06 December 2023
EMA/772580/2022
Veterinary Medicines Division

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

Version 1.7

Overview of changes:

The key changes in this version are listed below:

- **Updated information in several areas of section *2.1 'Volume of Sales data fields'* due to 'Creation Date of Package' and 'Deletion Date of Package' being now available**

- **A recommendation added in section *4.3.1 'Technical validations'* on how to approach when an error report file contains ER.36**

- **A new section *6.2.4 'Changes to MAH product grouping when possessing 3rd country product names'* has been added**

For full, complete list of changes made compared to version 1.6 please see the table on page 5 of this document.

Users are advised to read and consult the whole document.

Table of contents

Changes made compared to version 1.6

Section	Heading	Change applied
2.1.11 2.1.12 2.2.1 2.2.2	Creation Date of Package Deletion Date of Package Download of packages file Submission of volume of sales file	Updated information in those sections as the fields Creation Date of Package and Deletion Date of Package are already available in the system
2.3.2	Business validations	Removed ERR.15 as we have a similar one within the technical validations (ER.27)
2.4	MAH test environment for Validation of the sales data CSV	Provision of the test environment URL
4.3.1	Technical Validations	Recommendation added on how to approach when an error report file contains ER.36
5.2.3	Changing a MAH Product Group Identifier	Clarification on how to unlink MAH Product Group Identifier(s) and product(s) added
6.2.4	Changes to MAH product grouping when possessing 3rd country product names	New section on the interdependencies between MAH Product Grouping and Third Country Product Names added
6.3.1	List of validations on the submission file	Updated the description of the ER.35
Annex A	5.How to check the correct format of the submission file	Clarification added on the selection of the csv file format

1. Introduction

This chapter provides guidance on the process of downloading the portfolio of all packages and of submitting other post-authorisation data (Volume of Sales, Marketing Authorisation Status and Availability Status) into the Union Product Database (UPD).

This is applicable only for authorised veterinary medicinal products as referred to in Article 5(1) of Regulation (EU) 2019/6, registered veterinary homeopathic medicinal products as referred to in Article 85(1) and veterinary medicinal products intended for animals which are exclusively kept as pets as referred to in Article 5(6) of said Regulation.

The download of the portfolio of packages as a comma separated values (CSV) file is a mandatory preliminary step, as it will enable the marketing authorisation holder (MAH) to retrieve the package identifiers from the UPD which are needed for submitting annual volumes of sales and maintaining availability data. On an ongoing basis MAHs will need to continue to download available packages, to identify new packages for which sales data or availability status require submission into the UPD.

MAHs are only responsible for supplying volume of sales and availability status for those Member States where they either operate or have a distributor directly responsible for the sales in that Member State:

- Parallel Imports: a MAH may be aware that a product is sold/made available in a Member State through a parallel import, the MAH should not record these sales in that Member State, nor mark the availability status as 'marketed' in that Member State. In this, situation the sale should continue to be recorded against the Member State from which the parallel import was sourced.

- Special import permits (or equivalent): a MAH may be aware that a product is sold/made available in a Member State through special import permit, the MAH should not record these sales in that Member State nor mark the availability status as 'marketed' in that Member State. Where possible, the MAH should record the volume of sales for products with special import permit against the EEA country where the specific product/pack concerned was actually authorised. Special imports from countries outside the EEA should not be recorded against an EEA country but potentially, in certain situations, be part of the third country sales data reporting submission. For clarity if a product is marketed in Member State A and a special import permit allows it to be imported into Member State B, the sale for this product should, where possible, be recorded against Member State A.

In cases when the marketing authorisation is transferred from MAH A to MAH B, the MAH B takes over all responsibilities as the holder of the marketing authorisation which includes reporting of volume of sales for released batches by MAH A. Therefore, MAH A would have to provide the sales data to MAH B until end of shelf-life of those batches. It is for the MAH A and MAH B to discuss and decide how and when this information will be provided from MAH A to MAH B.

For the purpose of this chapter, annual volume of sales is defined as part of the *Other Post Authorisation Data* on a veterinary medicinal product authorised in a Member State with a marketing authorisation or registration valid on 28 January 2022. All the relevant data elements applicable to annual volume of sales are outlined in the section 2 of this Chapter.

2. Volume of Sales

During the process of record/submit Volume of Sales the following two operations shall take place sequentially in the UPD:

- **Download of packages**: The MAH shall download a structured CSV file from the UPD portal. This file shall include a portfolio of all packages under the user's responsibility. Such CSV file shall contain all the raw data stored in UPD for all applicable packages.

- **Submission of Volume of Sales**: The volume of sales is reported by the MAH for a specific package, species and country covering a concrete reference period. This information is submitted through a CSV file previously completed by the user. Information on how to complete the file is provided in the next sections.

Important note: It is highly recommended that MAHs do not to submit non-EEA volume of sales data until the specific training webinar, projected for September 2023, takes places.

2.1. Volume of Sales data fields

This section describes all fields related to the volume of sales data, either downloaded from the UPD or provided by the MAH user. The data downloaded from the UPD which are optional for the submission step (cf. section 2.2) are meant to assist the MAHs in the matching of the UPD Package Identifiers to the MAH Stock Keeping Units.

The title of each sub section provided below corresponds to the names of CSV file columns. For data to be entered by the MAH, refer to sections 2.1.11 to 2.1.15.

The "Conformance" attribute indicates whether a value is mandatory or optional to be provided during the submission of the CSV file.

2.1.1. Product identifier

The product identifier is applicable to all veterinary medicinal products created in the UPD regardless of the type of the authorisation procedure. For products registered by European procedures (MRP, DCP and/or SRP) it is common to all authorisations in the Reference Member State and Concerned Member States, in addition to e.g., the common authorisation procedure number. It enables linking of products based on the common/European data set.

Tag	Description
User Guidance	The product identifier as assigned by the UPD.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Identifier (max. 4000 characters)
Value(s)	ID generated by the system. MedicinalProductDefinition.identifier.system value is "http://ema.europa.eu/fhir/vmpId"

2.1.2. Product name

Tag	Description
User Guidance	The veterinary medicinal product name (invented name, strength, pharmaceutical dose form), as indicated in the relevant section of the corresponding SPC or other regulatory document, in line with the local language of the country where the product is authorised. Any trademark values shall not be included in the full veterinary medicinal product name.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	string (maximum length: 4000 characters)
Value(s)	The full veterinary medicinal product name as free text.

Example(s): Metacam 5 mg/ml solution for injection

2.1.3. Permanent identifier

As defined in point 3.1 of Annex III of Commission Implementing Regulation (EU) 2021/16, a Permanent Identifier (or Permanent ID) is a unique identifier of the veterinary medicinal product in the Union product database. This Permanent Identifier differentiates between the veterinary medicinal products authorised in multiple Member States from the same MRP/DCP or SRP (same Product ID (Level 1). It is generated based on the Product ID (Level 1) with the addition of the national information as authorised in the country by the relevant competent authority and representing the so-called 'national dataset'.

Tag	Description
User Guidance	The unique identifier of the veterinary medicinal product as assigned by the UPD.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	id
Value(s)	ID generated by the system

2.1.4. Authorisation Procedure Number

The procedure number assigned by the competent authority to a specific authorisation/registration procedure.

Tag	Description
User Guidance	Number of the initial procedure for marketing authorisation.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Identifier
Value(s)	The procedure number is specified as free text (max. 4000 characters) but formatted as: CC/V/nnnn/sss or EMEA/V/C/ for the core part.

Example(s): SE/V/1111/003, DE/V/1111/001, EMEA/V/C/001234

2.1.5. Package Identifier

Volume of Sales are submitted at package level. Therefore, in the submission file, the Package Identifier is mandatory to be provided. This field is also repeatable as each package can be authorized for more than one species.

Tag	Description
User Guidance	The package identifier is generated by the UPD and assigned by the system to each package.
	The package identifier is a mandatory field in the submission file. The system performs validations whether it belongs to the country indicated in the file.
	For non-EEA countries, the User shall submit only one (estimated equivalent) EEA package identifier for all non-EEA countries with the total volume of sales data.
Repeatable	Yes
Conformance	Mandatory
Data Type	Identifier (max. 4000 characters)
Value	The package identifier obtained from the UPD system.

2.1.6. Package description

Tag	Description
User Guidance	The description of the packaged veterinary medicinal product as specified in the corresponding SPC and eAF or another regulatory document.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Markdown
Value(s)	The description of the packaged medicinal product must be provided as free text (max. 4000 characters).

2.1.7. Pack size

For each Packaged Medicinal Product, the pack size is defined as the total number of units in the package after reconstitution.

2.1.7.1. Pack size_Numeric value

Tag	Description
User Guidance	The number of units of presentation of a manufactured item in a packaged medicinal product.

Tag	Description
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Quantity
Value(s)	Numeric value

2.1.7.2. Pack size_Unit of Presentation

Tag	Description
User Guidance	The unit of presentation describing the unit in which a manufactured item is presented to describe the strength or quantity as a term ID.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	CodeableConcept
Value(s)	As listed in Units of Presentation (200000000014)

2.1.7.3. Pack size_Unit of Presentation Identifier

Tag	Description
User Guidance	The identifier of the unit of presentation describing the unit in which a manufactured item is presented to describe the strength or quantity as listed in the RMS.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Identifier
Value(s)	As listed in Units of Presentation (200000000014)

2.1.8. Country

This section describes the country code of the country where the product is marketed/not marketed.

2.1.8.1. Country

This section describes how to record the country where the package of the medicinal product was sold in a specific period of time.

Tag	Description
User Guidance	This field indicates a short name[1] of the country for which the volume of sales is submitted. This is not a mandatory field. It can be repeatable depending on the number of different species for applicable package(s).

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[1] The short name of the country can be found in the RMS list under the column name "Term short name".

Tag	Description
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Text
Value	Short name as listed in the Country list (RMS list ID 100000000002), for all EEA countries. In the cases that volume of sales is being submitted in non-EEA countries, the country short name should be indicated as "non-EEA", as listed in the Country Grouping list (RMS list ID 100000000003)

Example(s): France, Netherlands, non-EEA

2.1.8.2. Country identifier

Tag	Description
User Guidance	This field indicates a country, for which the Volume of Sales is submitted. Country code is a mandatory field. It can be repeatable depending on the number of different species for applicable package(s). Country identifier is a mandatory field in the submission file and is validated by the system accordingly.
Repeatable	Yes
Conformance	Mandatory
Data Type	CodeableConcept
Value	As listed in the Country list (SPOR RMS list ID 100000000002) for all EEA countries. In the cases that volume of sales is being submitted in non-EEA countries, the country SPOR RMS term identifier submitted is "100000000028" ("non-EEA") from RMS list 100000000003 (Country Grouping list). In case MS Excel is used for modifying CSV files, the Number format should be used without decimals.

