EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Union Product Database Webinar for Marketing Authorisation Holders

Product Grouping and Third Country Product Names
18 September 2023

Presented by Beyhan Mustafov, UPD Product Owner, EMA
Presented by Laura Descalzo, UPhV Product Owner, EMA
Presented by Ana Vicente, Business Analyst Lead, EMA

An agency of the European Union

Welcome

Beyhan Mustafov, UPD Product Owner, EMA

Welcome and housekeeping notes

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Welcome and housekeeping notes

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1

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Webinar's Agenda

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Demonstrate how Marketing Authorisation Holders can submit annual volume of sales data in UPD

1	**Introduction** **14:00 – 14:05**	Beyhan Mustafov, *UPD Product Owner*
2	**Product grouping and third country product names** **14:05 – 14:40**	LauraDescalzo, *UPhV Product Owner* Ana Vicente, *EMA Business Analyst Lead*
3	**Q&A Session** **14:40 – 14:55**	All
4	**Closing** **14:55 – 15:00**	Beyhan Mustafov, *UPD Product Owner*

Importance of product grouping and 3rd country product names

Laura Descalzo, UPhV Product Owner, EMA

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VGVP on Signal Management – Grouping products

Guideline on veterinary good pharmacovigilance practices (VGVP) Module: Signal Management

2.4. Signal detection

If a marketing authorisation holder is responsible for the same or similar veterinary medicinal products in different Member States authorised through different authorisation procedures, signal detection and the signal management process shall be performed by grouping all products considered the same or similar

Why is product grouping important

Product grouping should lead to an overall reduction in administrative burden for nearly all MAHs.
For this reason, it is strongly recommended that MAHs apply appropriate product groups to all their products.

Key advantages

Will (soon) be able to run signal detection in EVWEB datawarehouse based on product group name

Will only need to submit third country sales data ONCE for a whole product group

Linking product grouping and third country product names should increase accuracy of signal runs

Simplifies process and will only need to submit third country product names ONCE to the product group

Will (soon) be able to submit signals in IRIS based on product group name (won't need to manually select products)

Will (eventually) be able to submit VNRAs in UPD using the product group name

Will (soon) be able to submit annual statements in IRIS based on product group name (won't need to manually select products)

Once set up – will only need to amend product groups as new products appear in UPD

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Third country sales data

Once the MAH has performed **product grouping,** they should **submit third country sales data for 2022**

Please review the relevant sections of **Chapter 7**

MAH only need to submit **third country sales data to one member of a product group**

MAH can either **map third country packages** to existing UPD packages **for the selected product** or, if appropriate, map **all third country sales** data to a single UPD package for the selected product

Why are product grouping and 3rd country names needed?

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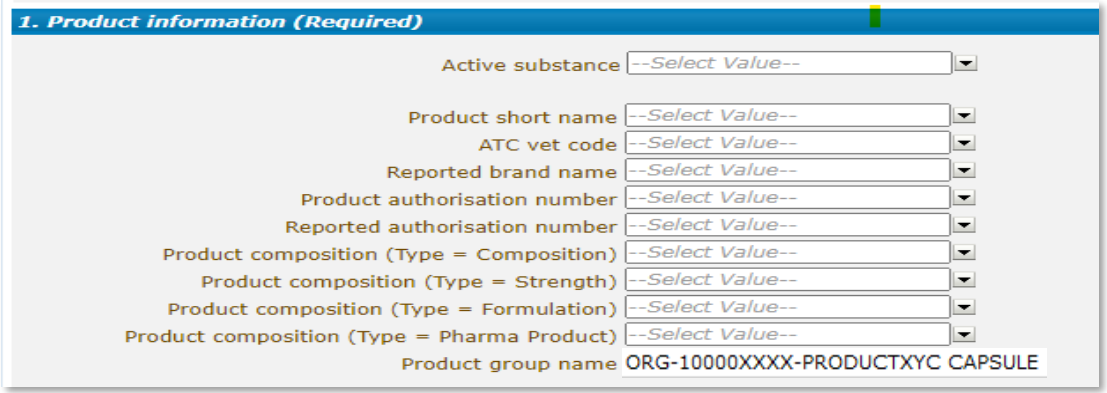
Product grouping will enable MAHs to group as 1 entry similar products that should be analysed together for signal detection, but may have multiple Product Short Names:

Product group name	Medicinal Product Name	Medicinal product shortname	Authorisation country
ORG-10000XXXX-PRODUCTXYC CAPSULE	PRODUCTX 150 MG - KAPSELN FÜR HUNDE	PRODUCTX	Austria
	PRODUCTX 150 MG CAPSULE, HARD	PRODUCTX	Ireland
	PRODUCTX 150 MG CAPSULES POUR CHIENS	PRODUCTX	France
	PRODUCTX 150 mg capsules voor honden en katten	PRODUCTX	Netherlands
	YPRODCEW vet. 150 mg Kapsel, hård	YPRODCEW	Sweden
	ISSSKYX 150MG	ISSSKYX	Germany
	UUUYYHH GOUTTES 150 MG	UUUYYHH	France



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Why are product grouping and 3rd country names needed?

