Veterinary Medicines Directorate

Technical guidance for completion of the Pharmacovigilance Sales Submission (PSS)

This guidance applies only to sales submissions. For signal notifications, refer to the guidance document 'Technical guidance for completion of Standard and Urgent Signal Notifications' and for BRSR submissions, refer to the guidance document 'Technical guidance for completion of the Benefit-Risk Submission Report (BRSR)' which can be found at Benefit-risk report (BRR) and signal notification submissions.

Related guidance can be found at Pharmacovigilance of Veterinary Medicinal Products in Great Britain.

1. General guidelines

1.1 Submissions

Sales submissions must be made if there have been any sales of the product(s) in the UK and/or any EEA country.

If there have been zero sales, sales submissions are not required.

Sales data must be submitted using the standalone Pharmacovigilance Sales Submission (PSS) Excel template at Benefit-risk report (BRR) and signal notification submissions.

PSSs should be submitted using the Veterinary Medicines Digital Service (VMDS), a secure messaging service. Any MAH not signed up to VMDS can register.

Once signed in to the VMDS account, the MAH should select the relevant group: Sales.

Note that if a Benefit-Risk Submission Report is submitted at the same time as a Pharmacovigilance Sales Submission, the BRSR must be submitted to the group 'BRR Submission' and the PSS must be submitted to the group 'Sales'.

Additional documents (for example detailed dose factor justification that is too lengthy to fit within the PSS template) can be submitted alongside the PSS within the same VMDS submission.

PSSs involving products within a PGC should not be submitted until this PGC has been agreed with the VMD. For further details see section 1.6 of this guidance document.

Sales submissions can be made at the same time as the Benefit-Risk Submission Report or split into multiple submissions throughout the year (submitted at any time).

UK and EEA sales data for relevant products must have been submitted at least up to the end of the previous calendar year by the time of the BRSR submission, although if more recent data are available their submission is preferable.

There must be no gaps in data.

PSSs may also be requested at any time by the VMD on an ad hoc basis.

If sales data has been incorrectly submitted or necessary corrections come to the attention of the MAH following submission, the sales data must be re-submitted and the error or correction required must be clearly stated within the VMDS secure message to which the re-submission is attached (including the row/rows affected).

Further information on submissions can be found in section 4.5 of Guideline IV of the Pharmacovigilance of Veterinary Medicinal Products in Great Britain guidance.

Submission queries should be sent to sales@vmd.gov.uk or via VMDS secure messaging to the Sales group.

1.2 Language and scope

All PSSs must be completed in English.

Local language product names as downloaded from the EMA Union Product Database will be accepted for EEA countries. Every effort should be made to ensure these remain consistent across subsequent PSSs.

Sales submissions should contain one or more of the following at each submission:

- Sales data for the UK as a whole (not separated into GB/NI)
- Sales data for EEA countries (per country)

UK sales data must be provided by individual pack size (one pack size per row).

EEA sales data must be provided by individual pack size or nominal pack size (one pack size or nominal pack size per row).

Sales data for multiple MAs or PGCs can be submitted within the same PSS.

The breakdown of sales data submitted should be per month. If monthly figures for sales data are unknown, an estimate should be calculated from the shortest time period available

to provide the most accurate data. For example, if both 3-monthly and 12-monthly sales data breakdowns are available, the 3-monthly data should be divided by 3 to achieve the estimated monthly sales, rather than using the 12-monthly sales data.

1.3 Document type and formatting

The template must be submitted in the Excel format type .xlsx

The layout of the template must remain the same to allow mapping into VMD systems. Data incorrectly entered into cells which does not follow the guidance/validation criteria for that cell or addition of data where it is not required (for example extra notes) will result in failed validation, and MAHs may be requested to make revisions

Note that for accessibility reasons, the template found on Gov.uk at Benefit-risk report (BRR) and signal notification submissions in ODS (OpenDocument) format.

If copying and pasting data from another source, only paste the values, not format or other parameters.

