The AI Act
Building Trust in EU Innovation

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REPORT

hosted by

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Organised by

CECIMO, COCIR, DIGITALEUROPE, MedTech Europe

Introduction

The European Commission's proposed Artificial Intelligence (AI) Act comes at a time of increasing technological changes and opportunities. To support Europe's technological prominence and provide citizens access to groundbreaking applications, the European Commission aims to create a balance between fostering and preserving innovation and enhancing people's trust in human-centric AI solutions. This balance depends on the collaboration of all relevant stakeholders and the exchange of best practices to establish an effective regulatory framework for AI technologies and their oversight in Europe.

The joint event, organised by CECIMO, COCIR, DIGITALEUROPE and MedTech Europe and co-hosted by MEP Svenja Hahn (DE, Renew), MEP Sergey Lagodinsky (DE, Greens), MEP Eva Maydell (BG, EPP) and Petar Vitanov (BG, S&D) seeks to serve as a platform of exchange on these priority areas and discuss how AI systems should be handled in Europe.

MEP Svenja Hahn

"*Despite our political differences, as democratic forces in the European Parliament, we share a common goal. To ensure that AI in Europe is trustworthy and human-centric, to foster European innovation and very importantly: To protect our citizens' fundamental rights!"*

MEP Sergey Lagodinsky

"*Trust must be earned. The AI Act should help AI producers and AI deployers earn this trust. That is why the Parliament is building on the Commission's high-risk approach, providing guardrails for AI systems. In particular where they pose a high risk to the health and safety of persons, to fundamental rights, and the environment.*"

MEP Petar Vitanov

"There is no doubt that AI has the power to revolutionise industries, drive economic growth, and enhance our daily lives. However, we must remain vigilant about the ethical and social ramifications. If not carefully designed and regulated, AI algorithms can inadvertently discriminate against certain groups or reinforce prejudiced practices. We need robust mechanisms to detect and rectify bias in AI systems, and we must ensure that the development process is inclusive and representative of diverse perspectives. Moreover, data privacy and security are paramount. The responsible collection and use of personal data in AI applications should be subject to strict regulations to safeguard individuals' rights and prevent abuse."

MEP Eva Maydell

"Since the beginning, almost two years ago, innovation has been at the heart of my work in the AI Act. It is about putting guardrails in place to create social trust while also spurring innovation and competitiveness in the European AI ecosystem. As Rapporteur in the ITRE Committee, I am glad to have pushed for an ambitious approach to regulatory sandboxes, a research exemption and improved measures for smaller companies. But work still remains to be done and we have yet to see what the final version of the AI Act will look like. We are in the make-it-or-break-it stage and the future of Europe's AI industry is on the line."

Fireside chat: "Powering the European AI ecosystem"

Discussions on the AI Act's impact, implementation, and support measures necessary to promote AI uptake were at the core of the fireside chat between Eva Maydell MEP and Cédric O, Co-founding Advisor of Mistral AI. Cecilia Bonefeld-Dahl, DIGITALEUROPE's DG, led the conversation.

Having gained perspectives from both his current position and his former role as French State Secretary for the Digital Economy, **Cédric O** expressed optimism about Europe's potential in the AI technology sector. He stressed that the EU is only one year behind other AI-leading regions: Europe has talent, but still needs substantial capital to ensure its active participation in the global tech industry. It is not only a matter of competitiveness, but also of sovereignty.

The AI Act should seek to oversee certain use cases while nurturing an ecosystem that allows and encourages technological advancement at a larger scale. This is particularly relevant for recent developments like generative AI: regulating too much and too soon without properly understanding the consequences will be detrimental to European companies' competitiveness. In this evolving field, Europe has a lot to bring, including its cultural diversity and values.

Eva Maydell noted that the sandboxes defended by the European Parliament would help foster innovation and ease the compliance burden by allowing access to pre-deployment services. Another way to facilitate compliance is through centralised enforcement measures. Because of the exceptionally fast pace of these technological developments, there is and will continue to be a scarcity of experts who understand large language models and AI in general.

While acknowledging Europe's pool of talent, **Cecilia Bonefeld Dahl** highlighted the challenges the EU faces due to the lack of scale and capital. To unlock Europe's full innovation potential, these issues will need to be addressed, beyond the regulatory framework. The EU's traditionally risk-averse culture is another obstacle to innovation, as remarked by Eva Maydell, who suggested that a mindset shift is needed for European companies to become global AI leaders.

