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Start of community reviews

CHMP meeting of 21-24 May 2012

Table 1. Start of reviews for centrally authorised medicines

Name	INN	Type of procedure	Scope
Evicel	human fibrinogen / human thrombin	Article 20 of Regulation (EC) 726/2004	Procedure triggered by the European Commission requesting the review of the benefit-risk balance of Evicel following reports of air embolism after administration of the product by spray application.

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

Name	INN	Type of procedure	Scope
Fibrinogen-containing solutions for sealant authorised for administration by spray application	Fibrinogen	Article 31 of Directive 2001/83/EC, as amended	The Committee started a referral procedure for fibrinogen-containing solutions for sealant authorised for administration by spray application. The procedure was initiated by the UK due to concerns related to the risk of air embolism with the spray application of these medicines.
Methysergide containing medicinal products	methysergide	Article 31 of Directive 2001/83/EC, as amended	Procedure triggered by France asking for an opinion on the benefit-risk balance of methysergide containing products in certain indications due to safety concerns related to fibrotic risks.

Table 3. Start of arbitration procedure

Name	INN	Type of procedure	Scope
Furosemide Vitabalans	Furosemide	Article 29(4) of Directive 2001/83/EC, as amended	The Committee started a referral procedure for Furosemide Vitabalans and associated names. The procedure was initiated by Estonia because of disagreements regarding the benefit-risk ratio of the product.