15 December 2023
EMA/CVMP/PhVWPV/470818/2023
Committee for Veterinary Medicinal Products (CVMP)

Overview of comments received on Guideline on the calculation of dose factor to be submitted to the Union Product Database (UPD) (EMA/CVMP/PhVWPV/399363/2023)

Interested parties (organisations or individuals) that commented on draft document as released for consultation.

Stakeholder no.	Name of organisation or individual
1	B. Braun Melsungen AG
2	Joint submission agreed by: AnimalHealthEurope, AccessVetMed and Association of Veterinary Consultants (AVC)
3	D. O'Rourke Eco Animal Health

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1. General comments – overview

Stakeholder no.	General comment	Outcome
1	None received.	Not applicable. The additional specific comments provided below are very much appreciated.
2	AnimalHealthEurope, AccessVetMed and AVC would like to thank the CVMP for this Guideline and is grateful for the opportunity to comment. Please find some comments and suggestions below. Should you have further questions, we are happy to provide any clarification needed. 1.1 General comment regarding method of displaying incidence data: MAHs would like to raise a concern about the proposed method of displaying the data (SOC and % of treated animals) for display to the general public. An individual can on 1 Jan 2024 record the number of reports showing an immune system disorder for a product and record it again on 1 Jan 2025. This gives the number of reports with this SOC during 2024. From the data % of reports showing a SOC disorder, the number of treated animals can be calculated. Understanding how the number of treated animals is calculated enables the sales data for the product to be derived or closely estimated. Is it the EMA's intention to enable sales data to be calculated because we believed that it was not (sales data is not otherwise published or is publicly available)? Note: MAH have no concern about % as a value being calculated for the EMA / NCAs and also being presented to an MAH for the MAHs own product. However, MAH believe that an alternative way of presenting this data to the general public is necessary and would recommend similar bandings to that used in the SPC but with a different descriptor e.g. 'Calculated incidence rates (number of reports / number of treated animals) is presented in bands of > 1/10, >1/100, >1/1,000, >10,000 or <1/10,000. Care should be taken in interpretation of these figures as they include all	The joint effort of AnimalHealthEurope, AccessVetMed and Association of Veterinary Consultants on the provision of extensive and constructive comments is very much appreciated and welcomed. This concern related to the displaying of reporting incidence in the public portal of Union Pharmacovigilance database has been noted. This aspect is out of scope of this specific guideline but will be addressed separately.

Stakeholder no.	General comment	Outcome
	reports whether or not the product is considered to be related to the actual event e.g. the cause of the adverse event could be another product administered at the same time'. 1.2 General comment regarding repeating data from other sources / guidelines. MAHs believe that the repetition (not necessarily entirely in context or fully accurately) of information from other documents e.g. Commission Implementing Regulation (EU) 47 2021/1281 (EU 2021/1281) or UPD implementation guide Chapter 7 (Ch7) is unhelpful and confusing (and should the UPD implementation guide Chapter 7 change, would also lead to inconsistency and potential confusion). It should be sufficient to repeatedly refer to these references throughout the document and only provide additional clarification where absolutely necessary. As such MAHs make a number of suggestions for text to be deleted in the specific comments below.	Repetition of existing legislation and guidance is noted. Appropriate changes to the guideline have been made. Specific comments related to repetition of existing legislation and guidance have been addressed below.
3	None received.	Not applicable. The additional specific comment provided below is very much appreciated.

