

SPECIFIC PRIVACY STATEMENT

Targeted stakeholder consultation on duplicate marketing authorisations for biological medicinal products

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 "Medicinal Products: policy, authorisation and monitoring", Directorate-General for Health and Food Safety, European Commission.

As this procedure collects and further processes personal data, it is subject to data protection rules as established by Regulation (EC) 45/2001¹.

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 (such as name, surname, profession, postal and e-mail addresses, signature, phone and fax numbers), as well as the views of contributors on the topics concerned.

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.

2.2. 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 general security and safety measures for the Commission infrastructure and networks (see Generic notification DPO-1.6 on IT infrastructure for Commission services by DG DIGIT).

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

Received contributions and/or a summary report, together with the identity of the contributor, will be published on the Internet, unless the contributor objects to publication of his/her personal data on the grounds that such publication would harm his or her legitimate interests. In this case, the contribution may be published without the name, surname, postal and e-mail addresses, signature, phone and fax numbers. Otherwise, in the absence of a legitimate interest to

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.

oppose publication of personal data, the contribution will not be published nor will, in principle, its content be taken into account.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 general security and safety measures for the Commission infrastructure and networks (see Generic notification DPO-1.6 on IT infrastructure for Commission services by DG DIGIT) 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.

5. HOW CAN YOU VERIFY, MODIFY OR DELETE YOUR INFORMATION?

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.

6. HOW LONG DO WE KEEP YOUR DATA?

Personal data are kept as long as follow-up actions to the targeted stakeholder consultation are necessary with regard to the purpose for which the data were collected and further processed.

All personal data will be deleted from databases one year after the last action in relation to the targeted consultation by default. During this period of one year, where needed, personal data will be part of a list of contact details shared internally amongst the staff of Commission services for the purpose of contacting data subjects in the future in the context of the Commission's activities. If you do not agree, please contact us using the Contact Information below and explicitly specifying your request.

7. 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:** "Medicinal Products: policy, authorisation and monitoring"
- **Functional Mailbox:** sante-pharmaceuticals-B5@ec.europa.eu

8. RECOURSE

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

9. WHERE TO FIND MORE DETAILED INFORMATION?

The Commission Data Protection Officer publishes the register of all operations processing personal data. You can access the register on the following link: <http://ec.europa.eu/dpo-register>

This specific processing has been notified to the DPO with the following reference: DPO-3411.