EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Veterinary Medicinal Products (CVMP)

Questions and answers

Standard animal weights for estimating worst-case consumer exposure scenarios

Background

This question and answer (Q & A) document is intended to provide further guidance on standard body weights used by CVMP when estimating consumer exposure. It is particularly meant to complement the 'Guideline on data to be provided in support of a request to include a substance in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009' (EMA/CVMP/516817/2009)[1], although may also be useful in other contexts. The present document provides guidance relevant specifically to point 10 of Annex I of the above-mentioned guideline, i.e. 'Worst-case estimation of dose to which a consumer may be exposed'.

In line with the 'Guideline on data to be provided in support of a request to include a substance in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009', applicants who consider that a component of their product is not pharmacologically active can submit a request to the CVMP to have the substance included in the above-mentioned list. Among the data to be provided in support of this request is a worst-case estimation of the dose to which a consumer may be exposed, using reasonable worst-case assumptions. One aspect to consider in such worst-case estimations is the bodyweight of the intended target animal species or target species sub-category, as applicable.

1. What standard animal weights should be used for estimating worst-case consumer exposure scenarios within a request to include a substance in the 'out of scope' list?

A review of available references[1, 2, 3, 4, 5] and the most recent out of scope requests (i.e. from 2020 to 2024) was made to standardise bodyweights used for the calculation of worst-case consumer exposure. As a result and bearing in mind that the intention is to estimate the worst-case exposure, recommended bodyweight values to be used are presented in the table below. Where alternative bodyweights are used, these should be justified.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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Animal type	Bodyweight (kg)
Calf	140
Cattle 0-1 year/ Heifer	200
Cattle > 2 years	450*
Dairy cattle	425*
Beef cattle	330
Weaner pig	12.5
Fattening pig	65
Sow with litter	240
Sheep	80
Goat	60
Lamb	36
Broiler (chicken)	1
Laying hen	1.6
Turkey	6.5
Duck	1.6
Rabbit	1.4
Horse	400*
Pony	250
Red deer	110

*For substances that may be injected subcutaneously or intramuscularly and for which dosing instructions will be expressed as mg/kg bodyweight, consideration should be given to the possibility that a consumer may ingest an injection site. The worst-case scenario should therefore consider a greater bodyweight of 600 kg.

References:

- 1. Guideline on data to be provided in support of a request to include a substance in the list of substances considered as not falling within the scope of Regulation (EC) No 470/2009 (EMA/CVMP/516817/2009)
- 2. Guideline on environmental impact assessment for veterinary medicinal products in support of the VICH guidelines GL6 and GL38 (EMA/CVMP/ERA/418282/2005-Rev.1- Corr.1)
- 3. Guideline on risk characterisation and assessment of maximum residue limits (MRL) for biocides (EMA/CVMP/SWP/90250/2010)
- 4. Trends in the sales of veterinary antimicrobial agents in nine European countries (EMA/238630/2011)
- 5. Question and answer document on the Guideline on assessment and control of DNA reactive (mutagenic) impurities in veterinary medicinal products (EMA/CVMP/SWP/377245/2016)