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Guideline on the calculation of dose factor to be submitted to the Union Product Database (UPD)

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Introduction

This guideline provides additional guidance to marketing authorisation holders (MAHs) that are required to submit annual volume of sales data, including dose factor for each veterinary medicinal product (VMP), to the Union Product Database (UPD). The data submitted by MAHs will be used to calculate an estimated number of treated animals (ENTA), and subsequently, in combination with the total number of animals displaying a suspected adverse event recorded for VMPs in EudraVigilance Veterinary (EVV), to derive an annual reporting incidence. In accordance with Regulation (EU) 2019/6 these annual reporting incidences of reported suspected adverse events will be made publicly accessible by 2024.

The overall objective of this guideline is to provide specific guidance on the considerations and calculations related to dose factor. The aim is to generate a simple, pragmatic, and harmonised approach to the dose factor. This in turn should provide consistency, stability, and comparability in the subsequent calculation of the reporting incidence.

This document serves to fulfil the requirement set out in the Commission Implementing Regulation (EU) 2021/1281 Article 14(3) and standardise approaches between concerned organisations and same or similar VMPs. This guidance should be implemented on all volume of sales submissions following the publication of this guideline.

Generation of this guideline has taken into account current guidance in Chapter 7 of EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union Product Database (europa.eu). Further relevant guidance can be found in UPD Q&As industry (europa.eu) and Union Product Database: webinar for marketing authorisation holders | European Medicines Agency (europa.eu).

Note that reference to EudraVigilance Veterinary (EVV) in this document implies the Union Pharmacovigilance database (UPhD) as stated in Regulation (EU) 2019/6.

1. Legal basis related to the generation and publication of reporting incidence in EudraVigilance Veterinary

There is a legislative requirement that the reporting incidence of suspected adverse events should be made publicly available in the Union Pharmacovigilance Database (UPhD) by 2024. There is also legislative guidance on how these reporting incidences should be derived. The relevant articles are stated below.

Regulation (EU) 2019/6 Article 58(12):

"*The marketing authorisation holder shall record in the product database the annual volume of sales for each of its veterinary medicinal products.*"

Regulation (EU) 2019/6 Article 75(3)(a):

"*The general public shall have access to the pharmacovigilance database, without the possibility to change the information therein, as regards the following information:*

(a) the number and at the latest within two years from 28 January 2022 the incidence of suspected adverse events reported each year, broken down by veterinary medicinal product, animal species and type of suspected adverse event;"

Commission Implementing Regulation (EU) 2021/1281 Article 14(2), (3), "Provision of additional data":

"2. The total number of animals displaying an adverse event during a defined period of time, multiplied by 100 and divided by an estimate of the number of animals treated during that period, shall provide the incidence of reported adverse events. To calculate the estimated number of animals treated from the information on volume of sales required under Article 58(12) of Regulation (EU) 2019/6, marketing authorisation holders shall identify and provide a factor to the Union product database for each of their veterinary medicinal products according to country, target species and pack size. According to the posology of the product, the factor will determine how many animals can be treated with one package of a given pack size, regardless of the formulation. To calculate the incidence for adverse event reports from third countries via the estimated number of animals treated, marketing authorisation holders shall provide information on volume of sales for each of their veterinary medicinal products, combined for all third countries according to target species, and in regard to the same or a comparable pack size.

3. The Agency shall publish guidance on the mathematical formula to calculate the factor. Marketing authorisation holders shall record their assumptions on distribution of sales per target species and treatment regimen per target species that they use for the calculation of the factor in the pharmacovigilance system master file. Marketing authorisation holders shall update the factor when necessary."

Commission Implementing Regulation (EU) 2021/1281 Article 22(3), "Content and structure of the pharmacovigilance system master file":

"3. The pharmacovigilance system master file shall contain the following Annexes:"

"(d) Annex IV: further details about the quality management system:"

"(v) the methodology to calculate the factor referred to in Article 14(2);"

EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the Union Product Database - Implementation of the requirements of Regulation (EU) 2019/6 for the Union database on veterinary medicinal products in the European Economic Area - Chapter 7: Submission of other post-authorisation data:

"2.1.15. Estimated distribution across target species

MAHs shall submit the estimated split of the use per species for each submitted package with sales (including non-EEA sales), and a dose factor, indicating how many animals of a specific species can be treated with one pack on average. In combination, this will allow the subsequent calculation of the estimated number of treated animals."

