EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Start of community reviews

CHMP meeting of 16-19 July 2012

Table 1. Start of reviews for centrally authorised medicines

Name	INN	Type of procedure	Scope
Temodal, Tygacil, Ribavirin Teva, Ribavirin Teva Pharma, PecFent, Torisel and Conbriza	Temozolomide, tigecycline, ribavirin, ribavirin, fentanyl citrate, temsirolimus, bazedoxifene	Article 20 of Regulation (EC) 726/2004	Procedure triggered by the European Commission asking for a review of products potentially impacted by inspection findings at the Cetero Research facilities in Houston, Texas, USA. An FDA inspection of this Contract Research Organization raised concerns that data generated at this site during a specific period may be unreliable. For Pecfent, Torisel and Conbriza the CHMP concluded the review during the July 2012

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Name	INN	Type of procedure	Scope
			meeting (see separate Q&A document). For Temodal, Tygacil, Ribavirin Teva and Ribavirin Teva Pharma the review is ongoing.

Table 2. Start of reviews for non-centrally authorised medicines

Name	INN	Type of procedure	Scope
Nicardipine-containing medicinal products for intravenous use	nicardipine	Article 31 of Directive 2001/83/EC	Procedure triggered by the United Kingdom asking for a review of the benefit-risk balance for nicardipine-containing medicinal products for intravenous use, due to efficacy and safety concerns in the approved indications.