



21 November 2013
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Press Office

Start of community reviews

CHMP meeting of 18-21 November 2013

Table 1. Start of arbitration procedure

Name	INN	Type of procedure	Scope
Tibolona Aristo 2.5mg tablets	tibolone	Article 29(4) of Directive 2001/83/EC	The Committee started a referral procedure for Tibolona Aristo 2.5mg tablets. The procedure was initiated by Spain because of disagreements regarding the evidence of bioequivalence of the generic product to its originator.



Name	INN	Type of procedure	Scope
Tibocina 2.5mg tablets	tibolone	Article 29(4) of Directive 2001/83/EC	The Committee started a referral procedure for Tibocina 2.5mg tablets. The procedure was initiated by Spain because of disagreements regarding the evidence of bioequivalence of the generic product to its originator.

Table 2. Start of harmonisation procedure

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