



EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL

Director General

Brussels, 17 OCT. 2014
ENTR/F4/CS/vv (2014) 3632018

James Murray
jim@eujim.eu

Subject: Your application for access to documents – Ref GestDem N° 4105/2014

Dear Mr Murray,

We refer to your e-mail dated 15/09/2014 in which you make a request for access to documents, registered on 15/09/2014 under the above mentioned reference number.

Your application concerns the following documents:

“All communications in any form and notes or records in any form of communications between DG Enterprise and any pharmaceutical Industry association concerning the policy, draft policy or decision making process of the European Medicines Agency on the issue of access to clinical trial results, after the closing of a public consultation on that issue on 30th September 2013 and before 21st May 2014”.

Please find in annex a list of disclosed documents. As some documents originate from third parties, pursuant to Article 4 (4) of Regulation (EC) No 1049/2001 these parties have been consulted and they have agreed to the disclosure of such documents.

Some of the documents to which you have requested access contain personal data.

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 regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data¹.

When access is requested to documents containing personal data, Regulation (EC) No 45/2001 becomes fully applicable². 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

¹ OJ L 8 of 12.1.2001, p. 1

² Judgment of the Court of Justice of the EU of 29 June 2010 in case 28/08 P, Commission/The Bavarian Lager Co. Ltd. not yet reported

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 this 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 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-5
BERL 5/327
B-1049 Bruxelles

or by email to: sg-acc-doc@ec.europa.eu

Yours faithfully,



Daniel Calleja

Antti I. Peltomäki
Deputy Director General