Example(s): 100000000529 (Spain), 100000000028 (non-EEA)

2.1.9. Marketing authorisation number

Tag	Description
User Guidance	Marketing Authorisation number is assigned to the veterinary medicinal product at product or at package level; - Marketing authorisation number for authorised veterinary medicinal products. - Registration number for registered homeopathic veterinary medicinal products. - Declaration number for veterinary medicinal products allowed to be used in a Member State in accordance with Article 5(6) of Regulation (EU) 2019/6 or exempted from the provisions in

Tag	Description
	Articles 5 to 8 of Directive 2001/82/EC in accordance with Article 4(2) of the same Directive, as applicable.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Identifier
Value(s)	The number assigned by the competent authority of a country/jurisdiction shall be specified as free text (max. 4000 characters).

2.1.10. Creation Date of Product

Tag	Description
User Guidance	The creation date of product describes the date when the product was created in UPD, as recorded in the audit trail.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Date
Value(s)	A date specified using the ISO 8601 date format. (YYYY-MM-DD) In case the MS Excel is used for modifying CSV files, the Date format should be used.

2.1.11. Creation Date of Package

Tag	Description
User Guidance	The creation date of package describes the date when the package was created in UPD, as recorded in the audit trail.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Date
Value(s)	A date specified using the ISO 8601 date format. (YYYY-MM-DD) In case the MS Excel is used for modifying CSV files, the Date format should be used.

2.1.12. Deletion Date of Package

Tag	Description
User Guidance	The deletion date of package describes the date when the package was deleted in UPD, as recorded in the audit trail. This element is added in the csv download file for convenience of users since packages deleted in the UPD continue to be present in the download file for 24 months post deletion.

Tag	Description
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Date
Value(s)	A date specified using the ISO 8601 date format. (YYYY-MM-DD) In case the MS Excel is used for modifying CSV files, the Date format should be used.

2.1.13. Year-Month

Year-Month represents the period for which the user is submitting the volume of sales at package level.

Tag	Description
User Guidance	The Volume of Sales must be provided in monthly increments (i.e., one line per month). The user must indicate for each line which month and year the volume of sales reported in that line refers to.
Repeatable	No
Conformance	Mandatory, entered by MAH user
Data Type	dateTime
Value	A date field shall be specified using the ISO 8601 date format (i.e., YYYY-MM). In case the MS Excel is used for modifying CSV files, the Date format should be used.

Example: 2023-01; 2024-04

2.1.14. Volume of Sales

This section describes the Volume of Sales of veterinary medicinal products per package, per species, per country and per month.

Tag	Description
User Guidance	The Volume of Sales must be provided as an integer number (positive, negative or 0). The system shall overwrite previous submissions that were presented for the same Package Identifier, reference period (month), species and country. The MAH should contact the relevant NCA/Agency[2] before overwriting any previously introduced data to ensure the consumers of such data are aware that changes have been made. For non-EEA countries, as the UPD does not contain data on non-EEA packages, the User shall convert all relevant non-EEA sales into the

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[2] https://www.hma.eu/veterinary-medicines/cmdv/procedural-contact-points.html

Tag	Description
	equivalent number of packs sold for a target EEA pack (see below). The volume of sales value shall display the total aggregated value for <u>all</u> species (in case a package is sold and designated to different/specific species). This means that the Volume of Sales value should be the same for each reported species for an individual pack/month (and not the amount estimated to be sold in that species).
	By default, UPD presents the Volume of Sales per package as zero even for the packages which have not yet been sold so there is no requirement to submit 0 sales against packs which have not been sold. Similarly, there is no requirement to submit 0 for non-EEA sales where there have been no non-EEA sales. Users shall be allowed to add negative values in order to reflect returns or recalls in the sales data in UPD.
Repeatable	No
Conformance	Mandatory, entered by MAH user
Data Type	Integer
Value	The value must be an integer (positive, negative or 0).

Example: 0; 500; -300

> **Important note:** many immunological veterinary medicinal products contain both lysophilate and solvent in the same registered package, however some immunological veterinary medicinal products (especially poultry vaccines) can have the lysophilate and solvent authorised as separately registered packages. In this situation the sales for the lysophilate packages must be submitted, but there is no requirement to submit sales for the separately registered solvent packages.

Possible options/calculations to represent non-EEA sales

Reporting of non-EEA volume of sales must be matched to one or more EEA package identifier(s) (the package identifier is either a package identifier from a product within the product group (see Section 5) or one or more package identifier(s) from the specific product for which the non-EEA sales are being reported). As the same packs are not necessarily sold in the EEA and outside the EEA, the following approaches should be followed:

Option 1 for non-EEA sales (same pack size exists in EEA):

In the EEA a 50-dose vaccine vial and in non-EEA countries the same 50 dose vaccine vial is used. Therefore, the volume of non-EEA sales can be reported against that package identifier without transformation.

For instance, in the Year-Month defined, the Volume of Sales in Brazil was 300,000 vials, in Chile 500,000 and Peru 100,000. Then, non-EEA sales will be reported as new row in the submission file.

     Volume of Sales = 900,000

     Package identifier = package identifier in EEA with the same combination of pack size/strength

     Country Identifier = 100000000028

Option 2 for non-EEA sales (different pack sizes):

In EEA only a 100 ml vial is sold, in non-EEA countries different pack sizes of the same formulation are sold which the MAH considers to be relevant. For example: 25 packs of 500 ml, 30 packs of 250 ml, 55 packs of 100 ml and 75 packs of 50 ml vials are sold of the same formulation outside the EEA and the MAH considers all of these relevant. In which case the total number of nominal 100 ml EEA packs sold = (25 x 500)+(30 x 250)+(55 x 100)+(75 x 50)/100 = 29250/100 = 293 of '100 ml EEA equivalent packs' (note volume of sales must be an integer so rounding has occurred).

As above

In the EEA a 50 mg tablet is sold in 10 tablet packs, in some non-EEA countries a 62.5 mg tablet is sold in 25 tablet packs and which the MAH considers to be relevant. For example: 31 packs of 25 tablets of the 62.5 mg tablet were sold outside the EEA. In which case the total number of equivalents to the EEA 50 mg/10 tablet packs presentation sold = ((31 x 25) x 62.5/50)/10 = 968.5/10 = 97 of '10 tablet 50 mg EEA equivalent packs' (note: volume of sales must be an integer so rounding has occurred).

Note: if an MAH is not sure about what third country products/presentations should be considered relevant, the Agency's or National Competent Authority's Pharmacovigilance groups should be consulted.

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.

2.1.15.1. Species name [3]

Tag	Description
User Guidance	This field enables a species name with the associated sales volumes to be recorded per package and country.
	This field is only provided for the convenience of MAH and there are no specific rules as to how the MAH uses it.
	Only species which are equivalent to those indicated on the EEA SPC should be included (species splits are not to be provided for non-target species). There is no requirement to list species which are not indicated in the EEA SPC.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Text
Value(s)	This field is only provided for the convenience of MAH and there are no specific rules as to how the MAH uses it

Examples: Dog; Cat; Cattle

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[3]Field is not currently available in download file and must not be included in upload file. It will be added in a later release.

2.1.15.2. Species identifier

Tag	Description
User Guidance	The species code provided, per package, in the submission file for which one volume of sales is split.
	Species identifier and species splits should only be provided for target species: no species identifier or species split should be provided for off-label use (i.e., use in a species not indicated in the EEA / non-EEA country SPC for EEA / non-EEA as appropriate). Do not list non-target species for either EEA or non-EEA species splits (based on local SPCs).
	For EEA species splits – only species which are equivalent to those target species indicated on the EEA SPC should be included however there is no requirement to list all species (for example if the product is not actually used in a target species, then this species does not need to be listed and if it is, the full set of data should be provided (e.g. a species split and a species factor).
	For non-EEA species sales data, relevant non-EEA SPC target species where the product is used should be listed (in practice this means that species may be listed for non-EEA sales which are not equivalent to any EEA SPC species). Again, there is no requirement to list all non-EEA SPC target species if the product is not used in some of them.
	In the situation where a 'broad' target species is listed on an EEA or non-EEA SPC (examples include but are not limited to 'fish', 'poultry' etc) and for which equivalent terms are not present in the RMS Species list, then the most appropriate term(s) from the RMS Species list should be used. For example, the indication may be 'poultry' but in practice the product is only used in chicken and turkeys: in this situation 'chicken' and 'turkey' should be species listed.
Repeatable	Yes
Conformance	Mandatory, entered by MAH user
Data Type	CodeableConcept
Value(s)	Term ID as listed in SPOR RMS list Species (200000000019) (Note: this is not the same as the SPOR RMS Target Species list referred to in the QRD template).
	In case the MS Excel is used for modifying CSV files, the Number format should be used without decimals.

Examples: 200000000200

2.1.15.3. Species %

Tag	Description
User Guidance	Many packages of authorised products are sold for use in different animal species.
	Species % represents the numerical value of the estimated percentage of use of the total sales for a specific package in a given animal species in the country of reporting.
	For EEA sales the total of the species % figures for a specific package should be 100.
	For non-EEA sales the total of the Species % figures for a specific package should be between 95 and 105.
	For packages with only one authorised species, the Species % should be 100.
Repeatable	Yes
Conformance	Mandatory, entered by MAH user
Data Type	Number (figure should not be submitted as a % figure but should be submitted as a number with or without decimal points – e.g., '30' not '30%')
	(Note: 0.35 as the representation of 35% is an incorrect value)
Value(s)	Positive number with or without decimal point, between 0 and 100.
	In case the MS Excel is used for modifying CSV files, the Number format should be used with or without decimals. There is no limitation to the number of decimal points used. However, the number of decimals that will be displayed when using MS Excel to view the file, depends on the user settings.

Example(s): Cattle: 35, Dog: 45.5, Cat: 19.5

2.1.16. Dose Factor

Tag	Description
User Guidance	The Dose factor represents the average number of animals of a particular species that can be treated using one package. The Dose factor is derived by the MAH based on his understanding of how the package in question is generally used in veterinary practice, e.g., taking into account the different indications for the species, average body weights of animals at treatment, and suggested treatment plans, i.e. dose, frequency and duration of treatment) .
	The appropriate dose factors should be provided for all volume of sales data and species per package identifier and per country.

