Veterinary Medicines Division
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Union Product Database (UPD) -Webinar on Product Grouping and 3rd country Product Names held on 18 September 2023

Questions and Answers

Disclaimer

This Questions and Answers (Q&As) document is for information only and it is based on questions raised during the UPD Webinar on Product Grouping and 3rd Country Product Names held on 18 September 2023. Nothing in this document should be taken as an explicit commitment on behalf of the EMA, or the UPD product team.

For convenience, many technical terms are explained in the table of abbreviations at the beginning of this document.

For general queries on UPD, including questions on guidance, scheduled deployments, bug fixes, Volume of Sales, please contact the Agency via AskEMA: Send a question to the European Medicines Agency. For any UPD technical issues, errors in the system, inability to log in, and expired passwords, please submit a ticket via ServiceNow.

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Acronym key and glossary terms

DWH	Data Warehouse
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
EVVET	EudraVigilance Veterinary
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
NZ	New Zealand
OPAD	Other Post-Authorisation Data
Q&A	Questions & Answers
UPD	Union Product Database
VMP	Veterinary Medicinal Product
VNRA	Variations not requiring assessment
VoS	Volume of Sales

1. Questions on Product Grouping

1.1. When a product grouping is completed in UPD, is it available for all MAH users in an organisation? For example, if one team member would like to submit a VNRA, and another member would like to submit sales data, can the same grouping be used by both?

The product grouping functionality enables users to combine safety information for similar EEA products (and similar non-EEA products via the 3rd country product name submission) in the EVVET DWH 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 3rd country product names within the UPD.

In other words, at present the product grouping will be primarily used for EVVET DWH queries and indirectly for Volume of Sales when submitting data for non-EEA products.

Please note that it is not possible to submit VoS data against a product grouping and for the time being it is not possible for users to submit VNRA submissions based on the submitted MAH Product Group Identifier. For further key advantages from the product grouping, please see slide 7 of the UPD webinar presentation.

1.2. How quickly is the MAH product grouping in UPD reflected in EVVET DWH?

The Product Grouping in UPD will normally be reflected in EVVET DWH the next day, or within a maximum of 2 days from submission.

1.3. What are the criteria for product grouping? (e.g., same active substance, same strength)

The MAH Product Group Identifier is defined and provided by the MAH user: it is used by the system to link similar products. The definition of VMP is available in section III of VICH GL24 PhV - Management of ADRs (step 7) (europa.eu).
A "similar pharmaceutical VMP" is defined as:

- originating from the same MAH being responsible for pharmacovigilance of this/these VMPs,
- the same active ingredients,
- major excipients with the same or similar pharmaceutical function,
- at least one common registered species.

1.4. When can a MAH start running their EVVET DWH queries based on MAH Product Grouping? Does this require 3rd country product name submission? If not, how do 3rd country products get linked to a MAH product group?

It is recommended that both Product Grouping and 3rd Country Product Names are submitted before using the Product grouping functionality in the EVVET DWH. Once these actions have been performed, MAHs can use the product grouping filter to run signal searches. This search should be no worse than the current short name or product name searches and over time as the third country product names are increasingly implemented by the EVVET team, such searches should improve in reliability and quality.

1.5. Does product grouping relate to the submission of Volume of Sales? Is it is required for 3rd country sales submission?

The product grouping functionality enables users to combine safety information for similar EEA products (and similar non-EEA products via the 3rd country product name submission) in the EVVET DWH queries, increasing the statistical power and decreasing the administrative burden for all stakeholders involved. In addition, this functionality aims at simplifying and reducing 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 3rd country product names within the UPD.

In other words, at present the product grouping will be primarily used for EVVET DWH queries and indirectly for VoS when submitting data for non-EEA products.

VoS data cannot be submitted against the product grouping, therefore, in this sense, product grouping and submission of VoS data are not related. However, it is very strongly recommended that all MAHs do consider using this functionality for all their products (the only exception where there would not be added value would be where a product is only authorised in one EEA country and not authorised in any other/3rd country). Please refer to VET EU IG Chapter 7, sections 5 and 6 for further guidance.

2. Questions on 3rd Country Product Names

2.1. What should be done in case of non-EEA products registered in markets that do not perform pharmacovigilance? Should they be added to UPD, or not?

From VET EU IG Chapter7, section 6: Important notes: It is recommended that MAHs include all relevant 3rd country product names whether these are fully authorised/registered in the 3rd country or not (e.g. import permit, conditional license or do not require a registration in the 3rd country). MAH responsibilities for 3rd country adverse event reporting include reporting relevant adverse events which come to the MAH's attention, from all countries (including those without local pharmacovigilance legislation) and submission of the 3rd country product name will improve the accuracy of product mapping in these situations.

2.2. What 3rd country names should be included? The ones that sell the specific product, or the ones in which the product is registered?

