1 6 November 2014
2 EMA/CVMP/505827/2014
3 Committee for Medicinal Products for Veterinary Use (CVMP)

4 Concept paper for the revision of the guidelines on data 5 requirements for veterinary medicinal products for minor 6 use minor species (EMEA/CVMP/IWP/123243/2006-Rev.2) 7 (EMEA/CVMP/QWP/128710/2004) 8 (EMEA/CVMP/SWP/66781/2005) 9 (EMEA/CVMP/EWP/117899/2004)

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Adopted by CVMP for release for consultation	6 November 2014
Start of public consultation	18 November 2014
End of consultation (deadline for comments)	15 February 2015

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1. Introduction

The European Medicines Agency (the Agency) together with the European Medicines Regulatory Network aim to facilitate the access to market of products indicated for MUMS/limited market as part of measures to promote the availability of veterinary medicines. One of the measures initiated by the CVMP was to review dossier requirements for veterinary medicinal products intended for minor uses or minor species (MUMS) and, if possible, to establish standards for demonstration of quality, safety and efficacy for these. Since the publication of the set of CVMP guidelines on data requirements for MUMS products in 2006/2007 the Agency Policy for classification and incentives for veterinary medicinal products indicated for Minor Use Minor Species (MUMS) /limited markets was established and implemented on 1 September 2009. Considerable experience has been gained in applying the guidelines for applications concerning veterinary medicinal products classified as MUMS/limited market. In light of the work undertaken so far it seems likely that revisions to the current MUMS guidelines may be warranted.

2. Problem statement

The current MUMS guidelines were elaborated in 2004 and 2005 and since that time there have been a number of applicant/companies who have availed of these amended data requirements for products classified as intended for MUMS/limited market. The guidelines are intended to reduce data requirements where possible for products classified as MUMS while still providing assurance of appropriate quality safety and efficacy and complying with the legislation in place and leading to an overall positive benefit-risk balance for the product. The reduction in data requirements has generated considerable debate since the guidelines on MUMS data requirements were introduced. Some stakeholders find this a very valuable component of the policy whereas others consider that in many cases data requirements are only slightly reduced or there are expectations that for any MUMS product all possible data reductions would be applicable. Based on the experience gained to date, after almost 10 years it is considered time to review these guidelines, to ensure that the current guidance is in line with current knowledge and best practice and also provides more predictability and regulatory certainty to applicants in terms of applicability to particular products.

3. Discussion (on the problem statement)

The following aspects will need to be discussed and covered as appropriate by the revised guidelines:

1. Update acceptable data requirements in the specific area of responsibility of the working party in light of experience gained.

2. Clarify in what cases these requirements may or may not apply e.g. new active substances, novel technology or first in class products.

4. Recommendation

The CVMP recommends that the relevant working parties review the existing MUMS guidelines within their area of expertise in view of experience gained with dossiers submitted for MUMS/limited markets and also taking into account the latest revised policy. The revised guidelines will include an update of where amendments to data requirements for these products may be considered.

5. Proposed timetable

February 2015	Deadline for comments during public consultation of concept paper
December 2015	Expected date for adoption of the revised guidelines by the CVMP working parties
Q1 2016	Revised draft guideline for discussion and adoption by CVMP for release for consultation

6. Resource requirements for preparation

Preparation of the revision would involve one rapporteur assisted by one or more co-rapporteurs, as appropriate, for each responsible CVMP working party (SWP, EWP, IWP, ERAWP and Joint CHMP/CVMP QWP). Preparation of the draft guidelines will require discussions at 2 – 3 working party meetings.

7. Impact assessment (anticipated)

The update of these guidelines is expected to provide clearer and up-to-date guidance to applicants and assessors.

8. Interested parties

Veterinary pharmaceutical industry and veterinary consultants.

Veterinarians.

Regulatory authorities for medicinal products for veterinary use.

9. References

1. Revised Policy on Classification and Incentives for Veterinary Medicinal Products indicated for Minor use Minor species (MUMS)/limited market (Draft) (EMA/308411/2014).
2. Quality data requirements for veterinary medicinal products intended for minor uses or minor species. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004277.pdf
3. Safety and Residue Data Requirements for Veterinary Medicinal Products intended for Minor Uses or Minor Species. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004581.pdf
4. Efficacy and target animal safety data requirements for veterinary medicinal products intended for minor uses or minor species. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004678.pdf

5. Data requirements for immunological veterinary medicinal products intended for minor use or minor species http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2010/04/WC500089628.pdf