

21 March 2013
EMA/177209/2013
Press Office

Start of community reviews

CHMP meeting of 18-21 March 2013

Table 1. Start of arbitration procedure

Name	INN	Type of procedure	Scope
Didanosine and associated names	didanosine	Article 29(4) of Directive 2001/83/EC	The Committee started a referral procedure for Didanosine and associated names from Aurobindo Pharma Limited. The procedure was initiated by the United Kingdom because of disagreements regarding the demonstration of bioequivalence under fed conditions between the generic and the reference product.

Name	INN	Type of procedure	Scope
Okrido and associated names	prednisolone	Article 29(4) of Directive 2001/83/EC	The Committee started a referral procedure for Okrido and associated names. The procedure was initiated by the United Kingdom because of disagreements regarding the applicability of a waiver for a bioequivalence study between Okrido and the reference product.
Valebo and associated names	alendronic acid and alfacalcidol	Article 29(4) of Directive 2001/83/EC	The Committee started a referral procedure for Valebo and associated names. The procedure was initiated by Germany because of disagreements regarding the demonstration of the role of alfacalcidol in the reduction in fall rate.