

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/DDG1/B5/OS/sgr(2016)3390195

By registered letter with acknowledgement of receipt

Dear Ms Tansey,

Subject: Your application for access to documents – GestDem 2016/2117

We refer to your email dated 20/04/2016 in which you make a request for access to documents, registered the same day under the above mentioned reference number.

You request concerns:

“– the meeting of Commissioner Vytenis Andriukaitis and Annika Nowak with the European Federation of Pharmaceutical Industries and Associations (EFPIA) on 24/02/2016, on the subject of ‘Access to Medicines, HTA, AMR’

- the meeting of Director-General Xavier Prats Monné with EFPIA on 25/11/2015, on the subject of ‘AMR’”

We enclose a copy of the following documents:

– communication with regard to the meeting of Director General Xavier Prats Monné with the European Federation of Pharmaceutical Industries and Associations-EFPIA on 25/11/2016, on the subject of AMR;

– communication with regard to the meeting of Commissioner Vytenis Andriukaitis with the European Federation of Pharmaceutical Industries and Associations – EFPIA on 24/02/2016 on the subject of Access to Medicines, HT, AMR.

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

Rachel Tansey
Corporate Europe Observatory
26 Rue d'Edimbourg
1050 Bruxelles

Advance copy by email: ask+request-2800-445eeb54@asktheeu.org

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.¹

When access is requested to documents containing personal data, Regulation (EC) No 45/2001 becomes fully applicable.² 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 that it cannot be assumed that such disclosure would not prejudice the legitimate rights of the persons concerned. Therefore, we are disclosing the documents requested expunged from these personal data.


If you wish to receive these personal data, we invite you to provide us with arguments showing the need for having these personal data transferred to you and the absence of adverse effects to the legitimate rights of the persons whose personal data should be disclosed.

In case you would disagree with the assessment that the expunged data are personal data which can only be disclosed if such disclosure is legitimate under the rules of personal data protection, you are entitled, in accordance with Article 7(2) of Regulation (EC) No 1049/2001, 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 unit SG-B-4
BERL 5/282
B-1049 Bruxelles
or by email to: sg-acc-doc@ec.europa.eu

Yours sincerely



Robert Vanhoorde

¹ Official Journal L 8 of 12.1.2001, p. 1.

² 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-6055.

Encl.:

– Communication with regard to the meeting of Director General Xavier Prats Monné with the European Federation of Pharmaceutical Industries and Associations-EFPIA on 25/11/2016, on the subject of AMR

– Communication with regard to the meeting of Commissioner Vytenis Andriukaitis with the European Federation of Pharmaceutical Industries and Associations – EFPIA on 24/02/2016 on the subject of Access to Medicines, HT, AMR