



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2022
EMA/134763/2022

European Medicines Agency's Data Protection Notice For certificates of medicinal products

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "Agency") in the context of companies requesting certificates of medicinal products relating to the certification scheme for human and veterinary medicines ([Link to certification of medicinal products](#)). This refers to:

- Requesting certificates via the standard procedure;
- Requesting certificates via the urgent procedure.

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 Division is appointed as 'Internal Data Controller' to ensure the lawful conduct of this processing operation.

You may contact the Internal Data Controller via the following email address:
Datacontroller.HumanMedicines@ema.europa.eu

2. Purpose of this data processing

The purpose of EMA's certification scheme for human and veterinary medicines is for EMA to issue such certificates on behalf of the European Commission to confirm the marketing authorisation status of products either authorised by the European Commission through the centralised procedure or products for which a centralised application has been submitted to the Agency, and products pursuant to Article 58 of Regulation (EC) No 726/2004. Further information is available [on the Agency's website \(see link here\)](#).

In this context, the data processing requires:

- the collection and storage of personal data included in the certificate application form ([Link](#)), which is submitted to request a certificate and the use for correspondence in this regard;
- the collection and storage of personal data included in the permission letters ([Link](#)) submitted by marketing authorisation holders in relation to requests for certification of medicinal products, and which are used for correspondence;
- the maintenance of internal records and the internal certificates database.

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

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An agency of the European Union



2.1. Personal data concerned

The processing of personal data provided in the application form and submitted as part of a request for certificates of medicinal products, includes the following:

- Details of the contact person for correspondence on behalf of the certificate requesting company: title, first name and surname, e-mail address, telephone number and fax number.
- Name of the person signing the application form.
- Supporting documentation (e.g. permission letter), where applicable.

2.2. Legal basis of the processing

The legal bases for the certification scheme are Article 127 of Directive 2001/83/EC (medicinal product for human use) and Article 93 of Directive 2001/82/EC (veterinary medicinal products) and other applicable Union legislation. EMA's certification scheme is based on World Health Organisation recommendations as set out in the [Guidelines on the Implementation of the WHO certification scheme on the quality of pharmaceutical products moving in international commerce](#).

EMA also certifies products pursuant to Article 58 of Regulation (EC) No 726/2004. Article 58 provides that the Agency can give a scientific opinion, in the context of cooperation with the WHO, for the evaluation of certain medicinal products intended exclusively for markets outside the European Community.

In view of the above, the lawfulness of this data processing is based on Article 5(1)(a) of Regulation (EU) 2018/1725 with reference to Recital 22 of that Regulation, namely that processing necessary for the performance of a task carried out in the public interest as mandated by Union legislation referenced above.

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?

This personal data will be kept in the application form for certificates of medicinal products ([Link](#)), internal records and internal certificates database.

Records which contain personal data shall be disposed of after 30 years from the date on which the certificate was issued.

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

The data collected can be accessed by EMA staff. The data will be processed internally by staff within the EMA Divisions responsible for issuing certificates of medicinal products and related processes (e.g. invoicing, IT maintenance).

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.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