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Press Office

Start of community reviews

CHMP meeting of 10-13 December 2018

Table 1. Start of reviews for non-centrally authorised medicines

Name	INN	Type of procedure	Scope
fosfomycin and associated names	fosfomycin	Article 31 of Directive 2001/83/EC	Procedure triggered by Germany asking for an opinion on the benefit-risk balance of the approved indications considering the current scientific knowledge. Its indications and dosage as well as the adequacy of information on safety and pharmacological properties need re-evaluating.

Table 2. Start of scientific review

Name	INN	Type of procedure	Scope
ethinylestradiol and norethisterone containing medicinal products	ethinylestradiol and norethisterone	Article 5(3) of Regulation (EC) No 726/2004	Procedure triggered by UK asking for a scientific opinion on a recently published metanalysis study on the developmental effect of norethisterone acetate and ethinylestradiol and the potential clinical implications on the human foetus.