2. Volume of sales submissions to Union Product Database

To fulfil the requirements of Regulation (EU) 2019/6 Article 58(12), MAHs should prepare and provide a volume of sales submission to the Union Product Database (UPD) portal. The volume of sales submission consists of three principal elements:

1. Annual volume of sales data.
2. Species split.
3. Dose factor.

These will be outlined and described further in the sections below, with the primary focus on dose factor. Examples are provided in the text to facilitate understanding and implementation of the guidance, however, the examples are not exhaustive. Guidance in this document may be updated in light of any experience gained after reporting incidences are calculated and published in EVV.

It is important to note that neither data on the ENTA nor the reporting incidence is to be submitted by MAHs, **only** the volume of sales, species split, and dose factor should be included in sales submissions to the UPD.

2.1. Annual volume of sales data

Volume of sales (VoS; including non-EEA sales) should be submitted in the appropriate structured CSV. The frequency of the submission of sales data can be determined by the MAH (e.g., monthly, quarterly or at least yearly).

The deadline for MAHs to submit the annual VoS data will be at the **end of February** of each calendar year.

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[1] Species list.

2.2. Species split

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)

Any assumptions taken to estimate the distribution of sales per target species should be recorded in the pharmacovigilance system master file (PSMF), in accordance with Art 14(3) of Commission Implementing Regulation (EU) 2021/1281. It is envisaged that species split may change over time i.e., addition of new target species, increased product use in a particular target species and/or region etc.

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.

2.3. Dose factor

According to Commission Implementing Regulation (EU) 2021/1281 Article 14(2), the dose factor should determine the average number of animals of a particular target species which can be treated by one package of a given pack size, regardless of the formulation. The appropriate dose factors should be provided for all volume of sales data and target species per package identifier and per country. The dose factor should be a positive numerical value with or without decimals (up to 4 decimal digits), as stated in Chapter 7 of the Vet EU IG (EMA/772580/2022). Furthermore, the methodology used to calculate the dose factor should be recorded in Annex IV of the PSMF.

It is generally recognised that the mathematical formulae used to generate dose factors will vary between products, formulations, and package sizes and thus it is not possible to publish a single universal formula. The dose factor should be derived by the MAH based on their expert understanding of how a specific package is generally used in veterinary practice, e.g., taking into account the different indications for the target species, average body weights of animals at treatment, and

[1] SPOR Web UI (europa.eu): data management services for substances, products, organisations and referentials (including species lists)

recommended posology, i.e., dose, frequency and duration of treatment. MAHs should also implement the key principles outlined below to harmonise approaches.

Wherever possible, MAHs are encouraged to harmonise the generation of dose factor to provide consistency, stability and comparability in the subsequent calculation of the reporting incidence. 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.

It is strongly recommended that changes to dose factors should be strictly **limited over time**. Dose factors should only be changed if significant changes are made to dosage regimes e.g., changes to antimicrobial dose rates. To facilitate and reduce administrative burden, the dose factor may be changed for the submission of sales data for the following years e.g., a change in July 2024 will be reflected in the sales data for January 2025 and onwards. This will also allow for a transition period where product information and labelling with the old dosage regimen will be replaced with the new dosage regimen. Any changes to dose factor should be recorded in the PSMF in accordance with the Commission Implementing Regulation (EU) 2021/1281 Article 14 (3).

When calculating the dose factor, standard average weights listed in the table in Appendix 1 should be used. These standard average weights are primarily derived from previous recommended standard weights published in VOLUME 9B of The Rules Governing Medicinal Products in the European Union (2021), although, some updates and additions have been made. Further instructions on the selection and use of weights in the standard average weights list are presented in Appendix 1. This list may undergo further revision with experienced gained. Suggestions for additions to the standard weights list can be submitted to the Pharmacovigilance Working Party - Veterinary (PhVWP-V) for consideration. Any suggestions or proposals should be submitted to Vet-PhV@ema.europa.eu. It should be noted that updates to this list will be limited to once a year.

2.3.1. VMPs indicated for single dose administration

For single dose VMPs, the dose factor is equivalent to the number of animals treated (e.g., vaccines, anthelmintic boli, flea collars). i.e., one dose equals to one treated animal.

When the dose factor is based on 1 dose = 1 treated animal, the following formula can be used:

$$Dose\ Factor = \frac{Package\ Volume\ [UoM]}{Dose\ [UoM]}$$

UoM Unit of measure (dose, millilitre, gram etc.)

