EU Policy and Regulatory updates by the RPP team

By the RPP Team

In the last two months of the year noteworthy developments on the Artificial Intelligence Act (AI Act) as well as the European Health Data Space (EHDS) took place. The European parliament's overwhelming vote in favour of the proposed EHDS is a big step forwards and great news to everyone involved in medical research and development. Simultaneously the European Parliament and the European Council reached a political agreement on the long-discussed AI Act, regulating the boundaries of AI while maintaining the benefits of it. This acceleration in decision-making can be explained with the upcoming European elections next year.

EHDS Proposal: MEPs Seal Approval in Strasbourg Plenary Vote

On 13 December during the Strasbourg plenary session, Members of the European Parliament (MEPs) overwhelmingly voted in favor of the proposal for the European Health Data Space (EHDS).

The EHDS is an initiative aimed at simplifying access to health data across the EU, benefitting both patients and healthcare workers by facilitating cross-border care. Furthermore, it seeks to harness the wealth of health datasets within the bloc for research and innovation purposes. The proposal garnered extensive support at the Parliament level, with an impressive 516 MEPs voting in favor, while 95 voted against, and 20 abstained.

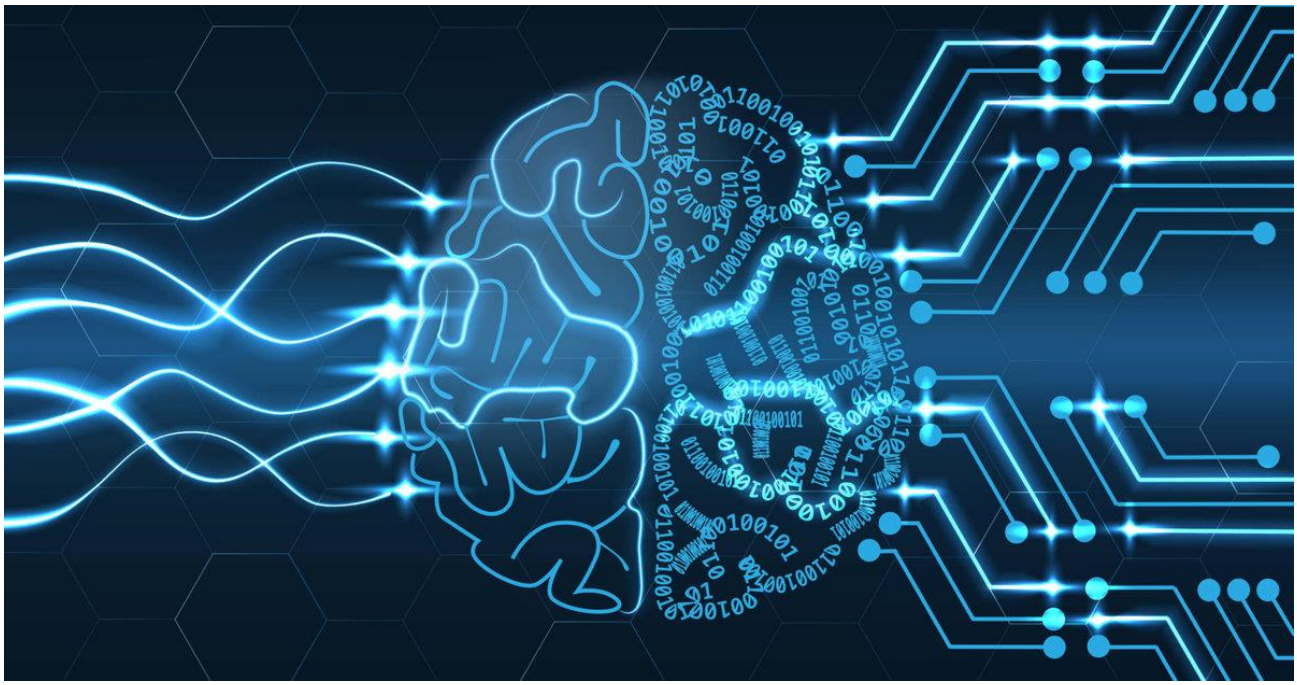
As we look ahead, trilogue negotiations are expected to conclude before the European Elections in June. However, potential delays may arise due to disparities between the Council and Parliament positions, particularly concerning the mandatory sharing of specific data types (Article 33) and data localization requirements. Negotiations between the Council, the Commission, and the Parliament are scheduled to commence on 14 December.

The ENVI and LIBE Committees advocated for enhanced patient control over their health data, proposing an opt-out mechanism for sharing health data for secondary use. MEPs voted in favor of an opt-in approach for sharing sensitive data types, such as genetic data, for secondary use purposes. During the vote, an approved amendment, proposed by 70 MEPs, grants countries the authority to allow patients to object to the inclusion of their health data in an electronic health record system.

This significant step marks a positive stride toward a more connected and accessible European health data landscape.

Navigating the AI Act: Balancing Innovation and Compliance

On December 8, the European Parliament and the Council reached a political agreement on the groundbreaking Artificial Intelligence Act (AI Act). This regulation aims to be a step towards safeguarding fundamental rights, democracy, the rule of law, and environmental sustainability from high-risk AI, all while fostering research and innovation.



The AI Act, proposed by the European Commission in 2021, stands as the world's first AI law. It establishes obligations for AI based on the potential risk it may pose. The trilogue's outcome includes a ban on certain uses of AI, addressing ethical concerns across various applications such as biometric categorization, untargeted facial image scraping, emotion recognition, social scoring, behavior manipulation, and exploitation of vulnerabilities based on personal characteristics.

MedTech Europe expressed concerns about the potential negative impacts on medical devices. They highlighted additional compliance procedures for AI-based medical devices, potentially delaying certifications and posing a risk of shortages.

The legislation will undergo a vote by the European Parliament and the Council, becoming law upon successful approval. The next IMCO meeting is scheduled for 24 & 25 January 2024.

Obligations for high-risk AI systems include a mandatory fundamental rights impact assessment, extending to sectors like insurance and banking. Citizens will have the right to lodge complaints about high-risk AI systems impacting their rights and receive explanations regarding their functioning and impact.

General-purpose AI (GPAI) systems and their models must meet transparency standards, including technical documentation, adherence to copyright law, and the dissemination of detailed training content summaries. High-impact GPAI models with systemic risk will face stricter obligations, including model evaluations, systemic risk assessments, adversarial testing, reporting incidents to the Commission, ensuring cybersecurity, monitoring energy efficiency, and adhering to codes of practice until harmonized EU standards are established.

Non-compliance with the rules can result in fines ranging from 35 million euros or 7% of global turnover to 7.5 million or 1.5% of turnover, depending on the infringement and company size.