29 July 2024
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European Medicines Agency's Data Protection Notice

For the Union Product Database

Regulation (EU) 2019/6 mandates that the European Medicines Agency (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 Data Protection Notice explains the most essential details of the processing of personal data by the Agency. This specifically relates to the name, address and email of a qualified person for pharmacovigilance (QPPV), as well as the name and organisation of an authorised 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.

The joint controllers ensure that processing of personal data in the context of the operation of the UPD complies with all applicable requirements of Regulation (EU) 2018/1725 (EUDPR) and Regulation (EU) 2016/679 (GDPR), respectively, and other applicable national rules on data protection.

1. Who is responsible for processing your data?

1.1 Who are the joint controllers?

The joint controllers under the Joint Controllership Arrangement ("JCA") for the UPD are:

European Medicines Agency and Member States.

The Parties to the JCA act as joint controllers for the purpose of processing operations of personal data provided, in structure data and documents, in UPD.

The contact points of joint controllers are the following:

European Medicines Agency: datacontroller.veterinary@ema.europa.eu

Member States: Annex I of the JCA

Marketing authorisation holders' contact points are identified at the time of their registration in UPD.

The respective roles and relationship vis-à-vis Data Subjects are explained in the JCA. In accordance with the applicable rules of EUDPR and GDPR, Data Subjects may exercise their rights in respect of, and against each of, the joint controllers. In order to ensure that any request can be handled as swiftly as possible, it is recommended that data subject contacts the joint controller who, in line with the activities allocated in the JCA, collected and mainly processes the personal data concerned.

1.2 Who is the data processor?

Marketing authorisation holders act as data processors when they upload/download documents in/from UPD, containing personal data.

The Agency engages third parties to provide support for the: maintenance of UPD functionalities, development of new UPD functionalities where applicable, assurance of data quality in UPD, provision of system support to UPD users. Contact details of the EMA processors (and, if necessary, of other Parties' processors), can be made available to the data subjects upon request.

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 are processed while creating new veterinary medicinal product entries and maintaining the QQPV information via variations not requiring assessment, as well as providing an audit trail and traceability of actions and changes to the datasets performed by registered users in the restricted areas of the UPD.

2.1. Personal data concerned

The QPPV personal data is processed when registered users in UPD 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
- Email address of QPPV

In addition, the personal data of the UPD authorised and 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. 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.

Such personal data includes the following:

- Name, surname and email address of a registered user.

These details are visible in the UPD secure domain to the Administrator(s) within the user's organisation for the purpose of administering users' profiles.

Name, surname and role of the users in UPD are visible to the other people within the organisation which originated the personal data at stake.

Users' names, surnames, roles and contact details will be visible only in the UPD secure domain, and not disclosed in the public domain.

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, namely 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. 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.

The data processing by Member States also relies on the lawful ground of public interest under Article 6(1)(e) of the GDPR [and Article 5(1)(a) of the EUDPR, respectively].

Data processing by marketing authorisation holders in UPD is necessary for compliance with their legal obligations under Regulation (EU) 2019/6, in accordance with Article 6(1)(c) of the GDPR.

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

2.3. Transfer of personal data outside of EU/EEA

The data centres used for UPD are stored in the following EU countries: Netherlands, Ireland and Germany.

Where personal data is made available to the public in the public domain of UPD and is accessed from outside the EU/EEA, this is based on Article 50(1)(g) of Regulation (EU) 2018/1725, or Article 49(1)(g) of Regulation (EU) 2016/679, i.e. the transfer is made from a register which, according to Union law, is intended to provide information to the public and which is open to consultation either by the public in general or by any person who can demonstrate a legitimate interest, but only to the extent that the conditions laid down in Union law for consultation are fulfilled in the particular case.

If a Party authorises a user to access the secure domain of UPD from outside the EU/EEA, that Party shall ensure that an appropriate data transfer mechanism is established prior to any access by that user, and that such international data transfers comply with the rules of Chapter V of Regulation (EU) 2018/1725 or Regulation (EU) 2016/679, respectively.

3. How long do we keep your data?

Information on veterinary medicinal products and, as such, personal data related to QPPVs 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 on access to the UPD and the actors to whom access should be granted are set out in 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 (as one of the users),] national competent authorities within the EU Member States and the Agency, including contractors and external service providers working for them on UPD-related matter.

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 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 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.
- **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 our functional mailbox 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