1.4 Naming convention for PSS template

The PSS should be named using the MA number (with an underscore rather than forward slash separation) or MAHORGID as used within the PGC (or equivalent to the MAHORGID if this has been agreed with the VMD) with an underscore rather than a dash, year, 'Sales' and a number identifier (so that every submission has a unique identifier) separated by underscores.

In the below examples, the number identifier is represented by an 'x':

MAnumber_YYYY_Sales_x

or

MAHORGID _YYYY_Sales_x

For a product with an MA number 09285/8019, for sales from the start of January to the end of July 2024, for example, the name of the document would be 09285_8019_2024_Sales_x.

If the sales runs across two calendar years, use:

MAnumber_YYYYYYYY_Sales_x

or

MAHORGID_YYYYYYYY_Sales_x

For a product with an MA number 09285/8019, for sales from the start of November 2024 to the end of February 2025, for example, the name of the document would be 09285_8019_20242025_Sales_x.

For a product with Product Group Code of GUOFGAND-BENEFITAS for sales from the start of January to the end of July 2024, for example, the name of the document would be GUOFGAND _2024_Sales_x.

No special characters other than underscores (_) should be used as separators. Spaces should not be used. The total number of characters should not exceed 40 characters (if the PGC is too long, and the total number of characters will exceed 40 characters, use only the overarching group name rather than the entire PGC e.g. BENEFITAS_2024_Sales_x).

1.5 Naming convention for additional documents

Multiple documents (for example including detailed explanations) can be submitted alongside the PSS per VMDS submission using any of the file types .pdf, .doc, .docx, .xls, .xlsx.

Additional documents should be named using above naming convention followed by an underscore, A and a unique number. If a single additional document is submitted alongside the PSS, 'A1' should be added' and if two documents were submitted alongside, this would be 'A2' should be added For example, if a dose factor explanation document related to the PSS named GUOFGAND _2024_Sales_1, the dose factor explanation document should be named GUOFGAND _2024_Sales_1_A1. A further additional document should be named GUOFGAND_2024_Sales_1_A2.

No special characters other than underscores (_) should be used as separators. Spaces should not be used. The total number of characters should not exceed 40 characters.

1.6 Product Group Codes (PGCs)

A Product Group Code (PGC) links a set of individual Marketing Authorisations together into a single group. It should be used to link both UK MAs and, at minimum, their EEA equivalent products if the product is authorised in EEA.

If one or more PGCs are to be used, they must be either proposed by the MAH and accepted by the VMD or requested by the MAH at least one month prior to the first BRSR or PSS submission using these PGCs, and a BRSR or PSS using these PGCs should not be submitted until these PGCs have been agreed.

Any future changes to products grouped within the Product Group Code should also be agreed at least one month prior to the next BRSR or PSS submission.

Further details on PGCs can be found in section 4.3 of Guideline IV of the Pharmacovigilance of Veterinary Medicinal Products in Great Britain guidance.

Queries related to Product Group Codes should be directed either via VMDS to the PSUR Queries group or via e-mail to psur.queries@vmd.gov.uk.

2. PSS template completion

The table below explains the required content of each cell in the template.

Validation rules **must** be followed for data entered within the cell. The 'Validation type' determines whether the field is mandatory or not (whether data must be provided or not) and which character and number types are allowed.

If data is not entered into a cell, leave the cell blank. Do not enter N/A or any other text unless requested to do so by the following guidance.

Ensure the cell format is correct as per the 'Required cell format' before submission. If data is copied into the Excel template, ensure only values, not formats are copied.

