



**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(2019)260993

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

Dear Ms Tansey,

**Subject: Your application for access to documents – Ref GestDem 2018/5864**

We refer to your email 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 e-mail of 29/11/2018 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;

(ii) minutes or other reports of those meetings;

(iii) all correspondence (including emails) between DG SANTE officials/representatives and private companies, industry associations, consultancies or law firms acting on their behalf, or patients groups, pertaining to the “Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe” conducted by Copenhagen Economics.

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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

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

You indicate that the scope of this request should be considered to concern the period between April 2017 and May 2018.

(iv) a list of the stakeholders that Copenhagen Economics interviewed in the preparation of its study (cf. page 11 of the study's Executive Summary refers to "more than 20 interviews with stakeholders" being conducted).

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

As mentioned in our email dated 29/11/2018, 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 Annexes II, III and IV the minutes requested under point ii) of your request, where available. Please note that the parts of the minutes falling 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 summaries of the meetings were 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. Devoid of purpose**

As regards the meetings that took place on 19/06/2017, 7/11/2017, 10/01/2018, 12/04/2018, and 2/05/2018, we regret to inform you that the Commission does not hold any documents that would correspond to the description given in your application.

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.

## **4. 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 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.

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.

In its judgment in Case C-28/08 P (Bavarian Lager), 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.

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.

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.

## **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  
Secretary-General  
Transparency, Document Management & Access to Documents (SG.C.1)  
BERL 7/076  
B-1049 Bruxelles

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

Yours sincerely,

*[Electronically signed]*

Olga Solomon