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Article 14 - Provision of additional data

"To enable comprehensive analysis of adverse event reports from third countries, marketing authorisation holders shall record in the Union product database the corresponding product names and authorisation numbers for the same product or, if the same product is not authorised in the Union, for a similar product authorised in the Union, as defined in the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) Guideline. Marketing authorisation holders shall update the information when necessary."

Submission of the 3rd country names will enable linking AE reports from 3rd countries to the relevant EEA product for grouped analysis:

Product group name	Medicinal Product Name	Medicinal product shortname	Authorisation country	3rd country product name	Country
ORG-10000XXXX-PRODUCTXYC CAPSULE	PRODUCTX 150 MG - KAPSELN FÜR HUNDE	PRODUCTX	Austria		
	PRODUCTX 150 MG CAPSULE, HARD	PRODUCTX	Ireland	Isskyx 150 mg capsules for dogs	United Kingdom
	PRODUCTX 150 MG CAPSULES POUR CHIENS	PRODUCTX	France		
	PRODUCTX 150 mg capsules voor honden en katten	PRODUCTX	Netherlands		
	YPRODCEW vet. 150 mg Kapsel, hård	YPRODCEW	Sweden		
	ISSSKYX 150MG	ISSSKYX	Germany		
	UUUYYHH GOUTTES 150 MG	UUUYYHH	France		

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Demo: product grouping and third country product names (UPD version 1.6.34)

Ana Vicente, Business Analyst Lead, EMA

Takeaway messages - MAH Product Grouping

- **It is very strongly recommended that all MAHs do consider using this functionality for all their products** as **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
- This functionality will allow MAH to group different but related products within the UPD, **similar to the grouping of products within the previous Periodic safety update reports** process
- The conditions to be met for products to be considered "similar" are defined in the **VICH guideline 24 (Pharmacovigilance)**, section III.1

Related to the **submission of MAH Product Grouping**:

- For users **developing systems to submit MAH Product Groupings**, it is essential that the file your system produces does display the mandatory data (exact copies of all column headings in the correct order and completion of the **mandatory fields** (Permanent Identifier and MAH Product Group Identifier)) → all data should be correctly formatted and follow the business rules identified in **chapter 7 – Vet EU IG**, and issues such as an extra line in the file (see later for an example) must be avoided.

	A	B	C	D	E	F	G	H
1	Product Identifier	Product Name	**Permanent Identifier**	Country	Country Identifier	Procedure type	Procedure number	**MAH Product Group Identifier**
2	632c465c-521f-41df-8208-4d7c1f103d74	inativada para prevenção da doença vírica hemorr	600010555727	Portugal	100000000501	National Procedure	N/A	ORG-100001772-CYLAP HVD
3	83d6ce05-b618-44b0-bbc0-788db782b2d8	CYLAP H.V.D. emulsione iniettabile per conigli	600010555733	Italy	100000000430	National Procedure	N/A	ORG-100001772-CYLAP HVD

- You do not need data in the columns which are not mandatory (A, B, D, E, F and G) – but also you may find it useful.

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Takeaway messages - MAH Product Grouping

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- In relation to the provision of MAH Product Grouping, a MAH can perform the following actions:
  - **Create a new group or add a product to an existing group** by adding the MAH product group identifier in the corresponding row/product of interest
  - **Delete an existing group or delete a product from a group** by deleting the MAH product group identifier from the corresponding row/products of interest
  - **Update an existing group** renaming the MAH product group identifier, the system will overwrite the previous record stored
- The **naming convention for the MAH Product Grouping identifier** is described in the Vet EU IG – chapter 7, section 5.1.7.
- When submitting the MAH Product Grouping file, the **time to completion of the business validation** will depend on server load. It may be better, especially for large files to come back and look again in a few hours.
- If there are **errors in your submission file**, the system will generate an **error report** containing an error message at the end of each row where it has encountered an issue. The chapter 7 - Vet EU IG contains the complete list of errors that might occur.
- **A single error prevents the data upload of the whole submitted CSV file**, so it is essential that a complete corrected file is resubmitted. These errors all need resolving and then the complete upload file should be resubmitted. Alternatively, you can delete in a consistent way the rows that are giving errors and send the data that is correct, handling the errors afterwards.
- **MAH changes**: if the MAH changes e.g. sale of a product to another MAH, then the existing product grouping for the affected product(s) will be automatically deleted when the MAH is changed in the UPD. However this also means that if the MAH changes the MAH for another reason (e.g. reorganisation / rationalisation of MAHs) then the MAH product grouping will also need to be reapplied.