Example 1: A dog receives 1 dose of a canine vaccine (Dose = 1 dose). A pack contains 10 doses (Package Volume = 10 doses). The dose factor of this pack size can be calculated as:

$$Dose\ Factor = \frac{10\ doses}{1\ dose} = 10$$

Example of relevant data presented in CSV file.

Year-Month	Volume of sales	Species Identifier	Species %	Dose Factor	Comment
2023-08	348	SPOR Species list identifier for dog	100	10	

Example 2: A long acting antiparasitic, target species cattle, recommended as a single dose (10 ml). Pack contains 50 ml. The dose factor of this pack size can be calculated as:

$$Dose\ Factor = \frac{50\ ml}{10\ ml} = 5$$

Example of relevant data presented in CSV file.

Year-Month	Volume of sales	Species Identifier	Species %	Dose Factor	Comment
2023-06	126	SPOR Species list identifier for cattle	100	5	

Example 3: According to the Product Information (PI), a VMP is a single dose local anaesthetic indicated in 4 different target species. The recommended dose is 2.5 - 10 ml of the VMP/target animal. The package size is 1 vial containing 50ml. When 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. In this example, the dose factor is calculated using the principle of **maximum recommended exposure** i.e., 10 ml per target species. The package size is 1 vial containing 50ml. Thus, a dose factor can be calculated as:

$$Dose\ Factor = \frac{50\ ml}{10\ ml} = 5$$

Example of relevant data presented in CSV file.

Year-Month	Volume of sales	Species Identifier	Species %	Dose Factor	Comment
2023-08	530	SPOR Species list identifier for dog	90	5	
2023-08	530	SPOR Species list identifier for cat	4	5	
2023-08	530	SPOR Species list identifier for horse	5	5	
2023-08	530	SPOR Species list identifier for pig	1	5	

For VMPs formulated as pastes, aerosols, shampoos, eye/ear preparations or spot on preparations where it is likely that each unit of VMP (e.g., syringe, single dose pipettes etc.) will be dispensed for the treatment of an individual animal, the dose factor is equivalent to one pack e.g., products for eyes or ears are usually administered 1 pack per individual animal due to risk of cross-contamination between animals. Therefore, the dose factor for these products would be 1, unless more than 1 pack is routinely needed to treat one animal.

For some single dose administration products, where a range of doses is indicated in the PI, dose factor should be calculated based on **maximum recommended exposure** (i.e., use of the upper limit of the dose range). The dose factor can be derived using the formula below:

$$Dose\ Factor = \frac{Package\ Volume\ [UoM]\ \times\ Conc_{\ API}}{BW\ \times\ Dose_{\ MAX}}$$

$Conc_{API}$ *Concentration active pharmaceutical ingredient PI (mg/ml or mg/mg)*
BW *Body weight (in kg) - taken from standard average weight table (see Appendix 1)*
$Dose_{MAX}$ *Dose (mg/kg or ml/kg) - maximum recommended exposure*
UoM *Unit of measure (millilitre, gram etc.)*

Example 1: A single dose injectable. Target species is dog. According to the PI, the active pharmaceutical ingredient (API) concentration is 3.4mg/ml and the recommended dose is 0.17mg/kg b.w. The package size is 1 solvent vial with 17 ml. Dose factor is calculated using the standard average weight in the table in Appendix 1 for a dog i.e., 20kg. Applying the formula stated above would result in:

$$Dose\ Factor = \frac{17\ \times\ 3.4}{20\ \times\ 0.17} = 17$$

Example of relevant data presented in CSV file.

Year-Month	Volume of sales	Species Identifier	Species %	Dose Factor	Comment
2023-11	122	SPOR Species list identifier for dog	100	17	

Example 2: A VMP is indicated for use in dogs and cats. Dose rates: Dogs 0.2 ml /kg b.w. Cats 0.3 ml /kg b.w. Package size: 1 bottle with 20ml. Distribution of sales per species: 70% dogs and 30% cats.

$$Dose\ Factor\ for\ dogs = \frac{20\ ml}{0.2ml\ \times\ 20kg} = 5$$

$$Dose\ Factor\ for\ cats = \frac{20ml}{0.3ml\ \times\ 5kg} = 13.33$$

Example of relevant data presented in CSV file.

