Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

EMEA/CMDv/652814/2009
London, 17 September 2009

# Question & Answer N. 113/2009

# Abridged (generic) application for an antibiotic injection

| Status | Public |
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**QUESTION**

The company intention is to submit an abridged (generic) application for an antibiotic injection. No excipients are used. The product is intended to be used for indications and species already approved for the original/reference product. Can withdrawal periods for the food producing animals established for the original/reference product be used for generic applications?

**ANSWER**

If the generic product:

- has the same qualitative and quantitative composition in terms of the active substance
- is of the same pharmaceutical form
- is bioequivalent to a suitable reference product, and
- is administered by the same route to the same target animal species

then it can be assumed that residues in most tissues will be equivalent between the two products. However, residue depletion at intramuscular or subcutaneous injection sites may be quite different depending on the formulation. Therefore, in addition to a bioequivalence study, a study is required to show that equivalent or faster depletion at the injection site occurs following administration of the generic product.

This advice is in accordance with the Note for Guidance: Approach towards Harmonisation of Withdrawal Periods (EMEA/CVMP/036/95), page 36. Further guidance can be found in the Guideline on Injection Site Residues (EMEA/CVMP/542/03).