Tag	Description
Repeatable	No
Conformance	Mandatory, entered by MAH user
Data Type	Number
Value(s)	Positive number with or without decimals. In case of decimals, up to 4 decimal digits can be used. In case MS Excel is used for modifying CSV files, the Number format should be used.

Example(s): 0.7; 1.5 ; 2 ; 1.35 ; 2.563

2.1.17. Comment

The comment field can be used to indicate any explanations, or to indicate which package the non-EEA sales for a product have been reported against.

Tag	Description
User Guidance	Free text field
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Text
Value(s)	Free text up to 250 characters. N/A

Example: "This package is reporting the non-EEA sales".

2.2. Submission of Volume of Sales file structure

This section describes the structure of download and submission files. The submission file will be validated by the system, and therefore the lists of technical and business validation rules are detailed further in subsection 2.3.

2.2.1. Download of packages file

The Marketing Authorisation Holder shall be able to download a structured CSV file from the UPD portal. This file includes the portfolio of packages which are under the user's responsibility, including the relevant data stored in the UPD.

The download file is composed of the fields below. Fields 1 to 15 are automatically pre-filled by the System (highlighted in bold) according to the rules described in section 2.1. Fields 16 to 21 are empty in the download file.

1. **Product Identifier**
2. **Product Name**
3. **Permanent Identifier**
4. **Authorisation Procedure Number**
5. **Package Identifier**
6. **Package Description**
7. **Pack size_Numeric value**
8. **Pack size_Unit of Presentation**

9. **Pack size_Unit of Presentation Identifier**
10. **Country**
11. **Country Identifier**
12. **Marketing Authorisation Number**
13. **Creation Date of Product (extracted from audit trail)**
14. **Creation Date of Package**
15. **Deletion Date of Package**
16. Year-Month
17. Volume of Sales
18. Species Identifier (RMS Term ID)
19. Species %
20. Dose Factor
21. Comment

The CSV files exported from the UPD use a comma as field separator. The handling of the downloaded CSV files depends on the regional settings used on the computer of the end user. Windows computers with, e.g., a regional setting from a European country is often using semicolons instead of commas to separate the fields of a CSV file. For more information, please refer to Annex A.

2.2.2. Submission of volume of sales file

The submission file must be submitted in a CSV file format. Further details on how to verify the format of the file are described in the section 5 from the Annex A.

The submission file is composed of the following fields: the order of the columns and names of the column headings <u>must</u> follow the structure below with the content of fields 5, 11 and 16 to 20 validated as mandatory to be provided by the user (highlighted in bold below). Data in other columns 1-4, 6-10, 12-15 do not need to be resubmitted and provided the column header is present, the columns can either be left blank or information can be included which helps the MAH (e.g., country name in the Country column).

1. Product Identifier
2. Product Name
3. Permanent Identifier
4. Authorisation Procedure Number
5. **Package Identifier**
6. Package Description
7. Pack size_Numeric value
8. Pack size_Unit of Presentation
9. Pack size_Unit of Presentation Identifier
10. Country
11. **Country Identifier**
12. Marketing Authorisation Number
13. Creation Date of Product (extracting from audit trail)
14. Creation Date of Package
15. Deletion Date of Package
16. **Year-Month**
17. **Volume of Sales**
18. **Species Identifier**
19. **Species %**
20. **Dose Factor**
21. Comment

2.3. List of validations on the submission file

This section describes technical and business validation rules for the submission file. During the submission process, the system verifies the data provided in the CSV file generating error messages per each row, if applicable.

2.3.1. Technical validations

Error code	Description	Error message while submitting the file
ER.01	Wrong file format. A CSV file is needed.	ER.01: Only CSV file format is allowed. Submit option not available for other file formats
ER.03	Different header column names expected	ER.03: Header column names are not as expected according to Vet EU IG Chapter 7
ER.04	Different number of columns expected	ER.04: The number of columns provided is not correct according to Vet EU IG Chapter 7
ER.07	Country Identifier cannot be empty	ER.07: Country Identifier cannot be empty
ER.08	Package identifier cannot be empty	ER.08: Package Identifier cannot be empty
ER.13	Year-Month is YYYY-MM (ISO 8601)	ER.13: Year-Month format is not as expected (YYYY-MM)
ER.17	Default String error message	ER.17: Comment length is more than 250 characters
ER.18	Volume of Sales is not an integer value	ER.18: Volume of sales format is not as expected (integer value)
ER.19	Species Identifier is not a valid value	ER.19: Species Identifier format is not as expected (SPOR RMS term ID from Species list 200000000019)
ER.20	Species % is not a positive number with or without a decimal point	ER.20 Species split format is not as expected (number with or without decimal point)
ER.21	Dose factor is not a positive number with or without a decimal point	ER.21: Dose factor format is not as expected (positive number with or without decimal point)
ER.22	Volume of Sales cannot be empty	ER.22: Volume of sales cannot be empty
ER.23	Species identifier cannot be empty	ER.23: Species identifier cannot be empty
ER.24	Species % cannot be empty	ER.24: Species % cannot be empty
ER.25	Dose Factor cannot be empty	ER.25: Dose Factor cannot be empty
ER.26	Year-Month cannot be empty	ER.26: Year-Month cannot be empty
ER.27	Species % value must be between 0 and 100 with or without decimal point	ER.27: Species % value cannot be negative or greater than 100
ER.28	Default Integer error message. In the message provided the (%) variable will be replaced by the corresponding column name.	ER.28 % is not an integer value

2.3.2. Business validations

Error code	Description	Error message while submitting the file
ERR.01	Package Identifier provided does not belong to a product under User's responsibility.	ERR.01: Package Identifier provided does not belong to a product under the User's responsibility

ERR.03	Country Identifier does not exist in RMS list	ERR.03: Country identifier does not exist in RMS list
ERR.05	Package Identifier provided does not belong to the country selected	ERR.05: Package identifier does not belong to the country selected.
ERR.12	Species Identifier needs to be unique per package, country Identifier and Year-Month.	ERR.12: Species Identifier cannot occur multiple times for same package, country in the same Year-Month.
ERR.13	Volume of Sales cannot be different within same package, country in the same Year-Month.	ERR.13: Volume of sales cannot be different within same package, country in the same Year-Month. (Volume of sales must always be the same figure for same package, country, Year-Month (for all different species listed))
ERR.14	Species identifier does not exist in RMS list	ERR.14: Species identifier does not exist in RMS list
ERR.16	The sum of the split sales per species is not 100, for EEA countries.	ERR.16: The sum of split sales per species is not 100 for EEA Sales.
ERR.17	Package Identifier provided was deleted more than 24 months ago.	ERR.17: Package Identifier provided was deleted more than 24 months ago.
ERR.18	Package Identifier provided belongs to nullified product.	ERR.18: Package Identifier provided belongs to a nullified product.
ERR.19	Authorisation status changed to revoked or surrendered more than 24 months ago.	ERR.19: Authorisation status changed to revoked or surrendered more than 24 months ago.
ERR.39	The sum of the split sales per species is not between 95 and 105 for non-EEA countries.	ERR.39: The sum of split sales per species is not between 95 and 105 for non-EEA Sales.

2.4. MAH test environment for Validation of the sales data CSV

MAH is able to perform a preliminary test of their CSV file for sales data prior its submission to the UPD. The submitted CSV file will go through all the same upload and validation steps (including using the current relevant package identifiers for that MAH) without actually populating the UPD. MAH may find this useful for the development and testing of their own systems or for checking a CSV file after corrections have been made. The URL for the test environment is https://upd-portal-prod-validation.azurewebsites.net/updwebui/.

3. Marketing Authorisation Status

In case of revocation or suspension of a veterinary medicinal product, the competent authority and the MAH should agree on who will update the marketing authorisation status in the UPD.

Note that competent authorities are also able to manage in the system the marketing authorisation status of the veterinary medicinal products under their responsibility and they are the only ones who can set the status of a veterinary medicinal product to 'Valid'.

This section describes how MAH is able to update the Marketing Authorisation Status and Marketing Authorisation Status Date for one product that belongs to the User's organization.

For the Marketing Authorisation Status update, the possible values to be provided by MAH for the product selected shall be "suspended" or "revoked".

Note: if the **MA Status is updated to 'suspended' or 'revoked'**, then the **Availability status is updated to 'Not marketed'** and the Availability Status Date to the date of suspension or revocation.

3.1. Marketing Authorisation status

Tag	Description
User Guidance	The possible values for the selected product shall be "suspended" or "revoked" when the Marketing Authorisation status is updated by the MAH. The remaining Marketing Authorisation statuses are managed exclusively by competent authorities. Further details can be found in Chapter 2 of the Vet EU IG. The status of the marketing authorisation of the medicinal product must be specified as a term ID.
Repeatable	No
Conformance	Mandatory, entered by MAH user
Data Type	CodeableConcept
Value	Must be valid or suspended from the list Regulatory Entitlement Status (100000072049).

Example: Revoked (100000072121), Suspended (100000072122)

3.2. Marketing Authorisation status date

Tag	Description
User Guidance	The date when the authorisation status changed must be specified. (This may not be the same as the date when the authorisation status was updated in the Union Product Database).
Repeatable	No
Conformance	Mandatory, entered by MAH user
Data Type	dateTime
Value	A date specified using the ISO 8601 date format. (YYYY-MM-DD)

Example: 2022-01-28

4. Availability status

During the process of availability status update, the following two operations shall take place sequentially in the UPD:

- Download of product data file: The Marketing Authorisation Holder shall download, as a result of a search, the list of packages of the products for which the information on the Availability Status will be reported. The selected packages are downloaded to the user's local machine as a CSV file format whose structure is defined below. See also Annex A for additional advice in handling CSV files.

- Availability status and availability status date: The Marketing Authorisation Holder shall submit into the UPD system a CSV file with a fixed structure, providing the Availability status and

EU Implementation Guide (Vet EU IG) on veterinary medicines product data in the
Union Product Database
EMA/772580/2022   Page 22/57

Availability status date per package and country. The full data set that is carried by the CSV file is presented below. See also Annex A for additional advice in handling CSV files.

4.1. Availability status data fields

This section describes the mandatory and optional fields related to the provision of the Availability status and Availability status date data. This mandatory data shall be submitted by Marketing Authorisation Holders through a file in CSV format (the submission file). The data downloaded from the UPD which are optional for the submission step (cf. section 4.2) are meant to assist the MAHs in the matching of the UPD Package Identifiers to the MAH Stock Keeping Units.

