

**Reply by the European Commission to a proposal for a solution from the European Ombudsman**  
**- Complaint by Mr [REDACTED], ref. 157/2023/VB**

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## **I. BACKGROUND/SUMMARY OF THE FACTS/HISTORY**

Article 51(1) of Regulation (EU) 2017/745 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 (hereinafter referred to as MDR) establishes that devices shall be divided in classes I, IIa, IIb, and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII of the MDR.

Some specific requirements applicable to medical devices depend on the device classification. Requirements applicable to higher classes of devices are more stringent, as their risk is higher.

According to point (b) of Article 51(3) of the MDR, at the request of a Member State the Commission shall, after consulting the Medical Devices Coordination Group (hereinafter referred to as MDCG), decide, by means of implementing acts, that a device or category or group devices is reclassified by way of derogation from Annex VIII of the MDR for reasons of public health. Such reclassification must be based on new scientific evidence or on any information which becomes available in the course of the vigilance and market surveillance activities.

Six Member States requested in July 2022 the reclassification of brain stimulators without a medical purpose as class III devices. Previously, such brain stimulators were classified as class I. The Member States request was based on available scientific evidence - including evidence generated after the adoption of the MDR - on equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain, such as those for transcranial magnetic stimulation or transcranial electric stimulation.

Following such request, the Commission consulted the Medical Device Coordination Group (MDCG) and published a draft decision on the reclassification of the above-mentioned brain stimulator as class III devices on the 'Have your say' portal (from 11 August 2022 to 8 September 2022) to collect public feedback. It further discussed the draft act with the Committee on Medical Devices. On 13 October 2022, the Committee issued a positive opinion on the adoption of the act. For public health reasons the devices in subject were therefore reclassified by Commission Implementing Regulation (EU) 2022/2347 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose.

On 12 December 2022, the complainant filed an access to documents request (EASE 2022/7371) to get access to the requests for reclassification from the 6 MSs and to the available scientific literature. On 30 January 2023, the Commission replied to the request providing the complainant with the requested correspondence and the references to the available literature. On the same date, the 6 requests were made available to the public on the transparency portal.

## II. THE COMPLAINT TO THE EUROPEAN OMBUDSMAN

On 15/03/2023 the Commission was informed that the Ombudsman's office had received a complaint against the European Commission filed by Mr [REDACTED] on behalf of a Danish company (PlatoScience ApS) manufacturing devices for neurostimulation. The complainant considers that the Commission failed to take an evidence-based and participative approach in the development and adoption of the implementing regulation that reclassifies brain stimulators for non-medical purposes as class III devices under the MDR.

The Commission provided all requested information in response to the Ombudsman's inquiry.

## III. EUROPEAN OMBUDSMAN'S INQUIRY

On 8/11/2023, the Commission received a letter from the Ombudsman setting out the proposed solution for the above case.

On the basis of the inquiry performed, the Ombudsman proposed a review of the scientific evidence on which the reclassification of brain stimulators without an intended medical purpose was based. The letter also included observations aiming to improve the process for collecting feedback from the public in future public consultations.

## IV. REPLY OF THE EUROPEAN COMMISSION TO THE OMBUDSMAN PROPOSED SOLUTION

The Commission acknowledges the additional comments provided by the complainant during the inquiry and the observations and solution proposed by the Ombudsman.

According to the proposed solution,

- (i) **the Commission should verify whether the scientific evidence provided with the Member States' request is comprehensive and representative of the most recent scientific evidence published on the risks linked to the use of brain stimulation devices. Should the Commission conclude that the most recent scientific evidence does not support the reclassification, it should take action to remedy the situation, for instance by adopting a new implementing act, on its own initiative, based on Article 51(4) of the MDR.**

The Commission assessed both the content of the Member States request for reclassification and the content of the scientific evidence referred therein. It welcomes the Ombudsman's proposed solution and, for the purpose of implementing it, it will mandate the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) with the task to issue a scientific opinion on the risks posed by the use of brain stimulators for non-medical purposes. The mandate will include the review of the scientific evidence provided by the Member States and most recent relevant scientific evidence issued after April 2017. The mandate will be presented and discussed during the SCHEER plenary meeting planned on 12 March 2024. Scientific evidence related to analogous brain stimulators with medical purposes will also be considered as the functioning mode and the risk profile are similar to that of the brain stimulator not having a medical purpose.

Based on the scientific opinion issued by the SCHEER, the Commission will assess the need to take further action. The MDCG and its Annex XVI subgroup will also be further consulted on that basis.

Concerning the observations on the feedback process, the Ombudsman noted that

- (ii) **the feedback received by the Commission on the draft implementing regulation was very limited and that in the interest of ensuring evidence-based decision making, the Commission should seek to ensure that it receives extensive feedback from those with practical and scientific expertise in such specialist fields.**

The Commission welcomes the Ombudsman's observations. It would like to note that in the area of medical devices, every time that a draft measure is published for feedback, the Commission invites all the members and stakeholders of the MDCG and of its interested subgroups to provide feedback and to further disseminate the published draft for consultation purposes. Moreover, before adopting Implementing Regulation (EU) 2022/2347, relevant stakeholders were made aware of the possibility to provide feedback on the draft measure and invited to do so. The information was provided via Circabc.

The Commission will continue to invite expert groups members and stakeholders to disseminate information about public consultations on draft tertiary legislation on medical devices. The Commission will also consider extending the consultation period of public consultations launched during the summer period, where the draft measure is not urgent, also in the case of new reclassification decisions or implementing acts in the field. It will also devote specific attention to ensure, where necessary, the inclusion of as much information as possible on scientific evidence supporting a draft measure.

However, the Commission would like to note that it has no control on the number of comments received when a draft measure is published for feedback and low participation to the feedback exercise from experts who are aware of the publication for feedback and the development of the measure might be interpreted as a signal of support for the measure.

The Commission will also assess whether it is appropriate to expand the participation of stakeholders to the meetings of MDCG and its subgroups. For the MDCG Annex XVI subgroup, the Commission will consider the participation of new stakeholders with specific expertise on the groups of products listed in Annex XVI to the MDR and, in particular, to organisations specialised on brain stimulation. Evaluations of eligibility of new stakeholders are ongoing and final decisions are expected by mid-2024.

## V. CONCLUSION

The Commission considers that both the proposed solution and the observations have been taken into consideration and addressed. The Commission will mandate the SCHEER to issue a scientific opinion, in March 2024, and will assess the need to take action on the basis of the scientific opinion adopted by the committee.

*For the Commission  
Stella KYRIAKIDES  
Member of the Commission*

## Links:

- Commission Implementing Regulation (EU) 2022/2347 laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards reclassification of groups of certain active products without an intended medical purpose – [http://data.europa.eu/eli/reg\\_impl/2022/2347/oj](http://data.europa.eu/eli/reg_impl/2022/2347/oj);
- 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 - <http://data.europa.eu/eli/reg/2017/745/2023-03-20>;
- The MSs' requests for reclassification are available on the [transparency portal](#) of the European Commission. The six letters ([BE](#), [NL](#), [PT](#), [FR](#), [ES](#), [LU](#)) present the same content and differ only for the Member State' representative who signed the document;
- Have your say portal of the European Commission - [https://ec.europa.eu/info/law/better-regulation/have-your-say\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say_en);
- MDCG members and observers - <https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3565>, tab 'Members'.