



Как Европейската комисия гарантира прозрачността на експертната група за координация на медицинските изделия

Непрекратен случай

Случай 2132/2022/KR - **Открит на** 19/12/2022 - **Засегната институция** Европейска комисия |

President

European Commission

Dear President,

I have received a complaint against the European Commission concerning the transparency of the Medical Device Coordination Group (MDCG), an 'expert group' providing advice on matters of policy related to medical devices. I have decided to open an inquiry.

I consider that the Commission's transparency in relation to expert groups is a matter of great importance. The Commission relies on expert groups for the development of EU legislative proposals and policy initiatives and for the implementation of existing legislation, programmes and policies. In view of this, facilitating the public scrutiny of the work of expert groups gives legitimacy to EU policy development. I have therefore looked in the past into the transparency and composition of expert groups [1] and was encouraged with the improvements the Commission introduced at the time, including the adoption of legally binding general rules [2] governing expert groups.

The complainant in this case considers that the Commission does not make available to the public sufficient information and documents about the deliberations of a specific expert group - the MDCG. He points to the rules governing the work of the MDCG, which require that all relevant documents, including the agendas, the minutes and the participants' submissions should be published. [3] He argues that the Commission's current practice, to publish the agendas and the minutes of the MDCG meetings only, is not sufficient.

The complainant would like the Commission to publish in a timely way all relevant documents from the group's meetings, except if their release would undermine the protection of a public or private interest.



According to the rules in place, all relevant documents should be made available to the public. The rules also say that “ *the agenda and other relevant background documents*” should be published “ *in due time ahead of the meeting, followed by timely publication of minutes*”. It appears this is not the case. I would therefore appreciate if the Commission could clarify its current practices in relation to the proactive publication of MDCG documents. It would also be useful if the Commission could explain what categories of documents exist in relation to the work of the MDCG.

The Commission told the complainant that it was currently reviewing its practice in this area. I invite the Commission to explain in its reply what exactly it is reviewing and what the envisaged changes are.

Please note that I am likely to send your reply and related enclosures to the complainant for comments. [4]

Once we have received the Commission’s reply, I will consider whether a meeting between the Commission representatives and my inquiry team would be helpful.

I would be grateful to receive the Commission's reply by 20 March 2023. Should the Commission have any questions, please contact the responsible inquiries officer, Ms Oana Marin.

Yours sincerely,

Emily O'Reilly European Ombudsman

Strasbourg, 19/12/2022

[1] Case OI/6/2014/NF concerning the composition and transparency of European Commission expert groups: <https://www.ombudsman.europa.eu/en/case/en/43789> .

[2] Commission Decision C(2016)3301 of 30 May 2016 establishing horizontal rules on the creation and operation of Commission expert groups, available at: [https://ec.europa.eu/transparency/documents-register/detail?ref=C\(2016\)3301&lang=en](https://ec.europa.eu/transparency/documents-register/detail?ref=C(2016)3301&lang=en) .

[3] Article 26 of the Commission Decision C(2016)3301 and Point 15 of the Rules of procedure of the Medical Device Coordination Group, available at: <https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&group> .

[4] If you wish to submit documents or information that you consider to be confidential, and which should not be disclosed to the complainant, please mark them ‘Confidential’. Encrypted emails can be sent to our dedicated mailbox.

