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Press Office

Start of community reviews

CHMP meeting of 13-16 February 2012

Table 1. Start of harmonisation procedure

Name	INN	Type of procedure	Scope
Rocephin	ceftriaxone	Article 30 of Directive 2001/83/EC, as amended	The Committee started a harmonisation exercise for Rocephin 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 2. Start of arbitration procedure

Name	INN	Type of procedure	Scope
Levothyroxine Alapis	levothyroxine sodium	Article 29(4) of Directive 2001/83/EC, as amended	The Committee started a referral procedure for Levothyroxine Alapis and associated names. The procedure was initiated because of disagreements regarding the benefit-risk ratio in the paediatric population.