



EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

SANTE.DDG1.B.6/JH

***By registered letter
with acknowledgment of receipt¹***
Peter TEFFER
Ekko Voorkamer
Bemuurde Weerd WZ 3 3513 BH
Utrecht
Netherlands

Advance copy by email:
ask+request-8008-
13922127@asktheeu.org

Dear Mr Teffer,

Subject: Your application for access to documents – GESTDEM 2020/3409

We refer to your e-mail dated 4 June 2020 in which you make a request for access to documents, registered on the same date under the above-mentioned reference number.

We also refer to our fair solution proposal sent to you on 24 June 2020 and to your reply of 29 June 2020 (Ares(2020)3424013) modifying the scope of your request and extending the time limit to respond to your request according to Article 7(3) of Regulation (EC) No 1049/2001.

1. Scope of your request

In your request, you ask on the basis of Regulation (EC) No 1049/2001² access to:

¹ According to standard operational procedure, the reply is usually also sent to you by registered post. Please note, however, that due to the extraordinary health and security measures currently in force during the COVID-19 epidemics, which include the requirement for all Commission non-critical staff to telework, we are unfortunately not in a position to follow this procedure until further notice. We would therefore appreciate if you could confirm receipt of the present e-mail.

² Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

- *All progress reports about the European database on medical devices ('Eudamed') that the Commission is required to set up due to article 33 of Regulation (EU) 2017/745;*
- *All e-mails (including any attachments) between DG SANTE and other DG's about the development of Eudamed;*
- *All documents related to the decision to delay deployment of Eudamed until 2022.*

In your reply to our fair solution proposal, you stated:

Regarding point 1 that you can accept the limitation of progress reports communicated to Member States, but would like to receive a description or list of documents that as a consequence will not be included.

Regarding point 2 that the transfer of competence of the development of EUDAMED from the Director General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) to DG SANTE is one of your interests. You therefore proposed to limit the temporal scope of this point of your request from 1 January 2019 to January 2020. You would also be satisfied with a limitation of only all e-mails (including any attachments) between DG SANTE and DG GROW, and not any other DG's.

2. Identification and assessment of relevant documents

We have identified 65 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.

Having examined all the documents under the provisions of Regulation (EC) No 1049/2001 and considered the opinion of the third party, we have come to the following conclusion, which is further explained below:

- Full access can be granted to documents No 2 and 7.1 – 8;
- Partial access can be granted to documents No 1, 3 – 6.2 and 9 -16.2 and 17 - 20 as their full disclosure is prevented by one or more exceptions to the right of access laid down in Article 4 of the Regulation;
- No access can be granted to document No 16.3 as disclosure is prevented by one or more exceptions to the right of access laid down in Article 4 of the Regulation.

We enclose a copy of the documents No 1 – 16.2 and 17 - 20 redacted of the parts, if applicable, which cannot be disclosed as further explained below. Parts of the documents falling out of the scope of this request are also withheld.

3. Restrictions to access

- a) *Protection of the privacy and integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data - Article 4(1)(b) of Regulation (EC) No 1049/2001*

With regard to documents No 1, 3 – 6.2 and 9 -16.2 and 17 - 20 listed above, a complete disclosure of the identified documents is prevented by the exception concerning the protection of privacy and the integrity of the individual outlined in Article 4(1)(b) of Regulation (EC) No 1049/2001, because they 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.

Article 9(1)(b) of the Data Protection Regulation does not allow the transmission of these personal data, except if you prove that it is necessary to have the data transmitted to you 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 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.

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.

b) Protection of the decision-making process - Article 4(3) second sub-paragraph of Regulation (EC) No 1049/2001

Article 4(3), second subparagraph, of Regulation 1049/2001 provides that access to a document containing opinions for internal use as part of deliberations and preliminary consultations within the institution concerned shall be refused even after the decision has been taken if disclosure of the document would seriously undermine the institution's decision-making process, unless there is an overriding public interest in disclosure.

Documents No 16.1 and 16.3 to which you seek access cover information on draft functional specifications of EUDAMED, which the Commission shall draw up in collaboration with the MDCG, as stipulated in Article 34 of Regulation (EU) 2017/745. These draft changes were part of internal deliberations. They were eventually and following further internal deliberations disregarded and therefore not circulated among members of the MDCG.

The functional specifications demonstrate the basis for the development and design of EUDAMED. As such, they also provide important information to all relevant parties who will use EUDAMED. The applicable functional specifications as agreed with the MDCG and used for the development process are already publicly available. Against this background, disclosure of functional specifications not in force and which contain information that have never been applicable is likely to give a wrong impression and misleading information to the reader, thereby creating uncertainty and undermining the overall decision-making process on the EUDAMED development.

Please note that documents that are preliminary drafts do not reflect the position of the Commission and cannot be quoted as such.

We have considered whether partial access could be granted to these documents, in accordance with Article 4(6) of the Regulation, which is possible for document No 16.1, expunging the information referred to above.

It follows, however, from the assessment made above that document No 16.3 is entirely covered by the exception laid down in Article 4(3), second subparagraph.

Therefore, partial access can be granted to document No 16.1 in accordance with the restrictions referred to above. No access can be granted to document No 16.3.

4. Overriding public interests

The exceptions to the right of access provided for in Article 4(2) and (3) of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosing the requested document. In your application, you did not submit any grounds concerning a public interest on the basis of which the interests protected in Regulation (EC) No 1049/2001 would have to be overridden, and we could not identify any such ground either. In these circumstances, we have to conclude that there is no evidence of an overriding public interest in disclosure, in the sense of Regulation (EC) No 1049/2001.

5. 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 Secretary-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 Bruxelles

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

Yours faithfully,

Anne BUCHER

Enclosure: ANNEX I: list of documents (included all documents listed)