The decision by the European Commission to revise the risk classification of devices involving brain stimulation under rules governing products without an intended medical purpose in the context of the EU Medical Devices Regulation

Case opened
Case 157/2023/VB - **Opened on** 15/03/2023 - **Institution concerned** European Commission |

Ms Ursula von der Leyen

President

European Commission

Dear President,

I have received a complaint about how the European Commission adopted an implementing regulation [1] to reclassify groups of certain active products without an intended medical purpose, in particular devices involving brain stimulation.

The complainant takes issue with the reclassification of equipment intended for brain stimulation as risk class III in the implementing regulation. In particular, it considers that the Commission failed to take an evidence-based and participative approach in the development and adoption of the implementing regulation.

I have decided to open an inquiry into this complaint and concluded that it would be useful for my inquiry team to meet with the relevant representatives from the Commission to receive additional information on the issue. I would appreciate it if, during the meeting, the Commission could address the questions set out in annex.

Please note that the inquiry does not concern the scientific assessment of the risks related to equipment intended for brain stimulation. It covers the Commission's actions in preparing

the draft implementing regulation and collecting feedback on it.

I would be grateful if your office could contact Mr Vieri Biondi, who is in charge of this inquiry, to agree the arrangements for the meeting to take place before 26 April 2023.

Information or documents that your institution considers to be confidential will not be disclosed to the complainant or any other person without the prior agreement of the Commission. [2]

Yours sincerely,

Emily O'Reilly European Ombudsman

Strasbourg, 15/03/2023

Annex
Evidence-based approach

1. Could the Commission please address the complainant's claim that the evidence the Commission used for the reclassification of equipment intended for brain stimulation is extremely limited (in light of the number of peer-reviewed articles on the issue that are published every year), outdated and, in certain cases, not peer-reviewed?

2. We understand, from the Commission's email to the complainant of 31 January 2023, that the Commission based its decision to reclassify the devices mentioned in the implementing regulation on the evidence provided by the Member States only. Could the Commission clarify the actions that it took when it received the Member States' request to reclassify certain active products? In particular, what assessment did the Commission carry out to evaluate the completeness and accuracy of the scientific evidence provided by the Member States and to conclude that such evidence was sufficiently new [3] to reclassify equipment intended for brain stimulation?

Stakeholders' feedback

3. Could the Commission please address the complainant's argument that the feedback received on the draft implementing regulation [4] was very limited, also in light of how feedback was gathered with regard to previous implementing acts related to the medical devices regulation?

4. Could the Commission clarify how it communicated to stakeholders its intention to adopt the implementing regulation and the opening of the feedback period?

5. Does the Commission consider that seeking feedback during the summer might have

negatively affected the exercise? Would it have been possible to extend the feedback period or to postpone the feedback exercise in light of the summer holidays?

[1] Commission implementing Regulation 2022/2347 laying down rules for the application of Regulation 2017/745 as regards reclassification of groups of certain active products without an intended medical purpose, https://eur-lex.europa.eu/eli/reg_impl/2022/2347/oj .

[2] Please clearly mark such material 'Confidential'. Encrypted emails can be sent to our dedicated mailbox. Information and documents of this kind will be deleted from the European Ombudsman's files shortly after the inquiry has ended.

[3] As required by Article 51(3)(b) of Regulation 2017/745 on medical devices, https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0745-20200424 .

[4] Ares(2022)5696071.