



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 above mentioned 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 do we 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>

Data subjects concerned by the processing of personal data of users within the EU Coding Platform are:

- EU Coding Platform authorized users (Commission staff) and;
- EU Coding Platform authorized users (Member States' competent authority users).

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 Member States' competent authority users are processed in the EU Coding Platform (mandatory data fields are marked with an asterisk):

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

3. On what legal ground(s) do we process your personal data

We process your personal data, because processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the Union institution or body, and, for complying with a legal obligation to which the controller is subject (Article 5(1)(a) and (b) of Regulation (EU) 2018/1725).

4. 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 only to the European Commission.

5. How do we protect and safeguard your information?

In order to protect data subjects, the Commission has put in place a number of technical and organisational measures. Technical measures include appropriate actions to address online security, risk of data loss, alteration of data or unauthorised access, taking into consideration the risk presented by the processing and the nature of the personal data being processed. Organisational measures include restricting access to the personal data solely to authorised persons with a legitimate need to know for the purposes of this processing operation.

All personal data in electronic format (e-mails, documents, databases, uploaded batches of data, etc.) are stored either on the servers of the European Commission or of its contractors. All processing operations are carried out pursuant to the Commission Decision (EU, Euratom) 2017/46 of 10 January 2017 on the security of communication and information systems in the European Commission.

6. How long do we keep your data?

EU Coding Platform authorized users will have their personal data stored in the EU Login/SAAS with an access to EU Coding Platform as long as they hold their capacity as authorised users of the system. It is the responsibility of the Local administrator to remove the access rights to a national EU Coding Platform user. Personal data will be deleted as soon as the Commission is notified that the person in question is no more recognized as being an authorised official user for a given Member State. This may lead to the deletion of the user in the EU Login/SAAS access system.

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. 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.

8. Contact information

- The Data Controller

If you would like to exercise your rights under Regulation (EU) 2018/1725, or if you have comments, questions or concerns, or if you would like to submit a complaint regarding the collection and use of your personal data, please feel free to contact the Data Controller, DG SANTE Unit D2 (SANTE-SOHO@ec.europa.eu).

- The Data Protection Officer (DPO) of the Commission

You may contact the Data Protection Officer (DATA-PROTECTION-OFFICER@ec.europa.eu) with regard to issues related to the processing of your personal data under Regulation (EU) 2018/1725.

- The European Data Protection Supervisor (EDPS)

You have the right to have recourse (i.e. you can lodge a complaint) to the European Data Protection Supervisor (edps@edps.europa.eu) if you consider that your rights under Regulation (EU) 2018/1725 have been infringed as a result of the processing of your personal data by the Data Controller.