



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/420350/2019

Record of data processing activity for the Small and Medium Enterprises Office (SME office) activities

1.	Last update of this record, version number:	12 May 2020, version 2
2.	Reference number:	TRS1
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of Regulatory Science and Innovation Task Force datacontroller.horizonsscanning@ema.europa.eu
4.	Name and contact details of DPO:	dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	Not applicable
6.	Name and contact details of processor (where applicable)	Not applicable
7.	Purpose of the processing	Handling of personal data in the context of companies' applications for SME status. This includes: <ul style="list-style-type: none">• The collection and storage of personal data included in the SME declaration form (Link) submitted by companies in relation to applications for SME status, and which are used for correspondence or other activities such as stakeholder events, surveys and newsletters (Section 8.2 below);• Maintenance of internal records and the internal SME database;• Maintenance of the public SME Register (Link).
8.	Description of categories of persons whose data EMA	The types of data subjects processed are as follows:

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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

An agency of the European Union



	processes and list of data categories	<ol style="list-style-type: none"> 1. Titles and names of principal directors of the applicant and its partner/linked enterprises, where applicable; 2. Details of the contact person for correspondence with the SME office: title, first name and surname, e-mail address, telephone number; 3. 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; 4. Name and position of the person signing the SME declaration form. 5. Supporting documentation (e.g. copy of passport or ID card) where applicable.
9.	Time limit for keeping the 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).
10.	Recipients of the data	The data contained in the SME declaration form and the internal records will be only accessed internally by the EMA's SME office. In the public SME Register, only the data mentioned in Section 8.3) will be available to the general public.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	Not applicable
12.	General description of security measures, where possible.	<p>The Agency has put in place appropriate technical and organisational measures (security policies and procedures) to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to your personal data. The Agency takes all the necessary measures to ensure the maximum safety and security of personal data held.</p> <p>The data provided are held in a secured and protected database hosted by EMA, the operations of which abide by EMA's security policy. The database is not accessible from outside EMA, with selected content published in the public SME Register as set out in the SME declaration form. Within EMA, the database is managed using a user ID and password.</p>
13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where	<p>Details concerning the processing of your personal data are available on the Agency's website at:</p> <p>https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement, where you may find the EMA General</p>

	applicable), see the privacy statement:	Privacy Statement as well as the privacy statements on specific data processing operations.
--	---	---