The "Conformance" attribute indicates whether a value is mandatory or optional to be provided during the submission of the CSV file.

4.1.1. Product identifier

The product identifier is applicable to all veterinary medicinal products created in the UPD regardless of the type of the authorisation procedure. For products registered by European procedures (MRP, DCP and/or SRP) it is common to all authorisations in the Reference Member State and Concerned Member States, in addition to e.g., the common authorisation procedure number. It enables linking of products based on the common/European data set.

It is applicable to all veterinary medicinal product submitted into the UPD regardless of the type of the authorisation procedure.

Tag	Description
User Guidance	The product identifier as assigned by the UPD.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Identifier (max. 4000 characters)
Value(s)	ID generated by the system. MedicinalProductDefinition.identifier.system value is "http://ema.europa.eu/fhir/vmpId"

4.1.2. Product name

Tag	Description
User Guidance	The veterinary medicinal product name (invented name, strength, pharmaceutical dose form), as indicated in the relevant section of the corresponding SPC or other regulatory document, in line with the local language of the country where the product is authorised.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	string (maximum length: 4000 characters)
Value(s)	The full veterinary medicinal product name as free text.

Example(s): Metacam 5 mg/ml solution for injection

4.1.3. Permanent identifier

As defined in point 3.1 of Annex III of Commission Implementing Regulation (EU) 2021/16, a Permanent Identifier (or Permanent ID) is a unique identifier of the veterinary medicinal product in the Union product database. This Permanent Identifier differentiates between the veterinary medicinal products authorised in multiple Member States from the same MRP/DCP or SRP (same Product ID (Level 1). It is generated based on the Product ID (Level 1) with the addition of the national information as authorised in the country by the relevant competent authority and representing the so-called 'national dataset'.

Tag	Description
User Guidance	The unique identifier of the veterinary medicinal product as assigned by the UPD.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	id
Value(s)	ID generated by the system

4.1.4. Authorisation Procedure Number

The procedure number assigned by the competent authority to a specific authorisation/registration procedure.

Tag	Description
User Guidance	Number of the initial procedure for marketing authorisation.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Identifier
Value(s)	The procedure number is specified as free text (max. 4000 characters) but formatted as: CC/V/nnnn/sss or EMEA/V/C/ for the core part.

Example(s): SE/V/1111/003, DE/V/1111/001, EMEA/V/C/001234

4.1.5. Package identifier

Availability status and date are to be provided at package level. Therefore, in the submission file, the Package identifier is mandatory to be provided.

Tag	Description
User Guidance	The package identifier is generated by the system and assigned to each package. The package identifier is a mandatory field in the submission file. The system performs validations whether Package ID belongs to the country indicated in the file.
Repeatable	Yes
Conformance	Mandatory
Data Type	Identifier (max. 4000 characters)
Value	The package identifier obtained from the UPD system.

4.1.6. Package description

Tag	Description
User Guidance	The description of the packaged veterinary medicinal product as specified in the corresponding SPC and eAF or other regulatory document.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Markdown
Value(s)	The description of the packaged medicinal product must be provided as free text (max. 4000 characters).

4.1.7. Pack size

For each Packaged Medicinal Product, the pack size is defined as the total number of units in the package after reconstitution.

4.1.7.1. Pack size_Numeric value

Tag	Description
User Guidance	The number of units of presentation of a manufactured item in a packaged medicinal product.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Quantity
Value(s)	Numeric value

4.1.7.2. Pack size_Unit of Presentation

Tag	Description
User Guidance	The unit of presentation describing the unit in which a manufactured item is presented to describe the strength or quantity as a term ID.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	CodeableConcept
Value(s)	As listed in Units of Presentation (200000000014)

4.1.7.3. Pack size_Unit of Presentation Identifier

Tag	Description
User Guidance	The identifier of the unit of presentation describing the unit in which a manufactured item is presented to describe the strength or quantity as listed in the RMS.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Identifier
Value(s)	As listed in Units of Presentation (200000000014)

4.1.8. Country

This section describes the country code of the country where the product is marketed/not marketed.

4.1.8.1. Country

This section describes how to record the country for availability data submission.

Tag	Description
User Guidance	This field indicates a short name[4] of the country for which the availability data are submitted. This is not a mandatory field.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Text
Value	Short name as listed in the Country list (RMS list ID 100000000002), for all EEA countries.

Example(s): France, Netherlands

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[4] The short name of the country can be found in the RMS list under the column name "Term short name".

4.1.8.2. Country identifier

Tag	Description
User Guidance	This field indicates a country as an identifier. Country identifier is a mandatory field in the submission file and is validated by the system accordingly. It can be carried over from the download file.
	For submission of availability status file – Country Identifier (field 11), for Centralised Products, the User shall submit one row per package assigned to each one of the European Union (EU) Member States, Iceland, Norway, Liechtenstein, and United Kingdom (Northern Ireland).
	Example: Metacam solution for injection with two packages: the download CSV file will contain 62 rows (one per each package and country), and the submission CSV file shall contain up to 62 rows (one row for each package with availability status changed assigned to each one of the countries).
Repeatable	Yes
Conformance	Mandatory
Data Type	CodeableConcept
Value	As listed in the Country list (SPOR RMS list ID 100000000002) for all EEA countries. In case MS Excel is used for modifying CSV files, the Number format should be used without decimals.

Example(s): 100000000529 (Spain)

4.1.9. Marketing authorisation number

Tag	Description
User Guidance	Marketing Authorisation number is assigned to the veterinary medicinal product at product or at package level: a.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Identifier
Value(s)	The number assigned by the competent authority of a country/jurisdiction shall be specified as free text (max. 4000 characters).

4.1.10. Creation Date of Product

Tag	Description
User Guidance	The creation date of product describes the date when the product was created in UPD.
Conformance	Optional (if provided it will be ignored by the system)

Tag	Description
Data Type	Date
Value(s)	A date specified using the ISO 8601 date format. (YYYY-MM-DD) In case the MS Excel is used for modifying CSV files, the Date format should be used.

4.1.11. Creation Date of Package[5]

Tag	Description
User Guidance	The creation date of package describes the date when the package was created in UPD.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Date
Value(s)	A date specified using the ISO 8601 date format. (YYYY-MM-DD) In case the MS Excel is used for modifying CSV files, the Date format should be used.

4.1.12. Availability

This section provides information on the availability status of the veterinary medicinal product at package level. Availability status refers to the concepts of veterinary medicinal product being placed in the market and the market cessation as applicable.

4.1.12.1. Availability status

Tag	Description
User Guidance	The status of the marketing of the veterinary medicinal product in the specified country must be provided by the Marketing Authorisation Holder as a term ID. • The term "marketed" should be defined as when the veterinary medicinal product is "released out of the control of the MAH and into the distribution chain in destination of a given country". • The term "not marketed" should be defined as the "cessation of release into the distribution chain in destination of a given country" with the consequence that the concerned product may no longer be available for supply. It is also the default term when a new product is created.

---

[5] Field is not currently available in download file and must not be included in upload file. It will be added in a later release.

Tag	Description
	• The term "temporarily unavailable" should be specified as a disruption of supply from the MAH which would lead to an extended disruption in supply to the retailers for a long period of time (e.g. for instance more than 3 months). Since this information is to be provided by the MAH, at the time of creation of a new veterinary medicinal product by a Competent Authority the availability status shall be specified with the value "Not marketed". Note: for legacy data (only) at the time the UPD goes live the value "No data provided" may be present until the MAH updates this. In some cases, the availability status will be automatically updated by the system as a result of a change in the marketing authorisation status: A change of the marketing authorisation status to 'Surrendered', 'Suspended', 'Revoked' or 'Expired' will result in a change of the Availability status to 'Not marketed'.
Repeatable	No
Conformance	Mandatory
Data Type	CodeableConcept
Value	As listed in Marketing Status (RMS list ID 100000072052). In case the MS Excel is used for modifying CSV files, the Number format should be used without decimals.

Example(s): 100000072083 (Marketed), 100000072074 (Not Marketed), 230000000000 (Temporarily unavailable) or for legacy data only (at the time the UPD goes live) 100000072075 (No Data Provided)

4.1.12.2. Availability status date

Tag	Description
User Guidance	The availability status date describes the date from when the change of availability status is effective (which may or may not be the date that the information is uploaded to the UPD). The first date value will be created by the system, at the time of initial entry of the product into the UPD by the NCA/Agency (availability status will be either "not marketed", "No data provided"). This date will be empty if at the time of creation the availability was not provided by the Competent Authority. When marketing authorisation holders change the availability status from this initial entry, the availability status date is mandatory to be provided. The "Availability Status Date" cannot be set more than the current date +1 day.

Tag	Description
	For the initial population of the UPD if the date when the availability status of the package became effective prior to 28 January 2022 is known, then this date can be used. If this date is not known or easily accessible, then the default date of 28 January 2022 (the date of coming into application of the Regulation) can be used. (Note: this information is not populated into the Public Portal)
	Until the end of 2023 (during which it is anticipated that the availability status date will be populated by MAH) there is no restriction on the Availability Status date. From the beginning of 2024, any new Availability Status date can only be after the current availability status date recorded in the UPD.
	Whenever marketing authorisation holders change the Availability Status, the Availability Status Date is mandatory to be provided.
Repeatable	No
Conformance	Mandatory
Data Type	Date
Value	A date shall be specified using the ISO 8601 date format (i.e., YYYY-MM-DD). ISO 8601 can accommodate year and month should day of the month not be known. (i.e., YYYY-MM). In case the DD is not known and only the YYYY-MM is provided, then as DD, the first day of the submitted month will be stored in UPD as the Availability Status Day.
	In case the MS Excel is used for modifying CSV files, the Date format should be used.

Example: 2022-01-01; 2023-01

4.2. Availability status data file structure

This section describes the structure of download and submission files. The submission file will be validated by the system; therefore, the lists of technical and business validation rules are detailed further in subsection 4.2.3.

4.2.1. Download product data file

The Marketing Authorisation Holder shall be able to download a structured CSV file from the UPD portal. This file will include the portfolio of packages which are under the user's responsibility and that match the search criteria selected. Such CSV file shall contain the relevant data stored in UPD for all applicable packages.

