



## EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies  
**Health Technology and Cosmetics**

Brussels,  
GROW/D4/AM/az  
grow.ddg1.d.4(2019)347733

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

**by e-mail only:**

*ask+request-6010-12b968b5@asktheeu.org*

Dear Ms Tansey,

**Subject: Your application for access to documents - GestDem No 2018/5802**

We refer to your e-mail dated 12/10/2018 in which you make a request for access to documents, registered on 6/11/2018 under the above-mentioned reference number. We also refer to our e-mail dated 27/11/2018 extending, in accordance with Article 7(3) of Regulation (EC) No 1049/2001<sup>1</sup>, the time-limit to respond to your request, and we sincerely apologise for a delay in replying to your request.

### **1. Scope of your request**

In your request, you asked access to:

- (i) *'a list of meetings of DG GROW 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 the plans for an EU regulation on Health Technology Assessment (HTA) were discussed (since January 2017);*
- (ii) *minutes and other reports of these meetings;*
- (iii) *all correspondence (including emails) between DG GROW officials and/or representatives (including the Commissioner and her 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 submitted on 12 October 2018.

<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).

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

At the outset, we would like to explain that the Commission's service responsible for the file on Health Technology Assessment (HTA) is the Directorate-General for Food and Health Safety. Therefore, it is mainly DG SANTE who follows on meetings and exchanges with the organisations specified in your request. We understand that your request registered under GestDem No 2018/5417 covered meetings and exchanges of DG SANTE, and that you received a reply to that GestDem request by letter dated 29/11/2018 (Ares(2018)6116431) and supplemented by letter of 7/1/2019 (sante.ddg1.b.4(2019)53750).

As regards the present GestDem No 2018/5802, we have identified 8 documents (some of them with the attachments or containing preceding correspondence) as falling under the scope of your request, and specified in the attached table. As regards point (i) of your request, we are not aware of any other meetings than those referred to in the disclosed documents.

Having examined these documents under the provisions of Regulation (EC) No 1049/2001 regarding public access to documents, full access can be given after redaction of personal data, for the reasons explained below.

In addition, some of the disclosed documents address also other issues than the draft EU legislation on Health Technology Assessment, and those parts have been redacted in the documents, as falling outside the scope of the request.

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.

Documents originating from third parties are disclosed for information only and cannot be re-used without the agreement of the originators, who hold a copyright on them. They do not reflect the position of the Commission and cannot be quoted as such.

## **3. Protection of the privacy and integrity of the individual – Article 4(1)(b) of Regulation (EC) No 1049/2001**

The disclosed documents contain personal data, such as the names, e-mail addresses, phone and office numbers of non-senior 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 EU legislation regarding the protection of personal data. The applicable legislation in this field is Regulation (EC) No 45/2001<sup>2</sup>.

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<sup>2</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).

When access is requested to documents containing personal data, Regulation (EC) No 45/2001 becomes fully applicable<sup>3</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.

#### **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 e-mail to: [sg-acc-doc@ec.europa.eu](mailto:sg-acc-doc@ec.europa.eu)

Yours sincerely,

Salvatore D'Acunto  
Head of Unit

Enclosures:

- list of the documents
- disclosed documents

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<sup>3</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.