

22 October 2015 EMA/677252/2015 Press Office

Start of community reviews

CHMP meeting of 19-22 October 2015

Table 1. Start of harmonisation procedure

Name	INN	Type of procedure	Scope
Etopophos and associated names	etoposide	Article 30 of Directive 2001/83/EC	The Committee started a harmonisation exercise for Etopophos 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.
Vepesid and associated names	etoposide	Article 30 of Directive 2001/83/EC	The Committee started a harmonisation exercise for Vepesid 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.

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Table 2. Start of arbitration procedure

Name	INN	Type of procedure	Scope
Levonelle and associated names	levonorgestrel	Article 13(1) of Commission Regulation (EC) No 1234/2008	The Committee started a referral procedure for Levonelle and associated names due to disagreement between member states on a Type II variation concerning information on interaction with other medicinal products.
Otipax and associated names	lidocaine hydrochloride	Article 29(4) of Directive 2001/83/EC	The Committee started a referral procedure for Otipax and associated names. The procedure was initiated because of disagreements regarding the demonstration of efficacy.
Tobramycin VVB and associated names	tobramycin	Article 29(4) of Directive 2001/83/EC	The Committee started a referral procedure for Tobramycin VVB and associated names. The procedure was initiated because of disagreements regarding the claim for clinical superiority.