Key EU Legislative Initiatives for the Life Sciences Industry in 2024

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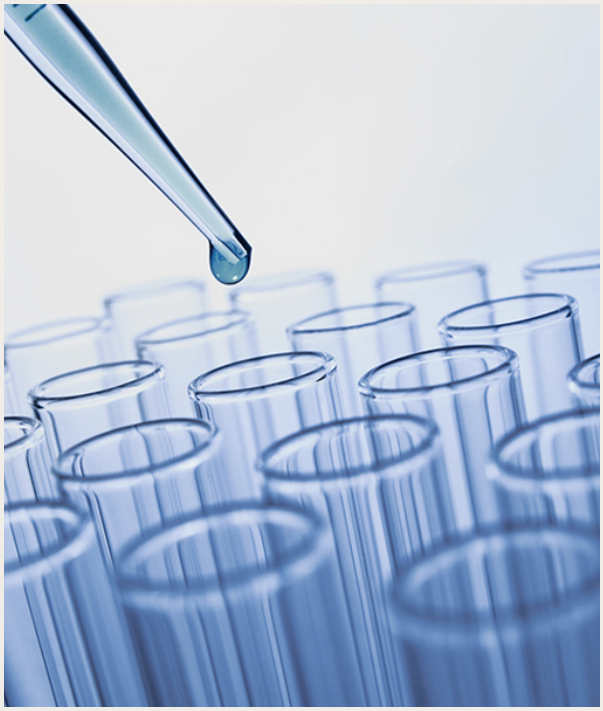
The Danish life sciences industry has been experiencing significant growth in recent years. Recent publications from the Danish Ministry of Industry, Business and Financial Affairs show record-breaking key figures for the industry with over 50,000 full-time equivalents employed in the industry, export of DKK 175 billion (corresponding to approximately 20 per cent of Danish product exports) and with Denmark being the country in the EU with the highest number of clinical trials per million inhabitants.[1]

In light of the importance that the life sciences industry has for not only economic growth but also public health on a global scale, it is interesting to take a look at how the legislative and regulatory framework will impact the industry in coming years.



Recent legislative initiatives in the EU illustrate some of the challenges and also opportunities for the life sciences industry on a pan-European level, including:

1) ensuring accessability and affordability of medicinal products for patients across the EU,

2) improving crisis preparedness and response mechanisms to limit supply shortages,

3) ensuring that the industry and healthcare communities have a sound framework for navigating digital advances,

4) addressing issues related to environmental sustainability and

5) ensuring that the EU remains a competitive and attractive environment for innovation, research, development and manufacturing.

Legislators and policymakers have made several efforts to balance these objectives.

In this newsletter, we highlight some of the legal topics that we consider key for the life sciences industry in 2024.

1. www.em.dk/aktuelt/udgivelser-og-aftaler/2023/sep/life-science-industriens-oekonomiske-fodaftryk

Reform of the EU Pharmaceutical Legislation

An initiative that has gathered much attention is the EU Commission's proposal to reform the EU pharmaceutical legislation.

In November 2020, the Pharmaceutical Strategy for Europe was adopted. The strategy aims to create a future regulatory framework in the EU and addresses the challenges facing the pharmaceutical sector, including the key challenges of ensuring availability and affordability of medicines across the EU, and ensuring that the EU remains an attractive and competitive space for innovation, research, development and manufacturing of medicines.

Building on the 2020 strategy, the EU Commission adopted a proposal to revise the general pharmaceutical legislation on 26 April 2023. The proposal consists of a "package" of two new pieces of legislation and a Commission Recommendation on combatting antimicrobial resistance.

In an attempt seeking to balance the abovementioned objectives, the proposed new legislation includes a large number of measures, including measures that will give pharmacies greater flexibility to prepare products for dispensing based on estimated prescriptions for certain fixed periods, measures on transparency and disclosure requirements, environmental risk assessment requirements and proposals to streamline the EU regulatory procedures.

Most notably, the reform includes a proposal to shorten the regulatory data protection afforded to manufacturers of novel medicinal products. Pursuant to the current system, innovators benefit from eight years of data exclusivity during which generic/biosimilars may not rely on the innovators' data to file applications for markeitng authorisations (and an additional two years of market exclusivity where the generic/biosimilars may not launch their products). The proposed reform would cut this data exclusivity period from eight to six years with limited possibilities of extension in case that the company launches and continuously supplies the medicinal products in all 27 EU Member States within two years from the grant of the marketing authorisation, which, however, seems very difficult to accomplish in practice.

This measure has been subject to extensive public debate and criticism:

- On the one hand, some will argue that a shortening of the data exclusivity may have a positive impact on access and affordability of medicines as generics will be able to reach the market at an earlier stage.

