EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Medical Products and Innovation
Medical Devices

SCIENTIFIC COMMITTEE ON HEALTH, ENVIRONMENTAL AND EMERGING RISKS (SCHEER)

Request for a scientific opinion on risks for the health associated to the use of brain stimulators not having an intended medical purpose described in the group 6 of Annex XVI to Regulation (EU) 2017/745

Commission Department requesting the update: Directorate-General for Heath and Food Safety – Unit D3 Medical Products and Innovation Medical Devices

1. Background

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 may, 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 adopted the 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. The brain stimulators are reclassified in class III.

During the adoption procedure, the Commission consulted the Medical Device Coordination Group (MDCG), published a draft measure on the reclassification of the brain stimulator as class III devices on the Have your say portal to collect public feedback and discussed the draft act with the Committee on Medical Devices.

2. Terms of reference

The SCHEER is requested to produce a scientific opinion on risks for the health of users and consumers associated to the use of brain stimulators not having an intended medical purpose described in the group 6 of Annex XVI to the MDR.

The opinion shall take into consideration and be based on new scientific evidence. For the purpose of identifying the new scientific evidence, the evidence dated after 5 April 2017 is considered as new.

The devices covered are the brain stimulators without an intended medical purpose described in group 6 of the Annex XVI to the MDR. In detail:

- 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.

Available evidence on risks for the health of users and patients associated to the use of brain stimulators for medical purposes can be also considered if the brain stimulators are analogous medical devices having similar functioning mode and risk profile of the products not having an intended medical purpose.

Devices for both professional and home uses shall be considered.

The scientific opinion shall:

- present the results of the review of the new scientific evidence and identify the hazards and the risks for the health of users and consumers/patients;
- highlight risks of permanent modifications of the structure or functioning of the brain and known safety limits for the use of the devices (e.g., duration of each session, frequency of sessions, maximum number of sessions);
- determine if and under what conditions the administration of energy to the human body is made in a potentially hazardous way, taking account of the nature, the density and the site of application of the energy.

3. Deadline

The final scientific opinion has to be adopted by SCHEER by the end of 2025.

4. Supporting documents

- 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.

- Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices – http://data.europa.eu/eli/reg_impl/2022/2346/2023-06-22.

- 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.

SCHEER approved this mandate during the SCHEER plenary meeting on 12 March 2024.