

DG SANTE
ARES/ 3885954
03 AOUT 2017
DEADLINE/ C.F/



**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL FOR HEALTH  
AND FOOD SAFETY

Director-General



**EUROPEAN MEDICINES AGENCY**  
SCIENCE MEDICINES HEALTH

EMA/490709/2017

**STATEMENT OF AUTHORITY  
AND  
CONFIDENTIALITY COMMITMENT FROM  
THE EUROPEAN COMMISSION'S DIRECTORATE-GENERAL FOR HEALTH  
AND FOOD SAFETY AND THE EUROPEAN MEDICINES AGENCY  
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION SHARED  
BY  
THE UNITED STATES FOOD AND DRUG ADMINISTRATION**

The United States Food and Drug Administration (FDA) is authorized under 21 C.F.R. § 20.89<sup>1</sup> to disclose non-public information to the European Commission's Directorate-General for Health and Food Safety (DG SANTE) and to the European Medicines Agency (EMA) regarding FDA-regulated drugs, including pre- and post-market activities, as appropriate, as part of cooperative law enforcement or cooperative regulatory activities. FDA is further authorized under section 708(c) of the Federal Food, Drug, and Cosmetic Act<sup>2</sup> to share with a foreign government, as it deems appropriate and under limited circumstances, certain types of trade secret information.

The Commissioner of FDA has certified DG SANTE and EMA as having the authority and demonstrated ability to protect trade secret information from disclosure. FDA therefore may provide DG SANTE and EMA with certain types of trade secret information at FDA's discretion and upon request by DG SANTE and EMA, based on the following certifications.

DG SANTE and EMA understand that some of the information they receive from FDA may include non-public information exempt from public disclosure, such as commercially confidential information, trade secret information, private personal information / personal data<sup>3</sup>, law enforcement information, designated national security information or internal,

<sup>1</sup> United States Code of Federal Regulations, Title 21, section 20.89.

<sup>2</sup> United States Code, Title 21, section 379(c).

<sup>3</sup> In disclosing personal data, DG SANTE and EMA are subject to Regulation (EC) No 45/2001.

**Directorate General for Health and Food Safety**  
**Postal address** Rue Breydel 4, B - 1049 • Brussels  
Belgium  
**Telephone** +32 2 299 11 11  
**Send a question via our website**  
[http://ec.europa.eu/dgs/health\\_food-safety/contact](http://ec.europa.eu/dgs/health_food-safety/contact)

**European Medicines Agency**  
30 Churchill Place • Canary Wharf London E14 5EU  
United Kingdom  
**Telephone** +44 (0)20 3660 6000  
**Send a question via our website**  
[www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

pre-decisional information. DG SANTE and EMA understand that this non-public information is shared in confidence and that it is critical that DG SANTE and EMA maintain the confidentiality of exchanged non-public information. Public disclosure of exchanged non-public information by DG SANTE and/or EMA could seriously jeopardize any further scientific and regulatory interactions between DG SANTE/EMA and FDA. FDA will advise DG SANTE and EMA of the non-public status of the information at the time that the information is shared.

Therefore, DG SANTE and EMA certify that:

1. they have the authority to protect from public disclosure such non-public information provided to DG SANTE<sup>4</sup> and/or EMA in confidence by FDA if and insofar as that information is covered by the exceptions provided for in Article 4 of Regulation (EC) No 1049/2001<sup>5</sup> as interpreted by the Court of Justice of the European Union<sup>6</sup>;
2. without prejudice to the provisions of Regulation (EC) No 1049/2001<sup>7</sup>, in the event that DG SANTE and/or EMA receive a request for disclosure of the non-public information provided by FDA that is held by DG SANTE and/or EMA, DG SANTE and/or EMA will in good faith rely on any appropriate exceptions provided for in Article 4 of Regulation (EC) No 1049/2001, to refuse disclosure of non-public information;
3. DG SANTE and/or EMA may not need to rely on any appropriate exceptions provided for in Article 4 of Regulation (EC) No 1049/2001, to refuse disclosure of non-public information, if they are in possession of a written permission for disclosure by the sponsor of the information provided by FDA, or alternatively of a declaration from the Commissioner of Food and Drugs of a public health emergency under section 319 of the Public Health Service Act that is relevant to the information;

---

<sup>4</sup> Without prejudice to the provisions of Regulation (EC) No 1049/2001 with respect to the mandatory treatment of possible confirmatory requests within the meaning of Article 7.2 and possible subsequent judicial proceedings under Article 8.1 of Regulation (EC) No 1049/2001.

<sup>5</sup> Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (Official Journal L 145, 31/05/2001, p. 43-48).

<sup>6</sup> Protection of public interest as regards public security, defense and military matters, international relations, the financial, monetary or economic policy of the Union or a Member State; protection of privacy and the integrity of the individual, in particular in accordance with Union legislation regarding the protection of personal data and exceptions pertaining to the protection of commercial interests of a natural or legal person, including intellectual property, court proceedings and legal advice, the purpose of inspections, investigations and audits, protection of the institution's decision-making process unless there is an overriding interest in disclosure.