Year-Month	Volume of sales	Species Identifier	Species %	Dose Factor	Comment
2023-09	52	SPOR Species list identifier for dog	70	5	
2023-09	52	SPOR Species list identifier for cat	30	13.33	

2.3.2. VMPs indicated for short-term treatment with a defined treatment course

For pharmaceutical VMPs used for short term treatments (i.e., courses up to 3 weeks), the dose factor will be a function of:

- Authorised treatment regimen (daily dose (mg/kg) x duration of treatment (days)) as detailed on the authorised PI. Where a range for dose or duration of therapy is indicated on the PI, it is appropriate to determine dose factor based on **maximum recommended exposure** (that is, use the upper limit of the dose range and/or longest duration of treatment). Any such alternative calculations should be justified in the pharmacovigilance system master file (PSMF).
- Average weight of target species/subpopulation (kg)(Appendix 1). The range of weights and production status within a target population should also be considered e.g., a product may be used in several different production status of individuals within the same species (e.g., cow 70% and beef calf 15%, newborn calf 15% or sheep 50% and lamb 50%). In these cases an average weight may be determined based on the estimated use within a species group. The assumptions underlying these calculations and the use of a calculated average weight other than the weights specified in Appendix 1, should be recorded in the PSMF.

Below are some examples of standard formulae to calculate the dose factor for short term, define treatment course products. These working examples are provided to facilitate understanding and implementation.

(i)

$$Dose\ Factor = \frac{Package\ Volume\ [UoM]}{Daily\ dose_{\ MAX}\ \times\ Duration}$$

Daily Dose $_{MAX}$ — *Dose (mg, g, ml etc.) based on maximum recommended dose (in mg/kg, ml/kg etc.)*
Duration — *Duration of treatment (days)*
UoM — *Unit of measure (millilitre, gram etc.)*

Example: An antimicrobial product indicated for the use in cows is administered on a farm. Daily dose of 50 ml per animal, for 5 consecutive days of treatment. Pack contains 500 ml. The dose factor of this pack size can be calculated as:

$$Dose\ Factor\ = \frac{500\ ml}{50\ ml\ \times\ 5\ days} =\ 2$$

Example of relevant data presented in CSV file.

Year-Month	Volume of sales	Species Identifier	Species %	Dose Factor	Comment
2023-12	300	SPOR Species list identifier for cow	100	2	

(ii)

$$Dose\ Factor = \frac{Package\ Volume\ [UoM]\ \times\ Conc_{API}}{BW\ \times\ ATR_{MAX}}$$

C_{API} Concentration active pharmaceutical ingredient PI (mg/ml or mg/mg)
BW Body weight (in kg) - taken from standard average weight table (see Appendix 1)
ATR_{MAX} Authorised treatment regimen (daily dose (mg/kg) x duration of treatment (days)
UoM *Unit of measure (dose, millilitre, gram etc.)*

NB. Where a range for dose or duration of therapy is indicated in the PI, dose factor should be calculated based on maximum recommended exposure (i.e., use of the upper limit of the dose range and/or longest duration of treatment).

Example: A product indicated for dogs is given with a dosage of 2 to 5 mg/kg for 2 to 5 days. The pack contains 75 ml with an active substance concentration of 30 mg/ml. The dose factor of this pack size can be calculated as:

$$Dose\ Factor = \frac{75ml\ \times\ 30mg/ml}{20kg\ \times\ (\ 5mg/kg\ \times\ 5\ days)} = 4.5$$

Example of relevant data presented in CSV file.

Year-Month	Volume of sales	Species Identifier	Species %	Dose Factor	Comment
2023-11	276	SPOR Species list identifier for dog	100	4.5	

Special considerations:

- The treatment course for inhalation anaesthetics should be based on a 45-minute duration anaesthesia at the typical rate used for maintenance.
- For dry cow intramammaries 1 dose is considered to be 4 intramammary syringes.
- For lactating cow intramammaries, the assumption should be that only 1 quarter is affected.

2.3.3. VMPs indicated for both short and long-term treatment without a defined length of treatment

Some VMPs are indicated for both short- and long-term treatment without a defined length of treatment course. In these cases, a 1-month (30 day) treatment basis should be used to derive a dose

factor. When the dose frequency is greater than 1 month, the dose factor should be calculated using the formula for a single dose administration product, see section 2.3.2.

The following formula can be used to derive a dose factor. Where unit dosing is not applied (e.g., 1 dose for 1 individual), then the individual daily dosage should be determined as the maximum dosage of the dose range outline in the PI.

$$Dose\ Factor = \frac{Package\ Volume\ [UoM]}{Dose\ [UoM]\ for\ 1\ month\ of\ treatment}$$

UoM Unit of measure (dose, millilitre, gram etc.)