The download file is composed of the fields below. Fields 1 to 13 are automatically pre-filled by the System (highlighted in bold) according to the rules described in section 4.1

1. **Product Identifier**
2. **Product Name**
3. **Permanent Identifier**
4. **Authorisation Procedure Number** (Blank when empty)

5. **Package Identifier**
6. **Package Description**
7. **Pack size_ Numeric value**
8. **Pack size_Unit of Presentation**
9. **Pack size_Unit of Presentation Identifier**
10. **Country**
11. **Country Identifier**
12. **Marketing Authorisation Number**
13. **Creation Date of Product (extracted from audit UPD trail)**
14. Availability Status
15. Availability Status Date

The CSV files exported from the UPD use a comma as field separator. The handling of the downloaded CSV files depends on the regional settings used on the computer of the end user. Windows computers with, e.g., a regional setting from a European country is often using semicolons instead of commas to separate the fields of a CSV file. For more information, please refer to Annex A.

4.2.2. Submission of Availability status file structure

The submission file must be submitted in a CSV file format. Further details on how to verify the format of the file are described in the section 5 from the Annex A.

The submission file is composed of the following fields and the order of the columns and names of the column headings <u>must</u> follow the structure below with the content of fields 5, 11, 14 and 15 validated as mandatory to be provided by the user (highlighted in bold below). Data in other columns 1-4, 6-10, 12-13 do not need to be resubmitted and provided the column header is present, the columns can be either left blank or information can be included which helps the MAH (e.g. country name in the Country column).

1. Product Identifier
2. Product Name
3. Permanent Identifier
4. Authorisation Procedure Number
5. **Package Identifier**
6. Package Description
7. Pack size_ Numeric value
8. Pack size_Unit of Presentation
9. Pack size_Unit of Presentation Identifier
10. Country
11. **Country Identifier**[6]
12. Marketing Authorisation Number
13. Creation Date of Product
14. **Availability Status**
15. **Availability Status Date**

4.3. List of validations on the submission file

During the submission process, the system verifies the data provided in the CSV file generating error messages per each row, if applicable. Technical and business validations rules are described in the next two sections.

4.3.1. Technical Validations

Error code	Description	Error message while submitting the file
ER.01	Wrong file format. A CSV file is needed.	ER.01: Only CSV file format is allowed. Submit option not available for other file formats
ER.03	Different header column names expected	ER.03: Header column names are not as expected according to Vet EU IG Chapter 7
ER.04	Different number of columns expected	ER.04: The number of columns provided is not correct according to Vet EU IG Chapter 7.
ER.06	Availability Status date cannot be empty	ER.06: Availability Status date cannot be empty
ER.07	Country Identifier cannot be empty	ER.07: Country Identifier cannot be empty
ER.08	Package identifier cannot be empty	ER.08: Package Identifier cannot be empty
ER.12	Availability status cannot be empty	ER.12: Availability status cannot be empty
ER.14	Availability Status date YYYY-MM-DD or YYYY-MM (ISO 8601)	ER.14: Availability Status date format is not as expected (YYY-MM-DD or YYYY-MM)
ER.36	Default Data error message when an update fails due to FHIR validations. As reason, the message returned from FHIR server will be displayed.	ER.36: Package could not be updated - Reason: <description as returned from FHIR>. Please try again later and if it still fails, please raise a Service Desk ticket.

> **Recommendation:** In case of receiving an error file after the AvS submission, please follow these steps:
>
> o If the errors in the file are due to business validations (see section 4.3.2), **fix the errors and resubmit the file**.
> o **If the file contains the above ER.36**, then you may receive two type of error files:
>   ▪ In the first case, **no updates have been processed successfully**. This can be evidenced by the fact that last column in the error report only contains ER.36 and values of type 'N/A'. In this case, capture the ER.36 errors in an Excel or CSV file and submit it as a ticket to [EMA Service Now: https://support.ema.europa.eu/](https://support.ema.europa.eu/), and then **resubmit the part of the file containing values 'N/A'**.
>   ▪ In the second case, **some updates have been processed successfully**. This can be evidenced by the fact that last column in the error report contains ER.36 values and values of the type 'Database updated - Submission 0000 - Product 00000'. In this case, just capture the ER.36 errors in an Excel or CSV file and submit it as a ticket to [EMA Service Now: https://support.ema.europa.eu/](https://support.ema.europa.eu/). No need to resubmit the part of the file containing values type 'Database updated - Submission 0000 - Product 00000'.
>
> o Once the errors of type ER.36 have been addressed, incorporate the AvS of those products into the next submission, and if you again receive any error repeat all the above steps.
>
> o Over time, as ER.36 issues are cleaned up, the size of the carry forward from month to month should diminish in size and eventually disappear.

4.3.2. Business Validations

Error code	Description	Error message while submitting the file
ERR.01	Package is not under User's responsibility.	ERR.01: Package Identifier provided does not belong to a product under the User's responsibility
ERR.02	Product Status is not 'Current' or 'Provisional'	ERR.02: Product Status is not 'Current' or 'Provisional' (Availability status can only be submitted for products with product record status "Current" or "Provisional")
ERR.03	Country Identifier does not exist in RMS list	ERR.03: Country Identifier does not exist in RMS list
ERR.04	Availability status does not exist in RMS list	ERR.04: Availability status does not exist in RMS list
ERR.05	Package Identifier provided does not belong to the country selected	ERR.05: Package Identifier provided does not belong to the country selected
ERR.06	Availability Status Date cannot be set more than current date + 1 day.	ERR.06: Availability Status Date cannot be set more than current date + 1 day.

ERR.11	Products' Marketing authorisation status cannot be 'Revoked' (100000072121), 'Surrendered' (200000010409), 'Suspended' (100000072122) or 'Expired'(100000072100)	ERR.11: Authorisation status cannot be 'Revoked', 'Surrendered', 'Suspended' or 'Expired' (Availability status can only be submitted for products with Authorisation status 'Valid' or 'Pending').
ERR.20	Package Identifier provided was deleted.	ERR.20: Package Identifier provided was deleted

5. MAH Product Grouping

This section describes how MAHs can group different, but related products within the UPD, similar to the grouping of products within the previous PSUR process.

Important note: It is strongly recommended that MAHs review the training webinar (event page link here) on this topic before performing product grouping in the UPD.

This functionality enables users to combine safety information for similar EEA products (and similar non-EEA products via the third country product name submission) in the EVVet datawarehouse queries, increasing the statistical power and decreasing the administrative burden for all stakeholders involved. In addition, this will simplify and reduce administrative burden for MAHs with the submission of Signals and Annual Statements in IRIS, as well as the submission of non-EEA sales data and third country product names within the UPD.

While this functionality was not envisaged in the Regulation and therefore is not mandatory for MAH to use, for the reasons above and the benefit of the MAH involved and other stakeholders, it is very strongly recommended that all MAHs do consider using this functionality for all of the their products (the only exception where there would not be added value would be where a product is only authorised in 1 EEA country and not authorised in any other/third country).

During the product grouping process, the following two operations do not necessarily need to take place sequentially in the UPD, however, it is highly recommended to perform the initial extraction, to verify the latest UPD product(s) version as well as preventing potential process failure.

- **Download of product grouping data**: The MAH can download a structured CSV file from the UPD portal. This file shall include a portfolio of all Permanent Identifiers under the user's responsibility.

- **Submission of product grouping data**: The MAH should submit a structured CSV file, previously completed by the user, to the UPD portal. Information on how to complete the file is provided in the next sections.

5.1. MAH Product Grouping data fields

This section describes the mandatory and optional fields related to the grouping of products process, represented by the "Conformance" attribute. The data downloaded from the UPD which are optional for the submission step (section 5.2.2) are meant to assist on a better understanding of the data presented.

5.1.1. Product identifier

The product identifier is applicable to all veterinary medicinal products created in the UPD regardless of the type of the authorisation procedure. For products registered by European procedures (MRP, DCP and/or SRP) it is common to all authorisations in the Reference Member State and Concerned Member States, in addition to e.g., the common authorisation procedure number. It enables linking of products based on the common/European data set.

It is applicable to all veterinary medicinal products submitted into the UPD regardless of the type of the authorisation procedure.

Tag	Description
User Guidance	The product identifier as assigned by the UPD.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Identifier (max. 4000 characters)
Value(s)	ID generated by the system. MedicinalProductDefinition.identifier.system value is "http://ema.europa.eu/fhir/vmpId"

5.1.2. Product name

Tag	Description
User Guidance	The veterinary medicinal product name (invented name, strength, pharmaceutical dose form), as indicated in the relevant section of the corresponding SPC or other regulatory document, in line with the local language of the country where the product is authorised.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	string (maximum length: 4000 characters)
Value(s)	The full veterinary medicinal product name as free text.

Example(s): Metacam 5 mg/ml solution for injection

5.1.3. Permanent identifier

As defined in point 3.1 of Annex III of Commission Implementing Regulation (EU) 2021/16, a Permanent Identifier (or Permanent ID) is a unique identifier of the veterinary medicinal product in the UPD. This Permanent Identifier differentiates between the veterinary medicinal products authorised in multiple Member States from the same MRP/DCP or SRP (same Product ID (Level 1). It is generated based on the Product ID (Level 1) with the addition of the national information as authorised in the country by the relevant competent authority and representing the so-called 'national dataset'.

Tag	Description
User Guidance	The unique identifier of the veterinary medicinal product as assigned by the UPD.

Tag	Description
	The permanent identifier is a mandatory field in the submission file and is validate by the system accordingly.
Conformance	Mandatory
Data Type	id
Value(s)	ID generated by the system

5.1.4. Country

This section describes the country code of the country where the marketing authorisation was granted.

5.1.4.1. Country

Tag	Description
User Guidance	This field indicates a short name[7] of the country where the marketing authorisation was granted. This is not a mandatory field.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Text
Value	Short name as listed in the Country list (RMS list ID 100000000002), for all EEA countries.

Example(s): France, Netherlands

5.1.4.2. Country identifier

Tag	Description
User Guidance	This field indicates a country as an identifier. Country identifier is an optional field in the submission file.
Repeatable	Yes
Conformance	Optional (if provided it will be ignored by the system)
Data Type	CodeableConcept
Value	As listed in the Country list (SPOR RMS list ID 100000000002) for all EEA countries. In case MS Excel is used for modifying CSV files, the Number format should be used without decimals.

Example(s): 100000000529 (Spain)

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[7] The short name of the country can be found in the RMS list under the column name "Term short name".

5.1.5. Procedure type

Tag	Description
User Guidance	The type of procedure (EU medicinal marketing authorisation approval routes) through which the initial marketing authorisation was granted by the regulatory authority.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	CodeableConcept
Value(s)	Short Name as listed in <u>EU Regulatory Authorisation Procedure</u> (100000154442).

Example(s): DCP

5.1.6. Authorisation Procedure Number

The procedure number assigned by the competent authority to a specific authorisation/registration procedure.

