



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical products: quality, safety, innovation

PRIVACY STATEMENT

EU CODING PLATFORM AUTHORISED USERS

1. The EU Coding Platform

The EU Coding Platform laid down by Directive 2006/86/EC as amended by Directive (EU) 2015/565 is the IT platform hosted by the Commission that contains the EU Tissue Establishment Compendium and the EU Tissue and Cell Product Compendium.

The EU Tissue Establishment Compendium is the register of all tissue establishments which are authorised, licensed, designated or accredited by the Member States' competent authority or authorities and which contains the information about these tissue establishments along with their corresponding TE codes.

The EU Tissue Establishment Compendium is hosted by the EC and maintained by the MS competent authority or authorities. Each competent authority is responsible for the accuracy of the entries of the tissue establishments that they have licensed/authorised and for keeping these entries up-to-date.

The abovementioned information is entered in the EU Coding Platform by the national competent authority's user and is stored under the responsibility of the European Commission's Directorate-General for Informatics via EU Login/SAAS and under the responsibility of a local administrator of each Competent Authority.

The related processing of personal data is subject to Regulation (EU) 2018/1725 of the European Parliament and of the Council of 11 December 2018 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.

2. What personal information does us collect and for what purpose?

The processing of personal data within the EU Coding Platform is based on the legal requirement of Article 9 of Commission Directive 2005/61/EC¹ on the communication of information between the Competent Authorities for Tissues and Cells and the European Commission.

¹Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:256:0032:0040:EN:PDF>

The following personal data relating to users are stored in the EU Coding Platform (mandatory data fields are marked with an asterisk):

- Name (*)
- Phone (*)
- Country (*)
- Email (*)

The following personal data relating to responsible persons are processed in the EU Coding Platform (mandatory data fields are marked with an asterisk):

- Name (*)
- Phone
- Country (*)
- Email (*)

3. Who has access to your information and to whom is it disclosed?

Data notified through the EU Coding under Article 9 of Commission Directive 2005/61/EC are made available to National Competent Authorities for “Tissues and Cells” and the European Commission.

However, where precautionary/corrective action taken is relevant an exchange of information should be ensured with the national and European regulatory authorities responsible for these sectors (e.g.: EMA, ECDC and/or other SANTE units).

4. How do we protect and safeguard your information?

The collected personal data are stored in servers of the Data Centre of the European Commission's Directorate-General for Informatics, the operations of which underlie the Commission's security decisions and provisions established by the Security Directorate for this kind of servers and services.

Access to personal data is only granted through personalized user ID and Password.

5. How can you verify, modify or delete your information?

If you are a "user" for a given competent authority and would like to have access to your personal data processed within the EU Coding Platform, or have them rectified, blocked or deleted, you should contact the responsible person who collected and entered your data in the EU Coding Platform.

The responsible person is able to retrieve your data in the EU Coding Platform e and perform the necessary correction, update or deletion. To exercise your rights with respect to data processing acts executed under the Commission's responsibility, you should contact the Controller at the Commission by using the "Contact information" below and explicitly specifying your request.

Legitimate requests will be replied by the Controller at the Commission within 30 working days as from receipt of the request.

6. How long do we keep your data?

Personal data of a "users" are kept in a form which permits identification and may be consulted by competent authorities and the European Commission. Personal data are deleted as soon as the individual is no longer designated as user in any valid notification in the EU Coding Platform.

For public health reasons, personal data on "users" are kept in a form which permits identification (and may be therefore consulted by EU Coding Platform users) during 30 years, starting from the date these data are entered into EU Coding, since some alerts can be produced during such a period.

7. Contact information

If you have questions concerning the processing of your personal data by the Commission within the EU Coding Platform, or your rights with respect to that processing, you may contact the responsible Controller at the Commission at the following address:

Unit B4 – Medical Products: quality, safety, innovation
Directorate General Health & Food Safety
European Commission
Rue Froissart 101
B - 1049 Brussels
Belgium
SANTE-SOHO@ec.europa.eu

8. Recourse

Complaints against any data processing act executed under the Commission's responsibility can be addressed to the European Data Protection Supervisor at the following address:

European Data Protection Supervisor (EDPS)
Rue Wiertz 60
B-1047 Brussels
Belgium
Phone: +32 2 283 19 00
Fax: +32 2 283 19 50
edps@edps.europa.eu