European Medicines Agency
Veterinary Medicines and Inspections

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PUBLIC STATEMENT
COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE
Meeting of 16-18 May 2006

Introduction

During the assessment of a Type II variation regarding the extension of the shelf-life for the antigen stocks it became apparent that further clarification was required regarding the need for sterility testing at the end of the proposed shelf-life. The issue arose due to a discussion on the interpretation of the VICH guideline on stability testing of new veterinary drug substances and medicinal products (CVMP/VICH/899/99) where it is stated that "A systematic approach should be adopted in the presentation and evaluation of the stability information, which should include, as appropriate, results from the physical, chemical, biological and microbiological tests, including particular attributes of the dosage form (e.g., dissolution rate for solid oral dosage forms)." This resulted in discussions about the necessity to request sterility testing at the end of the shelf-life, which indicated that there was potential for different interpretations and the CVMP consequently decided to issue a public statement in order to ensure a consistent approach across the European Union.

Statement

The CVMP agreed that for variations affecting the extension of the shelf–life for antigen stocks in immunological veterinary medicinal products sterility testing should not be required at the end of the proposed shelf-life.

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