EUROPEAN COMMISSION
Directorate-General for Trade

Directorate A - Resources, Information and Policy Coordination
Information, Communication and Civil Society

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By registered letter with acknowledgment of receipt

Rachel Tansey
Corporate Europe Observatory (CEO)
26 rue d'Edimbourg
1050 Brussels
Belgium

Advance copy by email:
ask+request-2801-31f5cabe@asktheeu.org

Subject: Your application for access to documents – Ref GestDem No 2016/2158

Dear Ms Tansey,

I refer to your e-mail dated 20 April 2016 in which you make a request for access to documents under Regulation (EC) No 1049/2001 ("Regulation 1049/2001"),[1] registered on 22 April under the above mentioned reference number.

1. SCOPE OF YOUR REQUEST

You requested access to the following documents:

"*all communication, including emails and documents (agenda, minutes, list of participants, etc.) relating to the meeting of Commissioner Cecilia Malmström with the European Federation of Pharmaceutical Industries and Associations (EFPIA) on 24/02/2016, on the subject of "TTIP, CETA, affordable medicines*".

We have identified the following documents as falling under the scope of your request:

1. The meeting report registered under Ares No(2016)980242) ("**document 1**");

2. A letter sent by Novartis to Commissioner Malmström on 9 March 2016 registered under Ares No(2016)1442682 ("**document 2**").

[1] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 20 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

Having carefully examined the documents identified above in light of the applicable legal framework, **we are pleased to release them in full.** Copies of the accessible documents are enclosed in Annex I.

Only names and other personal data have been redacted pursuant to Article 4.1(b) of Regulation 1049/2001.

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 Court of Justice has ruled that *"where an application based on Regulation 1049/2001 seeks to obtain access to documents containing personal data" "the provisions of Regulation 45/2001, of which Articles 8(b) and 18 constitute essential provisions, become applicable in their entirety".*[2]

Article 2(a) of Regulation 45/2001 provides that *"'personal data' shall mean any information relating to an identified or identifiable natural person [...]".* The Court of Justice has confirmed that *"there is no reason of principle to justify excluding activities of a professional [...] nature from the notion of 'private life'"*[3] and that *"surnames and forenames may be regarded as personal data",*[4] including names of the staff of the institutions.[5]

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"* and additionally *"if there is no reason to assume that the legitimate interests of the data subjects might be prejudiced".* The Court of Justice has clarified that *"it is for the person applying for access to establish the necessity of transferring that data".*[6]

The cocuments contain names and other personal information that allow the identification of natural persons.

We note that that you have not established the necessity of having these personal data transferred to you. Moreover, it cannot be assumed on the basis of the information available, that disclosure of such personal data would not prejudice the legitimate interests of the persons concerned. Therefore, these personal data shall be removed in order to ensure the protection of the privacy and integrity of the individuals concerned.

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2 Judgment in *Guido Strack v Commission,* C-127/13 P, EU:C:2014:2250, paragraph 101; see also judgment in *Commission v Bavarian Lager,* C-28/08 P, EU:C:2010:378, paragraphs 63 and 64.

3 Judgment in *Rechnungshof v Rundfunk and Others*, Joined cases C-465/00, C-138/01 and C-139/01, EU:C:2003:294, paragraph 73.

4 Judgment in *Commission v Bavarian Lager,* C-28/08 P, EU:C:2010:378, paragraph 68.

5 Judgment in *Guido Strack v Commission,* C-127/13 P, EU:C:2014:2250, paragraph 111.

6 *Id.*, paragraph 107; see also judgment in C-28/08 P *Commission v Bavarian Lager,* EU:C:2010:378, paragraph 77.

We do however disclose in the documents released the names of Commissioners, members of Cabinet, Directors General, members of European Parliament, Presidents and Directors of the companies invited.

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Please note that you may reuse the documents disclosed 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. The Commission does not assume liability stemming from the reuse.

