22 May 2017
EMA Management Board
EMA/215105/2017

Announcement of the EMA Management Board

Confirmation of full functionality of the EudraVigilance database

Basis for announcement

Pursuant to Article 24(2) third subparagraph of Regulation (EC) No 726/2004[1], the Management Board of the Agency shall on the basis of an independent audit report that takes into account the recommendation of the Pharmacovigilance Risk Assessment Committee (PRAC) confirm and announce when the EudraVigilance database has achieved full functionality and the system meets the functional specifications drawn up pursuant to Article 24(2) first subparagraph of Regulation (EC) No 726/2004.

In accordance with Article 24(2) first subparagraph of Regulation (EC) No 726/2004, the Agency in collaboration with the Member States and the Commission has drawn up the functional specifications for the EudraVigilance database. These functional specifications were incorporated in the document titled *"EudraVigilance functionalities to be audited"* (Doc. Ref. EMA/626168/2013) and were subsequently endorsed by the PRAC on 5 December and the EMA Management Board on 12 December 2013.

Moreover, an independent audit, mandated by Article 24(2) third subparagraph of Regulation (EC) No 726/2004, was conducted as to whether the EudraVigilance database meets the pre-agreed functional specifications.

Based on the pre-defined functional specifications and the independent audit report, in accordance with Article 24(2) third subparagraph of Regulation (EC) No 726/2004, the PRAC adopted on 3 May 2017 a recommendation concluding that the EudraVigilance database has achieved full functionality and the system meets the functional specifications.

Announcement

Having considered the independent audit report and the PRAC recommendation, the EMA Management Board confirms that the EudraVigilance database has achieved full functionality and that the system meets the functional specifications drawn up pursuant to Article 24(2) first subparagraph of Regulation (EC) No 726/2004.

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

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In accordance with Article 2(3) of Directive 2010/84/EU[2], the Member States shall ensure that the obligation on the part of the marketing authorisation holder to submit information on suspected adverse reactions electronically to the EudraVigilance database applies as from six months after the functionalities of the database have been established and have been announced by the Agency.

In summary, the simplified electronic reporting of suspected adverse reactions related to medicines by national Competent Authorities and marketing authorisation holders to EudraVigilance becomes mandatory six months after the functionalities of the EudraVigilance database have been established and have been announced by the Agency i.e. 22 November 2017.

Therefore, on 22 November 2017, the obligations set forth in the following legal provisions:

- Section 1 "*Recording and reporting of suspected adverse reactions*" of Chapter 3 "*Recording, reporting and assessment of pharmacovigilance data*" under Title IX "*Pharmacovigilance*" of Directive 2001/83/EC[3], and
- Articles 24(4), 28(1), 28a(1)(c) and 28c(1) of Chapter 3 "*Pharmacovigilance*" under Title II "*Authorisation and supervision of medicinal products for human use*" of Regulation (EC) No 726/2004

will become applicable to the mandatory electronic reporting through EudraVigilance.

London, 22 May 2017

Signature on file

Christa Wirthumer-Hoche, Chair of the EMA Management Board
On behalf of the EMA Management Board

[2] Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 348, 31.12.2010, p. 74).
[3] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).