New Pathway of Regulating Artificial Intelligence in Switzerland: Competitive Edge or Challenge?

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On February 12, 2025, the Swiss Federal Council unveiled its long-awaited approach to artificial intelligence (AI) regulation. Instead of adopting a comprehensive AI Act like the European Union, Switzerland has opted for a sector-specific framework, integrating AI considerations into existing laws rather than creating a standalone regulatory regime.

The Federal Council wants to regulate AI in such a way that its potential can be used to strengthen Switzerland as a location for business and innovation. At the same time, the risks to society should be kept as low as possible.

The Federal Council has decided to focus on the following parameters:

- The AI Convention of the Council of Europe will be incorporated into Swiss law. It will apply primarily to state actors.
- Where legislative changes are needed, they should be as sector-specific as possible. Only key areas relevant to fundamental rights, such as data protection, will be subject to general, cross-sectoral regulation.
- In addition to legislation, non-legally binding measures will be developed to help implement the convention. Measures may include self-disclosure agreements or industry solutions.

This decision aligns with three key objectives:

- Strengthening Switzerland's position as an innovation hub;
- Safeguarding fundamental rights, including economic freedom; and
- Enhancing public trust in AI.

Ensuring AI regulation does not stifle innovation

Switzerland's approach seeks to strike a balance between regulatory oversight and innovation-friendly conditions. As Switzerland refines its AI regulatory approach, several key challenges, including the following, should be addressed.

- **Avoiding regulatory uncertainty:** If AI rules are applied inconsistently across different sectors, companies may struggle with compliance. Clear, harmonized guidance will be essential.
- **Preventing a "Swiss Finish":** Switzerland has historically aligned with EU regulations in many sectors, sometimes adding national requirements that resulted in a so-called "Swiss finish"–an increased compliance burden without added benefit. In the case of AI, Switzerland is not adopting the EU AI Act and will instead develop its own regulatory approach. While regulatory autonomy can offer flexibility, there is a significant risk of fragmentation. Divergence from the EU framework may create legal uncertainty and increase complexity for developers of AI-driven medical technologies, particularly those operating across borders. To prevent unnecessary regulatory barriers, it will be essential that Swiss rules are interoperable with international standards and facilitate access to global markets rather than isolate Swiss innovation through incompatible or overly rigid requirements.

What it means for life sciences companies in Switzerland

The decision to regulate AI by sector rather than through a single legislative act has significant implications for life sciences companies. With AI increasingly shaping drug discovery, diagnostics, clinical decision-making, and digital therapeutics, regulatory clarity is essential. Switzerland's decision not to impose a horizontal AI Act means that compliance obligations will be determined by sector-specific laws, including those governing medical devices, pharmaceuticals, and data protection.

For the pharmaceutical sector, where regulatory frameworks are heavily shaped by global standards such as the International Conference on Harmonization guidelines and "good practice" requirements, Switzerland's AI requirements will likely be determined by these established global frameworks that are already directly applicable in Switzerland through legal references. AI applications such as in drug development and manufacturing will need to align with these internationally recognized requirements.

In MedTech, Switzerland's AI strategy presents a different challenge. As highlighted in the Sectoral Analysis that served as the basis for the Swiss Federal Council's decision, Swissmedic's market surveillance activities are expected to be affected. Moreover, based on the current assessment, legislative changes to the Swiss medical devices legal framework will be required.

However, while Switzerland's sectoral approach is intended to offer regulatory flexibility, AI-powered medical devices will still need to comply with the EU medical device regulation

(MDR)/in vitro diagnostic regulation (IVDR) requirements—not only for the entry into the EU, but also for the Swiss market. As long as and to the extent that Swiss companies are fully dependent on market access via the EU and certification by European Notified Bodies, they will also have to meet the requirements of the EU AI Act once it becomes applicable to medical devices.

A Swiss AI and Digital Health Authority for market access

However, Switzerland has an opportunity to move beyond regulatory alignment and establish a genuine competitive advantage. By creating a dedicated AI and digital health regulatory authority—a "Swiss Competence Center of Digital Health"—Switzerland could streamline approvals for AI-driven healthcare solutions, providing a faster and more predictable pathway to market access. This would reduce reliance on foreign notified bodies and position Switzerland as a leading innovation hub for AI-powered MedTech.

Such an institution could:

- Certify AI-based medical technologies for use in Switzerland, establishing a structured regulatory pathway that ensures both safety and efficiency;
- Develop mutual recognition agreements with international regulators, facilitating smoother transitions from Swiss approval to EU and U.S. compliance; and
- Provide regulatory sandboxes for AI in life sciences, enabling controlled real-world testing before full approval, thereby fostering innovation while maintaining patient safety.

Switzerland is already assessing how to adapt the regulatory framework to allow U.S. Food and Drug Administration (FDA)–approved medical devices to enter the Swiss market. Building on this approach, a dedicated AI and digital health authority could align more closely with a centralized market access authority framework, similar to the U.S. model, ensuring that AI-driven healthcare solutions benefit from a more efficient and predictable approval process.
If Switzerland successfully integrates sector-specific AI regulations within a globally recognized approval framework while offering a faster, independent market access route, it could establish itself as a leading hub for AI-driven life sciences, accelerating the pathway from Swiss approval to international adoption.

The path ahead for AI in Swiss life sciences

In conclusion, Switzerland's decision to regulate AI through sector-specific rules rather than a broad AI Act is a double-edged sword. On the one hand, it can provide an innovation-friendly environment, aimed at allowing AI-driven life sciences companies to test, iterate, and refine their solutions more freely than in heavily regulated markets. On the other hand, it places a

greater compliance burden onto companies, requiring them to navigate multiple legal frameworks—while ensuring alignment with EU, U.S., and international AI governance models. The coming years will determine whether Switzerland's AI regulatory model will be able to serve as a launchpad for global innovation or will further complicate market access for Swiss innovative solutions.