Newsletter

Horizon Scanning

In this newsletter we look at current key topics that are of relevance to the future in the therapeutic products sector and which could potentially be relevant to Swissmedic's specialist sectors.

In this issue

EU pharma reforms: The Council paves the way for modern medicinal products legislation

On 4 June 2025, the Council of the European Union formally adopted its position on the planned revision of European medicinal product legislation. By doing so, the EU is taking an important step towards a modernised, more resilient regulatory framework for human medicinal products. This is the first comprehensive reform of EU medicinal products legislation in over two decades, and it will have far-reaching consequences for medicinal product regulation, security of supply and innovation promotion in Europe.

The reform aims to achieve a better equilibrium between public health interests and economic competitiveness. It has four central aims:

1. To improve the availability of medicinal products throughout the EU
2. To promote research, development and industrial competitiveness

3. To combat shortages
4. To factor environmental considerations into pharmaceutical production and use

The position adopted by the Council sets the regulatory direction in a number of areas. Regulatory document protection for new medicinal products remains eight years followed by one year's market exclusivity, thus ensuring the core structure protecting intellectual property rights remains in place. As a new feature, however, it will be possible to extend document protection by a further year subject to certain conditions.

One innovative feature of the reforms is the introduction of transferable exclusivity vouchers for novel antibiotics. These will allow pharmaceutical companies to extend market exclusivity for a medicine that has already been authorised if they have developed a new, innovative antibiotic. The vouchers are intended to stimulate targeted investment in antimicrobial research and create incentives to develop new active substances to combat resistance. However, access to this scheme is severely restricted: Vouchers cannot be redeemed until the fifth year following authorisation and only by companies with comparatively low annual sales in the EU (not exceeding 490 million euros in any of the preceding four years).

Of particular interest from a regulatory perspective are the extended obligations to ensure security of supply. The new directive allows Member States to oblige companies to guarantee the continuous availability of certain medicinal products. Any marketing authorisation holder who fails to fulfil this obligation will be liable to the withdrawal of property rights or even revocation of authorisation. There are plans to supplement this with a European-level early warning system that will anticipate shortages and permit coordinated countermeasures.

A further key element is the "Bolar exemption", which aims to prepare manufacturers of generics and biosimilars for market entry at an early stage, including during public tenders held before existing protection periods expire. The aim is to reduce barriers to market access and promote the availability of low-cost alternatives.

Reactions to the Council's position vary. Whereas professional associations such as the Regulatory Affairs Professionals Society (RAPS) take an essentially positive view of the planned reforms – particularly as regards more efficient regulation and improved market availability – EFPIA, the European federation of industry associations, is much more critical. The federation see the reforms as a missed opportunity to make Europe more attractive as a location and warns against negative impacts on research and development investment. In particular, EFPIA feels the changes to intellectual property protections could increase global competition to Europe's detriment.

The next step will be trilogue negotiations between the Council, European Parliament and Commission. These negotiations will be crucial in deciding the definitive form of the new legal framework for pharmaceutical legislation.

By accepting the Council position on the pharma package, the EU has taken a significant step towards sustainable, crisis-resistant medicinal products regulation. The proposed measures address key weaknesses in the existing system, particularly as regards supply shortages, regulatory fragmentation and incentives to innovate. At the same time, it is apparent that a political balance between security of supply, equitable access and locational appeal has yet to be finally struck.

The further development of the package is highly relevant from Swissmedic's perspective – not least as regards existing cooperation mechanisms, international companies' authorisation strategies and potential areas of regulatory convergence. Close monitoring of the trilogue process and detailed analysis of the implementation steps are recommended.[1,2,3,4]

Future developments in the regulatory environment – 2025–2034 roadmap

An important part of the process of setting Swissmedic's strategic direction is to keep sight of upcoming developments at EU, EMA and international level. The overview below highlights key milestones and regulatory initiatives that will shape the medicinal product and health landscape over the next few years.