Cell	Type	Required content	Validation rules	Validation type	Required cell format
Column A (A2 onwards)	Product Group Code (PGC) or MA Number	Either: 1. For products without a PGC, enter the GB MA number as stated in the national MA and associated documentation, unless the MA number has been updated since initial authorisation, in which case the *current* MA number must be used Enter only the authorisation number **without Vm or Vh** preceding it. 2. For products with a PGC, enter the agreed Product Group Code (PGC).	MA number must be identical to that stated in the GB national MA and associated documentation, unless the MA number has been updated since initial authorisation, in which case the **current** MA number must be used. PGC must be identical to that agreed with the VMD.	Mandatory **Must be entered correctly to allow mapping** *Numbers, special characters*	General
Column B (B2 onwards)	Product Name	If an MA number has been entered in column A, enter the name of the product as stated in the national MA and associated documentation. If a Product Group Code (PGC) has been entered in column A, enter the applicable product name for the specific product within the PGC. For UK sales, use the name of the product as	For single MAs, the name must be identical to that within the national MA and associated documentation.	Mandatory *Numbers, special characters, text*	General

		stated in the national MA and associated documentation. For EEA sales, use either the name of the equivalent UK product as stated in the local MA or as it appears in the EMA Union Product Database. Ensure the name includes the appropriate strength if applicable. The names of individual products should be consistently used across PSSs wherever possible.			
Column C (C2 onwards)	Package Description	Text identifying the individual pack. This could include the number of tablets within a pack/bottle size/packaging materials. Can be used for clarification if the strength of a product is not evident from the Product Name or if multiple versions/sizes of the same Unit of Presentation exist for a product. If using nominal pack sizes within column D, it is recommended to reference this in column C. If data are not provided within this column, MAHs may be contacted to provide further	Not applicable	Non-mandatory *Numbers, special characters, text.*	General

		information in specific cases.			
Column D (D2 onwards)	Pack size Numeric value	For UK data, this must be the total number of units within a single pack. Each individual pack size should be entered into a separate row. Nominal pack sizes should not be used for UK data. However, if multiple pack sizes exist which have the same total number of units within each pack (e.g. a single pack with 100 tablets and a package containing 4 packs of 25 tablets), these can be amalgamated within the same row (see Annex 2). The same dose factor must be applicable to both package types. For EEA data, this must be either: 1. The total number of units within each pack, as separated by individual pack size 2. One or more nominal pack sizes The nominal pack may be different to any UK authorised pack, but the dose factor will relate to this nominal pack.	Enter a number (decimal or non-decimal).	Mandatory *Number*	General

		Further details can be found in Annex 2 of this guidance. If nominal pack sizes are used, they must be used throughout the template for all EEA data (cannot be used for UK data). For vaccines made up of two components where only one contains the active substance and this is to be combined with a solvent, as the Pack size Unit of Presentation is Doses, the total number of active substance-containing units within the pack rather than the individual total number of vials should be entered.			
Column E (E2 onwards)	Pack size Unit of Presentation	The unit of presentation of the units within the pack. Units used must remain consistent across PSS submissions.	Select from the codelist provided in Annex 1 of this guidance. Only units from this list should be used, and they must be entered exactly as written (not abbreviated).	Mandatory *Text*	General
Column F (F2 onwards)	Country	Country in which sales occurred. GB and NI sales should not be split. For total UK sales, enter the code GB. For GB only sales, enter the code GB. Do not enter NI sales separately.	In 2-character country code as per ISO 3166 format	Mandatory *Text*	General

Column G (G2 onwards)	Marketing Authorisation Number(s)	For UK sales only, enter the MA number(s) as stated in the national MA and associated documentation, unless the MA number has been updated since initial authorisation, in which case the *current* MA number must be used. Enter only the authorisation number **without Vm or Vh** preceding it. For UK sales, where both GB and NI MA numbers exist, enter both MA numbers separated by a comma e.g. 12345/1234, 67891/6789. For GB sales only, enter the single GB MA number. For EEA countries, this information is non-mandatory, however the local MA number or equivalent identifier can be entered.	MA number must be identical to that stated in the national MA and associated documentation, unless the MA number has been updated since initial authorisation, in which case the **current** MA number must be used.	Mandatory for UK only Non-mandatory for EEA countries *Text and special characters*	General
Column H (H2 onwards)	Year-Month	Enter the year and month for which the sales data is applicable (one row per month). If accurate monthly figures for sales data are unknown, an estimate should be calculated from the shortest time period available to	Enter in format YYYY-MM.	Mandatory *Numbers and special characters*	General

