EMA
EUROPEAN MEDICINES AGENCY

Impact of the EudraVigilance Signal Detection Pilot termination by MAHs:

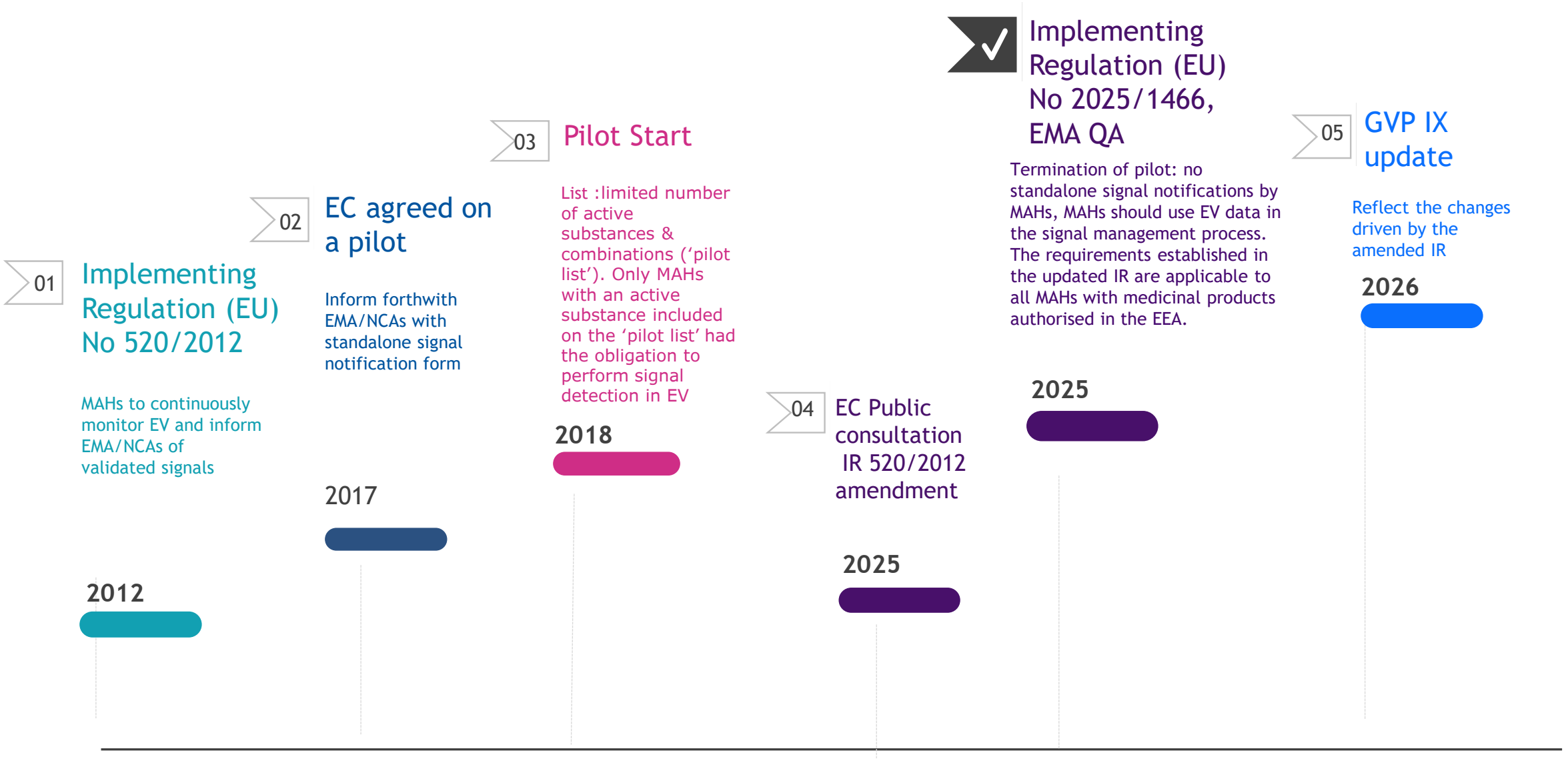
IR.(EU)2025/1466, amendment of IR (EU)520/2012

Presented by Eleni Savvaidou (EMA)

05 November 2025

Table of contents

Timeline of Key Milestones



EC Implementing Regulation (EU) No 2025/1466, amending IR (EU) No 520/2012

Minimum requirements for the monitoring of data in the Eudravigilance database

Article 18

~~2. Marketing authorisation holders shall monitor the data available in the Eudravigilance database to the extent that they have access to that database.~~

~~3. Marketing authorisation holders, the national competent authorities and the Agency shall ensure the continuous monitoring of the Eudravigilance database with a frequency proportionate to the identified risk, the potential risks and the need for additional information~~.

in Article 18, paragraphs 2 and 3 are replaced by the following:

2. Marketing authorisation holders shall monitor the data available in the Eudravigilance database and use it together with data from other available sources.

