EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

The Director General

Brussels,
SANTE/SG

By registered letter
with acknowledgment of receipt[1]

Mr Darío Ojeda
Vía de las Dos Castillas 33, Ática 7,
Planta 1, Oficinas E, F, G y H.
28224 Pozuelo de Alarcón, Madrid,
España

Advance copy by email to
ask+request-8667-9ff0ba22@asktheeu.org

Dear Mr Ojeda,

Subject: Your application for access to documents – Ref GestDem 2020/6250

We refer to your access to documents request of 19 October 2020 registered on the same date under the above-mentioned reference number. We also refer to our email of 10 November 2020 extending the time limit to respond to your request according to Article 7(3) of Regulation (EC) No 1049/2001 and to our email of 17 November in which we answered to the questions you posed with the initial request.

1. Scope of your request

In your request, you ask on the basis of Regulation (EC) No 1049/2001[2] access to:

— The contract with Gilead for the supply of 500.000 treatments of the medicinal product Veklury, trading name of the remdesivir, and the amount paid in total or for each of these treatments.

— All the documentation studied to justify the agreement to purchase the 500.000 treatments of Veklury.

[1] According to standard operational procedure, the reply is usually also sent to you by registered post. Please note, however, that due to the extraordinary health and security measures currently in force during to the COVID-19 epidemics, which include the requirement for all Commission non-critical staff to telework, we are unfortunately not in a position to follow this procedure until further notice. We would therefore appreciate if you could confirm receipt of the present e-mail.

[2] Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

We consider your request to cover documents held up to the date of your initial application, i.e. 19 October 2020.

1. Identification and assessment of relevant documents

We have identified two documents that fall within the scope of your request.

You will find attached a table listing the identified documents and summarising the outcome of the assessment carried out on the basis of Regulation (EC) No 1049/2001.

Since document No 2 originates/includes information referring to the third party, in accordance with Art. 4(4) of Regulation (EC) 1049/2001, the third party has been consulted in order to assess whether an exception established in Article 4 applies to these documents

Having examined all the documents under the provisions of Regulation (EC) No 1049/2001 and considered the opinion of the third party, we have come to following conclusion, which is further explained below:

- Full access can be granted to the recommendation from the European Medicines Agency to grant a conditional marketing authorization for remdesivir- document No 1.
- Partial access can be granted to the framework contract as its full disclosure is prevented by several exceptions to the right of access laid down in Article 4 of the Regulation- document No 2;

We enclose a copy of the document No 1 and a copy of the document No 2 redacted of the parts which cannot be disclosed as further explained below.

Moreover, the conditional marketing authorization is publicly available on Europa website and can be accessed through the following link:

- https://ec.europa.eu/health/documents/community-register/html/h1459.htm

- Decision https://ec.europa.eu/health/documents/community-register/2020/20200703148664/dec_148664_es.pdf

- Annex https://ec.europa.eu/health/documents/community-register/2020/20200703148664/anx_148664_es.pdf

You may reuse public documents, which have been produced by the European Commission or by public and private entities on its behalf based on the Commission Decision on the reuse of Commission documents. You may reuse the documents disclosed free of charge and 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 the reuse.

Please note that document originating from third parties are disclosed to you based on Regulation (EC) No 1049/2001. However, this disclosure is without prejudice to the rules on intellectual property, which may limit your right to reproduce or exploit the released document without the agreement of the originator/third party, who may hold an intellectual property right on it. The European Commission does not assume any responsibility from their reuse.

2. Partial disclosure of documents

a) Protection of the privacy and integrity of the individual, in particular in accordance with Community legislation regarding the protection of personal data - Article 4(1)(b) of Regulation (EC) No 1049/2001

Complete disclosure of the document No 2 is prevented by the exception concerning the protection of privacy and the integrity of the individual outlined in Article 4(1)(b) of Regulation (EC) No 1049/2001, because they contain the following personal data:

- the names/initials and contact information of staff of national authorities.
- the names/initials and contact information of staff of other natural persons.
- handwritten signatures/abbreviated signatures of natural persons.

When access is requested to documents containing personal data, Regulation (EU) 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[3] becomes fully applicable[4].

Article 9(1)(b) of the Data Protection Regulation does not allow the transmission of these personal data, except if you prove that it is necessary to have the data transmitted to you for a specific purpose in the public interest and where there is no reason to assume that the legitimate interests of the data subject might be prejudiced. In your request, you do not express any particular interest to have access to these personal data nor do you put forward any arguments to establish the necessity to have the data transmitted for a specific purpose in the public interest.

Consequently, we conclude that, pursuant to Article 4(1)(b) of Regulation (EC) No 1049/2001, access cannot be granted to the personal data contained in the requested documents, 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.

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[3] Regulation (EU) 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, OJ L 295, 21.11.2018, p. 39.

[4] 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.

In accordance with the above mentioned, partial access is granted to the documents No 2, expunged of personal data.

b) Protection of the commercial interests of a legal person - Article 4(2), first indent, of Regulation (EC) No 1049/2001

The principal objective of Union rules in the field of public procurement is the opening-up of public procurement to undistorted competition in all the Member States. We consider that granting access to this information in the context of the performance of public contracts could undermine the protection of the commercial interests of the bidders, as putting information related to the particular details of a bid in the public domain would affect their competitive position on the market.

This third party has objected to the disclosure of these documents invoking the argument that their disclosure may undermine the commercial interest of a legal person.

Therefore, having considered the opinion of the third party, we came to the conclusion that the exception laid down in Article 4(2) first indent of Regulation (EC) No 1049/2001 applies to parts of the framework contract – document No 2.

In accordance with the above mentioned, partial access is granted to the documents No 2 expunged of information that may undermine the protection of the commercial interests of the bidders.

3. Overriding public interest

The exceptions to the right of access provided for in the first indent of Article 4(2) of Regulation (EC) No 1049/2001 must be waived if there is an overriding public interest in disclosing the requested document. In your application, you did not submit any grounds concerning a public interest on the basis of which the interests protected in Regulation (EC) No 1049/2001 would have to be overridden, and we could not identify any such ground either. In these circumstances, we have to conclude that there is no evidence of an overriding public interest in disclosure, in the sense of Regulation (EC) No 1049/2001.

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
Secretariat-General

Transparency, Document Management & Access to Documents (SG.C.1)
BERL 7/076
B-1049 Bruxelles

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

Yours sincerely,

Sandra GALLINA
Director General

Enclosures: List of identified documents

Copies of disclosed documents