



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

27 July 2021  
EMA/686248/2020

## European Medicines Agency's Privacy Statement For the Union Product Database

Regulation (EU) 2019/6 mandates that the Agency establish and, in collaboration with the Member States and European Commission, maintain, a Union Product Database (UPD), containing information on authorised veterinary medicinal products, registered homeopathic veterinary medicinal products, veterinary medicinal products exempted from the marketing authorisation requirements, and approved parallel traded veterinary medicinal products, within the Union.

This Privacy Statement explains the most essential details of the processing of personal data by the Agency. This specifically relates to the name and address of a qualified person for pharmacovigilance (QPPV), as well as the name and organisation of a registered user whose actions and changes to the data sets in the restricted areas of the UPD database are recorded to provide the audit trail and traceability of data changes.

### 1. Who is responsible for processing your data?

#### 1.1. Who is the data controller?

The Agency is jointly responsible with the European Commission and Member States to comply with your data protection rights and freedoms.

On behalf of the joint controllers, the Head of Veterinary Medicines Division is appointed as a general contact point: [datacontroller.veterinary@ema.europa.eu](mailto: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 veterinary medicinal products authorised in the Union as mandated by Regulation (EU) 2019/6. In this context, the QPPV personal data is processed while creating new veterinary medicinal product entries and maintaining the QPPV information via variations not requiring assessment, as well as providing audit trail and traceability of actions and changes to the datasets performed by registered users in the restricted areas of the UPD.

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## **2.1. Personal data concerned**

The QPPV personal data is processed when competent authorities (i.e. the NCAs, EMA or EC) create new veterinary medicinal products entries in the UPD or update existing data via variations not requiring assessment. Such data includes the following:

- First name and last name of qualified person for pharmacovigilance (QPPV)
- Location (address) where QPPV operates

The personal data of the UPD registered users is also processed when their actions in the restricted areas of the UPD are logged for the purpose of the audit trail and traceability of data changes. Such personal data includes the following:

- Name of a registered user
- Organisation of a registered user

During the registration process to access the UPD, 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 data processing**

The processing of personal data in the context of the Union Product Database is necessary in view of Regulation (EU) 2019/6 implementation and for the performance of the related tasks carried out in the public interest, in particular, the processing of personal data in the Union Product Database necessary in accordance with Article 55 (3b) of Regulation (EU) 2019/6 as well as Commission Implementing Regulation (EU) 2021/16.

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, personal data related to QPPV 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 Union Product database, 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 of access to the Union Product Database and the actors, to whom access should be granted are set out in the Article 56 of Regulation (EU) 2019/6. 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 the Commission, national competent authorities and the Agency including contractors and external service providers working for them on the UPD related subjects.

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

Reports on the history of changes to the data sets already existing in the UPD can be obtained by competent authorities (i.e. NCAs, EC and EMA) and marketing authorisation holders only for their veterinary medicinal products.

## 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 Privacy Statement provides information on how EMA collects and uses your personal data. Requests for other information regarding the processing may also be directed to [datacontroller.veterinary@ema.europa.eu](mailto:datacontroller.veterinary@ema.europa.eu).
- **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](http://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 privacy notice, please refer to the contents of the general EMA Privacy Statement: [www.ema.europa.eu/en/about-us/legal/privacy-statement](http://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 Privacy Statement or the general EMA Privacy Statement, please contact the **general contact point of joint controllers** at [datacontroller.veterinary@ema.europa.eu](mailto:datacontroller.veterinary@ema.europa.eu) or the **EMA Data Protection Officer** at [dataprotection@ema.europa.eu](mailto: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](mailto:edps@edps.europa.eu)
- Website: [www.edps.europa.eu](http://www.edps.europa.eu)
- Further contact information: [www.edps.europa.eu/about-edps/contact\\_en](http://www.edps.europa.eu/about-edps/contact_en)