



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY  
The Director-General

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

Ms Rachel TANSEY  
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26 rue d'Edimbourg  
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***Advance copy by e-mail:***  
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Dear Ms Tansey,

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

We refer to your e-mail 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.

### **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);*

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

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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).

*(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)."*

We consider your request to cover documents held up to the date of your request received on 12 October 2018.

As mentioned in our letter dated 24 October 2018, some documents falling within the scope of your request (namely part (iii.)) originate from third parties, which are being consulted. As the consultations are still ongoing, we are sorry to inform you that we are not yet in the position to reply to part (iii.) of your request.

As soon as the consultations have been concluded, you will receive a second reply letter containing the assessment of the documents identified under the scope of part (iii.) of your request.

This first reply thus contains only the assessment of the documents falling within the scope of part (i.) and part (ii.) of your request.

For what concerns part (i.) of your request, please find enclosed the list of meetings (Annex I) you requested which was compiled according to the Code of Good Administrative Behaviour.

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

As regards part (ii.) of your request, we have identified 31 documents as falling under the scope of your request.

You will find attached a table (Annex II) 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:

- Full access can be given to documents 6, 7, 11, 16, 17, 18 and 23 that are indicated with "Yes" in the table of documents.
- Partial access can be given to documents 1, 2, 3, 4, 5, 8, 9, 10, 12, 13, 14, 15, 19, 20, 21, 22, 24, 25, 26, 27, 28, 29, 30 and 31 that are indicated with "Partial" in the table of documents.

You will find in annex to this letter all documents which are indicated with "Yes" or "Partial".

You may reuse the requested 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.

### 3. Reasons for refusal

- *Protection of the ongoing decision-making process – Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001*

Documents 1-31 are summaries and published minutes of the meetings held between DG SANTE and stakeholders.

The summaries of the meetings (documents 1, 2, 3, 4, 5, 8, 9, 10, 11, 12, 13, 14, 15, 19, 20, 21, 22, 24, 25, 26, 27, 28, 29, 30 and 31, in Annex II) were drawn up for internal use under the responsibility of the relevant service of DG SANTE. They solely reflect the service's interpretation of the interventions made and do not set out any official position of the third parties to which the document refers, which were not consulted on their content. They do not reflect the position of the Commission and cannot be quoted as such.

Certain documents contain references to the position of the stakeholders or that of the European Commission on the proposal for a Regulation on Health Technology Assessment (HTA).

Since the European Commission is still in the process of inter-institutional negotiations on its proposal for a Regulation on Health Technology Assessment<sup>2</sup> in which it needs to take a position, the disclosure of some parts of these documents at this stage would undermine the decision-making process of the Commission.

In particular, it would reveal preliminary views and policy options which are currently under consideration; the Commission's services must be free to explore all possible options in preparation of a decision on its position, free from external pressure.

Therefore, the exception laid down in Article 4(3), first subparagraph, of Regulation (EC) No 1049/2001 applies and thus only partial access can be given to certain documents as listed above.

- *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*

Documents numbered 1, 2, 3, 4, 5, 9, 10, 12, 13, 14, 15, 19, 20, 21, 22, 24, 25, 26, 27, 28, 29, 30 and 31 to which you have requested access, contain personal data, such as the names, e-mail addresses, phone and office numbers of non-senior managerial Commission and stakeholders representatives.

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 Community legislation regarding the protection of personal data. The applicable legislation in this field is Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of

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<sup>2</sup> Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU 2018/0018 (COD).

individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data<sup>3</sup>.

When access is requested to documents containing personal data, Regulation (EC) No 45/2001 becomes fully applicable<sup>4</sup>.

According to Article 8(b) of this Regulation, personal data shall only be transferred to recipients if they establish the necessity of having the data transferred to them and if there is no reason to assume that the legitimate rights of the persons concerned might be prejudiced.

We consider that, with the information available, the necessity of disclosing the aforementioned personal data to you has not been established and/or that it cannot be assumed that such disclosure would not prejudice the legitimate rights of the persons concerned. Therefore, we are disclosing a version of the documents requested in which these personal data have been redacted.

- *Out of scope*

Documents numbered 21 and 26 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, digital healthcare, European Reference networks or cancer screening. 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.

#### **4. Overriding public interest**

The exceptions to the right of access provided for in Article 4(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. Devoid of purpose**

As regards the meetings between Commissioner Andriukaitis and/or members of his private office and stakeholders (dates 10-02-2017, 10-02-2017, 11-05-2017, 22-06-2017, 24-01-2018, 07-02-2018, 21-02-2018, 03-05-2018, 29-05-2018, 13-07-2018), we regret to inform you that the Commission does not hold any documents that would correspond to the description given in your application.

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<sup>3</sup> 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 (OJ L 8, 12.1.2001, p. 1).

<sup>4</sup> Judgment of the Court of Justice of the EU of 29 June 2010 in case C-28/08 P, *Commission/The Bavarian Lager Co. Ltd.*, ECR 2010 I-06055.

As specified in Article 2(3) of Regulation (EC) No 1049/2001, the right of access as defined in that regulation applies only to existing documents in the possession of the institution.

Given that no such documents, corresponding to the description given in your application, are held by the Commission, the Commission is not in a position to handle your request for access to the minutes of these meetings.

## **6. 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,



Anne Bucher