



**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

**Health systems, medical products and innovation**  
**Medicines: policy, authorisation and monitoring**  
**Head of Unit**

Brussels,  
SANTE/B5/AL/mmc  
sante.ddg1.b.5(2018)7370731

**By registered letter with**  
**acknowledgment of receipt**

Dear Ms Tansey,

**Subject: Your application for access to documents – Ref GestDem 2018/5418**

We refer to your e-mail of 12/10/2018 in which you make a request for access to documents, registered under the above mentioned reference number.

We also refer to our letter of 14/11/2018 extending the time limit for responding to your application, pursuant to Article 7(3) of Regulation (EC) No 1049/2001 and to our letter dated 4 December 2018 providing the first part of the documents relating to points i) and ii) of your request mentioned below.

**1. Scope of your request**

In your request, you ask on the basis of Regulation (EC) No 1049/2001<sup>1</sup> access to:

- i) a list of meetings of DG SANTE officials and/or representatives (including the Commissioner and her 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 a manufacturing waiver for Supplementary Protection Certificates (SPCs) was discussed (since June 2016);

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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).

Ms Rachel Tansey  
Corporate Europe Observatory  
Rue d'Edimbourg 26  
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Belgium

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- (ii) minutes and other reports of these meetings;
- (iii) all correspondence (including emails) between DG SANTE officials and/or representatives (including the Commissioner and Cabinet) and representatives of companies and/or industry associations (including consultancies/law firms acting on their behalf), or patients groups, in which a manufacturing waiver for Supplementary Protection Certificates (SPCs) was discussed (since June 2016).

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

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

As mentioned in our letter dated 4/12/2018, some documents falling within the scope of your request originate from third parties. Please find in annex I the list of all correspondence related to point iii) of your request for access to documents, and in Annex II, III, IV, V and VI the corresponding documents. 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 they may be only partially disclosed as their full disclosure is prevented by the exceptions to the right of access laid down in Article 4 of Regulation (EC) No 1049/2001.

## **3. Reason 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 Community legislation regarding the protection of personal data. The applicable legislation in this field is Regulation (EC) No 2018/1725<sup>2</sup> 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

All documents to which you have requested access contain personal data such as names and surnames of Commission and company's staff.

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>.

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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 Novak v Data Protection Commissioner, request for a preliminary ruling, paragraphs 33-35, ECLI:EU:T:2018:560

In its judgment in Case C-28/08 P (Bavarian Lager)<sup>4</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>5</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.

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 application, 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.

Notwithstanding the above, please note that there are reasons to assume that the legitimate interests of the data subjects concerned would be prejudiced by disclosure of the personal data reflected in the documents, as there is a real and non-hypothetical risk that such public disclosure would harm their privacy and subject them to unsolicited external contacts.

Consequently, we conclude that, pursuant to Article 4(1)(b) of Regulation 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.

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<sup>4</sup> Judgment of 29 June 2010 in Case C 28/08 P, *European Commission v The Bavarian Lager Co. Ltd*, EU:C:2010:378, paragraph 59.

<sup>5</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.

#### 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 email to: [sg-xxxxxxx@xx.xxxxxx.xx](mailto:sg-xxxxxxx@xx.xxxxxx.xx)

Yours sincerely,

*[Electronically signed]*

Olga Solomon