

EU Policy and Regulatory updates by the RPP team

By the RPP Team

Belgian Presidency of the European Council

Belgium holds the Presidency of the European Council from January 1st, 2024, to June 30th, 2024. Among others, Health and Digital, as well as Cyber and Telecommunications are part of the 13 topics that can be found on the [Belgian Presidency Programme](#) published at the beginning of this year.



The three main topics of health under the Belgian Presidency are preparedness, care and protection. The Presidency intends to emphasize how crucial it is to strengthen crisis management, assist healthcare systems, and enhance the security of the pharmaceutical supply to make the EU more resilient to future health crises. The EU is required to take the initiative, to build a sustainable, innovative and resilient digital environment that benefits businesses and empowers citizens. The digital transformation in Europe will be prioritized by the Belgian Presidency, which will also tackle a range of telecommunications-related issues and fortify Europe's resistance to cybersecurity threats. The approach will be human-centered and sustainable. The objective is to promote open strategic autonomy and a clear internal and external digital policy.

The European Data Act

The European Data Act will enter into force, [as published by the European Commission](#) on January 11th. The Act will become applicable on September 12th, 2025. The key principle, promised through the implementation, is ensuring fairness in the digital environment by defining who can create value from data and under what circumstances. Enabling access to industrial data and bringing legal clarity to data use, will help foster a creative and competitive data market.

Users of connected products can now access and share the data produced by these items with third parties. As a result, consumers will have more control and aftermarket services as well as innovation will increase. Manufacturers will continue to get incentives to invest in data-generating goods and services, and their trade secrets will be protected.

When executing a legal mandate or responding to public emergencies, public sector organizations will have access to and use private sector data if it is not easily accessible through other means.

Additionally, unfair contractual terms that one contracting party unilaterally imposes on the other in data-sharing contracts are protected against by the Data Act for European firms. This will make it possible for small and medium-sized businesses (SMEs) to engage in the data market more actively.

Lastly, consumers will be able to move between cloud providers easily and eventually for free according to the Data Act. By taking these steps, vendor lock-in will be avoided while market competition and choice are encouraged. When enterprises and administrations transfer their data and apps to another cloud provider, the expenses will be significantly reduced.

Ongoing Trilogue Discussions on the European Health Data Space (EHDS)

The [European Federation of Pharmaceutical Industries and Associations \(EFPIA\) published its considerations for the ongoing trilogue discussions](#) on the EHDS on January 31st, 2024. The document follows an outline of recommendations for multiple aspects such as Data sharing and Intellectual property & trade secrets.

As trilogue negotiations move forward, it is essential, that a balanced compromise can be found. The compromise should aim at enhancing data-sharing mechanisms while preserving a competitive European innovation ecosystem and safeguarding individuals' rights to control health-related data. Additionally, EFPIA lists several aspects that are fundamental to the success of the proposal, including some considerations to prevent unintended consequences and maintain the competitiveness of EU businesses globally.

In terms of "Data sharing obligations and secondary use", the EFPIA welcomed the amendment aligning clinical trial data sharing with existing legislation for legal clarity. Nonetheless, they expressed concerns over the remaining uncertainty stemming from broadly defined concepts and terminologies related to other health data in scope for secondary use. Additionally, raised concerns about the broad disclosure requirements for non-clinical research data, potentially hindering investment in early research in Europe (Article 33 of the EHDS) were discussed. The EFPIA is calling for provisions in primary legislation or subsequent implementing acts that will clarify the specifics of data sharing for secondary use, to protect EU citizens from being left out of innovative healthcare research.

The current proposal raises concerns regarding "Intellectual property and trade secrets". Assigning Health Data Access Bodies (HDAB) the role of gatekeeper for assessing commercially confidential information lacks the tangible protections seen in the already finalized Data Act. To address this, the EHDS should incorporate recognized principles, ensuring data holders retain a crucial role, including the right to refuse data sharing if economic harm to the company is imminent.

EFPIA strongly believes that introducing an opt-out mechanism in the EHDS is unnecessary, as the original European Commission proposal adequately addresses patients' control over their health data. The inclusion of opt-out or opt-in mechanisms may potentially hinder future innovations by reducing overall data availability in the EHDS. In case that EU lawmakers decide to include a general opt-out right, EFPIA suggests limiting it to the data categories in Article 33 of the proposal where offering, changing, managing, and respecting the general opt-out choice can be reasonably accommodated without imposing undue burdens on the healthcare system and data holders.

Horizon Europe Program in the Context of the EU and UK

During a press conference in London on February 12th, both [EU and UK officials actively encouraged scientists to engage with the Horizon Europe research program](#). The Horizon Europe program, designed to drive research and innovation forward, is equipped with a substantial budget of € 95.5 billion. As part of its involvement, the United Kingdom is expected to make a yearly contribution estimated at € 2.43 billion.



Since January 1st, 2024, the UK has formally re-entered Horizon Europe as an associated country, thereby allowing its research community to participate in the European Union's research and innovation program. The UK's re-engagement with Horizon Europe marks a critical step in maintaining collaborative research and innovation ties with the EU.

Unfortunately, challenges with European researchers facing visa issues and higher costs in the UK were highlighted by British officials.

Iliana Ivanova (Commissioner for Innovation, Research, Culture, Education and Youth) warned that UK visa procedures might hinder the full benefits of Horizon participation. Her comments highlighted the need for simplifying visa procedures, emphasizing a call for reforms aimed at making collaboration easier and more effective.

In contrast to that, British Science Minister Michelle Donelan denied claims of recruitment challenges for the UK, highlighting the project's support for scientific, innovative, and business interests that contribute to the nation's economic growth and development. She emphasized the positive feedback from individuals who have chosen the UK and mentioned that the UK is open to collaborating with the EU on other projects on a case-by-case basis.

IMCO and LIBE Committees Endorse Artificial Intelligence Act

The [IMCO and LIBE Committees endorsed the AI Act text](#) on February 13th, 2024, with an overwhelming majority. The next step is for the European Parliament to adopt the text.

The Act aims to regulate how and for what purpose Artificial intelligence is used. The focus of the Parliament during the negotiations was on the classification of different AI models based on the risk they pose to Security, Health, and Environment.

The vote is scheduled to be adopted at the plenary session on the 10th to 11th of April. After that, the text will be voted on by the ministers at the Council level.