19 September 2013
EMA/565898/2013
Press Office

Start of community reviews

CHMP meeting of 16-19 September 2013

Table 1. Start of benefit-risk review

Name	INN	Type of procedure	Scope
Polymyxin-based products	colistimethate sodium, colistin	Article 31 of Directive 2001/83/EC	Procedure triggered by the European Commission, requesting the review of the benefit-risk balance of polymyxin-based products for parenteral and inhalation use. The Committee is requested to update the product information in line with the latest data on the use of these products.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8669
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Table 2. Start of harmonisation procedure

Name	INN	Type of procedure	Scope
Nasonex	mometasone furoate	Article 30 of Directive 2001/83/EC	The Committee started a harmonisation exercise for Nasonex and associated names. The review was triggered by the European Commission, due to the need of harmonisation of the Summary of Product Characteristics across Member States.

Table 3. Start of scientific review

Name	INN	Type of procedure	Scope
Polymyxin-based products	colistimethate sodium, colistin	Article 5(3) of Regulation (EC) 726/2004	Procedure triggered by EMA asking for a scientific opinion on the need to establish limits/ranges for the colisitimethate sodium subcomponents and on the adequacy of the *Ph. Eur.* Monograph and the control and bioassay methods described therein.