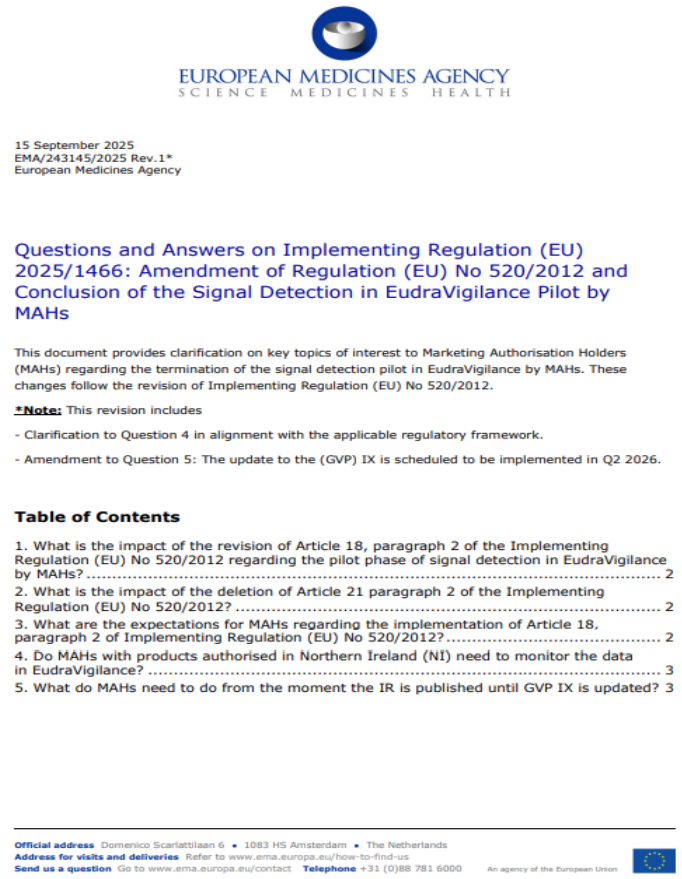
3. National competent authorities and the Agency shall ensure the continuous monitoring of the Eudravigilance database with a frequency proportionate to the identified risks, the potential risks and the need for additional information

Article 21 Signal management process

~~2. Where a marketing authorisation holder detects a new signal when monitoring the Eudravigilance database, it shall validate it and shall forthwith inform the Agency and national competent authorities.~~

In Article 21, paragraph 2 is deleted.

Q&A Conclusion of the Signal Detection in EudraVigilance Pilot by MAHs



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2025
EMA/243145/2025 Rev.1*
European Medicines Agency

Questions and Answers on Implementing Regulation (EU) 2025/1466: Amendment of Regulation (EU) No 520/2012 and Conclusion of the Signal Detection in EudraVigilance Pilot by MAHs

This document provides clarification on key topics of interest to Marketing Authorisation Holders (MAHs) regarding the termination of the signal detection pilot in EudraVigilance by MAHs. These changes follow the revision of Implementing Regulation (EU) No 520/2012.

***Note:** This revision includes

- Clarification to Question 4 in alignment with the applicable regulatory framework.

- Amendment to Question 5: The update to the (GVP) IX is scheduled to be implemented in Q2 2026.