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In accordance with Article 7(2) of Regulation 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
Secretary-General
Transparency unit SG-B-4
BERL 5/327
B-1049 Bruxelles
sg-acc-doc@ec.europa.eu

Yours sincerely,

Lutz Güllner
Head of Unit

Encl.:
Annex I: partially disclosed documents

(1)

To: [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE); [redacted] (TRADE)

Cc: BILLAUX Cecile (CAB-MALMSTROM)

Subject: Meeting report Cssr Malmström-Joe Jimenez (Novartis)

Dear all,

Please find below the report of the Cssr meeting with Joe Jimenez (CEO Novartis) and EFPIA yesterday. Thanks to those of you who provided input for the briefing.

Kind regards,

[redacted]

Meeting Commissioner Malmström and Novartis, 24 February 2016

Participants:

- *Joseph Jimenez (CEO Novartis), Max von Olenhusen (Novartis), [redacted] (EFPIA), [redacted] (EFPIA)*
- *Cssr Cecilia Malmström, Cécile Billaux (CAB), [redacted] (DG, B3), [redacted] (DG, G3)*

This meeting was requested by Mr Jimenez to exchange views on the TTIP agreement, CETA and the global debate on affordable medicines.

Mr Jimenez gave a brief presentation on Novartis in Europe and globally and on how the pharmaceutical sector is a driver for economic growth in the EU.
He also congratulated the EU with the conclusion of the FTA with Vietnam which provides a good deal for the pharmaceutical sector in terms of IPR, regulatory data protection, market access and pricing.

Mr Jimenez raised the issue on the 'promise doctrine' in Canada, which is a big concern for them.

Furthermore, Novartis and EFPIA expressed their support for TTIP, especially with regard to the ambitions on regulatory harmonisation. If TTIP could entail regulatory harmonisation, costs could be radically reduced for both regulators and companies; this would allow investment in other priority areas and enhance access to new treatments. The Commissioner explained that regulatory cooperation is the 'theme' of this 12th TTIP Round in Brussels as this is a priority deliverable for the EU, e.g. the mutual recognition of GMP inspections. Furthermore, both sides also discuss IPR cooperation, biosimilars, generics and scientific collaboration. Both Commission and industry underlined the importance of a vocal business community to explain the benefits of a possible TTIP agreement and to get rid of false myths around the negotiations and its impact. The Commissioner also shared her experience stating that local examples work best to show the benefits of a possible TTIP agreement to the public.

Mr Jimenez also briefly presented Novartis and Sanofi programmes which bring affordable medicines to patients in developing countries. His experience is that IP protection is important for companies to develop their business in developing countries which enables access to treatment.

Finally, Mr Bergström raised the UN panel on health technology innovation and access to medicines, EFPIA is concerned that IPR protection could be undermined in the outcome of the panel.

The Commissioner thanked EFPIA for their support to the EU's trade agenda and concluded the meeting by providing an overview of the upcoming trade negotiations.

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NOVARTIS

Ms. Cecilia Malmström
Commissioner for Trade
European Commission
200, rue de la Loi
1049 Brussels
Belgium

Basel, March 9, 2016

Dear Commissioner,

Thank you for taking the time to meet with us on February 24 to discuss key topics of interest to our industry, such as trade, IP and access to medicines.

Let me take this opportunity to reiterate our strong belief that free trade agreements are an excellent means to foster relationships with like-minded economies to the benefit of European consumers and the competitiveness of the EU.

In this context I would also like to emphasize that strong intellectual property frameworks are not the root cause for the lack of access to healthcare in many countries. Those living in economies with fair or strong IP have a 30% greater chance to benefit from access to new technologies as compared to those in weak IP environments, since companies are encouraged to introduce new products faster. IP has positive effects not only on strong R&D but also on market development, e.g. to set up local supply chains that ensure that medicines reach patients, and educating doctors and patients on proper use of medicines, which ultimately improves patient outcomes. Novartis is committed to improving access in low-income countries, as demonstrated by our recent launch of the "Novartis Access" program.

I would like to thank you for your continued support in addressing our industry's IP challenges, both in trade negotiations and in bilateral discussions. We look forward to continuing to work with you and your services in the months ahead.

If I can be of assistance, please reach out to me. In the meantime, Max von Olenhusen, our Head of the Novartis EU office, can be reached directly on [redacted] or at [redacted]@novartis.com to share the latest research on the benefits of IP for society.

Best regards,

[redacted]

Joseph Jimenez

[redacted]

cc: Max von Olenhusen