Example 1: A dog receives 2 tablets daily of a Non-steroidal anti-inflammatory drug (NSAID) with a pack size of 100 tablets. The dose factor for this pack can be calculated as:

$$Dose\ Factor\ = \frac{100\ tablets}{2\ tablet\ per\ day\ \times\ 30\ days} = 1.67$$

Example of relevant data presented in CSV file.

Year-Month	Volume of sales	Species Identifier	Species %	Dose Factor	Comment
2023-08	617	SPOR Species list identifier for dog	100	1.67	

Example 2: A cat receives regular antiparasitic treatments at a dose of 1 pipette per month. A pack contains 3 pipettes. The dose factor for this pack can be calculated as:

$$Dose\ Factor = \frac{3\ pipettes}{1\ pipette} = 3$$

Example of relevant data presented in CSV file.

Year-Month	Volume of sales	Species Identifier	Species %	Dose Factor	Comment
2023-06	546	SPOR Species list identifier for cat	100	3	

Example 3: A dog receiving 3 monthly antiparasitic tablet receives 1 tablet every 3 months with a pack size of 4 tablets. The dose factor of this pack size can be calculated as:

$$Dose\ Factor = \frac{4\ tablets}{1\ \ tablet} = 4$$

Example of relevant data presented in CSV file.

Year-Month	Volume of sales	Species Identifier	Species %	Dose Factor	Comment
2023-07	320	SPOR Species list identifier for dog	100	4	

2.3.4. VMPs indicated for long-term (life-long) treatment or continuous supplementation

This relates to VMPs where a continuous administration is needed to achieve and maintain efficacy. In these cases, a 6-month treatment basis should be used to derive a dose factor, as recommended in previous guidance related to PSURs. In these cases, the average estimated doses per animal over a

period of 182 days should be calculated. When alternative durations are proposed by the MAH, these should be appropriately justified and recorded in the PSMF. Once an approach is established, it should be retained for subsequent sale data submissions.

The following formula can be used to derive a dose factor. Where unit dosing is not applied (e.g., 1 dose for 1 individual), then the individual daily dosage should be determined as the maximum dosage of the dose range outline in the PI.

$$Dose\ Factor = \frac{Package\ Volume\ [UoM]}{Dose\ [UoM]\ for\ 6\ month\ (182\ days)\ of\ treatment}$$

UoM Unit of measure (dose, millilitre, gram etc.)

Example: A cat receives an antithyroid drug. The treatment is monitored, and dose adjusted accordingly over a 6-month period. A cat receives 1 tablet of the product per day as life-long treatment (6 months/182 days). A pack contains 182 tablets. The dose factor for this pack can be calculated as:

$$Dose\ Factor = \frac{182\ tablets}{1\ tablet\ per\ day\ \times\ 182\ days} = 1$$

Example of relevant data presented in CSV file.

Year-Month	Volume of sales	Species Identifier	Species %	Dose Factor	Comment
2023-11	623	SPOR Species list identifier for cat	100	1	

2.3.5. Special considerations

2.3.5.1. VMPs indicated for the treatment of animal groups

For VMPs that are indicated for the treatment of groups within a designated holding area (i.e., In-hive treatment), a dose factor at the level of number of animals may not be possible to estimate or calculate. In these scenarios, it is permitted to provide a dose factor at the level of the holding area (e.g., for bee populations, a dose factor per hive is considered appropriate).

2.3.5.2. VMPs indicated with 'step down' dose rates / frequencies

In order to simplify and facilitate interpretation by end users, the standard long-term maintenance dosages should be used. The estimation of number of treated animals and calculation of dose factor should be based on the long-term maintenance dose rate.

2.3.5.3. VMPs indicated with different dose rates / treatment courses across EEA or in non-EEA countries

It is appreciated that this may be a possible complication related to different dose rates between nationally authorised products and between products authorised in EEA and non-EEA countries.

Where there are differences between the dose rates of nationally authorised products, it is recommended that the **most common** dose rate is applied to all such products within the EEA. Most common implies the use of the most common dose rate stated in PI of members states or the use of the dose rate from a relevant DCP/MRP procedure.

Where there are differences between EEA and non-EEA dose rates, the EEA dose rate / dosing program should be used for non-EEA products.

2.3.5.4. 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 indicated 'for suckling piglets'. In this case the appropriate weight for the target species indication should be used. Other products maybe used in different weights / production types of animals within the same species (e.g. beef calf 75% and cows 25%). In these cases an average weight may be determined based on the estimated use within a species group. The assumptions underlying these calculations and the use of a calculated average weight other than the weights specified in Appendix 1, should be recorded in the PSMF.