The AI Act is a prime example of the opportunities and challenges European businesses face in the fast-evolving tech world. Concerted EU-wide efforts are needed to realise Europe's potential to become a major global AI player.

AI and manufacturing technologies: ethical and functional human-machine interaction

The panel explored the intersection of AI and manufacturing, addressing policy, technology, and ethics. The discussion between Paul Ribus, Vice President of Robot Sales General Industries - Partner Network Program at FANUC Benelux, Daniel Leufer, Senior Policy Analyst at Access Now and Tatjana Evas, Legal and Policy Officer at the European Commission emphasised the role of AI in fostering collaboration between machines, robots, and humans in the industry, while considering the need to balance innovation with safeguarding individual and collective rights.

Paul Ribus, FANUC Benelux, highlighted AI's versatility in benefiting both machine builders and operators. He discussed AI's contribution to sustainability, automation, and low-risk AI systems, emphasising efficiency and safety improvements.

Daniel Leufer, Access Now, cautioned against encouraging surveillance and spyware startups and stressed the need for ethical considerations, particularly regarding worker

surveillance. He advocated for collaboration between civil society organisations and the industry to ensure technology safeguards.

Tatjana Evas, European Commission, emphasised the need to shift from the innovation vs. regulation concept, focusing on effectively communicating the benefits of AI regulation and the EU's leadership in this area. She noted the importance of using existing product safety legislation to ensure AI technologies adhere to high safety and quality standards, while also highlighting the benefits of the AI Act.

In conclusion, the panel provided a comprehensive exploration of AI in manufacturing, underscoring the intertwined benefits and ethical considerations. It emphasized a balanced and thoughtful approach to harnessing the full potential of AI in the evolving industrial landscape.

Fit for the health sector: Re-imagining MDR/IVDR conformity assessment in light of the AI Act

The session delved into the conformity assessment process for medical technologies conducted by notified bodies under the Medical Device Regulation (MDR) and *In Vitro* Diagnostic Medical Devices Regulation (IVDR), as well as the potential implications of the AI Act. Notified bodies are third-party entities designated by Member States to assess product conformity before market placement.

Andreas Purde, TÜV SÜD noted that there are already multiple conformity rules in place for medical devices, and notified bodies are already assessing AI-based medical devices. However, a potential issue arises if the AI Act's provisions clash with those of the MDR/IVDR, possibly leading to some devices not being available in the EU market.

Geofrey De Visscher, SGS, explained that the duration of conformity assessments for AI medical devices varies based on risk classification, typically ranging from 9 months to several years, with an average of around 18 months. The incorporation of AI in these devices may extend assessment times and increase costs. There are concerns about notified bodies' capacity, as they already faced challenges during the transition from the Medical Device Directive (MDD) to the MDR. The NoBoCap project aims to address some of these challenges by creating a network with universities and industry to enhance knowledge within and outside notified bodies.

Concerns and hopes regarding the AI Act focus on the need for structured communication between different regulations and the importance of clear guidelines for working with these regulations. Regarding the participation of notified bodies in sandboxes and other EU projects, there is a general interest in such involvement, potentially offering valuable contributions to the development and implementation of regulatory frameworks.

Closing

Annabel Seebohm, the Secretary General of COCIR, has shared her insights on the AI Act, a legislation that emerged amidst a period of rapid technological advancements and opportunities. She underscored the ethical implications of AI, touching upon issues such as surveillance, worker safety, hiring practices, and job reduction.

Simultaneously, she highlighted new possibilities, such as saving economic and environmental costs, reducing waste, and improving the health conditions of operators. Given

these factors, Annabel Seebohm stressed the need for a robust regulatory framework that provides certainty to all actors as new technologies are being developed and introduced into the market.

Regulatory sandboxes enable guidance for businesses with among others risk categorisation, and conformity processes, to provide one-stop shops that can for instance be of service to companies and redirect them to competent sectoral authorities.

Lastly, Annabel Seebohm pointed out the need to ensure alignment concerning sectoral legislation. In this context, the AI Act must not duplicate or conflict with regulatory provisions already in place. Potential diverging requirements may hold back the functioning of highly regulated sectors, but also create inaccessible obligations on certification bodies.

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