- On the other hand, many stakeholders have argued that such a measure will remove important incentives for innovation in the EU as the innovator companies' abilities to get a return on their investments into R&D are substantially reduced. In other words, taking into account the significant resources required for novel medicines to reach the market, removal of two years of additional data protection could have a significant impact on the innovator companies' readiness and ability to go into the inherently 'risky business' of research and development of novel medicines for the benefit of patients.

Hopefully, the legislators and policymakers will see reason and not ignore the arguments put forward by the industry stakeholders with respect to the need to maintain a regulatory system that fosters the development of innovative medicinal products in the EU.

The legislative process for the reform is expected to be lengthy as many of the issues are touchy subjects for both industry stakeholders, policymakers and legislators. Most recently – on 19 March 2024 – the MEPs of the EU Parliament adopted a position on the new directives and the new regulation. With this, the EU Parliament also adopts its position on the matter of the revision of the data protection period, proposing a minimum regulatory data protection period of seven and a half years and with possibilities of extending this period in case of products addressing unmet medical needs, conduct of comparative clinical trials and if a share of research and development has taken place in the EU. This suggests that the MEPs have tried to reach a compromise on the data protection period and at least partly meet the innovator companies' concerns.

The MEPs are scheduled to debate and vote on the position during the plenary session on 10-11 April 2024, and – according to the press release from the EU Parliament – the file will be followed up by the new parliament after the European elections on 6-9 June 2024.

Detailed information on the reform of the EU pharmaceutical legislation can be found on the EU Commission's website: **link**.

Health Technology Assessments

Regulation (EU) 2021/2282 on health technology assessment ("**HTA Regulation**") entered into force in January 2022 and becomes applicable in January 2025.

Health technology assessments are part of the process by which competent authorities may determine the relative effectiveness, safety and cost-benefit of new and existing technologies (e.g. medicinal products), and health technology assessments are usually used to inform of decisions on patient access and allocation of budgetary resources within the national healthcare systems.

Currently, the systems of health technology assessments across the EU are somewhat fragmented with divergences between national laws and administrative procedures, where the companies developing health technologies often have to navigate multilple national systems and requirements.

The HTA Regulation seeks, amongst other, to improve availability of innovative health technologies (medicinal products and certain medical devices), to strengthen the quality of health technology assessments across the EU and to reduce the need for multiple national health technology assessments – thereby also ensuring better predictability for the companies within the industry.

In order to do so, the HTA Regulation will establish systems of joint clinical assessments, joint scientific consultations and joint identification of emerging health technologies.

The HTA Regulation is focused on clinical domains and not on economic assessments, pricing questions or reimbursement considerations, and the Member States will still be responsible for drawing their own conclusions on clinical value at national level.

Starting gradually in January 2025, certain selected medicinal products will be subject to joint clinical assessments:

- By January 2025: new oncology medicines and advanced therapy medicines will be subject to joint clinical assessments.
- After January 2025: the EU Commission will adopt decisions on the medical devices and in vitro diagnostical devices to become subject to the joint clinical assessments.
- By January 2028: orphan medicinal products will be subject to joint clinical assessments.
- By January 2030: all new medicinal products will be subject to joint clinical assessments.

The HTA Regulation is interesting in a 2024 context because the EU Commission is carrying out several activities in the preparation of implementing the regulation, including with respect to the adoption of methodological requirements and procedural guidance for the joint assessments and testing of the IT platform.

Naturally, it also remains to be seen how the national authorities will adopt and rely upon the joint assessments in practice.

Detailed information about the HTA Regulation and the implementation activities can be found on the EU Commission's website: **link**.

European Health Data Space

In May 2022, the EU Commission issued its proposal for a Regulation on the European Health Data Space ("**EHDS Regulation**").

The key objectives of the EHDS Regulation are i) to empower citizens through better digital access to their personal health data and to support free movement by ensuring that health data follow the citizens, ii) to foster a single EU market for digital health services and products; and iii) to provide rules for the use of health data for research, innovation and regulatory activities (i.e. secondary use of data).

The EU Parliament adopted its position on the EHDS Regulation in December 2023. With this, the trilogues regarding the final text of the regulation were initiated.

Several stakeholders, including the EFPIA, have called on the EU institutions to take the necessary time to address certain fundamental issues concerning the proposal, including the need to clarify the interaction of the HTA Regulation with other applicable legal frameworks (such as the GDPR and the medical device regulations).[2]

Detailed information about the EHDS Regulation can be found on the EU Commission's website: **link**.

2. www.efpia.eu/news-events/the-efpia-view/statements-press-releases/the-draft-text-of-the-european-health-data-space-ehds-in-trilogues-sparks-deep-concerns-in-the-european-healthcare-ecosystem/

Product Liability Directive

In efforts to modernise the EU product liability rules, the EU Commission published a proposal for a revision of the EU directive on liability for defective products in September 2022.