		provide the most accurate data. For example, if both 3-monthly and 12-monthly sales data breakdowns are available, the 3-monthly data should be divided by 3 to achieve the estimated monthly sales, rather than using the 12-monthly sales data.			
Column I (I2 onwards)	Volume of Sales	Equal to the number of packs sold for non-nominal pack sizes, or total number of units for nominal pack sizes. Whether nominal pack sizes are used or not, multiplication of the value in column D and column I should equal the total number of units sold in the applicable country for that month. This calculation is performed within VMD systems and the total number of *units* sold does not need to be entered anywhere within the PSS. Products for which there have been zero sales do not need to be included. Details regarding volume of GB versus NI sales can be provided within the Comments cell but this is non-mandatory.	Enter a number (decimal or non-decimal).	Mandatory *Number*	Number

Column J (J2 onwards)	VICH Species Code	Enter the target species based on the SPC. If there are multiple target species, these must be entered on different rows (one row per species per package/nominal pack per country). If zero sales occurred for a target species, this species does not need to be listed. The species must relate to the dose factor. Detailed dose factor guidance can be found in Annex 3. Further guidance on selection of codes for species not listed on the VICH list can also be found in Annex 3.	Select the most relevant species code from the VICH Guidelines Do not list non-target species.	Mandatory *Text*	General
Column K (K2 onwards)	Species %	Estimated percentage of the total sales for a specific package in each target species (per country). Do not enter sales data for non-target species. For single target species products, enter 100. If the target species are dog and cat and estimated percentage sales for each target species are equal, 50 should be entered for each species (not 50% or 0.5).	Enter a positive number only, between 0 and 100. Decimals can be used. Do not enter any special characters. For UK sales, the total of the species % figure for specific packs should be 100. For EEA sales the total of the species % figure for specific packs should be between 99 and 101.	Mandatory *Number*	Number

Column L (L2 onwards)	Dose factor	The dose factor is a positive numerical value which provides an estimate of the number of treated animals using the sales data. It should equal the average number of animals of a target population which can be treated by one package of a given pack size of a product, regardless of the formulation. Detailed dose factor guidance can be found in Annex 3.	Enter a positive number only. Decimals can be used (up to 4 decimal places).	Mandatory *Text*	Number
Column M (M2 onwards)	Comment	Enter any additional relevant comments.		Non-mandatory *Text, numbers and special characters.*	General

Annex 1: Sales units

Units should be selected from the following list for use within column E, Pack size Unit of Presentation:

Product type	**Pack size Unit of Presentation**
Vaccines	Doses
Liquids (e.g. within bottles or vials)	Litres
Powders	Kilograms
Tablets	Tablets
Capsules	Capsules
Sprays	Litres or Kilograms
Collars	Collars
Paste	Kilograms
Pipettes (e.g. spot-ons)	Pipettes
Boluses	Boluses
Implants	Implants
Patches	Patches
Sponges	Sponges
Strips	Strips

Only units listed within the above list will be accepted. If you have a request for a particular unit to be added to the list, send your request via VMDS secure messaging to the Sales group or via e-mail to sales@vmd.gov.uk.

If a single MA covers multiple presentations of a product e.g. 5ml and 10 ml bottle sizes, the sales volume should be expressed in litres. Selecting a unit e.g. bottle would not be appropriate.

If a single MA covers multiple presentations of a product that cannot be effectively expressed in litres/kilograms e.g. 2 separate collar sizes, details can be provided within the Package Description column of the PSS. If details are not provided, the VMD may request further information from the MAH.

Annex 2: Nominal pack sizes

Nominal pack sizes can be used for EEA data if sales data per specific pack size is not provided. These pack sizes may be different to any UK authorised pack, but the dose factor must relate to this nominal pack.

MAHs should choose one or the other of these options within a single submission and for ongoing submissions to allow for comparison of data over time.

For a specific pack size, the data can be entered as per UK data for the EEA country, with data for each individual pack size entered on a separate row.

