EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Medicinal products – authorisations, European Medicines Agency
Head of Unit

Brussels,
SANTE/D5/OS/an/ddg1.d.5(2015)5261469

By registered letter with acknowledgement of receipt

Advance copy by email: Giulia Paravicini
ask+request-2364-5f7c256c@asktheeu.org

Dear Ms Paravicini,

Subject: Your application for access to documents – Ref GestDem No 2015/5594

We refer to your e-mail dated 27/10/2015 in which you make a request for access to documents, registered on 27/10/2015 under the above mentioned reference number.

Your application concerns the following information and documents:

(1) all documents, correspondence, logs related to the establishment of the Expert Group on Safe and Timely Access to Medicines for Patients (E03213)

(2) all documents produced from the Expert Group up to now

(3) the name of the contact person from the EU commission who guides the expert group and his or her qualification (including details of the academic education).

(4) all the people rejected to join

(5) documents regarding personal invitation through email or verbally to inform the current members about the establishment of this expert group or telling them they should apply.

We enclose a copy of the documents requested.

The expert group on Safe and Timely Access to Medicines for Patients was created at the request of the Pharmaceutical Committee at its 73rd meeting on 22 October 2014 (recorded in the summary record of the meeting Pharma 676). The agenda and summary record as well as the background documents related to the establishment of the STAMP (Pharma 671 & 672) are available on the following link:

http://ec.europa.eu/health/documents/pharmaceutical-committee/human-meeting/index_en.htm

Ms Guilia Paravicini
POLITICO Europe
Rue de la Loi 62
1040 Brussels

As regards your request for documents produced from the Expert Group, please note that the expert group has not produced any documents so far. Meetings documents and summary records are published on the dedicated webpage under the following link:

http://ec.europa.eu/health/documents/pharmaceutical-committee/stamp/index_en.htm

The expert group has been set by DG Health and Food Safety. The expert group is chaired by the Deputy Head of the Unit "Medicinal products - authorisations, European Medicines Agency". The Chairperson is a Chemist with an MSc in Food Science who joined the Commission in 2000 and since then worked with policy and regulatory issues in the areas for food safety, substances of human origin and since 2011 in the area of pharmaceuticals.

As regards membership in the expert group, please note that the group is consisted of experts from the Member States' authorities, the European Medicines Agency and EEA countries.

The Commission services occasionally invite experts with specific competence in a subject on the agenda, to make a presentation or take part in the work of the group on an ad hoc basis. Only in one occasion there has been a request for participation from a PhD student from the University KU Leuven, however after discussion it was agreed that there was no particular link between the student's project and the work of STAMP and therefore the student did not attend the meeting.

As regards the members of the expert group these are appointed by the Member States on the basis of their expertise on the topics to be discussed. There has been no personal invitation or information sent to the current members. The invitation for STAMP was sent to Permanent Representations of the Member States to the European Union and the appointed members of the Pharmaceutical Committee.

Two of the documents that you have requested 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 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.

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[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 C-28/08 P, Commission/The Bavarian Lager Co. Ltd, ECR 2010, I-6055.

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 the documents requested expunged from this personal data.

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 5/327
B-1049 Bruxelles
or by email to: sg-acc-doc@ec.europa.eu

Yours sincerely,

Sabine Jülicher

Annexes:

1. Invitation to the Permanent Representations
2. Draft agenda
3. Privacy statement
4. Registration form
5. STAMP mandate
6. E-mail of invitation