2. Specific comments on text

Line no.	Stake-holder no.	Comment and rationale; proposed changes	Outcome
44-45	2	**"The aim being to generate a simple, pragmatic, and harmonised approach to dose factor."** MAH believe that this can be further strengthened by more appropriately including text from lines 176-177 so this would then read: *The aim being to generate a simple, pragmatic, and harmonised approach to dose factor so that, for example, reference and generic products will use the same dose factor*.	Not accepted. Although we agree with the simple, pragmatic and harmonised approach, the proposed exambple is outside the scope of this guidance.
49-50	2	**"This guidance should be implemented on Volume of sales submissions from 2023 and onwards."** MAH are not aware of what the proposed final publication date for this guideline is but comments close on 13 November 2023. Assuming a further 3-4 weeks until final publication, this leaves MAH with very little time to recalculate and implement revised values prior to the end of February 2024. Some MAHs may have already been submitting 2023 sales data. Is the expectation that these MAHs will resubmit such data following this issue of this guidance document? These are issues for both large MAH (potentially 1,000s of individual values to recalculate) and also smaller MAH (far fewer resources). MAH will continue to do their utmost to achieve this goal but given the continued challenges with UPD data and the timing of the publication of this guideline, cannot be fully confident of achieving what needs to be done by the end of February 2024. In addition some MAHs have already received notification of the need to continue to submit antimicrobial data separately to NCAs during the same time	Partly accepted. The timing of this guideline and the additional obligations of all MAHs around the current deadline for sales data submissions are appreciated. The sentence has been modified to indicate that "*this guidance should be implemented on all volume of sales submissions following the publication of this guideline*" in order to avoid any resubmission of sales data.

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		period (which creates duplicate effort for MAHs): for these reasons MAH suggest that the following is added to this paragraph: *Where a MAH has a has a particular problem in meeting this timeline, the MAH may apply for an extension until (at the latest) the end of May to the relevant authority given the specific reasons why this is needed.*	
120-123	2	**"Volume of sales (VoS; including non-EEA sales) should be submitted in the appropriate structured CSV file downloaded from the UPD portal with one line per package, country and target species. The frequency of the submission of sales data can be determined by the MAH (e.g., monthly, quarterly or at least yearly)."** It is recommended that the advice in Ch7 should not be repeated here as the advice in the middle of the paragraph is not fully correct (e.g. for non-EEA sales). Thus it is recommended that this section is therefore amended to read (includes lines 137-140): *"Volume of sales (VoS; including non-EEA sales) should be submitted in the appropriate structured CSV file.* *The frequency of the submission of sales data can be determined by the MAH (e.g., monthly, quarterly or at least yearly).* *The data specifications and detailed explanation of the information above is provided in Chapter 7 of EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union Product Database (europa.eu) and UPD Q&As industry (europa.eu)* *Sales submission per species will be based on the division in accordance with the SPOR Species list."*	Accepted. The repetition from Chapter 7 of EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union Product Database has been recognised and removed. It is also understood that any future updates to Chapter 7 of EU Implementation Guide (Vet EU IG) could result in inconsistencies between guidance documents which further supports removal of information that is repetition.
124-126	2	"**The deadline for MAHs to submit the VoS data for the calendar year 2023 has been set for the end of February 2024. Subsequently, the deadline for the annual VoS submission will be also at the end of February of each following year**."	Not accepted. We acknowledge the additional obligations and time pressures of all MAHs. This statement has been modified to be more general: "*The deadline for MAHs to submit*

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		In relation to 2023 data for submission in by February 2024 – please see comments against lines 49-50 (above) MAH understand the need for the end of February timeline for antimicrobial sales data (for use by NCAs for ESVAC purposes) however, this time of year is for many MAH already extremely busy and many MAH require the support of other departments (e.g. finance or manufacturing) to enable them to generate and submit this data. MAH would be very grateful for any possible flexibility around this timeline. In addition, where MAH use distributors, it is going to be challenging to meet the end February time period after year end 31 December because both the sales data (by EEA package and non-EEA sales) and species splits (EEA and non-EEA) require integration into the MAHs own systems prior to submissions. MAHs experience is that distributors have a variable ability to supply sales data soon after the month end (days to several weeks), use different IT systems and have different ways of recording sales – all of this needs to be addressed and integrated before the MAH can submit to the UPD.	*the annual VoS data will be at the **end of February** of each calendar year."* Any introduction of flexibility around the deadline for submission of volume of sales at the end of February 2024 can be discussed and addressed separately.
124-126	3	Comment: Sales data is generated by Finance. Completion of December sales will be by mid February. Therefore, submission of December sales by end of February may not be possible. Proposed change (if any): The deadline for MAHs to submit the VoS data for the calendar year 2023 has been set for the end of March 2024. Subsequently, the deadline for the annual VoS submission will be also at the end of March of each following year.	Not Accepted. We acknowledge the additional obligations and time pressures of all MAHs. This statement has been modified to be more general: "*The deadline for MAHs to submit the annual VoS data will be at the **end of February** of each calendar year."* Any introduction of flexibility around the deadline for submission of volume of sales at the end of February 2024 can be discussed and addressed separately.
127-136	2	**"MAHs should provide the data below … ix. Comment (optional field)** This is not technically correct as not all of these values are mandatory. This is also a repetition of Ch7 where it is better	Accepted. Considered repetition of Chapter 7 of EU Implementation Guide (Vet EU IG) and thus list of data elements removed from this guideline.

