



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 May 2021
EMA/550671/2020

European Medicines Agency's Privacy Statement

Small and Medium Enterprises (SME) status applications submitted by natural persons

This Privacy Statement explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "Agency") in the context of a natural person applying to be registered as a SME.

All personal data provided as a proof of establishment in the EEA or Northern Ireland as part of the application for SME status 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 data as data controller?

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 'Internal Controller' to ensure the lawful conduct of this processing operation.

You may contact the Internal Controller via the following email address:
datacontroller.horizonscanning@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 SME status at EMA, the legal name and place of residence in at least one of the Members States of EEA (i.e. all European Union Member States, as well as Iceland, Liechtenstein and Norway) or Northern Ireland.

2.1. Personal data concerned

EMA will process data regarding the applicants collected from a copy of an identification document (e.g. passport or ID card).

If you do not wish to provide your personal data, please note that such refusal might lead to your application for SME status not being validated.



2.2. Legal basis of the processing

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.

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?

Once received by EMA, the proof of establishment 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 within one calendar month.

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

Once EMA has received the application for SME status on behalf of a natural person, EMA will e-mail the applicant to ask for supporting documentation to verify the applicant's legal name and the place of residence in an EEA Member State or Northern Ireland.

The information collected will be processed internally by staff within the SME Office at EMA for the purpose of the SME status application.

In the public [SME Register](#), the legal name and place of residence of the natural person will be made available to the general public. There will be no further processing of your personal data for any other purposes outside the scope of this specific context.

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 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 privacy 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 Privacy Statement or the general EMA Privacy Statement, please contact the Internal Controller at datacontroller.horizonsscanning@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