



EMA/49053/2021

## Records of data processing activity regarding Small and Medium Enterprises (SME) status applications submitted by natural persons

1.	Last update of this record, version number:	19 May 2021, version 1
2.	Reference number:	TRS4
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of Regulatory Science and Innovation Task Force <a href="mailto:datacontroller.horizonscanning@ema.europa.eu">datacontroller.horizonscanning@ema.europa.eu</a>
4.	Name and contact details of DPO:	<a href="mailto:dataprotection@ema.europa.eu">dataprotection@ema.europa.eu</a>
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	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.
8.	Description of categories of persons whose data EMA processes and list of data categories	EMA will process data on the applicant collected from a copy of an identification document (e.g. passport or ID card).
9.	Time limit for keeping the data	Copy of an identification document shall be disposed of within one calendar month from of the date of the validation, withdrawal or closure of an application for SME status.

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](http://www.ema.europa.eu/how-to-find-us)

Send us a question Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) Telephone +31 (0)88 781 6000

An agency of the European Union



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, the legal name and place of residence 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 applicable), see the privacy statement:	<p>Details concerning the processing of your personal data are available on the Agency's website at: <a href="https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement">https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement</a>, where you may find the EMA General Privacy Statement as well as the privacy statements on specific data processing operations.</p>