATMPs. Leveraging Switzerland’s well-established infrastructure for clinical research – particularly in early-phase trials – the agency has introduced measures to enhance its attractiveness to both academic and commercial sponsors. These include reduced fees for academic institutions, efforts to streamline approval timelines, and a commitment to procedural flexibility, particularly for innovative products requiring tailored regulatory approaches. ATMPs, by their very nature, provide opportunities for Swissmedic to apply risk-based methodologies and adaptive evaluation models, allowing it to act swiftly and responsibly without compromising quality or patient safety.

This ambition is underpinned by a strong sense of responsibility and a high level of technical expertise. Reinforced by its recognised competence and collaborative relationships with international regulators such as EMA, Swissmedic’s global standing positions it as a trusted authority capable of facilitating first-in-class authorisations. The agency continues to refine its procedures to better align with the needs of a rapidly evolving therapeutic landscape, striving to combine scientific excellence with regulatory agility. With its depth of knowledge, international credibility, and openness to innovation, Swissmedic is firmly committed to shaping a regulatory environment that attracts cutting-edge therapies while maintaining the highest standards of safety and efficacy.

What concluding message would you share regarding Swissmedic’s vision for ATMPs?

Swissmedic views the continued development of ATMPs as both a responsibility and an opportunity, one that calls for regulatory ambition matched by scientific integrity. The agency is driven by the transformative promise of these therapies and remains deeply committed to fostering an environment where innovation can advance safely, efficiently, and responsibly. With a culture grounded in continuous improvement, Swissmedic is constantly refining its processes, expanding its expertise, and strengthening its engagement with academic and industry stakeholders. The expansion of its ATMP unit and the creation of structured outreach channels are a testament to this vision, reflecting a conscious effort to remain at the forefront of scientific and regulatory progress. Ultimately, Swissmedic seeks not merely to oversee innovation, but to play an active role in enabling it, positioning itself as a forward-thinking, trusted partner in shaping the future of advanced therapies.

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