European Parliament
2024-2029

Committee on Petitions

19.9.2024

NOTICE TO MEMBERS

Subject: Petition No 0254/2024 by D. W. V. C. (German) on the creation of an independent supervisory authority to ensure the ethical aspects of brain implants

1. Summary of petition

The petitioner highlights the ethical, regulatory, and research-related dimensions of brain implants, particularly in light of recent advancements made by Elon Musk's company Neuralink. He advocates for a critical dialogue regarding the ethical implications and potential risks, emphasizing the need to establish an independent regulatory authority to safeguard safety and preserve cognitive autonomy in this domain. Additionally, the petitioner underscores the significance of independent research for the ethically responsible and socially pertinent advancement of brain implant technology.

2. Admissibility

Declared admissible on 21 June 2024. Information requested from Commission under Rule 233(5).

3. **Commission reply**, received on 19 September 2024

Implantable medical devices, such as the Neuralink brain-computer interface currently undergoing clinical investigations in the United States, fall under the scope of Regulation (EU) 2017/745 on medical devices[1] (MDR) and must comply with relevant general safety and performance requirements set out in its Annex I to the above-mentioned Regulation. Devices

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. ELI current consolidated version: https://eur-lex.europa.eu/eli/reg/2017/745/2023-03-20?locale=en

intended to be implanted in the brain of human patients, being in contact with the central nervous system, are classified as high-risk devices (class III) taking into account the intended purpose of the devices and their inherent risks. Therefore, the applicable requirements are especially stringent and the conformity assessment procedure to obtain the CE marking requires the involvement of a third-party conformity assessment body ('notified body') designated under the MDR[2].

Ethical aspects of the use of medical devices are not specifically regulated in the MDR. However, this Regulation requires that any clinical investigation with a medical device, which is mandatory to gather pre-market clinical data for implantable and class III devices, is designed and conducted in such a way that the rights, safety, dignity and well-being of people participating in the clinical investigation are protected. Clinical investigations are subject to scientific and ethical review, performed by ethics committees in accordance with national law.

In addition, there are legislative and non-legislative ongoing initiatives related to the subject of the petition.

The European Group on Ethics in Science and New Technologies (EGE)[3] has set up a working group on ethics and governance of neurotechnology to issue policy recommendations by beginning of 2025. The EGE provides the Commission with high quality, independent advice on all aspects of EU legislation and policies, where ethical, societal and fundamental rights issues intersect with the development of science and new technologies.

The EU is supporting research and innovation in neurotechnology via its framework programmes for research and innovation, Horizon 2020 and Horizon Europe. For instance, the Horizon 2020 CORE-MD project[4] was set up to improve methods for clinical investigation and evaluation of high-risk medical devices. The project concluded that an ethics charter to guide all parties in the process of developing, evaluating, and regulating high-risk medical devices would be helpful, and recommendations were put forward[5]. Another Horizon 2020 research project, BrainCom, dealt with the current challenges of neural nanotechnology, in particular the development of brain implants[6]. It aimed at developing novel medical devices for restoration of speech and communication in aphasic patients suffering from upper spinal cord, brainstem or brain damage. At the same time, the researchers also tackled the ethical aspects of the innovative technology.

All actions carried out under the framework programme for research and innovation have to comply with ethical principles and relevant EU, national and international law, including the Charter of Fundamental Rights of the European Union. In this regard, stringent ethics

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[2] List of designated notified bodies under the MDR: https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies/notified-body-list?filter=bodyTypeId:3,legislationId:34

[3] https://research-and-innovation.ec.europa.eu/strategy/support-policy-making/scientific-support-eu-policies/european-group-ethics_en

[4] Coordinating Research and Evidence for Medical Devices (CORE-MD): https://www.core-md.eu/. It has received funding from the European Union's Horizon 2020 research and innovation programme.