2.3.5.5. VMPs indicated in undefined species

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.) using the species list in Appendix 1 and based on the knowledge and understanding of the use of the product. The assumptions underlying the calculations and the use of a calculated average weight other than the weights specified in Appendix 1, should be recorded in the PSMF.

2.3.5.6. VMPs indicated in multiple animals (e.g., ointments, infusion bottles, water for injection)

For infusions, ointments, creams, water for injection etc. which are commonly used in multiple animals, it is acceptable to assume 1 pack = 1 treated animal. This assumption is most appropriate for product packages containing one "single pack/single dosage form" for the treatment of one individual (e.g., 1 x 500 ml bottle). In situations, where packages contain multiple "single pack/single dosage form" for the treatment of several individuals (e.g., 10 x 500 ml bottles), the follow formula may be used to derive a dose factor.

$$Dose\ Factor\ = \frac{G}{\left[\frac{n\ \times\ D}{E}\right]}$$

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)

Example: A pack contains 10 single dosage bottles, indicated for the use in horse. Each bottle contains 0.5 litres. Dosed at 0.2 litres over an average of 2 days.

$$Dose\ Factor\ = \frac{10}{\left[\frac{2\ \times 0.2}{0.5}\right]} = 12.5$$

Example of relevant data presented in CSV file.

Year-Month	Volume of sales	Species Identifier	Species %	Dose Factor	Comment
2023-11	127	SPOR Species list identifier for horse	100	12.5	

For separately authorised water for injection, buffers etc. the species dose factor calculation should be based on the knowledge and understanding of how the product is used.

Appendix 1: List of standard average weights for target species

Below are the tabulated standard average weights for target species to be used when calculating dose factors. The standard average weights should be used for all calculations unless the VMP is only indicated for a particular size of animal, in which case a representative weight for this size of animal will be used. Use of any other standard average weights, including for those species not listed in the table, should be justified and assumptions recorded in PSMF, together with assumptions use for the calculation of the dose factor.

As experience is gathered, the content of this list may change. Suggestions of additions or changes to the standard average weights list should be submitted to the Pharmacovigilance Working Party - Veterinary (PhVWP-V) for consideration. Any suggestions or proposals should be submitted to Vet-PhV@ema.europa.eu. It should be noted that updates to this list will be limited to once a year.

Species and subpopulations	**Standard average weight (kg)**
Cattle	
Cattle (beef calf)	150*
Cattle (adult cow)	550*
Cattle (newborn calf)	50*
Pigs	
Pigs (fattening/finishing)	60*
Pigs (breeding sow)	240
Pigs (sow/gilt/boar)	160*
Pigs (weaner)	25*
Pigs (piglet)	2
Caprinae	
Sheep/Goat (adult)	60*
Sheep/Goat (breeders)	75
Sheep/Goat (less than 12 months)	20
Sheep/Goat (lamb/kid)	10*
Poultry	
Chicken	1.5
Chicken (broiler)	1*
Chicken (layer hen)	2*
Turkey	10*
Turkey (poult)	4
Turkey (up to 28 days)	1

Duck	2
Goose	5
Ostrich	100
Partridge	0.3
Quail	0.1
Pheasant, Guinea fowl	0.5
Aquatic species	
Salmon	3
Companion and other animals kept or bred	
Horse/Equids	550*
Donkey	160
Horse (foal)	80
Dog	20*
Cat	5*
Rabbit	1.5*
Ferret	1.4
Guinea pig	1
Chinchilla	0.5
Gerbil	0.095
Mouse	0.04
Rat	0.25
Hamster	0.12
(Grey) Parrot, Racing pigeon	0.45
Chick (ornamental and singing birds)	0.04
Canary	0.02
Budgerigar	0.03
Zoo, wild and exotic animals	
Buffalo	550
Dromedary	500
Camelidae	200
Red deer	200
Roe deer	25
Reindeer	150
Fallow deer	60
Mink	2

Polar fox	5
Foxes	7
Polecat	1.2
Hare	3.5
Frog	0.022
Tortoise (e.g., Pet, Greek, Hermann's)	2
Snake (e.g., Green rat snake)	0.04
Lizard (e.g., Bearded dragons, Pogona)	24
Gecko, Common lizard	0.07

* Recommended standard weights previously published in VOLUME 9B of The Rules Governing Medicinal Products in the European Union (2011).