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		explained and in context. MAH recommend that this text is not appropriate in this guideline and should be deleted.	
142-145	2	**"To accompany sales volume data, MAHs should submit the estimated percentage split of the use per target species for each submitted package to the UPD portal. "Species split" should represent the numerical value of the estimated percentage of use of the total sales for a specific package in each animal target species in the country of reporting."** MAH recommend that the details provided in Ch7 are not repeated here and therefore this paragraph should read (includes lines 157-159): *"To accompany sales volume data, MAHs should submit the estimated percentage split of the use per target species for each submitted package to the UPD portal. The data specifications and further explanation of species split is provided in Chapter 7 of EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union Product Database (europa.eu) and UPD Q&As industry (europa.eu)"*	Accepted. Appropriate modification has been made to the guideline.
146-152	2	**"Species split should be reported …. The species spread/split will be 100%"** MAH recommend that this does not need repeating as the detailed information is provided in Ch7 or in EU2021/1281. In addition, the text is not entirely correct in that Ch7 allows 'a positive number with or without a decimal point' and that it would be better to refrain from reference to 'target species' as there is possible confusion with the SPOR Target Species list whereas species split reporting is based on the SPOR Species list. MAH therefor recommend that this text is deleted from the guideline.	Accepted. Text is considered repetition of Chapter 7 of EU Implementation Guide (Vet EU IG) and thus omitted.
153-156	2	**"For VMPs authorised for more than one target species, species split should be derived by the MAH based on their expert understanding of how a specific product is generally used in veterinary practice. Any estimations should take into**	Accepted. Second sentence has been removed.

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		account the recommended treatment regimen (e.g., initial course plus booster doses) of the VMP." MAH believe that the first part of this paragraph is helpful and should remain in the guideline whereas the second sentence is not actually correct (as 1 vaccine dose = 1 treated animal – see section 2.3.2). Therefore, MAH recommend that this paragraph should be amended to read: *For VMPs authorised for more than one target species, species split should be derived by the MAH based on their expert understanding of how a specific product is generally used in veterinary practice.* I.e. the second sentence should be deleted.	
163	1	Comments: a **single pack** of a specific size of a product may be misleading; according to COMMISSION IMPLEMENTING REGULATION (EU) 2021/1281, Art. 14 the wording is "one **package** of a given pack size"; according to EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union Product Database; Chapter 7: Submission of other post-authorisation data Version 1.6: "The Dose factor represents the average number of animals of a particular species that can be treated using one **package**." In the UPD List of packages (volume of sales), sales data is provided on **package level** (e.g. 10 x 500 ml or 1 x 500 ml) with respective dose factor for each specific pack size (e.g. different dose factor for 10 x 500 ml and for 1 x 500 ml). **Single pack** (line 163) may be interpreted as "1x 500 ml" in both szenarios, leading to the same dose factor for both packages. Proposed change (if any): ~~a single pack~~ one package of a ~~specific size of a product~~ given pack size	Accepted. The identification of this potential area of confusion is much appreciated. The proposed change to the guideline has been implemented.
176-177	2	**"For example, reference and generics products should ideally use the same dose factors."** MAH are not clear what this means in practice. The purpose of this guideline should be to harmonise the approach to dose factors	Accepted. This sentence has been deleted.

