1 26 January 2018
2 EMA/CVMP/SWP/779037/2017
3 Committee for Medicinal Products for Veterinary Use (CVMP)

4 Concept paper for the revision of the guideline on safety 5 and residue data requirements for pharmaceutical 6 veterinary medicinal products intended for minor use or 7 minor species (MUMS)/limited market

Agreed by Safety Working Party (SWP-V)	November 2017
Adopted by CVMP for release for consultation	18 January 2018
Start of public consultation	26 January 2018
End of consultation (deadline for comments)	28 February 2018

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1. Introduction

In order to stimulate the development of veterinary medicines intended for minor uses or minor species (MUMS)/limited market the CVMP has developed guidelines on data requirements for MUMS/limited market veterinary medicinal products for quality, safety and efficacy for pharmaceuticals, as well as a guideline for immunologicals. The guideline that focuses on safety requirements for pharmaceuticals includes a section on extrapolation of maximum residue limits (MRLs) from major to minor species. In May 2017 the Commission published a regulation laying down rules for extrapolation of MRLs and these rules are now those used by CVMP in relation to extrapolation of MRLs. There is now an inconsistency between the CVMP guideline and the Commission Regulation.

2. Problem statement

On 24 May 2017 Commission Regulation (EU) 2017/880, laying down rules on the use of maximum residue limits established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species and a maximum residue limit established for a pharmacologically active substance in one or more species for other species, in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council, was published.

The rules included in Commission regulation (EU) 2017/880 go beyond those described in the existing CVMP guideline on safety and residues data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market (EMA/CVMP/SWP/66781/2005-Rev.1). As the rules described in the Commission Regulation describe the approach now used by the CVMP in relation to extrapolation of MRLs, there is a need to update the CVMP guideline, bringing the section on extrapolation of MRLs in line with the Commission Regulation.

3. Discussion (on the problem statement)

The information provided in the current CVMP guideline on safety and residues data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market no longer reflects the approach employed by the CVMP and the document should therefore be updated. This will ensure that the approach employed is consistently described and so avoid the potential confusion.

4. Recommendation

The CVMP guideline on safety and residues data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market should be updated to take account of the rules described in Commission Regulation (EU) 2017/880.

5. Proposed timetable

January 2018 – Concept paper released for consultation.

February 2018 – End of consultation period.

Quarter 4 2018 – release of revised draft guideline for one month public consultation.

Quarter 1/2 2019 – Expected date for adoption by CVMP.

In light of the fact that the work proposed is not expected to be considered controversial by stakeholders, and with a view to minimising the time period during which inconsistent information on the approach taken for extrapolation of MRLs is available, a consultation period of one month is considered to be sufficient for both this concept paper and the draft guideline.

6. Resource requirements for preparation

The new guideline will involve the SWP-V, SWP-V secretariat and the CVMP. The SWP-V will need to appoint a rapporteur from amongst its members. As well as work by the SWP-V rapporteur, development of the revised guideline will require discussion and review by SWP-V plenary, the SWP-V secretariat and CVMP. It is anticipated that the draft guideline may need to be discussed at two plenary SWP meetings.

7. Impact assessment (anticipated)

The revised guideline will ensure clarity in relation to the approach taken by CVMP for extrapolation of MRLs.

8. Interested parties

Veterinary pharmaceutical industry, EU Competent Authorities, Consultants.

9. References to literature, guidelines, etc.

- CVMP guideline on safety and residues data requirements for pharmaceutical veterinary medicinal products intended for minor use or minor species (MUMS)/limited market (EMA/CVMP/SWP/66781/2005-Rev.1)
- Commission regulation (EU) 2017/880 of 23 May 2017 laying down rules on the use of maximum residue limits established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species and a maximum residue limit established for a pharmacologically active substance in one or more species for other species, in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council.