Alternatively, if using nominal pack sizes, the following method should be used. Using an example, if pack sizes of 10, 20 and 50 tablets are sold in the EEA country, one nominal pack size of 1 can be entered into the Pack size Numeric value cell (column D of the PSS), which will represent the pack sizes combined. In this example, if 100 packs of the 10-tablet pack size, 50 packs of the 20-tablet pack size and 50 packs of the 50-tablet pack size were sold, then a total of 5500 tablets ((100 x 10) + (50 x 20) + (50 x 50)) would have been sold in that EEA country, and 5500 should be entered for Volume of Sales (column I of the PSS).

Any number can be entered as a nominal pack size, however, the total of the value for the Pack size Numeric value multiplied by the value for the Volume of Sales (column D and column I) must equal the total number of units (in the above example, tablets) sold in the EEA country. The total would equal the sum of all the Volume of Sales values for that country had the data been entered per pack size.

UK amalgamated packs

Nominal pack sizes must not be used for UK data.

However, if multiple pack sizes exist which have the same total number of units within each pack (e.g. a single pack with 100 tablets and a package containing 4 packs of 25 tablets), these can be amalgamated within the same row. The Pack size Numeric value cell would contain (in this example) ‘100’, the Pack size Unit of Presentation cell would contain ‘Tablets’, and the Volume of Sales cell would contain the total number of packs sold across the two package types (sales volume of the single 100-tablet package type added to the sales volume of the 4 pack of 25 tablets package type). Details can be provided within the Package Description column; however, this is an non-mandatory cell. The same dose factor must be applicable to both package types.

Annex 3: Dose factor

The dose factor is a positive numerical value which provides an estimate of the number of treated animals using the sales data. It should equal the average number of animals of a target population which can be treated by one package of a given pack size of a product, regardless of the formulation.

The calculation of an appropriate dose factor will depend on factors such as the type of product, target species, body weights, production status, formulation, indication and treatment regimen, and should be determined by the MAH. Any suggestions for methods for calculation should only be used if deemed representative of the conditions of use of the product.

Key principles are listed in the subsections below to aim for as much harmonisation as possible.

Dose factors must be justified either within the PSS Comments column (column M) or within a separate document submitted alongside the PSS (see section 4.5 of the Pharmacovigilance of Veterinary Medicinal Products in Great Britain guidance).

If an MAH maintains a large file of multiple dose factor justifications, the VMD may be able to accept regular submissions of this file rather than a separate submission alongside each PSS submission. For proposals, contact sales@vmd.gov.uk.

A separate dose factor should be calculated and submitted for each pack size where sales have occurred or for EEA data, each pack size or nominal pack size where sales have occurred.

If multiple pack sizes contain the same number of individual units e.g. a tub of 250 tablets and a pack of 50 blister strips containing 5 tablets per strip with use in the same species, only one Pack size Numeric Value (and therefore dose factor) needs be submitted.

Where nominal pack sizes are used for EEA sales, the dose factor must be calculated for this pack size. For example, where a nominal pack size of 1 is used, the dose factor must equal the average number of animals of a target population which can be treated by one nominal pack of a product.

As much as possible, dose factors should be kept consistent across reporting periods to allow comparability of incidence calculations, and ideally be kept consistent between reference and generic products for which the MAH has responsibility. Any changes to the dose factor should be highlighted and justified within the related BRSR.

Where nominal pack sizes are used for EEA sales, the dose factor must be calculated for a pack size of 1 (i.e. equal the average number of animals of a target population which can be treated by one nominal pack of a product).

If no dose factor is provided by an MAH, the VMD will determine a dose factor based on the product, previous PSURs/BRSRs and other relevant data.

Single dose administration

Examples include flea collars, vaccines, long-acting injectable preparations, wormers and flea spot-ons.

For VMPs that are administered as a single dose and where the pack contains 1 dose, the number of doses equals the number of animals treated and the dose factor would be 1.