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Takeaway messages - Third country product names

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- **It is strongly recommended that all MAHs** submit Third country product names data **once** Product Groupings have been created in UPD

Related to the **submission of the Third country product names**:

- The **information contained in the Download file** for Third country product names will be presented in the following order:
  - ✓ First, EEA products without group and with no Third country product names
  - ✓ Second, EEA products without group with Third country product names
  - ✓ Third, groups without Third country product names
  - ✓ Finally, groups with Third country product names
- For users **developing systems to submit Third country product names**, it is essential that the file your system produces does display the mandatory data (exact copies of all column headings in the correct order and completion of the **mandatory fields** (Either Group Identifier or Product Identifier, 3rd Country Product Name, 3rd Country Identifier and Delete)) → all data should be correctly formatted and follow the business rules identified in **chapter 7 – Vet EU IG**, and issues such as an extra line in the file must be avoided.

	A (either A or B)	B	C	D	E	F	G	H	I
1	Group Identifier	Product Identifier	Product Name	Country	Permanent Identifier	3rd Country Product Name	3rd Country Identifier	3rd Country Name	Delete
2		1f0aab26-6ec6-4bac-813f-c6e9cdf8ea56	DCP webinar 5mg/tablet			Webinar new name for DCP product	100000000556	United Kingdom	FALSE
3	ORG-100001772-CYLAP HVD					CYLAP HVD	100000000556	United Kingdom	FALSE
4	ORG-100001772-CYLAP HVD					CYLAP RCD VACCINE	100000000329	Australia	FALSE
5	ORG-100001772-CYLAP HVD					CYLAP RCD VACCINE	100000000482	New Zealand	FALSE

- You do not need data in the columns which are not mandatory (C, D, E and H) – but also you may find it useful.
- The **3rd Country Product Name** value accepts all the characters under the **UTF-8 standard**.

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Takeaway messages - Third country product names

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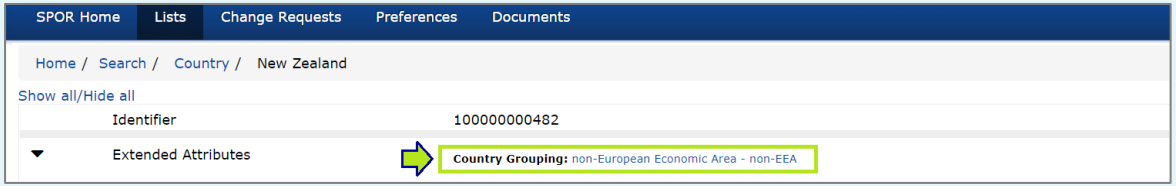
- The **3rd Country Identifier** must be a value from **the RMS list ID 100000000002**. Only terms having the Extended attribute **Country Grouping** equal to "**non-European Economic Area – non-EEA**" will be accepted by the system (see example).



- The column delete only accepts two values, **TRUE** or **FALSE / true** or **false** (case insensitive).
- In relation to the provision of Third country product names, a MAH can perform the following actions:
  - **Provide a new name** by setting up the value in the *column Delete* to FALSE
  - **Delete an existing name** by setting up the value in the *column Delete* to TRUE
  - **Replace an existing name** by first, deleting the existing name and second providing the new name
- When submitting the Third country product names, the **time to completion of the business validation** will depend on server load. It may be better, especially for large files to come back and look again in a few hours.
- If there are **errors in your submission file**, the system will generate an **error report** containing an error message at the end of each row where it has encountered an issue. The chapter 7 - Vet EU IG contains the complete list of errors that might occur.
- **A single error prevents the data upload of the whole submitted CSV file**, so it is essential that a complete corrected file is resubmitted. These errors all need resolving and then the complete upload file should be resubmitted. Alternatively, you can delete in a consistent way the rows that are giving errors and send the data that is correct, handling the errors afterwards.

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Q&A Session

14:40 – 14:55

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How to find information and User support

Beyhan Mustafov, UPD Product Owner, EMA

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Industry supporting materials

- Bite size videos published on the EMA website
- Webinars and training activities on the EMA website

- UPD Release notes
- UPD Implementation Guide VET EU IG (revised Chapter 7 updated on 15/09/23)

- Quarterly system demo - 21/09/23 EMA website

- List of contacts per NCA published on the CMDv website

Please share this information within your network

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Industry support channels and VoS deadline reminder

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UPD provides dedicated User support

Issue Type	Channel
System-related and product/procedure specific issues	EMA ServiceNow
General queries	AskEMA

Urgent notice regarding the Volume of Sales submission deadline

- **The deadline for submission of sales data for the calendar year 2022 ended on 30 June 2023**. We strongly encourage MAHs to submit this data without further delay.
- **The deadline for submission of sales data for the calendar year of 2023 is the end of February 2024**. Subsequently, the deadline for the annual Volume of Sales submission will be also at the end of February of each following year.

Thank you!

Further information

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