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		between MAHs. As suggested above, MAH believe that this sentence would be more relevant earlier in the guideline – for instance in lines 43-44 (as identified above) and it should thus be deleted here.	
177-180	2	**"Although, in some cases, dose factors may differ due to markets in different territories, differences in animal populations and the recommended use of products e.g., extension of some products to include new target species, indications etc."** MAH are not clear why dose factors will differ if a product includes new target species. The existing dose factor will stay the same, but a new dose factor (for the new species) will need to be generated (and the species split would need to be revised). This is a bit confusing. MAH recommend that this is amended to read: *Although, in some cases, dose factors may differ due to markets in different territories, differences in animal populations and the recommended use of products e.g., extension of some products to include new indications etc.*	Accepted. Reference to "New target species" has been removed.
187-188	2	**"Any changes to dose factor should be recorded in the PSMF in accordance with the Commission Implementing Regulation (EU) 2021/1281 Article 14 (3)."** MAH believe that this is a repetition of other guidance and does not need to be repeated in this guideline. Therefore, this sentence can be deleted.	Not accepted. This information is considered useful and aids to reaffirm the existing guidance provided in Chapter 7 of EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union Product Database.
190-195	2	**"2.3.1. Newly authorised VMPs …. sales data become available."** The purpose of the guideline is to base the dose factor on the SPC and reduce variation between MAHs or between products. Therefore, there should be no problem in generating a dose factor for a newly authorised product and this dose factor should remain stable (unless the SPC dose rate or dosing regimen changes) and future sales will not have any impact on the calculated dose factor. This section appears to be more relevant for species splits (which MAH may need	Accepted. This entire section has been removed.

<table>
<tr><th>Line no.</th><th>Stake-holder no.</th><th>Comment and rationale; proposed changes</th><th>Outcome</th></tr>
<tr><td></td><td></td><td>to periodically check or revise) but doesn’t seem appropriate for dose factors. MAH recommend that this whole section is therefore deleted.</td><td></td></tr>
<tr><td>196</td><td>2</td><td>General comment on section 2.3.2 and examples of CSV file. MAH agree that the examples are very useful, but they are not immediately clear as to what they refer to. It would be helpful if the title ‘Example of relevant data presented in CSV file’ is above the example and the examples more closely mimic the CSV file for example:</td><td>Accepted. The CSV examples have been modified and/or introduced throughout the guideline in order to increase clarity.</td></tr>
<tr><td colspan="4"><table>
<tr><td>Year-Month</td><td>Volume of Sales</td><td>Species identifier</td><td>Species %</td><td>Dose factor</td><td>Comment</td></tr>
<tr><td>2023-04</td><td>467</td><td>SPOR Species list identifier for dog</td><td>70</td><td>3</td><td></td></tr>
<tr><td>2023-04</td><td>467</td><td>SPOR Species list identifier for cat</td><td>30</td><td>3</td><td></td></tr>
</table></td></tr>
<tr><td>207-217</td><td>2</td><td>“Example 2”

MAH appreciate the point that this example is making – even though the situation is considered to be very rare. As such MAH recommend that either a new Example 2 which is more common / relevant is generated and this example is moved to Example 4. Or, alternatively the current Example 3 (which is more common) is moved to be before Example 2.

Furthermore, MAH believe that Example 2 could be made clearer with the additional explanation of:

If a maximal dose of a local anaesthetic is recommended in the target animal species, this maximal dose shall be used for calculation of the dose factor the individual target animal species.</td><td>Partly accepted. The order of examples has been amended. A modified version of the text proposal has been added to the relevant example.</td></tr>
<tr><td>253</td><td>2</td><td>“Dogs 0,2 ml”

Should read for consistency:

