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Start of community reviews

CHMP meeting of 16-19 January 2012

Table 1. Start of safety reviews for centrally authorised medicines

Name	INN	Type of procedure	Scope
Gilenya	fingolimod	Article 20 of Regulation (EC) 726/2004	Procedure triggered by the European Commission asking for a review of Gilenya. This follows information provided by the company (Novartis Europharm Ltd.) on cardiovascular events.
Doribax	doripenem monohydrate	Article 20 of Regulation (EC) 726/2004	Procedure triggered by the European Commission asking for a review of Doribax. This follows information provided by the company (Janssen Cilag International NV) on

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Name	INN	Type of procedure	Scope
			the termination of the study DORINOS-3008.

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

Name	INN	Type of procedure	Scope
Ergot derivatives containing medicinal products	Dihydroergocryptine/caffeine containing-products Dihydroergocristine/raubasine containing-products Nicergoline containing-products Dihydroergotoxine containing-products Dihydroergotamine containing-products	Article 31 of Directive 2001/83/EC, as amended	Procedure triggered by France asking for an opinion on the benefit-risk balance of some ergot derivatives in several indications due to limited efficacy and safety concerns related to fibrotic risks, thrombopenia, pancreatic and hepatic adverse events.

Table 3. Start of arbitration procedure

Name	INN	Type of procedure	Scope
Loraxin	loratadine	Article 29(4) of Directive 2001/83/EC, as amended	The Committee started a referral procedure for Loraxin and associated names. The procedure was initiated because of disagreements regarding the benefit-risk ratio.
Affilia & Iffeza	Fluticasone propionate Formoterol fumarate	Article 29(4) of Directive 2001/83/EC, as amended	The Committee started a referral procedure for Affilia and associated names and Iffeza and associated names. The procedure was initiated because of disagreements regarding the benefit-risk ratio.