European Parliament
2014-2019

Committee on Petitions

28.2.2018

NOTICE TO MEMBERS

Subject: Petition No 0639/2017 by R. B. (Danish) on implementation of the EU pharmacovigilance legislation after Brexit

1. Summary of petition

The petitioner is concerned with Commission Implementing Regulation No 520/2012 and in particular articles 25 and 26 identifying use of internationally agreed forms and standards on pharmacovigilance. In view of the petitioner, industries are uncertain about the future use of standards of communication between national competent authorities on pharmacovigilance. The petitioner considers that problems with implementation of Regulation 520/2012 by the European Medicines Agency after Brexit will have a negative impact on patient safety.

2. Admissibility

Declared admissible on 7 November 2017. Information requested from Commission under Rule 216(6).

3. **Commission reply**, received on 28 February 2018

Commission Implementing Regulation (EU) 520/2012 promotes and requires the use of internationally agreed terminology, format and standards to facilitate the interoperability of systems used for the performance of pharmacovigilance activities and to avoid the duplication of encoding activities concerning the same information.

This includes the use of standards developed by the International Organisation for Standardisation for the Identification of Medical Products (ISO IDMP). However, to ensure a better transition from previous encoding standards to the ISO IDMP format an incremental model for the phasing-in of those standards is used. Stakeholders are regularly informed on the progress of the ISO IDMP database[1].

[1] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001821.jsp

The timelines for this phased implementation will only be marginally concerned by business continuity considerations related to the withdrawal of the United Kingdom from the European Union.

The Management Board of the European Medicines Agency (EMA) endorsed in October 2017 a Business Continuity Plan (BCP) in view of the withdrawal of the UK from the Union, which provides all stakeholders with transparent information on reprioritisation of operations in the Agency.

Within this BCP framework, the Agency's tasks related to Commission Regulation 520/2012, including the implementation of the ISO IDMP database, have been ranked as a high priority. A six months stop period has however been foreseen between late 2018 and early 2019, to take into account the move of the Agency from London to its new location in Amsterdam.

Conclusions

The Commission and the Agency are confident that the transition from previous encoding standards to the new ISO IDMP standards will continue and that implications related to the withdrawal of the UK from the Union will have minor impact on the foreseen timelines for implementation.