4 October 2018
EMA/MB/493254/2018
Management Board meeting of 4 October 2018

Update on the pilot of signal detection in EudraVigilance by marketing authorisation holders

Issues for consideration

- On 22 February 2018, a one year pilot period started on the implementation of the legal requirement for marketing authorisation holders (MAHs) to perform signal detection in EudraVigilance. This pilot involved a limited number of active substances. This phased implementation was agreed with the European Commission (EC) in order to mitigate the risk of overloading the EU network with signals from MAHs, while gaining experience with the new process.
- It is considered that more experience is needed during the pilot phase. In addition, the initially planned end of the pilot (22 February 2019) will coincide with the period in which the Agency relocates to Amsterdam and, unless a ratified withdrawal agreement establishes another date, at the end of March 2019, the EU treaties will cease to apply to the UK. Both these events will significantly impact operations and resources amongst the stakeholders involved in the process (the Agency, Member States and MAHs).
- Therefore, a prolongation of the pilot period beyond 22 February 2019 has been agreed with EC. By September 2019, the Agency will finalise a report on the first year of experience, including both workload and process aspects, and this will be used as the basis to agree and communicate on the next implementation phase, including the scope of products to be included and date of coming into effect.

Background

EU pharmacovigilance legislation[1] requires MAHs to continuously monitor data in EudraVigilance to the extent of their access to the database and to inform forthwith the Agency and National Competent Authorities (NCAs) of validated signals detected in the database. It is then the responsibility of the NCAs and the PRAC rapporteurs to confirm or not these signals with coordination by the Agency and decision-making through the Pharmacovigilance Risk Assessment Committee (PRAC). These new responsibilities come in addition to the existing monitoring activities of EudraVigilance data performed by the NCAs and Agency.

[1] Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council – Chapter III: Minimum requirements for the monitoring of data in the Eudravigilance database

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

The extended access to EudraVigilance allowing MAHs to fulfil their obligations came into effect on 22 November 2017. Regulatory guidance on the detection and reporting of signals from EudraVigilance is provided in the Good pharmacovigilance practices (GVP) Module IX on Signal Management.

As the above legal requirements for MAH signal detection are applicable to all medicinal products authorised in the European Union without distinction, their full implementation may be associated with a risk of duplication of signal detection activities, as well as a high volume of signal notifications by MAHs to EMA and NCAs, which will have to be processed within the legal timeline of 30 days.

In order to mitigate this risk, EC agreed in July 2017 to a phased implementation of the legal requirements for MAHs. The initial phase started on 22 February 2018 and concerns approximately 300 substances selected based on the list of medicinal products subject to additional monitoring[2].

The Agency has already delivered a number of guidance documents and training initiatives to support MAHs, in particular those involved in the pilot. The Agency will use the prolongation of the pilot period to offer more training opportunities with a view to support more MAHs. The extra-time will also allow the Agency to further optimise the processes as well as the tools developed to support MAHs in their signal detection activities in EudraVigilance.

Next steps

The Agency aims to finalise a report outlining the first year of experience (February 2018 - February 2019) by September 2019. This takes into account Brexit-related disruptions and the time required to discuss the pilot findings through the EU pharmacovigilance governance, including PRAC.

By end of December 2019, a decision on the next implementation phase, including scope and date of coming into effect, should be made and communicated to stakeholders.

[2] List of active substances and combinations involved in the pilot on signal detection in EudraVigilance by marketing authorisation holders (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/10/WC500237839.xls)