



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Innovation and Advanced Manufacturing
Intellectual Property and Fight Against Counterfeiting

Head of Unit

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Ms Rachel Tansey
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Dear Ms Tansey,

Subject: Your application for access to documents – Ref GestDem N° 2018/5805

We refer to your e-mail of 12 October 2018 in which you make a request for access to documents, registered on 6 November 2018 under the above-mentioned reference number.

You request access to the following:

"(i) a list of meetings; (ii) minutes or other reports of those meetings; and (iii) all correspondence (including emails) between DG GROW 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. The scope of this request should be considered to concern the period between April 2017 and May 2018.

In addition, I would like to request (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)."

With our apologies for the delay, we have identified the following documents as matching the scope of your request:

- an email, sent by EuropaBio, serving as a cover for a list of case studies;
- that list of case studies; and
- a list of all interviews conducted by the contractor (Copenhagen Economics), which he sent to us – in which personal data has been redacted..

Please note that no detailed reports/summaries of the interviews conducted by the contractor were provided to the Commission. The final report (available on our website) includes all material sent to the Commission by the contractor (with the exception of purely legal and administrative documents, such as contracts, invoices, meeting requests, etc.).

Apart from this, the Commission did not have interactions with industry as regards this study. In fact it is precisely an objective of such studies to ensure that the (time-consuming) interactions with stakeholders are managed by the contractor and not by the Commission. It is also a standard policy of the Commission to ensure that all material it receives from the contractor is published in the study report.

Please note that these documents were received by the Commission from EuropaBio and Copenhagen Economic. They are disclosed for information only and cannot be re-used without the agreement of the originator, who may hold a copyright on it. In addition they do not reflect the position of the Commission and cannot be quoted as such.

Some of the documents 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 European Union 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 and Decision No 1247/2002/EC ('Regulation 2018/1725').

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.¹

In its judgment in Case C-28/08 P (Bavarian Lager) , 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.

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

¹ 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](#).

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 request, 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.

Notwithstanding the above, please note that there are reasons to assume that the legitimate interests of the data subjects concerned would be prejudiced by disclosure of the personal data reflected in the documents, as there is a real and non-hypothetical risk that such public disclosure would harm their privacy and subject them to unsolicited external contacts.

Consequently, I 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.

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.

Such a confirmatory application should be addressed within 15 working days upon receipt of this letter to the Secretariat-General of the Commission at the following address:

European Commission

Secretariat-General

Unit C.1. 'Transparency, Document Management and Access to Documents'

BERL 7/076

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

Yours sincerely,

Amaryllis VERHOEVEN
Head of Unit

Contact: D. Dambois (denis.dambois@ec.europa.eu)