For VMPs that are administered as a single dose and where the pack contains more than 1 dose:

$$\text{Dose factor} = \frac{\text{Package Volume (number of units)}}{\text{Dose (number of units)}}$$

For example, if a single dose of an injectable that is recommended for use as a single dose of 5 ml comes in a pack size of 20 ml, the dose factor would be 20 divided by 5 = 4.

For VMPs where one unit of product is administered for the entire course of treatment for an individual animal, the number of units again equals the number of animals treated (1 unit = 1 animal treated), and therefore the dose factor would be 1.

Examples include VMPs for topical use, such as shampoos, pastes, eye preparations or ear preparations.

For single dose administration VMPs where there is a range of doses that could be administered as per the SPC, the dose factor should be calculated using the maximum dose in this range; divide the package volume by the single maximum dose amount (e.g. 1 dose or 10ml).

For example, if a single dose product where the package size is 1 vial containing 10 ml and which is indicated for use in 2 different target species with a recommended dosage of a single dose in the range 1-5 ml per animal, the maximum dose should be used (5 ml).

The dose factor would be 10 divided by 5 = 2.

If an active substance concentration is applicable to the product:

1. Multiply the concentration of the active substance (in mg/ml or mg/mg) as stated in the product literature by the package volume (ml, g)
2. Multiply the weight of the target species (derived from the table provided below) by the maximum dose (in mg/kg or ml/kg) as stated in the product literature
3. Divide the result of step 1 by step 2

Short-term treatments with a defined treatment course

This applies to products used for courses of treatment up to 3 weeks.

Where there is a set dose and duration of treatment that should be administered as per the SPC:

1. Multiply the recommended dose based on standard weight (in mg, ml, tablet etc) as stated in the product literature by the duration of treatment (days)
2. Divide the package volume by the result of step 1.

Where there is a range of doses and durations that could be administered as per the SPC, the dose factor should be calculated using the maximum dose in these ranges, for example:

1. Multiply the recommended maximum dose based on standard weight (in mg, ml, tablet etc) as stated in the product literature by the maximum duration of treatment (days)
2. Divide the package volume by the result of step 1

Where there is a range of doses and durations that could be administered as per the SPC and If an active substance concentration is applicable to the product:

1. Multiply the package volume by the concentration of the active substance (in mg/ml or mg/mg) as stated in the product literature.
2. Multiply the weight of the target species (derived from the table provided below) by the maximum dose (in mg/kg or ml/kg) and by the maximum duration (days) as stated in the product literature
3. Divide the result of step 1 by the result of step 2

If there is a range of weights or production status within a target population e.g. use in newborns as well as adults, an average weight should be determined based on the estimated use within a species group.

For dry cow intramammary products, 1 dose is considered equivalent to 4 intramammary syringes, and for lactating cow intramammary products, 1 dose is considered equivalent to 1 intramammary syringe.

For inhalation anaesthetics, a duration of anaesthesia of 45 minutes at the typical rate used for maintenance should be used.

Products for which treatments can be either short or long-term without a defined treatment course

For products indicated for both short and long-term treatment without a defined length of treatment course, a 30-day treatment course should be used to calculate the dose factor.

If the dose is not 1 dose per individual, the maximum dosage of the dose range listed within the product literature should be used within the following formula:

$$\text{Dose factor} = \frac{\text{Package Volume (number of units)}}{\text{Dose (number of units) over 30 days of treatment}}$$

For example, a product given at a dose of 2 tablets daily, where the pack size is 60 tablets, would have a dose factor of 60 divided by (2 x 30) = 1.

When the dose frequency is more than 1 month (for example, a product administered once every 3 months), the dose factor should be calculated as per single dose administration products.

For example, a product given at a dose of 2 tablets every 3 months, where the pack size is 4 tablets, would have a dose factor of 4 divided by 2 = 2.

Products for long-term/continuous treatment

For products where continuous administration is required, a 6-month (182 day) treatment course should be used for dose factor calculation.

Alternative durations can be proposed by the MAH if this is considered more appropriate for the product, but full justification should be provided.

As much as possible, dose factors should be kept consistent across reporting periods to allow comparability of incidence calculations.