From VET EU IG Chapter7, section 6: Important notes: It is recommended that MAHs include all relevant 3rd country product names whether these are fully authorised/registered in the 3rd country or not (e.g. import permit, conditional license or do not require a registration in the 3rd country).

2.3. Can you explain the two different ways 3rd country product names can be submitted?

Information on 3rd country product names is available VET EU IG Chapter7, section 6.

The submission of 3rd 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 3rd country product name(s) require mapping to MAH owned EEA products not currently within an MAH product Group, then all relevant 3rd country product names should be submitted against the Product Identifiers of all relevant MAH owned EEA products (note: this is the reason why MAH product grouping is strongly recommended - it avoids the repeated submission and maintenance of the same data set).

2.4. Is the 3rd country product name always necessary, or just when the drug name is different between countries?

MAH should include all relevant 3rd country product name combinations, whether these are fully authorised/registered in the 3rd country or not (e.g. import permit or conditional license or other regulatory approaches may not require a registration in the 3rd country).

2.5. Who will be responsible for the creation of 3rd country product data? The webinar presentation seems to be working from the assumption that data is already in the UPD.

MAH are responsible for the initial submission and later maintenance of 3rd country product names via the relevant OPAD submenu.

2.6. In order to develop our systems, can you provide guidance on how to upload 3rd country sales in the future?

Information on possible options/calculations to represent the 3rd country sales in the reporting file is available in VET EU IG Chapter7, section 2.1.14.

2.7. Will the update of 3rd country product names impact the recording of cases in EVVET? And if so, would this be for new cases only or retrospectively?

Yes, it will impact the recording of cases in EVVET retrospectively, for all cases related to the product.

2.8. Our company has a sister company (different company that sells the same product) located in Australia, who is the Marketing Authorisation Holder for the product in many countries such as Australia, NZ and Japan. How should we proceed?

Product names should be submitted if both companies are part of the same group. Non-EEA sales for the products sold in those countries should be submitted, selecting one or more EEA Package Identifier existing in UPD and that matches with those products.

2.9. Can you please explain in more detail how establishing MAH product grouping/3rd country names will reduce admin burden with regards to the submission of non-EEA sales data? E.g., what is the impact on volume of sales upload file?

The Product grouping functionality serves the purpose to link similar products.

UPD does not contain non-EEA packages information, so the 3rd country product names functionality will fulfill this need. During the submission of 3rd country product names, a MAH can submit against a Product Identifier, or in case of existing groups, against a Group Identifier and in this case, all the 3rd countries are linked to each one of the products belonging to the Group Identifier. When submitting VoS for non-EEA packages, the Package Identifier is either a Package Identifier from a product within the Group Identifier or one or more Package Identifier(s) from the specific product for which the non-EEA sales are being reported. Selecting 1 Package Identifier belonging to a Group Identifier decreases the number of rows to be submitted for non-EEA sales.

Refer to VET EU IG Chapter7, section 2.1.14 for guidance with examples.

2.10. How should we manage a product in a 3rd country that is registered and sold by another company simply because local laws require that? Are these products to be included in the EU group counterpart?

Yes, these products shall be included in the EU group counterpart as they belong to company portfolio even when they are registered under another organisation. The UPD does not verify the organisation(s) under which non-EEA products for which non-EEA sales and 3rd country product names are to be provided are registered.

However, in a different situation (i.e. not required by local laws) where there is a relationship between two different MAHs where the second MAH sources the product

from the first MAH and the MAH for the product is the second MAH, then each MAH is responsible for the necessary actions for their own products only.

2.11. It was understood that only EU sales should be submitted for 2022. Please clarify whether this is correct, and whether 2023 VoS data should include sales for 3rd countries.

This is correct, for the 2022 calendar year, only EU sales need to be submitted (however, MAH can still submit non-EEA sales – for example as part of system validation exercises). For further details, please see the recording of webinar held on 24 April 2023 (Union Product Database: Submission of volume of sales data). The functionality for 3rd country product names was released on 15 September 2023 and the deadline for submission of sales data for the calendar year of 2023 is the end of February 2024. Therefore, the submission of sales data for the calendar year of 2023 must include sales for 3rd countries.

2.12. Should non-EEA product names which are not registered in a 3rd country but imported by Import-Licence via an EEA MA reported on?

It is strongly recommended that MAHs include all relevant 3rd country product names whether these are fully authorised/registered in the 3rd country or not (e.g. import permit, conditional license or do not require a registration in the 3rd country). For more information, please review the section *6. Third Country Product Names* in the VET EU IG Chapter7.

2.13. Will retrospective mapping of 3rd country product names create false signals during next year signal detection in the DWH due to historic (remapped) cases?

Mapping all 3rd country product names will increase the statistical power of the DWH, as all relevant data for a product will be available for analysis. Accurate mapping of data should reduce the overall false signal rate (caused by 3rd country products being incorrectly mapped). It is acknowledged that different results may be received for a previous time period, but the intent is to improve the accuracy of the signal detection calculations.