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[REDACTED]

Brussels, 4 October 2018

IMI reference: IMI2/2018-06364

Subject: Your confirmatory application for access to documents – IMI2/INT/2018-06194

DECISION OF THE IMI2 JU EXECUTIVE DIRECTOR PURSUANT TO ARTICLE 7(2) OF THE REGULATION (EC) No 1049/2001 AND ARTICLE 6 OF THE DECISION IMI-GB-036v1-24092008 OF THE IMI GOVERNING BOARD IMPLEMENTING REGULATION 1049/2001.

Dear Sir,

We refer to your e-mail dated 13/09/2018 in which you make a confirmatory application for access to documents in accordance with Article 7(2) of the Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents (hereinafter "Regulation 1049/2001")¹, registered on 18/09/2018 under the above-mentioned reference number.

1. SCOPE OF YOUR REQUEST

In your initial request of 25/07/2018, registered on the 30/07/2018, you requested access to "*Autism Innovative Medicine Studies-2-Trials (AIMS-2-Trials) grant agreement and its appendices*".

In our reply of 10/09/2018, we identified one document falling under the scope of your request, namely the Grant Agreement No 777394 Autism Innovative Medicine Studies-2-Trials (AIMS-2-Trials).

Having examined the requested document under the provisions of the Regulation 1049/2001 regarding public access to EU documents, IMI2 JU concluded that it should be partially disclosed.

Some parts of the document have been redacted as their disclosure is prevented by exceptions to the right of access laid down in Article 4 of this Regulation. The redacted parts of the document contain commercially sensitive business information of the AIMS-2-Trials consortium or personal data, in particular names and surnames of certain members of staff of IMI2 JU and external entities. Disclosure of these parts would undermine the protection of the commercial interests of the Consortium, including its intellectual property, and of privacy and integrity of individuals.

In particular:

- the Grant Agreement was partially disclosed with redaction of commercially sensitive information and personal data of the individuals;
- the Annex 1 was withheld in its entirety considering that access to a redacted document would be meaningless;
- The Annex 2 was withheld because it contains commercially sensitive information;
- The Annex 3 contains personal data of individuals, IMI2 JU therefore shared the relevant template which is available at the following link as part of the IMI2 JU Model Grant Agreement:

¹ Official Journal L 145, 31/05/2001, p. 0043 - 0048.

https://www.imi.europa.eu/sites/defaultfiles/uploads/documents/reference-documents/h2020-mgarn_i_en_v5.pdf

- the remaining Annexes (4, 5 and 6) being templates to be used by the consortium can also be consulted as part of the IMI2 JU Model Grant Agreement at the link mentioned above.

Through your confirmatory application, you request to review this position only regarding the part of Annex 1 of the Grant Agreement that relates to the ethics requirements ("the 'ethics requirements' part of Annex 1").

2. ASSESSMENT UNDER REGULATION 1049/2001 AND ARTICLE 6 OF THE DECISION IMI-GB-036v1-24092008 OF THE IMI GOVERNING BOARD IMPLEMENTING REGULATION 1049/2001.

When assessing a confirmatory application for access to documents submitted pursuant to the Regulation 1049/2001, the IMI2 JU Executive Director conducts an independent review of the reply given by the IMI2 JU Head of Scientific operations at the initial stage. Third parties may be consulted, in case the document requested is a third-party document.

As the 'ethics requirements' part of Annex 1", we have identified the specific "Ethics and Security" chapter of Annex 1, as well as Work package 7 of the same Annex. For the rest of the document concerned by your initial application, to which partial access has been granted, based on IMI2 reply of 10/9/2018, no confirmatory application has been submitted.

Following this assessment, I am pleased to inform you that I have concluded that the part of Annex 1 of the Grant Agreement that relates to the ethics requirements may be partially disclosed, with some of its parts redacted based on Article 4(1) (b) of Regulation (EC) No 1049/2001 (protection of personal data).

You may reuse the enclosed part of the document free of charge 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 document.

Please note that IMI2 JU does not assume liability stemming from the reuse.

3. PROTECTION OF PERSONAL DATA

Some parts of the document have been redacted as their disclosure is prevented by exceptions to the right of access laid down in Article 4 of this Regulation. These parts contain personal data, in particular names of persons working in the project.

Article 4(1)(b) of Regulation 1049/2001 provides that *[t]he institutions shall refuse access to a document where 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 withheld names are clearly personal data, as defined in Article 2(a) of 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 (hereinafter Regulation 45/2001²). Surnames and forenames constitute personal data³. According to Article 2(a) of Regulation (EC) No 45/2001, personal data means *any information relating to an identified or identifiable natural person [...]*.

As was stated by the Court of Justice in case C-465/00, there is no reason of principle to justify excluding activities of a professional nature from the notion of "private life"⁴.

² Official Journal L 8, 12/1/2001, p. 1–22.

³ C-28/08 P, Commission v. The Bavarian Lager Co. Ltd [2010], ECR 2010 I-06055, para.68.

⁴ Joined Cases C-465/00, C-138/01 and C-139/01, Court of Auditors v ORF [2003], ECR 2003 I-04989, para. 73.

The Court of Justice has confirmed that where a request based on Regulation No 1049/2001 seeks to obtain access to documents including personal data, the provisions of Regulation 45/2001 become applicable in their entirety, including Articles 8 and 18 thereof. Pursuant to Regulation 45/2001, personal data must be processed fairly and lawfully. Any processing must be necessary for a specific purpose and proportionate to this purpose.

Furthermore, pursuant to Article 8 of Regulation 45/2001, IMI2 JU can only transmit personal data to a recipient subject to Directive 95/46/EC (now replaced by the General Data Protection Regulation Regulation (EU) 2016/679) if the recipient establishes that the data are necessary for the performance of a task carried out in the public interest or subject to the exercise of public authority or if the recipient establishes the necessity of having the data transferred and if there is no reason to assume that the data subject's legitimate interests might be prejudiced.

In your confirmatory application, you do not establish that the personal data are necessary for the performance of a task carried out by yourself in the public interest. Nor do you demonstrate that there is the necessity of having the data transferred and that the legitimate rights of the data subjects concerned would not be prejudiced by such disclosure.

Moreover, please note, that Article 4(1)(b) does not provide for a possibility for the interests protected to be overridden by a public interest in disclosure.

4. MEANS OF REDRESS

Finally, I draw your attention to the means of redress available against this decision. You may either bring proceedings before the General Court or file a complaint with the European Ombudsman under the conditions specified respectively in Articles 263 and 228 TFEU.

Yours sincerely,



Pierre Meulien

Enc. - Ethics-related excerpt of ANNEX I of the AIMS-2-TRIALS Grant Agreement (partly redacted);
- Work Package 7, described in Annex 1 of the AIMS-2-TRIALS Grant Agreement.