1 April 2016
EMA/CHMP/224042/2016

CHMP List of questions

To be addressed by the marketing authorisation holders for medicinal products containing vancomycin

Article 31 of Directive 2001/83/EC

Procedure number: EMEA/H/A-31/1440

INN: vancomycin

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

The marketing authorisation holders are requested to provide the following for their vancomycin containing products:

1. Information on currently approved indications, posology and method of administration, special warnings and precautions, undesirable effects, pharmacodynamic properties and pharmacokinetic properties, for products available on the EU market, in the tabular format below [1]. The table should also identify the main differences between the SmPCs/PLs in the different EU Member States.

INN	Product name	Section 4.1 Indications	Section 4.2 Posology and method of administration	Section 4.4 Special warnings and precautions	Section 4.8 Undesirable effects	Section 5.1 Pharmaco-dynamic properties	Section 5.2 Pharmaco-kinetic properties	Main differences between the SmPC in the different EU member states

2. A discussion on the appropriate dosing recommendations to ensure the efficacy of your product in the approved indications, taking into accounts all available data and current knowledge regarding pharmacokinetics.

3. A discussion on the appropiate dosing recommendations should also be provided for vancomycin when used orally for the treatment of *Clostridium difficile*-associated diarrhoea (CDAD), taking into account all available data and current knowledge regarding pharmacokinetics.

4. A discussion on the optimal way of expressing the strength of vancomycin-containing products in view of the current clinical practices.

5. A discussion on the origin of the active substance and on the suitability of the current limits for components and impurities in the drug substance (and in drug products if appropriate).

6. Proposals for updates of relevant sections of the product information in line with current data and in accordance to the guideline on summaries of product characteristics and available QRD referral templates http://www.ema.europa.eu/htms/human/qrd/qrdtemplate.htm.

   The proposals should take into account the responses to the above questions and consider in particular (but not only) the posology (optimal dose, recommendations for paediatric patients), and pharmacodynamic/pharmacokinetic data to be reflected in the PI.

[1] If you are the MAH of a generic product, it is sufficient to identify any divergences between the PI of your product and that of the originator