



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18/01/2021
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European Medicines Agency's privacy statement

For the usability testing of the restricted area of the Union Product Database

This Privacy Statement explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "Agency") in the context of user research to inform the design of the restricted area of the Union Product Database, which EMA is required to set up under the Veterinary Medicines Regulation (EU) 2019/6.

In the restricted area of the Union Product Database, controlled users from the national competent authorities (NCAs, veterinary medicines regulatory authorities in EU Member States) and EMA will be able to perform actions based on their specific access rights. These actions include:

- creating new data sets for veterinary medicinal products;
- approving or rejecting certain post-authorisation changes to veterinary medicinal products;
- searching for, retrieving and editing a wider range of information on existing veterinary medicinal products;
- downloading data and files.

The purpose of the usability-testing exercise is to ensure that the restricted area of the Union Product Database is as user-friendly as possible.

1. Who is responsible for your data?

1.1 Who is the data controller?

The European Medicines Agency ("EMA") is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Head of Stakeholders & Communication Division (S) is appointed as a 'Internal Controller' to ensure the lawful conduct of this processing operation.

The contact details of the Internal Controller are the following: s-datacontroller@ema.europa.eu.

1.2 Who is the data processor?

EMA engages a third party to process data on behalf of the Agency and, in particular, to carry out the stakeholder interviews and usability testing sessions.

The contact details of the data processor(s) are the following:

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



European Service Network S.A.
Galerie Ravenstein 4
B-1000 Brussels - Belgium
E-mail: esn@esn.eu

2. Purpose of this data processing

The purpose of this data processing activity is to collect feedback from impacted stakeholders to ensure a user-centred approach for the design of the restricted area of the 'Union Product Database', which EMA is required to set up under the [Veterinary Medicines Regulation](#) (EU) 2019/6.

2.1. Personal data concerned

In this processing operation, we process data directly collected from you when you participate in the usability testing. Such data include the following:

- Video recording (to record the answers of questions asked to the participant during usability testing);
- Screen recording (including cursor movements) of the computer used by the participant during usability testing;
- Names of participants of the usability testing.

Please note that no IP address will be collected from the participants of the remote usability-testing sessions.

3. Legal basis

When providing your personal data and by participating in the usability testing, you consent to the processing of your data in accordance with this Privacy Statement. You have the right to withdraw your consent later at any time. If you decide to withdraw your consent, you may specify which personal data you want to exclude and the actual processing activity that you do not want the EMA to carry out.

Please note that such withdrawal does not affect the lawfulness of processing carried out by EMA before the withdrawal of your consent.

4. How long do we keep your data?

Participants' personal data will only remain available until the results of the usability testing can be fully analysed and results can be aggregated and anonymised (no later than 1 month after usability-testing sessions take place), or until the participant requests deletion of his/her data.

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

The data collected will be processed by the data processor, the European Services Network (ESN), that will deliver to EMA only aggregated and anonymised results of the user research.

To protect your data, the data processor has appropriate technical and organisational measures in place, including organisational policies, to safeguard the security of personal data and ensure the confidentiality, integrity and availability of the relevant systems, services and the personal data processed within them. In particular, the data of the participants will be stored on the internal ESN file

server. They will be kept in a dedicated folder accessible only to ESN staff members working on projects for EMA.

Anonymized and aggregated results may also be shared with EMA's partners and stakeholders or published on the EMA corporate website or another website owned by EMA. This will not contain any personal data.

6. Your data protection rights

As data subject (i.e. the individual whose personal data is processed), you have a number of rights:

- **Right to be informed** – This Privacy Statement provides information on how EMA collects and uses your personal data.
- **Right to access** – You have the right to access your personal data. You have the right to request and obtain a copy of the personal data processed by EMA.
- **Right to rectification** – You have the right to obtain - without undue delay - the rectification or completion of your personal if it is incorrect or incomplete.
- **Right to withdraw consent** – You have the right to withdraw your consent to the processing of your personal data. However, this will not affect the lawfulness of any processing carried out before consent is withdrawn.
- **Right to erasure** – You have the right to require EMA to delete or stop processing your data, for example where the data is no longer necessary for the purposes of processing. In certain cases your data may be kept to the extent it is necessary, for example, to comply with a legal obligation of the Agency or if it is necessary for reasons of public interest in the area of public health.
- **Right to restrict processing** – In a few, codified cases, you have the right to obtain the restriction of the processing, meaning that your data will only be stored, but not actively processed for a limited period of time. For more information about this right and its limitations, see the EMA General Privacy Statement, hosted at www.ema.europa.eu/en/about-us/legal/privacy-statement.
- **Right to portability** - Where the processing is carried out in automated means you have the right to receive your personal data (which was provided to the EMA directly by you) in a machine-readable format. You may also ask the EMA to directly transfer such data to another controller.

The rights of the data subject can be exercised in accordance with the provisions of Regulation (EU) 2018/1725. For anything that is not specifically provided for in this privacy notice, please refer to the contents of the general EMA Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

7. Recourse

In case you have any questions regarding the processing of your personal data, or you think that the processing is unlawful or it is not in compliance with this Privacy Statement or the general EMA Privacy Statement, please contact the **Internal Controller** at s-datacontroller@ema.europa.eu or the **EMA Data Protection Officer** at dataprotection@ema.europa.eu.

You also have the right to lodge a complaint with the **European Data Protection Supervisor (EDPS)** at any time at the following address:

- E-mail: edps@edps.europa.eu
- Website: www.edps.europa.eu
- Further contact information: www.edps.europa.eu/about-edps/contact_en