



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/420340/2019 rev. 1

European Medicines Agency's Privacy Statement Small and Medium Enterprises (SME) Office activities

The European Medicines Agency (hereinafter "EMA" or "Agency") is committed to respect the right to data protection of its staff members and the public. The Agency collects and uses personal data in accordance with Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 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.

This Privacy Statement explains the most essential details of the processing of personal data carried out by the EMA's SME Office in the context of companies' and natural persons' applications for SME status, the maintenance of the public SME Register (a public database of companies that are registered with the Agency), SME external stakeholder events, surveys and newsletters.

1. Who is responsible for 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 the Regulatory Science and Innovation Task Force is appointed as a 'Data Controller' to ensure the implementation of the processing of personal data.

The contact details of the Data Controller are the following:
datacontroller.horizonscanning@ema.europa.eu

2. Purpose of this data processing

The purpose of this data processing activity is to handle personal data included in companies' and natural persons' applications for SME status. This includes:

- The collection and storage of personal data included in the SME declaration form ([Link](#)) submitted in relation to applications for SME status, and which are used for correspondence or other activities such as the organisation of stakeholder events, surveys and newsletters (Section 3.1.b below).
- Maintenance of internal records and the internal SME database.
- Maintenance of the public SME Register ([Link](#)).
- For the verification of legal name and place of residence in at least one of the Members States of EEA in the specific case of natural persons applying for SME status, please refer to the corresponding privacy statement ([Link](#)).

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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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3. What personal data do we process and how?

3.1. Personal Data concerned

We will process personal data provided in the SME declaration form, submitted as part of applications for SME status. Such data include the types of data subjects as follows:

- a) Titles and names of principal directors of the applicant and its partner/linked enterprises, where applicable;
- b) Details of the contact person for correspondence with the SME office: title, first name and surname, e-mail address, telephone number;
- c) Details of the contact person published in the public SME Register, where provided: title, first name and surname, e-mail address, fax and telephone number;
- d) Name and position of the person signing the SME declaration form.
- e) Supporting documentation (e.g. copy of passport or ID card) where applicable.

These personal data will be kept in the SME declaration form ([Link](#)), internal records, internal SME database, and the data declared under c) published in the public SME Register ([Link](#)).

3.2. Legal Basis

The processing of data as explained in this privacy statement is necessary for the performance of EMA's tasks carried out in the public interest, in accordance with Article 70(2) of Regulation (EC) No 726/2004, and mandated for SME activities by:

- Commission Regulation (EC) No 2049/2005 introducing provisions aimed at promoting innovation and the development of new medicinal products for human and veterinary use by small and medium-sized enterprises;
- Regulation (EU) No 658/2014 of the European parliament and of the Council of 15 May 2014 on fees payable to the European Medicines Agency for the conduct of pharmacovigilance activities in respect of medicinal products for human use;

The lawfulness of this data processing is based on Article 5(1)(a) of Regulation (EU) 2018/1725.

4. How long do we keep your data?

Records which contain personal data shall be disposed of 5 years as of the date of the SME status expiry, withdrawal or closure of an application for SME status (Retention is reset if a company reapplies for SME status within these 5 years).

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

The data contained in the SME declaration form and the internal records will only be accessed internally by the EMA's SME office. In the public SME Register only the data mentioned in Section 3.1.c will be available to the general public.

6. Your data protection rights

As data subjects (i.e. the individual whose personal data is processed), you have a number of rights:

- **Right to be informed** – This Privacy Statement is aimed at informing data subjects how EMA collects and uses their personal data.
- **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 held 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** – Data subjects have the right to object at any time to the processing of data relating to him or her, except in certain cases, such as where the processing is based on a legal obligation of the data controller.

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

7. 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 Data Controller at: datacontroller.horizonscanning@ema.europa.eu

Data subjects may lodge a complaint with the **EMA Data Protection Officer**: dataprotection@ema.europa.eu.

You also have the right to lodge a complaint with the **European Data Protection Supervisor**:

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