Dogs 0.2 ml</td><td>Accepted</td></tr>
</table>

Line no.	Stake-holder no.	Comment and rationale; proposed changes	Outcome
270-271	2	**"Any such alternative calculations should be justified in the pharmacovigilance system master file (PSMF)."** This is a repetition of guidance provided in EU2021/1281 and is therefore not needed in this guideline. MAH recommend that this can be deleted.	Not accepted. This information is considered useful and aids to reaffirm the Commission Implementing Regulation (EU) 2021/1281.
272-279	2	**"Average weight of target … will be limited to once a year"** MAH believe that this is an important part of calculating dose factors and should be earlier in the guideline for instance before Section 2.3.2. Given that MAH have recommended the deletion of Section 2.3.1 then this text could form the new Section 2.3.1 and MAH would recommend that a reference should be provided to the appendix i.e. *Average weight of target … will be limited to once a year. For further details see Appendix 1.*	Accepted. A text introducing and describing the use of the standard average weights list has been moved to the introduction of section 2 (dose factor).
270-284	2	**"Use of any other standard average weight … form the weight ranges should be used.** MAH believe that the first sentence is repetition of other guidance and the second part is covered in the lines 272-279 where it clearly states that the standard weight should be applied in such situations (this may be different from the worst case – so this creates confusion). MAH believe that these lines would be better deleted to simplify and ensure that the guideline is consistent.	Partly accepted. Minor modification to the text has been made. Text related to other standard weights has been retained in this paragraph and the Annex as it is foreseen that the table of standard average weights will not be exhaustive.
285	2	**"Below are some examples of standard formulae to calculated dose factor for repeat dose/use products"** MAH believe that this description is potentially a bit confusing as many products are 'repeat dose/use'. MAH believe that the title of the section would be more appropriate here i.e. *Below are some examples of standard formulae to calculated dose factor for short term, define treatment course products.*	Accepted. Text proposal introduced.
290	2	**"Daily Dose $_{max}$ Dose (mg/kg or ml/kg) – maximum recommended exposure"**	Accepted. Text amendment introduced revision.

Line no.	Stake-holder no.	Comment and rationale; proposed changes	Outcome
		MAH believe that this doesn't quite reflect the intended formula and that the following would make more sense: *Daily Dose $_{max}$ Dose (mg, g, ml etc) based on maximum recommended dose (in mg/kg, ml/kg etc)*	
318	2	**"20kg x (5mg\ml x 5 days)"** MAH believe that the dose rate mg\ml should be consistent with that indicated in line 314 i.e. mg/kg: *20kg x (5mg/kg x 5 days)*	Accepted
323	2	Based on MAH experiences of different approaches recommended by rapporteurs during PSUR assessments, MAH believe that it would make sense to add an additional line to clarify the approach for lactating cow intramammaries as well. I.e. MAH recommend to add *For lactating cow intramammaries, the assumption should be that only 1 quarter is affected.*	Accepted
324	2	**"2.3.4. Short-term treatment VMPs with undefined treatment course"** MAH believe that this title is a bit ambiguous and is better described in line 325 and therefore the title of this section should be consistent. I.e. MAH recommend that this should read: *2.3.4. VMPs indicated for both short and long-term treatment without a defined length of treatment*	Accepted. All titles in section 2 have been modified for consistency.
330	2	**"The individual daily dosage should be determined as the average dosage of the dose range outlined in the product SPC."** MAH are not sure what average dose means in this context. In line with elsewhere in this guideline and to be consistent, would it not make more sense for this to be the maximum dosage of the dose range. I.e. phrased something like:	Accepted. It is agreed to be consistent throughout the guideline. A modification of the text proposal has been introduced into the guideline.