If the dose is not 1 dose per individual, the maximum dosage of the dose range listed within the product literature should be used within the following formula:

$$\text{Dose factor} = \frac{\text{Package Volume (number of units)}}{\text{Dose (number of units) over 182 days of treatment}}$$

For example, a product given at a dose of 1 tablet daily, where the pack size is 300 tablets, would have a dose factor of 300 divided by (1 x 182) = 1.65.

Products for the treatment of groups

For VMPs indicated for the treatment of groups of animals within a designated area where the number of animals is not possible to estimate, a dose factor can be provided for the group as a whole. For example, for a population of bees within a hive, the dose factor can be populated per hive.

Products with tapered dosing

Standard long-term dosages should be used to calculate the dose factor.

Products with differences in dosing/treatment courses across different countries

The dose factor should be harmonised as much as possible for the same product across different countries to allow accurate comparison of data.

Using the UK dose rate/treatment course is preferable, however, the most common dose rate/treatment course listed within the product literature across countries can be used for all products listed within the PSS if this is deemed to be more appropriate. Explanation should be provided.

Products indicated for use in animals of a specific weight or production type

If a product is used in different weights or production types (e.g. newborns and adults) of the same species, either the standard weight for the species, or an average weight based on the estimated use can be used. The reasoning should be detailed within the justification.

Products used in undefined species

If there is a range of species within a target population where the estimated use per species cannot be defined (e.g. 'poultry'), separate dose factors should be provided for each of the most appropriate species within that species group e.g. chickens and turkeys for 'poultry' if in practice the product is used only in chickens and turkeys.

Products routinely used for multiple animals

Products that are routinely used multiples times for multiple animals such as water for injection, infusions, ointments and creams, it can be assumed that 1 pack = 1 treated animal.

If the pack contains multiple individual single packs, such as 10 x 100 ml bottles, designed for the treatment of several individual animals, the following should be used to calculate the dose factor:

1. Multiply volume of a single (estimated) dose (e.g. litres) by the average duration (days) of the treatment course
2. Divide the result of step 1 by the volume of a single pack (e.g. bottle) within the pack
3. Divide the total pack size (total volume e.g. of all bottles within the pack) by the result of step 2.

Standard weights

The average weight of the target species should be derived from the table below.

Species, sub-population	**Standard weight (Kg)**
Cattle (beef calf)	150
Cattle (adult cow)	550
Cattle (newborn calf)	50
Pigs (fattening/finishing)	60
Pigs (breeding sow)	240
Pigs (sow/gilt/boar)	160
Pigs (weaner)	25
Pigs (piglet)	2
Sheep/Goat (adult)	60
Sheep/Goat (breeders)	75
Sheep/Goat (less than 12 months)	20
Sheep/Goat (lamb/kid)	10
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
Salmon	3
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
Buffalo	550
Red deer	200
Roe deet	25
Reindeer	150
Fallow deer	60
Mink	2
Foxes	7

Polecat	1.2
Hare	3.5
Frog	0.002
Tortoise	2
Snake	0.04
Lizard (e.g. Bearded dragons, Pogona)	24
Gecko, Common lizard	0.07

Species selection

MAHs who submit sales data to the EMA may routinely use species available on the SPOR RMS Species list which do not appear on the above VICH species list. On these occasions, MAHs are requested to select the most appropriate species group from the VICH list.

For example, if an MAH were to usually submit sales data using the species Atlantic salmon and Trout on the SPOR RMS Species list, the most appropriate VICH equivalent would be Fish (species code FIS).

If there is a species split for a particular product involving multiple species with a group (e.g. using the above example, Atlantic salmon 60% and Trout 40%), the MAH should either:

1. Maintain the dose factors already calculated for the individual species but complete all the applicable rows in the PSS with the same species code:

UPD (RMS) Name	Species %
Atlantic salmon	60.00
Trout	40.00

VICH Species Code	Species %
FIS	60.00
FIS	40.00

2. Calculate a dose factor which is applicable across the species group to create a single row with the same VICH species code and Species % 100.00