EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 May 2015
EMA/CVMP/QWP/360463/2015
Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper on the need for revision of the note of guidance on manufacture of the finished dosage form

Agreed by Quality Working Party	28 May 2015
Adopted by CVMP for release for consultation	9 July 2015
Start of public consultation	17 July 2015
End of consultation (deadline for comments)	17 October 2015

The proposed guideline will replace the Note for Guidance: Manufacture of the Finished Dosage Form (EMEA/CVMP/126/95).

Comments should be provided using this template. The completed comments form should be sent to vet-guidelines@ema.europa.eu

Keywords	Veterinary, Guideline, Manufacture, Finished Dosage form, Dosage form

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1. Introduction

This concept paper addresses the need to update and revise the veterinary Note for Guidance on Manufacture of the Finished Dosage Form (EMEA/CVMP/126/95) (Ref 1). This guideline was originally adopted in December 1995 and came into operation in June 1996. Since then, the references to directives applicable to veterinary medicinal products have changed, revised Annex I to the Directive 2001/82/EC (i.e. Directive 2009/9/EC) was introduced and several aspects described in the current guideline were further elaborated within other regulatory documents. Also the manufacture of finished dosage forms has spread worldwide and terms like holding time and bulk product are now important parts of the description of the manufacturing process. The guideline therefore needs to be revised to be in line with all these changes.

2. Problem statement

The current guideline does not fully reflect recent developments and changes both in the legislation and available guidance documents. The text of the guideline should be brought up to recent manufacturing practices and should allow different approaches to the manufacture of the finished dosage form.

3. Discussion (on the problem statement)

The objective of the guideline on the manufacture of the finished dosage form (veterinary) is to underline all aspects of manufacture that are important, both for applicants and regulators. The guideline also indicates that information which falls under Good Manufacturing Practice should not be part of the marketing authorisation file and that only product specific issues need to be described. The intention of the revision is not to repeat the information already stated in other guidance documents or to create new guidance, but to update the information to be in line with recent developments. The following issues will be taken into account during the revision:

The current guideline (EMEA/CVMP/126/95) was developed before introduction of the current Directive (2001/82/EC) and its Annex I (2009/9/EC). The guideline should thus be updated to be in line with the current Directive and its Annex I.

In addition, other related guidelines were developed like Process validation (Ref 2) and Parametric release (Ref 3) and these also have an impact on the current guideline on manufacture of finished dosage form, especially on chapter 6. ‘Validation data of the manufacturing process’ and chapter 7. ‘Special Items’. Therefore the relevant information will be used for its revision.

With new manufacturing practices and more complex manufacturing chains a need to incorporate holding times and conditions, as well as shipping transportation conditions, has been identified and will be discussed.

There are also advanced concepts in the manufacturing process of the final dosage forms outlined in ICH Q8, Q9 and Q10 (Refs 4, 5 and 6) regarding medicinal products for human use which can also be optionally used by the veterinary industry and the revised guideline shall reflect on this.

4. Recommendation

The Quality Working Party recommends revision of the Note for guidance on Manufacture of the Finished Dosage Form in order to update information about the manufacture of finished veterinary dosage forms in line with recent developments and the current EU legislation.

The revised guideline will not introduce new requirements on medicinal products already authorised and on the market.

5. Proposed timetable

It is anticipated that the draft guideline could be available within 6 months after the end of the consultation period of the concept paper and that this would then be released for external consultation for 6 months before its finalisation within another 6 months.

It is expected that the guideline will come into operation 6 months after adoption.

6. Resource requirements for preparation

The revision will involve the EMA-QWP Secretariat, the Joint CHMP/CVMP Quality Working Party, the CVMP, and the GMP/GDP Inspectors Working Group, who would be consulted, as necessary. The QWP should appoint a rapporteur from within the members of the QWP.

7. Impact assessment (anticipated)

No adverse impact on industry with respect to either resources or costs is foreseen.

The guidance will clarify requirements for regulators and industry with respect to manufacture of finished (veterinary) dosage forms taking into account the concepts of recent developments. Elaboration of the guideline will facilitate different approaches to manufacturing processes than currently detailed in the guideline and thus increase flexibility for industry.

8. Interested parties

Pharmaceutical Industry, EU Competent Authorities and GMP/GDP Inspectors Working Group.

References

1. EMEA/CVMP/126/95 Note for Guidance on Manufacture of the Finished Dosage Form;
2. EMA/CHMP/CVMP/QWP/BWP/70278/2012-Rev1 Guideline on process validation for finished products;
3. EMEA/CVMP/QWP/339588/2005 Guideline on Parametric release;
4. ICH Q8(R2) Pharmaceutical Development;
5. ICH Q9 Quality Risk Management;
6. ICH Q10 Pharmaceutical Quality Systems.