Tag	Description
User Guidance	Number of the initial procedure for marketing authorisation.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Identifier
Value(s)	The procedure number is specified as free text (max. 4000 characters) but formatted as: CC/V/nnnn/sss or EMEA/V/C/nnnnnn for the core part.

Example(s): SE/V/1111/003, DE/V/1111/001, EMEA/V/C/001234

5.1.7. MAH Product Group Identifier

Tag	Description
User Guidance	The MAH Product Group Identifier is defined and provided by the MAH user: it is used by the system to link similar products. Guidance for assessment of similar products can be found in VICH GL24 (https://vichsec.org/en/guidelines/pharmacovigilance/vich-gls-24-29-35-42.html)
Conformance	Conditional. When the value is left blank, the product is deleted from the group.
Data Type	String (max. 4000 characters)
Value(s)	The naming convention for the MAH Product Group Identifier is defined by the reference ORG-ID, which must be one of the user's affiliations, followed by a hyphen (-), and the desired MAH variable product group name or

Tag	Description
	reference number. The system supports special characters, as per UTF-8 standard.

Example(s): ORG-100033055-Simparica_Ext

5.2. Product Grouping data file structure

5.2.1. Download Product Grouping data file

The Marketing Authorisation Holder shall be able to download a structured CSV file from the UPD portal. This file includes the portfolio of products which are under the user's responsibility, including the relevant data stored in the UPD.

The download file is composed of the fields below. All fields are automatically pre-filled by the System (highlighted in bold) according to the rules described in section 5.1.

1. **Product Identifier**
2. **Product Name**
3. **Permanent Identifier**
4. **Country**
5. **Country Identifier**
6. **Procedure type**
7. **Authorisation Procedure number** (Blank when empty)
8. **MAH Product Group Identifier** (Blank when empty)

The CSV files exported from the UPD use a comma as field separator. The handling of the downloaded CSV files depends on the regional settings used on the computer of the end user. Windows computers with, e.g., a regional setting from a European country is often using semicolons instead of commas to separate the fields of a CSV file. For more information, please refer to Annex A.

5.2.2. Submission of Product Grouping file

The submission file must be submitted in a CSV file format. Further details on how to verify the format of the file are described in section 5 of Annex A.

The submission file is composed of the fields below: the order of the columns and names of the column headings must follow the structure below with the content of fields 3 and 8 validated as mandatory to be provided by the user (highlighted in bold below). As previously described in 5.1.7. MAH Product Group Identifier, field 8 should be submitted empty/blank in order to ungroup a product, therefore, the submission of an empty value is also processed by the system.

Data in other columns 1-2, 4-7, do not need to be resubmitted and can either be left blank or information can be included which helps the MAH (e.g., Country name in the Country column).

1. Product Identifier
2. Product Name
3. **Permanent Identifier**
4. Country
5. Country Identifier
6. Procedure type
7. Procedure number
8. **MAH Product Group Identifier**

Once the initial MAH Product Group Identifiers have been set up, then products which do not have a group identifier can be easily identified by filtering the CSV download file for blank values in the MAH Product Group Identifier column. Products with existing MAH Product Group identifiers should be deleted from the upload CSV file and only those with new Product Group Identifiers submitted. (To keep this clean, and to aid the performance of other actions linked with the MAH Product Group Identifier, it may help MAH to ensure that all products in the UPD have a group identifier even if there are no other similar EEA or non-EEA products – although this is not mandatory).

5.2.3. Changing a MAH Product Group Identifier

MAH can change the product group identifier for a product or group of products by submitting a new MAH Product Group Identifier – which will overwrite existing values.

Following the same overwrite approach, when a product or a group of products need to be deleted from a MAH Product Group Identifier, the correspondent MAH Product Group Identifier (column 8) cell(s) must be submitted blank/empty to the portal. The UPD interprets this action as a deletion of the linkage between the submitted product(s) and the MAH Product Group Identifier.

For cases where a MAH sells a product to another MAH, once the relevant NCA launches the corresponding transfer of ownership process in UPD, the system will automatically ungroup the divested product from any other similar products still owned by the original MAH in the EEA or non-EEA.

5.3. List of validations on the submission file

This section describes technical and business validation rules for the submission file. During the submission process, the system verifies the data provided in the CSV file generating error messages per each row, if applicable.

5.3.1. Technical validations

Error code	Description	Error message while submitting the file
ER.01	Wrong file format. A CSV file is needed.	ER.01: Only CSV file format is allowed. Submit option not available for other file formats
ER.03	Different header column names expected	ER.03: Header column names are not as expected according to Vet EU IG Chapter 7
ER.04	Different number of columns expected	ER.04: The number of columns provided is not correct according to Vet EU IG Chapter 7.
ER.30	Permanent Identifier cannot be empty	ER.30: Permanent Identifier cannot be empty
ER.31	File size limit exceeded	ER.31: File limit (10MB) exceeded

5.3.2. Business validations

Error code	Description	Error message while submitting the file

ERR.02	Product Status is not 'Current' or 'Provisional'	ERR.02: Product Status is not 'Current' or 'Provisional'.
ERR.33	Product is not under User's responsibility.	ERR.33: Product is not under the User's responsibility.
ERR.35	Product grouping naming convention not as expected according to Vet EU IG Chapter 7	ERR.35: Product grouping naming convention not as expected according to Vet EU IG Chapter 7.
ERR.36	The ORG-ID referenced in the MAH Product Group Identifier is not under the User's responsibility.	ERR.36: The ORG-ID referenced in the MAH Product Group Identifier is not under the User's responsibility.

6. Third Country Product Names

This section describes how MAH can add or update third country product names for products that belong to the User's organization. The submission of third country product names can be performed in two different ways:

- By submitting the information against a MAH Product Group Identifier, impacting all the products conforming the group of interest.

- Or, in the case MAH third country product name(s) require mapping to MAH owned EEA products not currently within an MAH product Group (see 5 above), then all relevant third country product names should be submitted against the Product Identifiers of all relevant MAH owned EEA products (note: this is a reason why MAH product grouping is strongly recommended - as it avoids this repeated submission and maintenance of the same data set)

The process of provisioning the third country product names consists in the following two steps:

- **Download of Third country product names**: This step is not mandatory but highly recommended as it allows the user to verify the current information in UPD related to the third country product names. The MAH can download a structured CSV file including the user's portfolio.

  Related to the rows generated for representing the user's portfolio, when a product is assigned to a group via the MAH product grouping (process described in Section 5), the system will not generate a row for each individual EEA product, instead, EEA products belonging to a group will solely be represented by the MAH Product Group Identifier:

  - If a MAH product group does not have any third country product names already assigned, the system will show an informative row for the relevant MAH Product Group Identifier.

  - If a MAH product group already has third country product names assigned, there will be as many rows as third country product names provided for the group.

  As per the rows generated for products not belonging to any MAH product group, the system will represent the product(s) at the EEA product permanent identifier level:

  - If a (non-MAH grouped) EEA product does not have any third country product names assigned, the system will show an informative row for the relevant product.

  - If a (non-grouped) EEA product already has third country product names assigned, there will be as many rows as third country product names provided for the relevant product.

- **Submission of Third country product names**: The Marketing Authorisation Holder shall submit the information related to third country product names in a structured CSV file to the UPD portal (information on how to complete the file is provided in the next sections).

Important notes:

It is recommended that MAH's include all relevant third country product names whether these are fully authorised/registered in the third country or not (e.g. import permit, conditional licence or do not require a registration in the third country).

6.1. Third country data fields

This section describes the fields related to the submission of Third Country product names. For each of these fields, the attribute "Conformance" included in all the tables within this section will indicate whether they are mandatory, conditional or optional. Part of the fields downloaded from the database in the CSV file whose submission is optional (see section 6.2.2 for more detail), are meant to assist users on a better understanding of the data presented.

6.1.1. MAH Product Group Identifier

Third country product names can be submitted at MAH Product Group identifier or Product identifier level, depending on whether the product is within a group or not. Therefore, in the download file this column will be populated if there is any MAH Product Group identifier already submitted to the portal. In the submission file, a MAH Product Group Identifier or a Product Identifier is mandatory to be provided. The MAH Product Group Identifier field is also repeatable as each Group can have more than one third country product name.

Tag	Description
User Guidance	The MAH Product Group identifier has been assigned by the User following specifications for the Product grouping management in the section 5 of this guide.
	If the products to which a name is to be associated are already within a MAH Product Group identifier, then the provision of this field is mandatory to assign, edit or delete third country product names assigned to that group. The system performs validations whether all the products within the group belong to the user responsibility.
	If the products to which a third country product name is to be associated are not linked to a MAH Product Group identifier, then this field is blank in the download file.
Repeatable	Yes
Conformance	Conditional
Data Type	String (max. 4000 characters)
Value	The MAH Product Group identifier obtained from the UPD system.

Example(s): ORG-100001772-CYLAP HVD,

6.1.2. Product Identifier

Third country product names are submitted at Product Identifier level whenever the product is not within a MAH Product Group. Therefore, in the submission file, a Product Identifier is mandatory to be provided for products that are not included in MAH Product Groups. The Product Identifier field is also repeatable as each Product can have more than one third country product name.

Tag	Description
User Guidance	The Product identifier is generated by the UPD and assigned by the system. The Product identifier is a mandatory field in the submission file whenever a product is not included in a MAH Product Group. The system will automatically assign the third country product names to the permanent identifiers under the submitted product identifier for which the user is responsible for. Product identifier will be available in the download file if the product does not belong to any MAH Product Group Identifier.
Repeatable	Yes
Conformance	Conditional
Data Type	Identifier (max. 4000 characters)
Value	ID generated by the system. MedicinalProductDefinition.identifier.system value is "http://ema.europa.eu/fhir/vmpId"

Example(s): 011f12bf-b267-4ce5-a7d2-1084bfc5d367, 01e08e9d-fa3f-4a1b-b588-2037a10bce5f

6.1.3. Product name

Tag	Description
User Guidance	The veterinary medicinal product name (invented name, strength, pharmaceutical dose form), as indicated in the relevant section of the corresponding SPC or other regulatory document, in line with the local language of the EEA country where the product is authorised. EEA product names are recorded in the UPD by Competent Authorities at the time of the product creation.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	String (maximum length: 4000 characters)
Value(s)	The full veterinary medicinal product name as free text.

Example(s): Metacam 5 mg/ml solution for injection

6.1.4. Country

This section describes the EEA country where the marketing authorisation was granted.

