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Press Office

Start of community reviews

CHMP meeting of 24-27 June 2013

Table 1. Start of harmonisation procedure

Name	INN	Type of procedure	Scope
Seroquel/ Seroquel XR and associated names	quetiapine	Article 30 of Directive 2001/83/EC	The Committee started a harmonisation exercise for Seroquel/Seroquel XR (quetiapine) 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
Dexamed and associated names	Dexamfetamine Sulphate	Article 29(4) of Directive 2001/83/EC	The Committee started a referral procedure for Dexamed and associated names. The procedure was initiated because of disagreements regarding the enhanced risk for dependence and abuse potential of this product and the lack of convincing evidence for the efficacy in a second line setting in ADHD.