



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 November 2022
EMA/285766/2020 Rev. 1¹

Data Protection Notice for validation of proof of establishment when natural persons apply for orphan designation or a transfer of an orphan designation

This Data Protection Notice provides details on how the European Medicines Agency (hereinafter “EMA” or “Agency”) will process your personal data that was submitted for the purpose of proving your establishment as a natural person in the European Economic Area (EEA).

All personal data provided as for proof of establishment in the EEA will be processed in accordance with [Regulation \(EU\) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data](#) (“EUDPR”).

1. Who is responsible for processing your personal data?

EMA is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Head of Human 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.HumanMedicines@ema.europa.eu

2. Purpose of this data processing

The purpose of this personal data processing is to verify, in the case of natural persons applying for orphan designation of a medicinal product (or a transfer thereof), that they are established within the EEA, i.e. that they are citizens of at least one of the Members States of EEA (all European Union Member States, as well as Iceland, Liechtenstein and Norway).

Please note that if the application for orphan designation of a medicinal product or transfer of an orphan designation is submitted on behalf of a legal entity (e.g. a

¹ “Privacy Statement” has been replaced with “Data Protection Notice”.



company) no personal data of a natural person is collected and processed for the proof of establishment within the EEA.

Once EMA has received application for orphan designation or transfer of an orphan designation on behalf of a natural person, EMA will e-mail the applicant outside the orphan submission portal (hereinafter "IRIS") to ask for the proof of establishment so that EMA can verify that the applicant is a citizen of an EEA Member State. The information collected will only be used by EMA staff members for the purpose of proving such establishment in the EEA. No further processing of your personal data for any other purposes outside the scope of this specific context is envisaged.

2.1. Personal data concerned

EMA will collect and process the following the personal data:

- Copy of identification document provided as proof of citizenship (e.g. passport);
- Your name, email address, telephone number.

If you do not wish to provide your personal data, please note that such refusal might lead to your application for orphan designation be declined.

2.2. Legal basis of the processing

In accordance with Article 2(c) of Regulation (EC) No 141/2000, a 'sponsor' seeking to obtain the designation of a medicinal product as an orphan medicinal product, shall be a legal or natural person established in the EEA.

Accordingly, when a natural person is seeking to obtain an orphan designation for a medicinal product (including the case of a transfer from the previously approved orphan designation holder), his or her personal data is necessary to be processed to verify citizenship in order to carry out the procedure of orphan designation in accordance with Regulation (EC) No 141/2000. Accordingly, this personal data processing is necessary for the performance of a task carried out by the Agency in the public interest as mandated by Union law (in accordance with Article 5(1)(a) of EUDPR).

3. How long do we keep your data?

Once the proof of establishment has been received by EMA, proof of citizenship is verified by EMA within the time needed for validation of the application. At the end of the validation process all your personal data are deleted from EMA's systems.

4. Location of data storage and recipients of the data

All data is stored within secure systems of EMA with password protection. Personal data processed in this activity are only accessible to EMA staff members. None of the data processed will be published or shared outside of the EMA.

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 is aimed at informing you 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 object** – You have the right to object at any time to this processing on grounds related to your particular situation.

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 Data Protection Notice: [Data protection and privacy | European Medicines Agency \(europa.eu\)](#)

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 Data Protection Notice, please contact the **Internal Controller** at datacontroller.HumanMedicines@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