

EMA/MB/303824/2015
Management Board meeting of 11 June 2015

Announcement of the EMA Management Board

Confirmation of functionality of the PSUR repository

Basis for announcement

Pursuant to Article 25a of Regulation (EC) No 726/2004, 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 repository for periodic safety updates (PSUR repository), provided for in this Article, has achieved full functionality and meets its functional specifications.

Based on the same Article, the PRAC was consulted on drawing up the functional specifications for the PSUR repository on 5 December 2013. These functional specifications contained in the document 'PSUR Repository functionalities to be audited' (EMA/681848/2013) were subsequently endorsed by the EMA Management Board on 12 December 2013. The PSUR repository that was first released into its live pilot environment on 26 January 2015 complies with these functionalities and, thus, has the "full functionality" referred to in Article 25a of Regulation (EC) No 726/2004.

The independent audit of the repository, mandated by Article 25a of Regulation (EC) No 726/2004, was conducted by PricewaterhouseCoopers from January to March 2015. The audit report was finalised on 20 March 2015.

Based on the functional specifications and the independent audit the PRAC adopted on 10 April 2015 a positive recommendation concluding that the PSUR repository meets the requirements of the functional specifications.

Announcement

Based on the independent audit report and the PRAC recommendation, the EMA Management Board confirms that the repository meets the pre-agreed full functional specifications as per Article 25a of Regulation (EC) No 726/2004.

Pursuant to Article 2(7) of Directive 2010/84/EU, the use of the PSUR repository will become mandatory 12 months after the functionalities of the repository have been established and have been announced by the Agency. The use of the PSUR repository becomes, therefore, mandatory on 13 June 2016.