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Press Office

Start of community reviews

CHMP meeting of 29 March 2016 – 01 April 2016

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

Name	INN	Type of procedure	Scope
Alkem		Article 31 of Directive 2001/83/EC	Procedure triggered by Germany in relation to findings of non-compliance with good clinical practice (GCP) at the Alkem Bioequivalence Centre in Mumbai, India. This follows a joint inspection by DE and NL which raised concerns about the reliability of data from bioequivalence studies conducted at Alkem Bioequivalence Centre in support of several marketing authorisations and marketing authorisation applications.

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Name	INN	Type of procedure	Scope
Symbioflor 2 and associated names	Escherichia Coli bacteria (cells and autolysate)	Article 31 of Directive 2001/83/EC	Procedure triggered by Germany requesting the review of the benefit-risk balance for Symbioflor 2 and associated names following concerns that the effectiveness of the medicine(s) has not been adequately demonstrated.
Vancomycin-containing products	vancomycin	Article 31 of Directive 2001/83/EC	Procedure triggered by Spain requesting the review of the benefit-risk balance of vancomycin-containing products. The Committee is requested to update the product information in line with available data.