[5] https://ec.europa.eu/research/participants/documents/downloadPublic?documentIds=080166e50d38f50a&appId=PPGMS

[6] https://cordis.europa.eu/project/id/732032; https://digital-strategy.ec.europa.eu/en/news/current-challenges-neural-nanotechnology-developing-brain-implants

procedures are in place regarding the selection and monitoring of actions. Furthermore, through the Horizon 2020 and Horizon Europe funded projects TechEthos[7], CHANGER[8] and following the call for proposals '*Next generation AI and Human Behaviour: promoting an ethical approach*[9]*',* the Commission is investing in research and capacity building projects to advance relevant ethics expertise, ethics oversight and governance frameworks for an ethical approach in neurotechnology and artificial intelligence (AI), including the development of guidelines, various toolboxes, training and educational materials. Furthermore, the Commission facilitates dialogue on the ethical issues and challenges related to new and emerging technologies, including neurotechnology and AI, through several initiatives including the National Ethics Councils Forum[10]. The Commission is cooperating with the Council of Europe and the Organisation for Economic Co-operation and Development (OECD) in the context of the Recommendation on Responsible Innovation in Neurotechnology[11], towards the development of a robust international framework in that regard.

The final report of the Special Committee of the European Parliament on Artificial Intelligence in a Digital Age (AIDA)[12] also raises the issue of neuro-rights.

On 1 August 2024, Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act- AIA)[13] entered into force. Among other aspects, the AIA also addresses the issue of human dignity and personal autonomy, based on the seven ethical principles for AI developed by the High-Level Expert Group on Artificial Intelligence (AI HLEG). The AIA covers AI applications, which are embedded or which constitute products under other EU legislation, including the MDR. The regulation follows a risk-based approach and introduces requirements for AI systems commensurate to the level of risk, in particular introducing strict requirements for high-risk AI systems. If a medical device implanted into the brain relies on AI, the AI will be considered a high-risk AI system and covered by the AIA. Among other requirements, high-risk AI systems must allow human oversight aiming at preventing or minimising the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used in accordance with its intended purpose or under conditions of reasonably foreseeable misuse.

The European Artificial Intelligence (AI) Office[14], established in February 2024 within the

[7] https://cordis.europa.eu/article/id/451298-ethics-by-design-in-cutting-edge-tech-development
[8] https://cordis.europa.eu/project/id/101131683
[9] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/horizon-widera-2024-era-01-12
[10] The National Ethics Councils Forum is an independent informal network of representatives of the National Ethics Councils for the exchange of information, experience, and best practices on issues of common interest in the field of ethics and science. The NEC Forum organises meetings in the Member State holding the Presidency of the Council of the European Union. The NEC Forum brings together the EU National Ethics Committees, the European Group on Ethics in Science and New Technologies (EGE), representatives of the Council of Europe (CoE), the United Nations Educational, Scientific and Cultural Organization (UNESCO), the World Health Organisation (WHO) and Ethics Committees from Horizon 2020/Horizon Europe Associated Countries, Neighbouring Countries of the EU and other non-EU countries in order to enrich the work of the network and to build awareness and good practice based on European ethics standards and legislation.
[11] https://www.oecd.org/science/recommendation-on-responsible-innovation-in-neurotechnology.htm
[12] https://www.europarl.europa.eu/doceo/document/A-9-2022-0088_EN.html
[13] http://data.europa.eu/eli/reg/2024/1689/oj
[14] https://digital-strategy.ec.europa.eu/en/policies/ai-office

Commission, oversees and coordinates the AIA's enforcement and implementation with the Member States. It aims to create an environment where AI technologies respect human dignity, rights and trust. It also fosters collaboration, innovation and research in AI among various stakeholders. Moreover, it engages in international dialogue and cooperation on AI issues, acknowledging the need for global alignment on AI governance.

Conclusion

On the basis of the above, the Commission does not identify for the time being any need to establish a new independent regulatory authority to safeguard and protect individual freedom, protect privacy, prevent abuse and discrimination, and promote responsible research and development.

In any case, the Commission invites the petitioner to share his concrete proposals on the matter via the Commission's website 'Have Your Say'[15], to be taken into consideration for any possible future developments.

[15] https://ec.europa.eu/info/law/better-regulation/have-your-say_en