Table of Contents

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

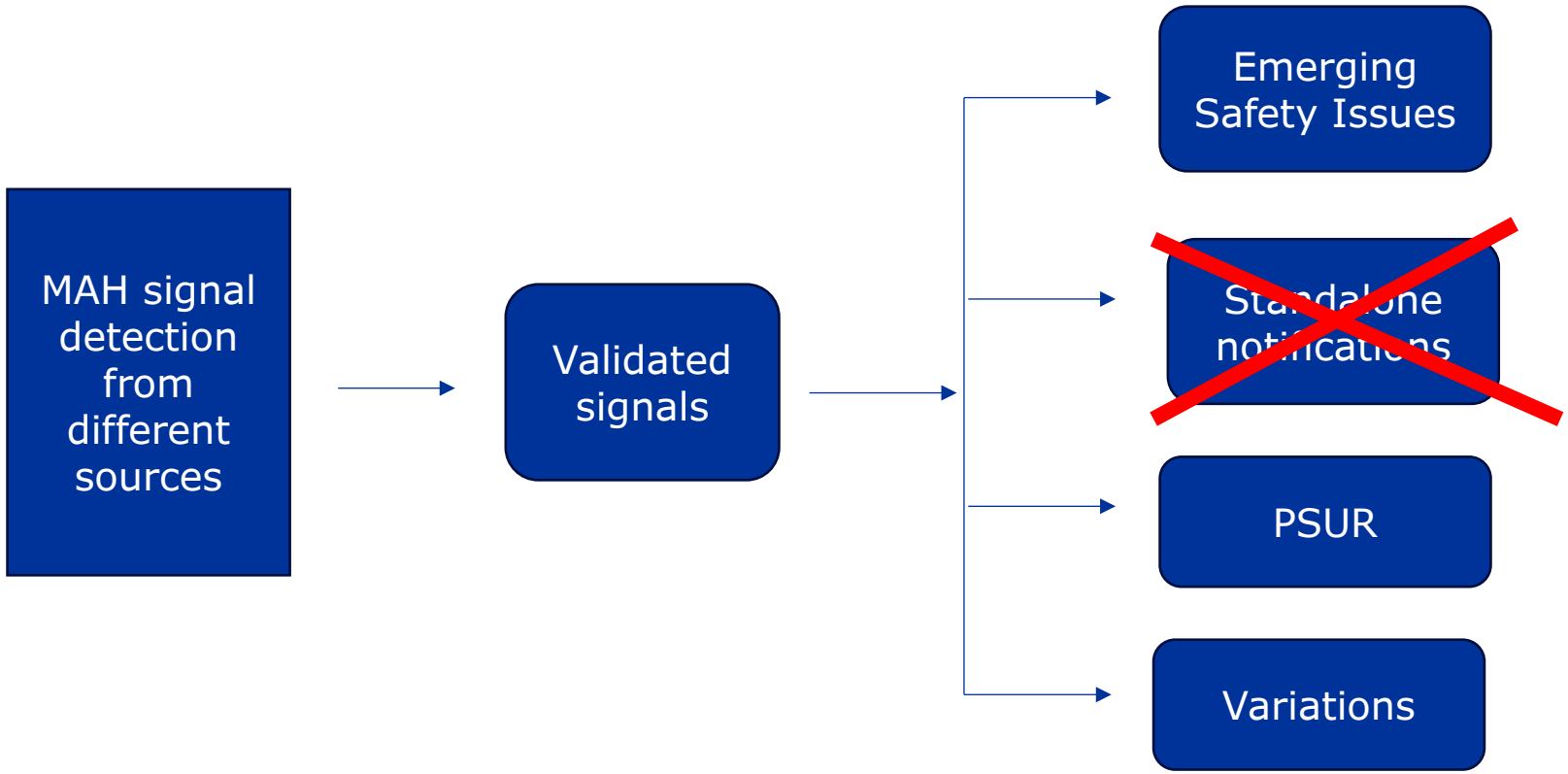
All MAHs with medicinal products authorized in the EEA shall monitor the data available in the EV database and use it as additional source of safety information to support their processes and enhance signals detected through other sources

MAHs no longer expected to submit validated signals to the EMA&NCAs via the standalone notification form.
Actions triggered by signal assessments should be performed using existing legal framework in the EU as appropriate, taking into account the general obligations of the MAHs to keep their product information up-to-date throughout the product's lifecycle by variation applications and to present the signal evaluation in the PSURs (see GVP Module VII) for the MAHs with obligation to submit PSURs.

MAHs shall monitor the EV data in conjunction with other available sources within their established processes and frequency proportionate to the risk, safety profile and characteristics of the product.

MAHs with EU products authorised in NI should monitor EudraVigilance, even if they are not authorised in an EU/EEA Member State

What is changing?



Clarifications and Next Steps

Queries from MAHs

Clarifications on guidance

GVP IX update

2026

Are MAHs required to monitor EV for signal detection or use it as additional source to signal validation/evaluation?

MAHs should determine at which step in the signal-management process EudraVigilance data will be used.

MAHs may decide to screen the EV database for signal-detection purposes as a primary source with an established frequency.

The use of EudraVigilance should be proportionate to the safety profile and characteristics of the product and should be integrated and coherent within the MAH's established pharmacovigilance procedures and other sources of information.

It is expected that MAHs use EudraVigilance data during the validation and evaluation stages of signal management.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

eleni.savvaidou@ema.europa.eu

Follow us