



**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)1182837

**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, our previous letter dated 23 January 2019 and our email dated 14 February 2019.

**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  
1050 Brussels  
Belgium

**Advance copy by email:** [ask+request-6014-a31cf941@asktheeu.org](mailto:ask+request-6014-a31cf941@asktheeu.org)

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 letter dated 23 January 2019, some documents falling within the scope of your request originate from third parties, which were consulted. Please find in annex I the list of documents relating to points iii) and iv) of your request for access to documents.

## **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 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<sup>2</sup>.

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 Nowak v Data Protection Commissioner*, request for a preliminary ruling, paragraphs 33-35, [ECLI:EU:C:2017:994](https://eur-lex.europa.eu/eli/ju/c/2017/994).

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.

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.

#### **4 Means of redress**

In case you would disagree with the assessment that the redacted data are personal data which can only be disclosed if such disclosure is legitimate under the applicable rules on the protection of personal data, you are entitled, in accordance with Article 7(2) of Regulation 1049/2001, to submit a confirmatory application requesting the Commission to review this position.

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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.

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-acc-doc@ec.europa.eu](mailto:sg-acc-doc@ec.europa.eu)

Yours sincerely,

*[Electronically signed]*

Olga Solomon