EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Pilot project 'Market Launch Intentions of Centrally Authorised Products'

Practical Questions and Answers

This document is intended to complement, with practical aspects, the pilot description published by the European Commission.

1. What is the aim of this pilot?

The pilot's overall objective is to improve regulators' knowledge of the planned marketing of centrally authorised products and on the mechanism behind delayed market launch by engaging with prospective marketing authorisation holders.

2. Which products fall within the scope of the pilot?

The pilot concerns orphan and/or oncology medicinal products for which the initial marketing authorisation application is being reviewed under the centralised procedure during the duration of the pilot.

3. For how long will the pilot run?

The pilot is intended to be run for 18 months, from March 2021 until August 2022.

4. Which information will be asked to provide?

Applicants will be asked to declare to the best of their current knowledge, on a voluntary basis, their market launch intentions in each EU/EEA Member State including challenges and limiting factors encountered having an impact on access and availability to patients at MSs level and/or across the Union.

The information provided via this pilot is without prejudice to the legal obligation of marketing authorisation holders under Article 13(4) of Regulation (EC) 726/2004 using the existing EMA reporting channels.

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

5. How will Applicants be invited to participate and at which timepoint in the procedure?

A link to a secure online questionnaire hosted by the European Commission (EU Survey[1]) will be provided to the concerned applicants:

- at validation (as part of the EMA validation letter) and/or

- at CHMP (positive) opinion stage (as part of the EMA letter to the MAH).

Depending on the timelines of their procedure, some Applicants may be invited to participate both at time of validation and CHMP opinion, or solely at one of these two timepoints during the ongoing phase of the pilot.

Applicants will have to complete the survey within 4 weeks. Once the questionnaire submitted, Applicants will not be able to update their market launch intentions.

To access the online questionnaire, applicants need to have an EU Login account (formerly known as European Commission's main authentication service, ECAS), which allows authorised users to access a wide range of Commission web services, using a single email address and password. To create an EU Login account, please click here and then click 'Create an account'. A short tutorial for the registration process is also available here.

6. Who to contact in case of technical issues?

Should you face any technical issue with the EU Login account, please contact the EU Login External Support team of the European Commission IT Helpdesk at:
https://webgate.ec.europa.eu/cas/contact.html

[1] EUSurvey is a web application for online survey creation and publication developed and maintained by DG DIGIT, the Director-General for Informatics of the European Commission - EUSurvey - Terms of Service (europa.eu)