Tag	Description
User Guidance	This field indicates a short name[8] of the EEA country where the marketing authorisation was granted. This is not a mandatory field.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Text
Value	Short name as listed in the Country list (RMS list ID 100000000002), for all EEA countries.

Example(s): France, Netherlands

6.1.5. Permanent identifier

As defined in point 3.1 of Annex III of Commission Implementing Regulation (EU) 2021/16, a Permanent Identifier (or Permanent ID) is a unique identifier of the veterinary medicinal product in the Union product database. This Permanent Identifier differentiates between the veterinary medicinal products authorised in multiple Member States from the same MRP/DCP or SRP (same Product ID (Level 1).

Tag	Description
User Guidance	The unique identifier of the veterinary medicinal product as assigned by the UPD. Permanent Identifier will be available in the download file if the product does not belong to any MAH Product Group Identifier.
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Identifier (max. 4000 characters)
Value(s)	ID generated by the system

Example(s): 600000239090, 600000242073

6.1.6. Third country product name

The provision of the third country name is mandatory when trying to submit, edit or delete third country product names.

Tag	Description
User Guidance	The name of the veterinary medicinal product authorised in a country which is not a member of the European Economic Area.
Repeatable	Yes
Conformance	Mandatory
Data Type	String (max. 4000 characters)

---

[8] The short name of the country can be found in the RMS list under the column name "Term short name".

Tag	Description
Value	The relevant third country product name as free text. The system supports special characters, as per UTF-8 standard.

Example(s): CYLAP HVD, CYLAP RCD VACCINE

6.1.7. Third Country identifier

Tag	Description
User Guidance	This field indicates the third country, for which the product name(s) is/are submitted. Country code is a mandatory field. It can be repeatable depending on the number of different product names for applicable product. Country identifier is a mandatory field in the submission file. The system only accepts RMS terms having as Extended Attribute[9]; Country Grouping equal to "non-Eeuropean Economic Area – non-EEA".
Repeatable	Yes
Conformance	Mandatory
Data Type	CodeableConcept
Value	As listed in the Country list (RMS list ID 100000000002)

Example(s): 100000000354 (Canada), 100000000361 (Republic of Chile)

6.1.8. Third Country Name

Tag	Description
User Guidance	This field indicates a short name[10] of the non-EEA country for which the product name(s) is/are submitted. This is not a mandatory field. It can be repeatable depending on the number of different product names for applicable product.
Repeatable	Yes
Conformance	Optional (if provided it will be ignored by the system)
Data Type	Text
Value	As listed in the Country list (RMS list ID 100000000002)

Example(s): Canada (100000000354), Chile (100000000361)

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[9] All RMS Terms from SPOR – Referentials Management System are defined by a set of attributes: Identifier, Operational Attributes, Term Name, Status, Short Name, Domain, Mapping, Data Classification and Extended Attributes. The Country Grouping is a representative Extended Attribute from the Country RMS terms available in the Country RMS list.

[10] The short name of the country can be found in the RMS list under the column name "Term short name".

6.1.9. Delete

This column is to define the action the user wants to undertake, per row, at the submission file. This is always empty for a download file but must be defined for a submission file. The user can add new third country product name(s) for a MAH Product Group identifier or a Product Identifier assigning the value *FALSE* to the column Delete. If the user needs to remove or rename an existing third country product name, the value to be assigned to the column Delete for that specific row must be *TRUE.*

Tag	Description
User Guidance	Delete column is mandatory to define the action, add or remove, of a third country product name, per row. For updating a third country product name, the record to be renamed should be submitted with "Delete=True", and the new desired name of interest should be submitted in a separate row with "Delete=False".
Repeatable	Yes
Conformance	Mandatory (for submission file)
Data Type	Binary (True or False)
Value	True = to remove an existing third country product name. False = to add a new third country product name to a MAH Product Identifier or to a Product Identifier (if the Product Identifier does not belong to a MAH Product Group Identifier). It is case insensitive.

Example(s): True, TRUE, False, FALSE

6.2. Third country data file structure

6.2.1. Download Third Country Product Names file

The Marketing Authorisation Holder shall be able to download a structured CSV file from the UPD portal. This file includes the portfolio of products which are under the user's responsibility, including all relevant third country product names submitted to the UPD.

The download file is composed of the fields below. Fields 1 to 8 are pre-filled by the System (highlighted in bold), according to rules described in the introduction of section 6. Field 9 is always empty in the download file.

1. **MAH Product Group Identifier**
2. **Product Identifier**
3. **Product Name**
4. **Country**
5. **Permanent Identifier**
6. **3rd country product name**
7. **3rd country identifier**
8. **3rd country name**
9. Delete

The CSV files exported from the UPD use a comma as field separator. The handling of the downloaded CSV files depends on the regional settings used on the computer of the end user. Windows computers with, e.g., a regional setting from a European country is often using semicolons instead of commas to separate the fields of a CSV file. For more information, please refer to Annex A.

6.2.2. Submission Third country product names file

The submission file must be submitted in a CSV file format. Further details on how to verify the format of the file are described in section 5 of Annex A.

The submission file is composed of the fields below: the order of the columns and names of the column headings <u>must</u> follow the structure below.

- Content of fields 1 or 2, are mutually exclusive, one of them must contain data.

- Content of fields 6, 7 and 9 are validated as mandatory to be provided by the user.

- Data in columns 3,4,5 and 8 do not need to be submitted, can either be left blank or information can be included which helps the MAH (e.g. country name in the Third country name column).

1. **MAH Product Group Identifier**
2. **Product Identifier**
3. Product Name
4. Country
5. Permanent Identifier
6. **3rd Country Product Name**
7. **3rd Country Identifier**
8. 3rd Country Name
9. **Delete**

6.2.3. Uploading or updating Third country product names

MAH can upload third country product names or update (rename) or delete existing ones against a Product identifier or a MAH product group identifier. The user specifies these actions to the system through the column *Delete* in the CSV file. This column only accepts two values, true or false, and it enables MAHs to perform the following actions:

- If the MAH wants to submit a new non-EEA product name, a row with the new record should be submitted with Delete = False. The system will store the new third country name to the group or product of interest.
- If the MAH wants to delete a non-EEA product name stored for a group or a product, a row with this third country name record should be submitted with Delete = True. The system will erase the existing third country name of interest from the relevant group or product of interest.
- If the MAH wants to update/rename a non-EEA product name stored for a group or a product, two different rows should be submitted to result in an update operation; the old record to be renamed should be submitted with "Delete=True", and the new desired name of interest should be submitted with "Delete=False"

These actions can be submitted simultaneously within the same submission file.

6.2.4. Changes to MAH product grouping when possessing Third country product names

- UPD will automatically perform certain actions when a MAH Product Group Identifier has already Third country product names stored in the database, and the composition of the MAH Product Group varies as a result of products additions and deletions to the group. If a product or group of products are successfully submitted to a MAH Product Group Identifier (section

5.2.2), and the system recognizes that the group already has Third country product names assigned to it, the UPD will automatically link the Third country product names to the new product(s) conforming the group. MAHs are not requested to resubmit this information in a later stage.

– If a product or group of products are deleted from a MAH Product Group Identifier (section 5.2.3), and the system recognizes that the group already has Third country product names assigned to it, the UPD will automatically unlink the Third country product names to the product(s) removed from a group. MAH are not requested to resubmit this information in a later stage.

6.3. List of validations on the submission file

This section describes technical and business validation rules for the submission file. During the submission process, the system verifies the data provided in the CSV file generating error messages per each row, if applicable.

6.3.1. Technical validations

Error code	Description	Error message while submitting the file
ER.01	Wrong file format. A CSV file is needed.	ER.01: Only CSV file format is allowed. Submit option not available for other file formats.
ER.03	Different header column names expected.	ER.03: Header column names are not as expected according to Vet EU IG Chapter 7.
ER.04	Different number of columns expected.	ER.04: The number of columns provided is not correct according to Vet EU IG Chapter 7.
ER.32	Group Identifier OR Product Identifier must be populated. Cannot have both empty.	ER.32: MAH Product Group Identifier OR Product Identifier cannot be empty.
ER.33	Both Group Identifier AND Product Identifier both populated. Cannot have both with data.	ER.33: MAH Product Group Identifier AND Product Identifier cannot be simultaneously provided in the same row.
ER.34	Delete column is empty.	ER.34: Delete field cannot be empty.
ER.35	3rd Country Product Name cannot be empty.	ER.35: 3rd Country Product Name cannot be empty.
ER.37	3rd Country Identifier cannot be empty.	ER.37: 3rd Country Identifier cannot be empty.

6.3.2. Business validations

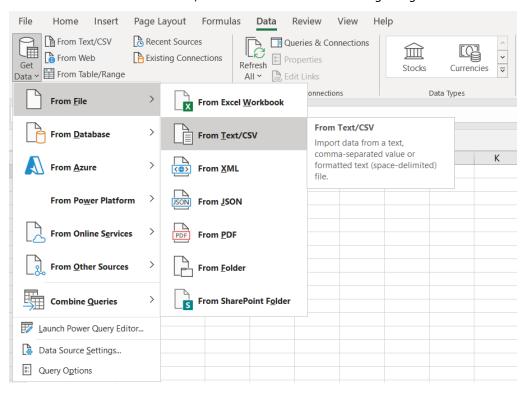| Error code	Description	Error message while submitting the file
ERR.02	Product Status is not 'Current' or 'Provisional'	ERR.02: Product Status is not 'Current' or 'Provisional'.
ERR.03	Country Identifier does not exist in RMS list	ERR.03: Country Identifier does not exist in RMS list.
ERR.25	Group Identifier exists in the UPD.	ERR.25: MAH Product Group Identifier does not exist in the UPD.

