



**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)6830576

**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.

**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);
  
- (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).

Ms Rachel Tansey  
Corporate Europe Observatory  
Rue d'Edimbourg 26  
1050 Brussels  
Belgium

**Advance copy by email:** [ask+request-6014-a31cf9xx@xxxxxxxx.xxg](mailto:ask+request-6014-a31cf9xx@xxxxxxxx.xxg)

- (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 14/11/2018, some documents falling within the scope of your request originate from third parties, which are being consulted. The consultation is not yet finalised, however we would like to send you by this letter the first part of the documents, which relate to points i) and ii) of your request. The other documents will be sent to you in a separate letter as soon as the consultation procedure is closed.

Please find in annex I the list of meetings relating to point i) of your request for access to documents, and in Annex II the minutes requested under point ii) of your request. Please note that only one item of the agenda of the meeting listed in annex I relates to the manufacturing waiver for Supplementary Protection Certificates. Therefore, the other parts of the minutes, which fall out of scope of your request mentioned under point 1 of this letter, have been blackened.

Having examined the part of the minutes falling in the scope of your request under the provisions of Regulation (EC) No 1049/2001 regarding public access to documents, we have come to the conclusion that it may be only partially disclosed as its full disclosure is prevented by the exceptions to the right of access laid down in Article 4 of Regulation (EC) No 1049/2001.

The summary of the meeting was drawn up for internal use under the responsibility of the relevant service of DG SANTE. They solely reflect the Commission Services' 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.

## **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*

The document contains personal data (names and surnames Commission, and company's staff). 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 individuals with regards to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

When access is requested to documents containing personal data, Regulation (EC) No 45/2001 becomes fully applicable. 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 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 the document requested expunged from this personal data.

#### 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

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