Line no.	Stake-holder no.	Comment and rationale; proposed changes	Outcome
		Where unit dosing is not applied (e.g. 1 dose for 1 dog), then the individual daily dosage should be determined as the maximum dosage of the dose range outline in the product SPC.	
358-361	2	**"The principle of maximum recommended … on the standard and average use of a product."** MAH believe that much of this paragraph is not very clear, nor is it consistent with the approach of the guideline where a dose factor should be set based on the SPC and that harmonisation can only be achieved by following the guideline. In addition, the concept of a 182 day treatment course has already been introduced in the paragraph above. Therefore, MAH believe that this paragraph doesn't add anything further and should be deleted.	Accepted.
362-363	2	**"The individual daily dosage should be determined as the average dosage of the dose range outlined in the product SPC."** MAH are not sure what average dose means in this context. In line with elsewhere in this guideline and to be consistent, would it not make more sense for this to be the maximum dosage of the dose range. I.e. phrased something like: *Where unit dosing is not applied, then the individual daily dosage should be determined as the maximum dosage of the dose range outline in the product SPC.*	Accepted. It is agreed to be consistent throughout the guideline. A modification of the text proposal has been introduced into the guideline.
378-379	2	**"…dose factor at the level of the holding area (e.g., for bee populations, a dose factor per seam or hive is considered appropriate)."** MAH would recommend deletion of the words *'seam or'* as all bee treatments are on a hive basis.	Accepted.
389	2	**"… recommended that the most common dose rate is applied to all such products within the EEA."**	Partly accepted. An additional sentence has been added to provided further clarity.

Line no.	Stake-holder no.	Comment and rationale; proposed changes	Outcome
		MAH suggest that a bit more clarity would help here in terms of common: *…recommended that the **most common** (most member states or that of a DCP/MRP/procedure) dose rate is applied to all such products within the EEA*.	
392-396	2	**"2.3.6.4 VMPs primarily used in … can be applied to the dose factor calculation."** MAH believe that the section title and text are a bit ambiguous and don't reflect the situation which is that some products are only indicated in a specific weight or production type of animal. MAH believe the following text may be clearer: *2.3.6.4 VMPS indicated for use in a specific weight or production type of animal.* *In some cases, a product is only indicated for a specific weight or production type of animal e.g. only indicating 'for suckling piglets'. In this case the appropriate weight for the target species indication should be used.* *However in the situation where the product can be used in different weights / production types of animal, then the standard species weight should be used.*	Accepted. A modified version of the text proposal has been introduced.
398	2	**"With products with undefined species, the species splits, and species dose factors should be provided for the appropriate species terms (e.g., chickens, turkey, fish, poultry, equids etc.) …"** MAH believe that examples would help here, and also that poultry should be removed from the example list as this is not a term in the SPOR Species list. Fish is an exception here as it is both an 'undefined species' and a term existing in the SPOR Species list so it may be better to also remove this from the list of examples.	Accepted.

Line no.	Stake-holder no.	Comment and rationale; proposed changes	Outcome
		"With products with undefined species (e.g. poultry), the species splits, and species dose factors should be provided for the appropriate species terms (e.g., chickens, turkey, pheasant etc.) …	
401-404	1	Comments: For infusions, the single use of one bottle (single pack/single dosage form) in one animal is assumed for single-use products. General formula for calculation of dose factor for infusions (Gauß´sche ceiling function): G = Pack size (number of E per package) E = Volume of a single dosage form (l) n = Average treatment time (days) D = Estimated dosage (l) A = Dose factor $\frac{G}{\left\lceil \frac{n * D}{E} \right\rceil} = A$ E.g. for a **package** consisting of 10 bottles of 500 ml, the dose factor has not necessarily to be 1. The dose factor is 1 for packages consisting only of one single pack/single dosage form (e.g. 1 x 500 ml). Proposed change (if any):	Accepted. The identification of a potential issue with the original generic approach to infusions together with the proposal of a general formula is much appreciated. Modifications have been introduced in the modified guideline.
406-407	2	**"e.g., dose factors for solvents supplied with vaccines will be based on the species dose factor for that vaccine."** MAH agree that the instructions for water for injection, buffers etc are appropriate but the second part of the paragraph repeated above is inconsistent with Ch7 where it is stated that 'but there is no requirement to submit sales for the separately registered solvent packages.' MAH therefore recommend that the phrase above should be deleted.	Accepted.

