The European Agency for the Evaluation of Medicinal Products
Veterinary Medicines and Information Technology

EMEA/CVMP/198/99 – FINAL

COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

NOTE FOR GUIDANCE: MAXIMUM SHELF-LIFE FOR STERILE MEDICINAL PRODUCTS AFTER FIRST OPENING OR FOLLOWING RECONSTITUTION

RELEASED FOR CONSULTATION BY CVMP	APRIL 1999 & MARCH 2000
ADOPTION BY CVMP AS FINAL	18 – 20 JULY 2000
DATE FOR COMING INTO EFFECT	1 FEBRUARY 2001

Public

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.eudra.org http://www.eudra.org/emea.html

EMEA 2000 Reproduction and/or distribution of this document is authorised for non-commercial purposes only provided the EMEA is acknowledged

MAXIMUM SHELF-LIFE FOR STERILE VETERINARY PRODUCTS AFTER FIRST OPENING* OR FOLLOWING RECONSTITUTION

GENERAL STATEMENT

This guideline applies to all sterile veterinary medicinal products but does not apply to immunological medicinal products.

Because it is difficult to predict all the possible conditions under which the product will be opened, diluted, reconstituted and stored, etc., the user is responsible for maintaining the quality of the product that is administered to the animal.

The Applicant should conduct appropriate studies and provide the relevant information in the User Information Texts, (e.g. SPC, Package inserts, labels) See also separate CVMP guideline on *In-use stability testing of veterinary medicinal products,* which provides specific guidance for multidose products.

The Applicant should also take note of the recommendations contained in the European Pharmacopoeia, with respect to storage times and conditions for specific categories of sterile products, once opened.

UNPRESERVED AQUEOUS STERILE PRODUCTS

In general, the user information includes "*The product should be used immediately and not stored after opening/reconstitution/dilution."* Where justified, storage at 2 to 8°C for no longer than 24 hours may be proposed for preparations for infusion after reconstitution/dilution. In that case the user information should include *"After reconstitution/dilution, the product may be stored at 2 to 8°C for no longer than x hours"*. Chemical and physical stability for x hours should be demonstrated.

AQUEOUS PRESERVED STERILE PRODUCTS (including antimicrobial preservatives or intrinsically self-preserving) & NON-AQUEOUS STERILE PRODUCTS, E.G. OILY PREPARATIONS

The user information should include *"After first opening/reconstitution/dilution, the product may be stored for x hours/days at y°C"*. Chemical and physical stability for x hours/days at y°C should be demonstrated. Moreover, x and y should be justified from a microbiological point of view. Normally, x should not be greater than 28 days.

* opening includes broaching