Subject: Your applications for access to documents – Ref EASE 2023/6754

Dear Mr Teffer,

We refer to your email of 1 November 2023 in which you make a request for access to documents, registered on 13 November 2023 under the above-mentioned reference number.

We also refer to our email of 4 December 2023 extending the time limit to respond to your request according to Article 7(3) of Regulation (EC) No 1049/2001 (1).

1. Scope of your request

In your application, based on Regulation (EC) No 1049/2001, you requested access to the following Commission document(s):

All documents - including but not limited to minutes, (hand-written) notes, audio recordings, verbatim reports, operational conclusions, lines to take, briefings, e-mails, letters, and presentations - related to meetings and/or contact with the following companies:

Swedish Match, from 28 November 2022 until 1 November 2023
Fertin Pharma, from 15 September 2021 until 1 November 2023
Vectura Group, from 15 September 2021 until 1 November 2023
OtiTopic, from 9 August 2021 until 1 November 2023
Biofourmis, from 21 May 2019 until 1 November 2023
Biognosys, from 12 July 2017 until 1 November 2023
Biovotion, from 10 July 2017 until 1 November 2023
Comet Bio, from 28 February 2017 until 1 November 2023
Softiale, from 20 June 2016 until 1 November 2023
Syqe Medical, from 1 January 2016 until 1 November 2023

2. **Identification and assessment of relevant documents**

We have identified 5 documents corresponding to 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 some documents originate from a third party in accordance with Art. 4(4) of Regulation, the originator of the documents has been consulted in order to assess whether an exception established in Article 4 applies to these documents.

Following our assessment and considering the opinion of the consulted third party we have come to the conclusion that:

- partial access can be granted to the 5 documents, as their disclosure is prevented by some exceptions to the right of access laid down in Article 4 of the Regulation (EC) No 1049/2001 listed below.

All five documents are provided as annexes to this letter, redacted of the parts that cannot be disclosed, as further explained below.

Please note that documents 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 documents without the agreement of the originator, who may hold an intellectual property right on them. The European Commission does not assume any responsibility from their reuse.

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.

3. **Reasons for partial disclosure of documents 1-5**

3.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*

A complete disclosure of documents 1-5 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/initiats and contact details of natural persons;
- other information relating to an identified or identifiable natural person.

Article 9(1)(b) of the Data Protection Regulation(2) does not allow the transmission of these personal data, except if you prove that it is necessary to have the data transmitted to

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(2) 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
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 can 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. In accordance with the above mentioned, partial access is granted to the
mentioned documents, expunged of personal data.

6. 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 to the Secretariat-General of the
Commission within 15 working days upon receipt of this letter. You can submit it in one of
the following ways:

by mail:
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

7. Acknowledgment of receipt

According to the standard operational procedure, the reply is sent by e-mail only. We
would therefore appreciate if you could explicitly confirm receipt of the e-mail within
5 working days by replying to SANTE-PHARMA-POLICY@ec.europa.eu.

Yours sincerely,

[e-signed]

Olga Solomon
Head of Unit

Enclosure: List of the documents and disclosed documents