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427	2	**"It should be noted that updates to this list will be limited to once a year"** MAHs have a question about what to do pending the update of the list and when the list should be updated. Given the principle is that updates should be applied for the following calendar year MAH believe that the updates to the list need to be made during the 3rd quarter of each year (to allow MAHs to make adjustments as needed). Therefore MAH would suggest that this sentence could read: *It should be noted that updates to this list will be limited to once a year in the 3rd quarter and that MAH may have to use their proposed species weights until the list is published.*	Not accepted. The proposed text is considered to introduce too much detail.
428	2	General comment regarding the species tables. MAH believe that it would be more helpful to have two separate tables: (1) list of standard species weights to be used when the indication is a general species indication or covers a range of different weights / production types. E.g. if the indication is 'cattle' or indicates different types of cattle, then the standard 'cattle' dose rate should be used. (Note: this standard weight can be the same as one of the specific indication (or sub-population) weights in (2) below). (2) list of specific indication related (or subpopulation) species weights where (1) is not applicable. The adult cow, beef calf, new-born calf weights would be appropriate. All of these entries would then have a note similar to 'For VMPs exclusively indicated in new-born calves'. At the moment the differentiation between a standard species weight (all animals of the species) and specific species weights (only indicated in this type of animal) is not sufficiently clear.	Not accepted. Similar to previous practice in PSURs, when the product was used in different production types within e.g. the same species (e,g, beef calves 75% and cows 25%), a subsequent average weight should be calculated accordingly. The underlying assumptions for the determined average weight should be described in the PSMF. Further text to clarify has been included in the relevant sections.
428	2	Specific comments regarding the species weights in the table	

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		Adult Cow – MAH recommend that the weight remains consistent with Volume 9b (550kg) since this is what MAH have been working with and this would avoid MAH having to rework all their current dose factors. Sow/boar vs Porcine (breeders) – MAH recommend that this should also remain consistent with Volume 9b (160kg) as this is more representative if gilts are also included. Both descriptors are not need and one could be deleted Sheep and Goat, adult – the weights are the same and sheep / goats are combined in all other values. Could be combined to Sheep & goat, adult. This would also be the 'general' sheep / goat weight. Kid and lamb can also be combined. Poultry / Poultry, broiler, Poultry / layer hen – should be renamed to Chicken, Chicken, broiler, Chicken / layer hen as there are no chicken values in the current proposal and Poultry is not a valid value in the SPOR Species list. In addition, 4kg seems a bit heavy as a standard chicken weight – 1.5 kg (between boiler and adult layer) would seem to be more appropriate. Additional values suggested (and the reference for these values) include:	Partly accepted. Volume 9b derived weights have been maintained where possible. Further weight categories have been added and names have been amended. The concept of "general weights" has been removed as it is expected that for situations where products are used in different categories of e.g. the same species (e.g. beef calves and cows), that an average weight is determined and used for the calculation of the dose factor. The underlying assumptions and the calculation should be described in the PSMF.

Line no.	Stake-holder no.	Comment and rationale; proposed changes	Outcome

Species	Proposed Average weight (kg)	Source	Weight in Source document
Roe Deer	25	WorldDeer.org	10-35kg
Polecat	1.2	WildLifeTrust.Org	0.5-1.9kg
Hare	3.5	WildLifeTrust.Org	2-5kg
Pet tortoise, Greek tortoise, Hermann's tortoises	2	https://en.wikipedia.org/wiki/Greek_tortoise, https://en.wikipedia.org/wiki/Hermann%27s_tortoise	0.7 - 7 kg
Frog (aquarium)	0.022	WildLifeTrust.Org	22g
Snake (pet, e.g., green rat snake)	0.04	https://weighttop.com/snake-weight/	31 - 45 g
Lizard (Pearded dragons, Pogona)	24	nationalgeographic.com	24 kg
Ferret	1.4	MSD Veterinary Manual	0.8 - 2kg
Gecko, Common lizard	0.07	WildLifeTrust.Org	70g
Donkey	160	https://www.ed.ac.uk/files/imports/fileManager/donkey%20fact%20sheet.pdf	160kg