European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

CONCEPT PAPER ON THE DEVELOPMENT OF A GUIDELINE ON PARAMETRIC RELEASE

AGREED BY QUALITY WORKING PARTY	April 2005
ADOPTION BY CVMP FOR RELEASE FOR CONSULTATION	14 April 2005
END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 July 2005

Comments should be provided by 31 July 2005 to the Quality Working Party Secretariat: QWP@emea.eu.int; Fax +44 20 7418 8661

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1. INTRODUCTION

A CPMP (CHMP) Note for Guidance on Parametric Release (CPMP/QWP/3015/99) (1) came into operation in September 2001 for medicinal products for human use.

This guideline explains how a medicinal product must comply with the requirements in the approved specifications at time of release and over the shelf-life of the product. However, this does not mean that all tests in the specifications have to be carried out on the finished product before release (2). Manufacturers may obtain assurance that the product is of the stipulated quality – that is, meets its specification – through a system called parametric release. Parametric release is based on evidence of successful validation of the manufacturing process and review of the documentation on process monitoring carried out during manufacturing to provide the desired assurance of the quality of the product.

The definition of parametric release used in the document (and in the guideline for human products) is based on that proposed by the European Organisation for Quality, EOQ. Parametric release is "a system of release that gives the assurance that the product is of the intended quality based on information collected during the manufacturing process and on the compliance with specific GMP requirements related to Parametric Release.

Parametric release is therefore used as an operational alternative to routine release testing of certain, specific, parameters. The implementation of parametric release is in line with the text in the European Pharmacopoeia.

2. PROBLEM STATEMENT

No guidance is currently available within the EU concerning parametric release of Veterinary medicinal products. This currently causes confusion, for example, whether a Qualified Person may permit the omission of sterility re-testing of finished veterinary medicinal products for which parametric release is implemented.

3. DISCUSSION (ON THE PROBLEM STATEMENT)

Parametric release has been used for several years and guidance has been available within the EU for medicinal products, but for human use only.

The European Pharmacopoeia refers to parametric release without making a distinction between human and veterinary medicinal products, for example, the monograph "Methods of preparation of sterile products" (3) states "When a fully validated terminal sterilisation method by steam, dry heat or ionising radiation is used, parametric release, that is the release of a batch of sterilised items based on process data rather than on the basis of submitting a sample of the items to sterility testing, may be carried out, subject to the approval of the competent authority."

Furthermore, the scope of Annex 17 "Parametric release" of the EU GMP Guide, Volume 4 also extends to both human and veterinary medicinal products (4).

4. RECOMMENDATION

In the absence of clear guidance on parametric release for veterinary medicinal products, the QWP recommends that such guidance be produced.

It is anticipated that such guidance would be very similar to the existing guidance for human medicinal products and be in line with the requirements of both the European Pharmacopoeia and also Annex 17 of the EU GMP Guide.

The scope of such guidance would be restricted to veterinary medicinal products which are not of immunological, biotechnological or biological origin.

5. TIMETABLE

It is anticipated that a draft Guideline could be available 6 months after adoption of the concept paper, and that this would then be released for external consultation for 3 months (as it would not differ fundamentally from the human guideline so a longer consultation period would not be required), before its finalisation within another 6 months.

6. RESOURCE REQUIREMENTS FOR PREPARATION

Rapporteur to prepare the draft Guideline. Member States to provide input via their Quality Working Party Members. CVMP to review and comment on the draft guideline prior to its release for consultation.

7. IMPACT ASSESSMENT (ANTICIPATED)

No adverse impact on industry with respect to either resources or costs is foreseen. The anticipated benefit to industry of having an option to use parametric release would be that testing of products, both at release and on import into the EU, could be reduced. This would have benefits by reducing the time, money and proportion of each batch of product required for testing. A consequent reduction in waste materials derived from testing could also be anticipated.

The guidance will also help in clarifying testing requirements for veterinary medicinal products for regulators, GMP inspectors and the industry (applicants for marketing authorisations and also product manufacturers).

8. INTERESTED PARTIES

None specific.

9. REFERENCES TO LITERATURE, GUIDELINES ETC

1. CPMP Note for Guidance on Parametric Release (EMEA/QWP/3015/99)
   http://www.emea.eu.int/pdfs/human/qwp/301599en.pdf

2. Ph.Eur. 5th Ed., 1.1, General Statements

3. Ph.Eur. 5th Ed., 5.1.1, Methods of preparation of sterile products

4. The Rules Governing Medicinal Products in the European Community, Volume 4, Annex 17
   http://pharmacos.eudra.org/F2/eudralex/vol-4/pdfs-en/v4an17.pdf