<sup>7</sup> With respect to the mandatory treatment of possible confirmatory requests within the meaning of Article 7.2 and possible subsequent judicial proceedings under Article 8.1 of Regulation (EC) No 1049/2001.

---

**Directorate General for Health and Food Safety**  
**Postal address** Rue Breydel 4, B - 1049 • Brussels  
Belgium  
**Telephone** +32 2 299 11 11  
**Send a question via our website**  
[http://ec.europa.eu/dgs/health\\_food-safety/contact](http://ec.europa.eu/dgs/health_food-safety/contact)

**European Medicines Agency**  
30 Churchill Place • Canary Wharf London E14 5EU  
United Kingdom  
**Telephone** +44 (0)20 3660 6000  
**Send a question via our website**  
[www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

4. with respect to trade secret information concerning the inspection of a drug facility, DG SANTE and EMA have the authority to otherwise obtain such information and will use such FDA-provided information only for civil, administrative regulatory purposes in the context of their missions;

5. they will inform FDA promptly of any effort made by judicial mandate or parliamentary inquiry to obtain FDA-provided non-public information from DG SANTE and/or EMA, insofar as it does not harm that judicial investigation or parliamentary inquiry. DG SANTE and/or EMA will request permission from the respective Parliament or Court to inform FDA of the existence of such a mandate or inquiry. If such judicial mandate or parliamentary inquiry requires disclosure of FDA-provided non-public information, DG SANTE and/or EMA will take all appropriate measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure; and

6. they will promptly inform FDA of any changes to the European Union's laws, or to any relevant policies or procedures, that would affect DG SANTE's and/or EMA's abilities to honor the commitments in this document.

DG SANTE and EMA may share information received from FDA with representatives of EU Member States Regulatory Authorities provided that these Authorities and FDA have concluded an applicable arrangement covering the exchange of the same information as per the present arrangement. FDA will inform DG SANTE and EMA of such arrangements that have been concluded with the EU Member States Regulatory Authorities. Until FDA has concluded such arrangements, EMA may continue sharing with the EU Member States Regulatory Authorities the non-public information (other than trade secrets) provided by the FDA which is covered by the Cooperation Agreement between EMA and the EU Member States Regulatory Authorities. FDA understands that DG SANTE and EMA may share FDA provided information with each other.

With respect to trade secret information exchanged under this arrangement, if DG SANTE and EMA share information received from FDA with EU Member States Regulatory Authorities, as described above, DG SANTE and EMA will keep FDA informed promptly about such information sharing. At the time the information is shared, DG SANTE and EMA will advise the EU Member States Regulatory Authorities of the non-public, trade secret status of the FDA-provided information shared.

DG SANTE, EMA, and FDA do not intend for this text to create rights and obligations under international or other law. This text partially replaces the Confidentiality


---

**Directorate General for Health and Food Safety**  
**Postal address** Rue Breydel 4, B - 1049 • Brussels  
Belgium  
**Telephone** +32 2 299 11 11  
**Send a question via our website**  
[http://ec.europa.eu/dgs/health\\_food-safety/contact](http://ec.europa.eu/dgs/health_food-safety/contact)

**European Medicines Agency**  
30 Churchill Place • Canary Wharf London E14 5EU  
United Kingdom  
**Telephone** +44 (0)20 3660 6000  
**Send a question via our website**  
[www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

arrangement (exchange of letters) between DG SANCO<sup>8</sup> and FDA concluded on 6 June 2005 and the Confidentiality arrangement (exchange of letters) between EMA and FDA concluded on 14 September 2010 in as far as FDA-regulated drugs and EU-regulated medicinal products are concerned. As a result, the two above-mentioned previous Confidentiality arrangements will remain in effect with respect to information exchanged in accordance therewith on any other products. Information that was considered non-public information under the previous Confidentiality arrangements will continue to be treated as such.

Signed on behalf of DG SANTE

  
Xavier Prats Monné  
Director-General

3. 8. 17  
Date

European Commission  
Directorate-General for Health and Food Safety  
Rue Breydel 4, B-1049 Brussels  
Belgium

Signed on behalf of EMA

  
Guido Ras  
Executive Director

01. 08. 17  
Date

European Medicines Agency  
30 Churchill Place,  
Canary Wharf, London E14 5EU  
United Kingdom

<sup>8</sup> DG SANTE was called DG SANCO in 2005. In case of future changes in the organisation chart of the Commission regarding assignment of responsibilities between different Directorates-General, this confidentiality commitment will continue to be applicable to the Directorate-General of the Commission which has within its remit responsibility for medicinal products.

**Directorate General for Health and Food Safety**  
Postal address Rue Breydel 4, B - 1049 • Brussels  
Belgium  
Telephone +32 2 299 11 11  
Send a question via our website  
[http://ec.europa.eu/dgs/health\\_food-safety/contact](http://ec.europa.eu/dgs/health_food-safety/contact)

**European Medicines Agency**  
30 Churchill Place • Canary Wharf, London E14-5EU  
United Kingdom  
Telephone +44 (0)20 3660 6000  
Send a question via our website  
[www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)