15 December 2011
EMA/968891/2011
Press Office

Start of community reviews

CHMP meeting of 12-15 December 2011

Table 1. Start of safety reviews for centrally authorised medicines

Name	INN	Type of procedure	Scope
Mabthera	rituximab	Article 20 of Regulation (EC) 726/2004	Procedure triggered by the European Commission asking for a review of Mabthera. This follows information provided by the company (Roche) on the unexpected detection of a contaminant at an early stage of the manufacturing of drug substance at a site in the US. The contaminant was not detected at later stages of manufacturing of drug substance or

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			the finished product. The review is ongoing and aims to look for the root cause and continue to ensure safe supply to patients. The European Medicines Agency will provide updates as new information becomes available.
Alli, Mircera, Pegasys, Tamiflu, Xeloda, Xenical.	Orlistat, Methoxy polyethylene glycol-epoetin beta, Peginterferon alfa-2a, Oseltamivir, Capecitabine, Orlistat	Article 20 of Regulation (EC) 726/2004	Procedure triggered by the European Commission asking for a review of products manufactured using active substances or other materials produced at a site in the US. This follows information provided by the company on concerns identified in the quality management systems in place at this site. The review is ongoing and the European Medicines Agency will provide updates as new information becomes available.

Table 2. Start of safety reviews for non-centrally authorised medicines

Name	INN	Type of procedure	Scope
Iron containing medicinal products (solution for injection, intravenous use)		Article 31 of Directive 2001/83/EC, as amended	Procedure triggered by France asking for an opinion on the benefit-risk balance of solutions for injection containing iron due to safety concerns of allergic reactions after the administration of the products.
Metoclopramide containing medicinal products	metoclopramide	Article 31 of Directive 2001/83/EC, as amended	Procedure triggered by France asking for a an opinion on the benefit-risk balance of medicinal products containing metoclopramide due to efficacy concerns and safety concerns related to neurological and cardiovascular events.
Preflucel	Purified Influenza split virus	Article 36 of Directive 2001/83/EC, as amended	Procedure triggered by Austria asking for an opinion on the benefit-risk balance of Preflucel due to concerns of an increase in reports of hypersensitivity reactions, flu-like symptoms and ocular reactions in particular with one batch of this medicinal product. As a precautionary measure the Marketing Authorisation Holder – Baxter - has voluntarily recalled all batches distributed in the European market.

Table 3. Start of harmonisation procedure

Name	INN	Type of procedure	Scope
Sandimun / Sandimun Neoral	ciclosporin	Article 30 of Directive 2001/83/EC, as amended	The Committee started a harmonisation exercise for Sandimun and Sandimun Neoral and associated names. The review was triggered by the European Commission, due to the need of harmonisation of the Summary of Product Characteristics across various Members States.