SPECIFIC PRIVACY STATEMENT

PUBLIC CONSULTATION ON DETAILED ARRANGEMENTS FOR GOOD CLINICAL TRIAL INSPECTION PROCEDURES INCLUDING THE QUALIFICATIONS AND TRAINING REQUIREMENTS FOR INSPECTORS, PURSUANT TO ARTICLE 78(7) OF REGULATION (EU) NO 536/2014

1. OBJECTIVE

The objective of this consultation is to receive the views of stakeholders and potentially to publish the received contributions on the Internet, under the responsibility of the Head of Unit "D6 – Medicinal products – Quality, Safety and Efficacy", Directorate-General for Health and Food Safety, European Commission.

As this online service collects and further processes personal data, it is subject to data protection rules as established by Regulation (EC) 45/2001[1].

2. WHAT PERSONAL INFORMATION DO WE COLLECT AND THROUGH WHICH TECHNICAL MEANS?

2.1. Identification Data

Personal data collected and further processed are only those data which are necessary for the management of contributions (name, surname, profession, postal and e-mail addresses, phone number/fax number).

The processing operations on personal data linked to the management of this consultation are necessary for the functioning of the Commission as mandated by the Treaties, and more specifically by Articles 5 and 13 TEU and Articles 244 - 250 TFEU.

Technical information

Your contribution will be collected, together with your personal data, through e-mail. The e-mail system of the European Commission abides by the Commission's security decisions and provisions established by the Directorate of Security.

3. WHO HAS ACCESS TO YOUR INFORMATION AND TO WHOM IS IT DISCLOSED?

Received contributions, together with the identity of the contributor, will be published on the Internet, unless the contributor objects to publication of his/her

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[1] Regulation (EC) 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

personal data on the grounds that such publication would harm his or her legitimate interests. In this case, the contribution may be published in an anonymous form. Otherwise, in the absence of a legitimate interest to oppose publication of personal data, the contribution will not be published nor will, in principle, its content be taken into account. Any objections concerning publication of personal data should be sent to the service responsible for the consultation (*see* Contact information below).

4. HOW DO WE PROTECT AND SAFEGUARD YOUR INFORMATION?

Received contributions will be recorded in a secured and protected database hosted by the Data Centre of the European Commission, the operations of which abide by the Commission's security decisions and provisions established by the Directorate of Security for this kind of servers and services. The database is not accessible from outside the Commission. Inside the Commission, the database can be accessed using a UserID/Password.

In case you want to verify which personal data is stored, have it modified, corrected or deleted, please contact us using the Contact Information below and explicitly specifying your request.

5. HOW LONG DO WE KEEP YOUR DATA?

Your personal data will remain in the database until the results of the consultation have been completely analysed and usefully exploited. Personal data will be deleted, at the latest, 1 year after the last action in relation to the consultation in question.

6. CONTACT INFORMATION

In case you wish to verify which personal data is stored, have it modified, corrected, or deleted, or if you have questions regarding the information processed in the context of the consultation, or on your rights, feel free to contact the support team at:

Unit D6 – Medicinal products – Quality, Safety and Efficacy
Functional Mailbox SANTE-PHARMACEUTICALS-D6@ec.europa.eu

7. RECOURSE

Complaints, in case of conflict, can be addressed to the European Data Protection Supervisor.