



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 February 2024
EMA/104751/2023

European Medicines Agency's Data Protection Notice For the Antimicrobials Sales and Use platform

Regulation (EU) 2019/6 mandates that the Agency, in collaboration with the Member States, establish and maintain a system to collect, in the Union, information on the volume of sales and on the use of antimicrobial medicinal products in animals.

This Data Protection Notice explains the most essential details of the processing of personal data by the Agency. This specifically relates to the contact details of the national contact points and data managers appointed in each Member States with the collection and provision of the above-mentioned data on antimicrobials medicinal products in animals.

1. Who is responsible for processing 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 Veterinary Medicines Division is appointed as 'Internal Controller' to ensure the lawful conduct of this processing operation.

You may contact the Internal Controller via the following email address:
datacontroller.veterinary@ema.europa.eu.

2. Purpose of this data processing

The purpose of this data processing activity is to collect and maintain information on antimicrobials sales and use in the Union as mandated in Article 57 of Regulation (EU) 2019/6, Article 7(2) of Commission delegated Regulation (EU) 2021/578, and Annex I and II of Commission Implementing Regulation (EU) 2022/209, this includes:

- Contact details of the national contact points and data managers

2.1. Personal data concerned

As per Article 7(2) of Commission delegated Regulation (EU) 2021/578 "*Member States shall nominate a national contact point and data managers in accordance with the data quality management procedures defined in the data quality management plan.*", and Annex I and II of Commission Implementing Regulation (EU) 2022/209 request the Member States to provide each year "*Contact*

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

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details of the national contact point and data managers”, the Agency will record the following data as provided by the Member States:

- First name and last name of national contact points and data managers;
- Affiliation of national contact points and data managers (organisation name);
- Functional email address of national contact points and data managers;

During the registration process to access the UPD and the ASU platform, EMA collects personal data to open a user account and request a user role in the EMA Account Management system. The [EMA Privacy Statement for the Account Management system](#) outlines how EMA collects and uses personal data for the aforementioned purpose.

2.2. Legal basis of the processing

The processing of personal data in the context of the Antimicrobials Sales and Use platform is necessary in view of Regulation (EU) 2019/6 implementation and for the performance of the related tasks carried out in the public interest, namely the processing of personal data in the Antimicrobials Sales and Use platform necessary in accordance with Article 57 of Regulation (EU) 2019/6, Article 7(2) of Commission delegated Regulation (EU) 2021/578, and Annex I and II of Commission Implementing Regulation (EU) 2022/209. Therefore, this data processing by the Agency is lawful under Article 5(1)(a) of the EUDPR and justified on the grounds of public interest.

In this regard, please note that you have the **right to object** against the processing as explained in Section 5 below.

3. How long do we keep your data?

Information on veterinary medicinal products and, as such, related personal data as well as data history which relates to the audit trail and traceability of data changes performed by registered users are kept for 30 years in the Antimicrobials sales and Use platform, upon which the retention of the data will be subject to review and may be extended if justified based on the purposes of the processing.

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

The provisions on access to the Antimicrobials Sales and Use platform and the actors to whom access should be granted are set in Article 7(2) of Commission delegated Regulation (EU) 2021/578 and Annex I and II of Commission Implementing Regulation (EU) 2022/209. The [Union Product Database Access Policy](#) further details the different levels of access provided to these actors, taking into account the need to protect personal data as well as their obligations or interests. As far as the handling of the personal data concerns, these actors refer to national competent authorities within the EU Member States and the Agency, including nominated experts, contractors and external service providers working for them on ASU-related matters.

History of actions and changes to the data sets performed by the registered users in the restricted areas of the ASU platform can only be accessed by the EMA administrators (technical staff).

5. 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 Data Protection Notice provides information on how EMA collects and uses your personal data. Requests for other information regarding the processing may also be directed to the Internal Controller.
- **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 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 object** – You have the right to object at any time to this processing on grounds related to your particular situation. If you do so, EMA may only continue processing your personal data if it demonstrates overriding legitimate grounds to do so or if this is necessary for the establishment, exercise or defence of legal claims.

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 Data Protection Notice, please refer to the contents of the general EMA Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

6. 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 Data Protection Notice or the general EMA Privacy Statement, please contact the **Internal Controller** at datacontroller.veterinary@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:

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