EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 December 2010
EMA/CVMP/SWP/736014/2010
Committee for Medicinal Products for Veterinary Use (CVMP)

Concept paper on revision of note for guidance for the determination of withdrawal periods for milk

Agreed by SWP	19 November 2010
Adoption by CVMP for release for consultation	9 December 2010
End of consultation (deadline for comments)	31 March 2011

Comments should be provided using this template. The completed comments form should be sent to vet-guidelines@ema.europa.eu or by fax +44 20 7418 8447

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

1. Introduction

In 2000 the note for guidance for the determination of withdrawal periods for milk (EMEA/CVMP/473/98-FINAL) was adopted by the CVMP. Paragraph 2.1.10. thereof addresses dry cow products. Dry cow products are antibiotic preparations for intramammary use, aimed to protect cows from developing mastitis after cessation of milking (the dry period) preceding calving. This may result in antibiotic residues in the milk after delivery. For this reason a withdrawal period for milk is required.

2. Problem statement

The note for guidance defines the withdrawal period based on the last time of administration and gives no recommendation for establishment of the withdrawal period specifically for dry cow products. Also it recommends a limited span of dry periods when testing for the depletion and withdrawal.

For dry cow products the withdrawal period for milk is normally expressed as the number of milkings after birth. However, it appears that for some products significant depletion already occurs during the dry period, in particular in the early phase (the first 30 days). Hence in the case of short dry periods, the withdrawal period would depend on the length of the dry period in addition to the number of milkings. For preparations for which there is no known depletion during the dry period, for instance as no early data are available, the withdrawal period is solely based on the number of milkings, starting from a defined period after treatment, established on the basis of depletion data and the Time to Safe Concentration (TTSC) approach. However, when a depletion occurs in a certain period of the study, applying the TTSC approach will lead to an overestimation of the withdrawal period at longer dry periods.

3. Discussion (on the problem statement)

Since the guideline does not encompass the potential early depletion during the dry period, there may be a need to revise the note for guidance in this respect. Also a limited span in the dry period as indicated in the note for guidance appears not always to reflect practical conditions in the field.

Depletion during drying off may therefore require different withdrawal periods, based on the rate of depletion, the length of the dry period and the number of milkings after calving.

It is recommended though that the proposal should be not too complicated for use under practical conditions.

4. Recommendation

The CVMP recommends revision of the Note for Guidance for the determination of withdrawal periods for milk, taking into consideration the abovementioned potential residue depletion during the dry period.

5. Proposed timetable

The following timetable is foreseen for the review of the guideline further to consideration of the comments received during the public consultation of the Concept Paper:

Released for consultation on	13/12/2010
Deadline for comments	31/3/2011
Discussion in SWP	May to September 2011

Adoption by CVMP for release for 6 month consultation	13/10/2011
Deadline for comments	30/4/2012
Rediscussion in SWP	May to September 2012
Expected date for adoption by CVMP	November 2012

6. Resource requirements for preparation

The preparation of the revision of the guidance will require one rapporteur and one co-rapporteur from the SWP. Additional expertise regarding statistics and modelling may be needed.

Interested parties are invited to submit relevant data that has not previously been submitted for the working party to review.

7. Impact assessment (anticipated)

Revision of the guideline may result in a harmonised approach to authorisation of dry cow products in Member States; in particular it allows for differentiation of withdrawal periods in the event of early calving, resulting in a timely delivery of milk without harm to the consumer.

Interested parties are invited to comment on the need for this guideline in view of the anticipated number of applications for dry cow products.

8. Interested parties

Veterinary pharmaceutical industry, veterinary practitioners, dairy farmers, regulatory authorities.

9. References to literature, guidelines, etc.

Note for Guidance for the Determination of Withdrawal Periods for Milk; EMEA/CVMP/473/98-final