The proposal seeks among others to ensure that the product liability rules work as a better framework for emerging digital technologies, e.g. by explicitly including software, AI systems and certain product-related digital services.

The negotiators of the EU Parliament and the Council reached a provisional agreement on the proposal in December 2023. However, the text must to be formally adopted by the EU Parliament and the Council before it can be published and enter into force. This may be expected during early 2024.

Detailed information about the modernisation of the Product Liability Directive can be found on the EU Commission's website: **link**.

The AI Act

As part of the digital strategy in the EU, the EU Commission issued its proposal for a regulation laying down harmonised rules on artificial intelligence ("**AI Act**").

The AI Act will impact articifial intelligence used in the lifescycle of medicinal products and on medical devices relying on artificial intelligence.

The AI Act operates with three risk levels of AI systems. The highest risk level is AI systems that are regarded as presenting an unacceptable risk; such systems are prohibited. The next risk level comprises the so-called 'high-risk' AI systems that are intended to be used as a safety component of a product, or is itself a product, covered by the legislation listed in Annex II of the AI Act, and where such product is required to undergo a third-party conformity assessment with a view to placing on the market.

In this regard, it should be noted that medical devices are subject to systems of risk level assessments and conformity certifications pursuant to Regulation (EU) 2017/745 on medical debvices ("**MDR**") and Regulation (EU) 2017/746 on in vitro diagnostic medical devices ("**IVDR**") that are required prior to the placing of a medical device on the market. Pursuant to these systems, devices falling within certain risk classes (e.g. classes IIa, IIb and III under the MDR) must be subjected to conformity assessments involving an independent notified body.

The majority of AI systems that qualify as medical devices will be categorised under classes IIa, IIb and III of the MDR, and therefore, such medical devices will also be considered high-risk pursuant to the AI Act.

Detailed regulatory requirements apply with respect to AI systems that are categorised as high-risk pursuant to the AI Act. For example, the manufacturer must establish quality management systems and carry out conformity assessments prior to placing the systems on the market, and the AI systems will be subject to post-market surveillance requirements and registration requirements.

The (presumably) final text of the AI Act was published in January 2024. The EU Parliament approved the AI Act on 13 March 2024. If the AI Act is also formally endorsed by the Council, then the AI Act will be adopted.

Detailed information on the AI Act can be found on the EU Parliament's website: **link**.

The Danish Life Sciences Strategy

On a Danish national level, the current Danish life sciences strategy expired in 2023. On the request of the Danish Government, the Danish Life Sciences Council delivered its recommendations for a new Life Sciences Strategy for Denmark in December 2023.

Considering the importance of the life sciences industry for the Danish society, the overall objectives of the Council's recommendations are, firstly, to ensure innovation in the Danish healthcare system, secondly, to create a stronger foundation for the life sciences industry in Denmark, thirdly, to ensure a competitive framework for the life sciences industry by Denmark taking on a stronger international role and forthly, to position Denmark as an attractive country for life sciences manufacturing and investments.

Having these overall objectives in mind, the Danish Life Sciences Council has issued 12 recommendations which include among others:

1) Prioritisation of innovation for the benefit of patients as well as for the benefit of the Danish healthcare system, e.g. by ensuring fast and effective market access and use of novel medicinal products and devices, by creating better tools for tendering and procurement and by faciliating testing, implementing and scaling of labour-liberating healthcare solutions in public-private collaborations.

2) Enable the conduct of clinical research as an integrated part of patient treatment.

3) Realise the potential of Danish health data, e.g. by establishing a national health data infrastructure and ensuring clear framework for use of health data.

4) Ensure a better system for the transfer of technology and IP rights from universities and public hospitals to start-ups and private companies.

5) Strengthen Denmark's role as an attractive country for manufacturing of life sciences-related products, e.g. by assigning specific industry zones suitable for life sciences companies and by making the approval procedures more flexible and

6) Enhance the framework for education and attract the future work force within the life sciences industry.

The new life sciences strategy for 2024-2030 is expected to be presented by the Danish Government in the spring of 2024.

The publication from the Danish Life Sciences Council can be found here: **link** (in Danish only).

Contact the Authors

The above initiatives show that the framework of the life sciences industry is very much on the radar of policymakers, legislators and other stakeholders, and it emphasises the importance of the industry in the EU and on national level as well as the difficult balancing of interests across securing sufficient innovation, availability and affordability of medicines and technologies, a reasonable digital framework and patient safety to name a few.

We at Gorrissen Federspiel are following the above developments closely. Please do not hesitate to reach out to us in case of any questions to the above.

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