



**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY  
Health systems, medical products and innovation  
The Director

Brussels,  
SANTE/B4/ON/ab(2019)53750

***By registered letter with acknowledgement of receipt***

Ms Rachel TANSEY  
Corporate Europe Observatory  
26 rue d'Edimbourg  
1050 Brussels  
Belgium

***Advance copy by email:***  
ask+request-6014-a31cf941@asktheeu.org

Dear Ms Tansey,

**Subject: Your application for access to documents – Ref GestDem 2018/5417**

We refer to your email dated 12/10/2018 in which you make a request for access to documents, registered on 15/10/2018 under the above-mentioned reference number.

We also refer to our letter dated 24/10/2018 extending, in accordance with Article 7(3) of Regulation (EC) No 1049/2001<sup>1</sup>, the time-limit to respond to your request

Finally, we refer to our letter dated 29/11/2018 in which we already released a first batch of 29 documents.

## **1. Scope of your request**

In your request, you asked access to:

*“(i.) a list of meetings of DG SANTE officials and/or representatives (including the Commissioner and his Cabinet) and representatives of individual companies and/or industry federations (such as, but not limited to, EFPIA and/or its member companies); consultancies or law firms acting for companies/industry groups; and/or, patients groups, at which the plans for an EU regulation on Health Technology Assessment (HTA) were discussed (since January 2017);*

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

*(ii.) minutes and other reports of these meetings;*

*(iii.) all correspondence (including emails) between DG SANTE officials and/or representatives (including the Commissioner and his Cabinet) and representatives of companies and/or industry associations (including consultancies/law firms acting on their behalf), or patients groups, in which the plans for an EU regulation on Health Technology Assessment were discussed (since January 2017)”.*

As the first reply contained the assessment of documents falling within the scope of part (i.) and (ii) of your request, this final reply contains the assessment of the documents falling within the scope of part (iii.) of your request.

## **2. Identification and assessment of the documents**

As regards part (iii.) of your request, we have identified 54 documents as falling under the scope of your request.

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

Having examined these documents under the provisions of Regulation (EC) No 1049/2001 regarding public access to documents, we have come to the conclusion that:

- Partial access can be given to documents 1-54 which are indicated with “Partial” in the table of documents.

You will find in annex to this letter all documents which are indicated with “Partial”.

You may reuse the requested Commission documents free of charge 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 such reuse.

Documents originating from third parties are disclosed for information only and cannot be re-used without the agreement of the originators, who hold a copyright on them. It does not reflect the position of the Commission and cannot be quoted as such.

## **3. Reasons for refusal**

- *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*

Pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access to a document has to be refused if its disclosure would undermine the protection of privacy and the integrity of the individual, in particular in accordance with European Union legislation regarding the protection of personal data.

Documents numbered 1-54 to which you have requested access contain personal data, such as the names, email addresses, phone and office numbers of non-senior managerial Commission and stakeholders representatives.

The applicable legislation in this field is Regulation (EC) No 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC<sup>2</sup> ('Regulation 2018/1725').

Indeed, Article 3(1) of Regulation 2018/1725 provides that personal data "means any information relating to an identified or identifiable natural person [...]". The Court of Justice has specified that any information, which by reason of its content, purpose or effect, is linked to a particular person is to be considered as personal data.<sup>3</sup>

Please note in this respect that the names, signatures, functions, telephone numbers and initials pertaining to staff members of an institution are to be considered personal data.<sup>4</sup>

In its judgment in Case C-28/08 P (*Bavarian Lager*)<sup>5</sup>, the Court of Justice ruled that when a request is made for access to documents containing personal data, the Data Protection Regulation becomes fully applicable<sup>6</sup>.

Pursuant to Article 9(1)(b) of Regulation 2018/1725, "personal data shall only be transmitted to recipients established in the Union other than Union institutions and bodies if '[t]he recipient establishes that it is necessary to have the data transmitted for a specific purpose in the public interest and the controller, where there is any reason to assume that the data subject's legitimate interests might be prejudiced, establishes that it is proportionate to transmit the personal data for that specific purpose after having demonstrably weighed the various competing interests'".

Only if these conditions are fulfilled and the processing constitutes lawful processing in accordance with the requirements of Article 5 of Regulation 2018/1725, can the transmission of personal data occur.

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<sup>2</sup> Official Journal L 205 of 21.11.2018, p. 39.

<sup>3</sup> Judgment of the Court of Justice of the European Union of 20 December 2017 in Case C-434/16, *Peter Nowak v Data Protection Commissioner*, request for a preliminary ruling, paragraphs 33-35, ECLI:EU:C:2017:994.

<sup>4</sup> Judgment of the General Court of 19 September 2018 in case T-39/17, *Port de Brest v Commission*, paragraphs 43-44, ECLI:EU:T:2018:560.

<sup>5</sup> Judgment of 29 June 2010 in Case C-28/08 P, *Commission v Bavarian Lager*, paragraph 59, EU:C:2010:378.

<sup>6</sup> Whereas this judgment specifically related to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, the principles set out therein are also applicable under the new data protection regime established by Regulation 2018/1725.

According to Article 9(1)(b) of Regulation 2018/1725, the European Commission has to examine the further conditions for a lawful processing of personal data only if the first condition is fulfilled, namely if the recipient has established that it is necessary to have the data transmitted for a specific purpose in the public interest. It is only in this case that the European Commission has to examine whether there is a reason to assume that the data subject's legitimate interests might be prejudiced and, in the affirmative, establish the proportionality of the transmission of the personal data for that specific purpose after having demonstrably weighed the various competing interests.

In your request, you do not put forward any arguments to establish the necessity to have the data transmitted for a specific purpose in the public interest. Therefore, the European Commission does not have to examine whether there is a reason to assume that the data subject's legitimate interests might be prejudiced.

Consequently, we conclude that, pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access cannot be granted to the personal data, 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.

Moreover, biometric data, such as the handwritten signatures, were redacted as well, as there is a risk that their disclosure would prejudice the legitimate interests of the persons concerned.

- *Out of scope*

Documents numbered 12, 16, 27, 33, 34, and 50 cover issues unrelated to the discussion on the proposal for a Regulation on Health Technology Assessment (HTA), such as Supplementary Protection Certificates (SPC) and pharmaceutical incentives on innovation, or pharmaceutical cost allocation model. This information has therefore been redacted in the documents, as it falls outside the scope of the request, as defined in point 1 of this reply letter.

Note that for document 46, the third party has requested the addition of the following watermark "*The information contained in this document is for educational purposes only and cannot be used for promotional purposes*".

#### **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 Secretary General of the Commission at the following address:

European Commission  
Secretary-General  
Transparency, Document Management & Access to Documents (SG.C.1)  
BERL 5/282  
B-1049 Bruxelles

or by e-mail to: [sg-acc-doc@ec.europa.eu](mailto:sg-acc-doc@ec.europa.eu)

Yours faithfully,

A handwritten signature in black ink, consisting of a stylized 'A' followed by 'RYS'.

Andrzej RYS