EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical devices, Health Technology Assessment

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Subject: Your application for access to documents – GESTDEM 2022/1665

Dear Mr Teffer,

I refer to your letter of 22 March 2022, registered on the same day under the above-mentioned reference number, in which you make a request for access to documents.

I also refer to the email of 12 April 2022 extending the time limit to respond to your request according to Article 7(3) of Regulation (EC) No 1049/2001[1].

1. Scope of your request

You request, on the basis of Regulation (EC) No 1049/2001, access to the following documents:

- *The minutes, both internal and public, of the 21-22 March 2022 meeting of the Medical Device Coordination Group, in particular about the recall case involving Philips RespironicsAll e-mails sent by members of the Medical Device Coordination Group, about Philips Respironics*
- *All presentations given and other documents shared by participants in the MDCG about Philips Respironics*

2. Identification and assessment of relevant documents

We have identified seven documents that fall within the scope of your request.

You will find attached a table listing the identified documents and summarising the outcome of the assessment carried out on the basis of Regulation (EC) No 1049/2001.

[1] Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

Having examined all the documents under the provisions of Regulation (EC) No 1049/2001, we have come to the conclusion that partial access can be granted to all documents, as their full disclosure is prevented by one of the exceptions to the right of access laid down in Article 4 of the Regulation as further explained below.

We enclose copies of the four documents redacted of the parts which cannot be disclosed.

Please note that minutes of the meeting of the Medical Device Coordination Group (MDCG) held on 21-22 March 2022 are currently being finalised. After MDCG approval they will be published in the Register of Commission Expert Groups and Other Similar Entities.

3. Reasons for partial access

With regard to all the documents, a complete disclosure is prevented by the exception concerning the protection of the privacy and integrity of the individual, in particular in accordance with EU legislation regarding the protection of personal data, as laid down in Article 4(1)(b) of Regulation (EC) No 1049/2001. The documents contain the following personal data:

- the names/initials and contact information of Commission staff members not pertaining to the senior management;
- the names/initials and contact details of other natural persons;
- handwritten signatures/abbreviated signatures of natural persons;
- other information relating to an identified or identifiable natural person such as office/phone numbers or email addresses.

Article 9(1)(b) of the Data Protection Regulation does not allow the transmission of these personal data, except if the applicant proves that it is necessary to have the data transmitted for a specific purpose in the public interest and where there is no reason to assume that the legitimate interests of the data subject might be prejudiced.

In your request, you do not express any particular interest to have access to these personal data nor do you put forward any arguments to establish the necessity to have the data transmitted for a specific purpose in the public interest.

Consequently, we conclude that, pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access cannot be granted to the personal data contained in the requested documents, as the need to obtain access thereto for a purpose in the public interest has not been substantiated and there is no reason to think that the legitimate interests of the individuals concerned would not be prejudiced by disclosure of the personal data concerned.

In accordance with the above mentioned reasons, partial access is granted to the mentioned documents, expunged of personal data.

Please note that documents originating from third parties are disclosed to you based on Regulation (EC) No 1049/2001. However, this disclosure is without prejudice to the rules on intellectual property, which may limit your right to reproduce or exploit the released documents without the agreement of the originator, who may hold an intellectual property right on them. The European Commission does not assume any responsibility from their reuse.

You may reuse public documents, which have been produced by the European Commission or by public and private entities on its behalf based on the Commission Decision on the reuse of Commission documents. You may reuse the documents disclosed free of charge and for non-commercial and commercial purposes provided that the source is acknowledged and that you do not distort the original meaning or message of the documents. Please note that the Commission does not assume liability stemming from the reuse.

4. Means of redress

In accordance with Article 7(2) of Regulation (EC) No 1049/2001, you are entitled to make a confirmatory application requesting the Commission to review this position.

Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the Secretariat-General of the Commission at the following address:

European Commission
Secretariat-General
Transparency, Document Management & Access to Documents (SG.C.1)
BERL 7/076
B-1049 Brussels

or by email to: sg-acc-doc@ec.europa.eu

Yours sincerely,

Anna-Eva Ampelas
Head of Unit