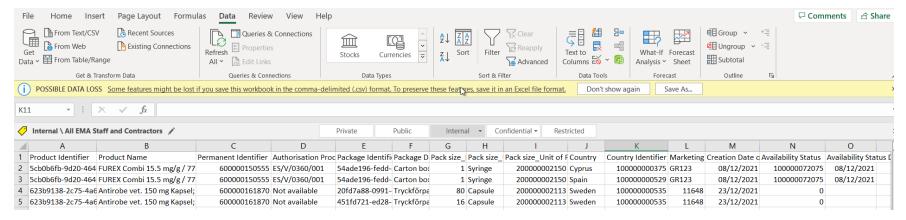| ERR.26	User is not affiliated to the Organization Identifier linked to the MAH Product Group Identifier.	ERR.26: Product(s) comprising the MAH Product Group Identifier is/are not under User's responsibility.
ERR.27	3rd Country Identifier RMS does not have the extended attribute of country grouping as non-European Economic Area - non-EEA.	ERR.27: 3rd Country Identifier is not an RMS term with a non-EEA recognized Identifier
ERR.28	3rd data set is not associated to the Product Identifier (when delete=TRUE)	ERR.28: 3rd country data submitted for deletion does not exist for the Product Identifier of interest.
ERR.29	3rd data set is not associated to the Group identifier (when delete=TRUE)	ERR.29: 3rd country data submitted for deletion does not exist for the MAH Product Group Identifier of interest.
ERR.33	Product is not under the user's responsibility	ERR.33: Product is not under the User's responsibility.
ERR.37	Product identifier is associated to a MAH Product Group Identifier. User can submit 3rd country data to a product identifier, when the product has no group assigned	ERR.37: Product Identifier belongs to the MAH Product Group Identifier "*Identifier of interest*". Consider submitting 3rd Country product names against the group.

Annex A

1. How to check if the format of the downloaded CSV file is correct

Depending on the configured region in the windows installation and mainly due to different decimal separators, the downloaded templates cannot be properly opened as excel files and all data split across the specified columns.
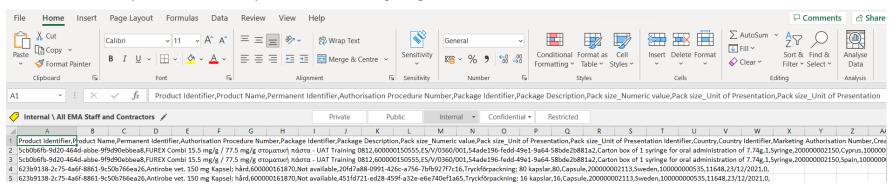
A. In order to check this, the downloaded comma separated values (CSV) files should be right-clicked and opened as Excel file (if it is not possible to directly open it as an Excel file). It is highly recommended to open a CSV file by using the Excel menu option Data → Get Data → From File → From Text/CSV as shown in the following image

B. A correctly delimited file should open as in the following image:

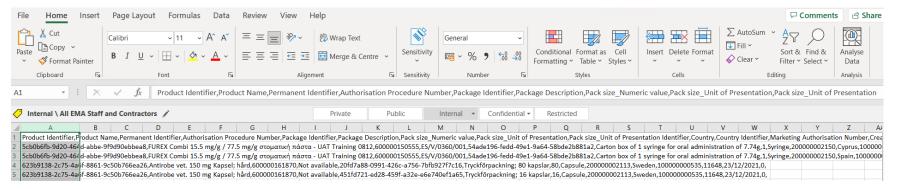C. An incorrectly delimited file will open as in the following image:

D. As you can see the first file has data in clearly separated columns whereas in the second case all data are packed in the first column (column A). As the first case does not need any modifications, we are going to focus on how to upload a comma separated values (CSV) file that is downloaded and then opened in Excel as it is depicted in the second case.
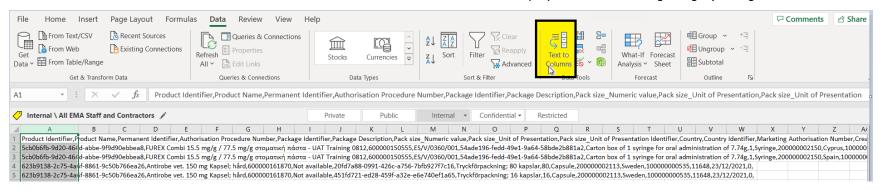
2. How to change the format of an incorrectly formatted comma separated values (CSV) file

In case the downloaded comma separated values (CSV) file is presented as in the second case of the above section then perform the following steps:
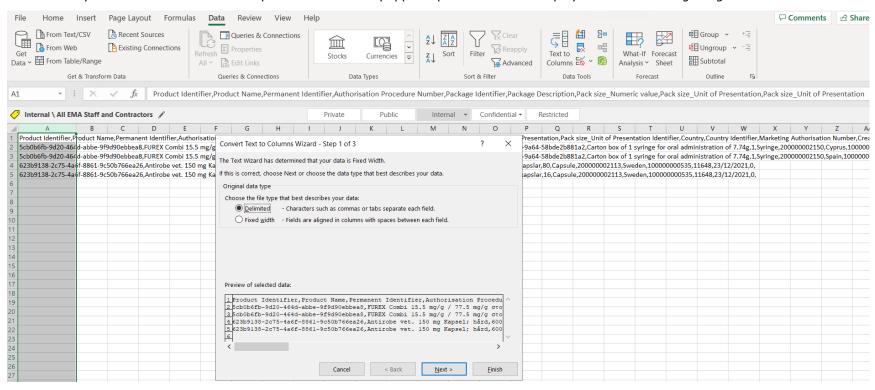
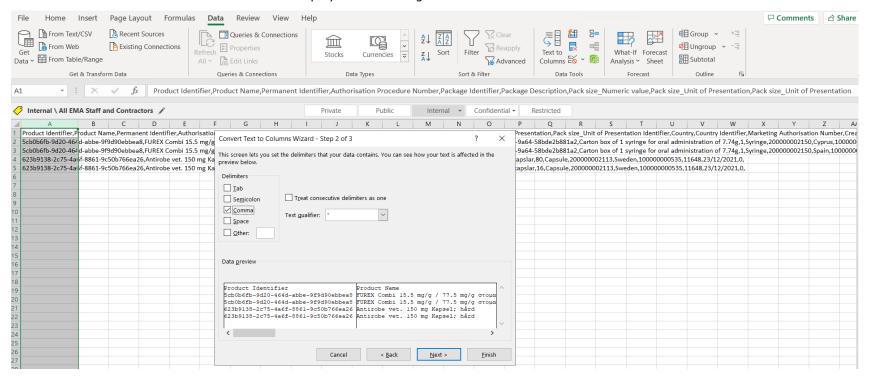A. Select Column A as it is displayed in the following image:

B. Press "Data" menu and then select "Text to Columns" in the ribbon as it is displayed in the following image (having Column A still selected):
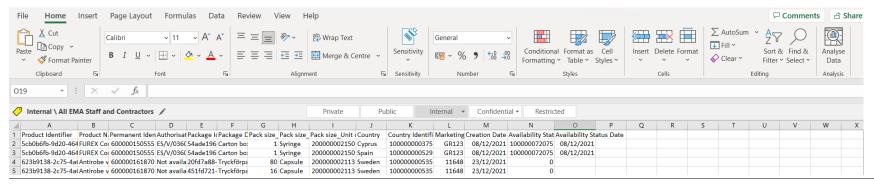
C. Verify "Delimited" is selected and press "Next" in the popped-up screen as it is displayed in the following image:

D. Uncheck "Tab" and check "comma" as displayed in the image below:

E. Press "Next" and then "Finish" to complete the conversion. The result should be a correctly delimited Excel file as it is displayed below:
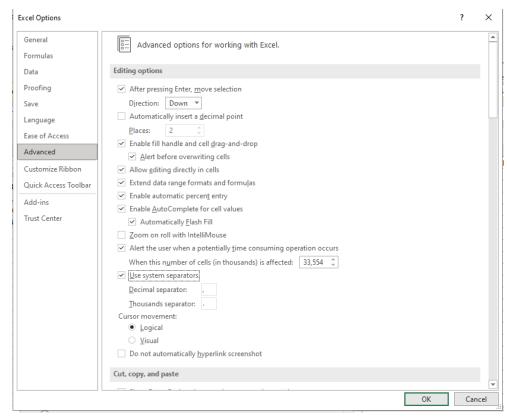
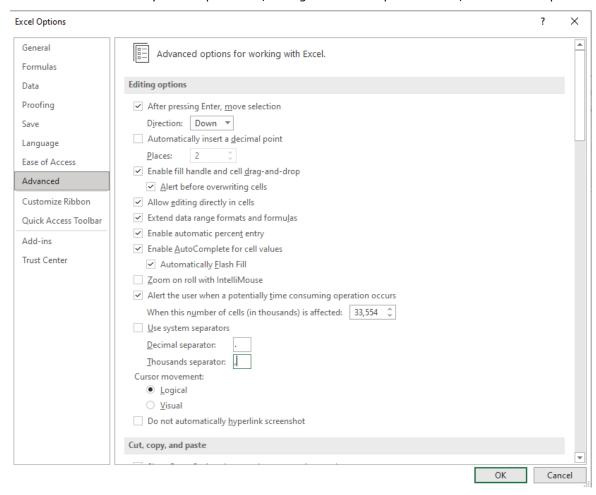### 3. How to change the Decimal and Thousands separator in MS Excel

As soon as the format is fixed and the comma separated values (CSV) file is properly delimited, the Decimal and Thousands separators should be changed. Otherwise, Excel will replace ',' with ';' as soon as save is pressed.

The following steps should be performed:

A. Navigate to File → Options in Excel;

B. Select Advanced as it is shown in the following image:

C. Uncheck "Use system separators", change Decimal separator to '.', Thousands separator to ',' and press "OK" button to proceed:
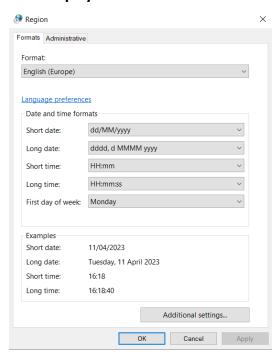
4. How to change the default Date format for your workstation

In case the date format displayed for CSV files opened with MS Excel application, is not the desired one, please perform the following steps:

A. Click the Windows Start button at the bottom left corner of your screen

B. Click on the Settings

C. From the Region tab, select the "Additional date, time & regional settings"

D. Select the "Change date, time or number formats" option

E. The Region window will open as shown below, from where you can define the date format.

Important note: Please not that this change to the date format will affect how all dates will be presented in your computer and not only the ones displayed in the MS Excel file.

5. How to check the correct format of the submission file

Please note that when converting an Excel or other spreadsheet file type into the CSV format, the correct type of CSV file format must be chosen: "CSV UTF-8 (Comma delimited) (*.csv)".

When an Excel file is converted back to a CSV file, the file format can be checked by opening the file in a simple text app such as Notepad to ensure that it is commas (without surrounding spaces) which separate the values. If creating a CSV file, from for example a database, ensure that this program does not create invalid values e.g., on the last line. If a Windows computer was used where the setting for the list separator was not set to comma, then it will be necessary to replace the list separator with Notepad to comma. You can use the default available "Replace" functionality and select to use any separator character to comma as depicted below