Roadmap 2025–2034

2025

- 12 January: HTA Regulation enters into force, start of joint assessments
- February and August: Artificial Intelligence Act (AIA)[5] , ongoing entry into force until 2027
- March: EHDS Regulation[6] enters into force, marking the start of the transitional phase
- From June: COMBINE Programme EC[7] (first of seven pilot projects)
- 1 July: EU ATMP guideline[8] takes legal effect
- By 2027: MHRA Data Strategy[9] implementation
- By 2028: EMA-HMA Network Data Steering Group (NDSG)[10]
- By 2034: Data standards, IT Acquisition Strategy[11], FDA (USA)
- Acceptance of Critical Medicines Act[12] proposals expected for Q4

2027

- March: Deadline for the adoption of several important Commission Implementing Regulations (EHDS)
- Mid 2027: Full application of SoHO Regulation (EU 2024/1938)[13]
- Conclusion of MHRA Data Strategy implementation

2028

- EMA network strategy "Seizing opportunities"[14]
- Likely entry into force of revised EU medicinal products legislation[15]
- Conclusion of EMA-HMA Network Data Steering Group (NDSG)

2029

- Entry into force of key parts of the EHDS Regulation

2031

- Exchange of the second group of priority categories of health data should be functional for primary use in all EU Member States (EHDS)

2034

- Third-party countries and international organisations can apply for participation in secondary use (EHDS)
- Conclusion of FDA IT Acquisition Strategy

FDA launches Elsa AI tool to optimise internal processes – Initial positive experience from pilot phase

The US medicinal products agency FDA is making a major step towards digital transformation. Since the start of June 2025, it has been using a generative artificial intelligence (AI) tool named Elsa throughout the agency. The tool assists FDA employees in processing scientific information, analysing documents and conducting evaluations. The aim is to optimise internal processes, accelerate scientific reviews and improve the efficiency of regulatory processes while maintaining the highest standards of safety and data protection. Experience gained during the pilot phase shows that targeted use of AI can perceptibly reduce employees' workload and modernise everyday work.

The roll-out follows on from a successful pilot programme with the FDA's scientific reviewers, during which Elsa accelerated clinical protocol review and delivered consistent evaluations.

Elsa is powered by a large language model and was developed specifically for the FDA's requirements within a GovCloud environment. All data remain within the agency, and the model does not train on sensitive data submitted by industry or on confidential NDA dossiers. The first applications of Elsa are:

- Summarising adverse events to support safety profile assessments;
- Rapidly comparing medicinal product labels;
- Generating text for reports and internal communication;
- Generating code to help develop non-clinical databases;
- Identifying high-priority inspection targets.

FDA Chief AI Officer Jeremy Walsh described the launch of Elsa as the "dawn of a new era, in which AI is a dynamic force enhancing and optimising the performance and potential of every employee". Further development of the tool will be closely geared to employees' hands-on experience. The FDA plans to further expand Elsa as part of a broader AI strategy that will include the integration of data-processing and generative functions into other regulatory processes.

The initiative is an impressive illustration of how a public health authority can use AI responsibly, safely and appropriately to strengthen innovation and efficiency alike. At the same time, the roll-out of Elsa makes it clear that issues such as result reliability, legally sound integration and trust and acceptance still require particular attention.

Feedback

If you have any feedback on this newsletter, please send it to horizonscanning@swissmedic.ch.
We will be glad to receive it!

Sources

1 'Pharma package': Council agrees its position on new rules for a fairer and more competitive EU pharmaceutical sector - Consilium

2 EU Council adopts compromise position on pharma reforms | RAPS

3 Newly proposed EU drug regulations a ‚missed opportunity' to support innovation, industry says | Fierce Pharma

4 EU Council's decision on pharmaceutical legislation: A missed opportunity for European innovation

5 Artificial Intelligence Act AIA

6 European Health Data Space Regulation (EHDS) - European Commission

7 Combined studies - European Commission

8 Guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials

9 MHRA Data Strategy 2024 -2027 - GOV.UK

10 PowerPoint Presentation

11 FDA IT Acquisition Strategy 2024-2034 | FDA

12 Critical medicines Act - European Commission

13 EU Regulation 2024/1938 on standards of quality and safety

14 The European medicines agencies network strategy 2028

15 The pharma package: new EU rules on medicines - Consilium