

## Union Product Database Webinar for Marketing Authorisation Holders

Submission of volume of sales data 24 April 2023

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





### Welcome

Beyhan Mustafov, UPD Product Owner, EMA

#### Welcome and housekeeping notes





Please note that **this session is being recorded** and **will be made available** through **EMA Corporate Website.** 

If you are experiencing video or audio issues, first please exit the meeting and log in again.

Make sure you selected the correct audio outputs.

Should you continue experiencing issues, please contact <u>virtualmeetings@ema.europa.eu</u>

Throughout the session, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.

Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the <u>EMA Data</u>

<u>Privacy Statement for Slido</u>.

#### Welcome and housekeeping notes



Join via QR code or slido.com

Join at slido.com
#3024 790

Send or upvote the questions
you want to hear answered

Questions will be shown on the screen and managed live in the Q&A session



Questions not addressed during this session may be addressed in subsequent webinars and/or in FAQ document

### Webinar's Agenda





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

Introduction 14:00 – 14:05 Beyhan Mustafov, UPD Product Owner

Submission of volume of sales data and most common issues reported to Service Desk 14:05 – 14:40

Ana Vicente, EMA Business Analyst Lead

Q&A Session 14:40 - 14:55

All

Closing 14:55 - 15:00

Beyhan Mustafov, UPD Product Owner



# Demo: end-to-end flow of submission of annual VoS (UPD version 1.6.24)

Ana Vicente, Business Analyst Lead, EMA

#### Scenario 1



#### Submission of annual VoS for a product authorised under national procedure



- 1 Download VoS file
- 2 Prepare VoS file for submission (excel)
- 3 Submit VoS file
- 4 Check status VoS submission
- 5 View VoS recorded in UPD



UPD - webinar on VoS for MAHs



### Most common issues reported to EMA Service Desk

Ana Vicente, Business Analyst Lead, EMA

### Most frequent challenges experienced by users



- **Opening the download file of VoS** data may appear corrupt: while for some users the file appears correct by simply double clicking and opening in Excel, for others the file appears corrupt due to the user's regional configuration.
- Submission of **VoS failed ER.04: The number of columns provided is not correct** error mainly caused by Excel corrupting the data when converting to csv format due to user's regional configuration.
- 3 VoS Data format
  - Numbers turned by Excel into scientific notation (e.g. 6E+11 instead of 600000023340)
  - Addition of multiple values in the same cell
  - Empty lines (extra row) after the last row of data, also causing ER.04
  - Use semicolon as separator instead of comma, the accepted separator in csv files
- 4 ) Use of **RMS terms** from the Target Species list instead of terms from <u>Species list</u> (20000000019)

In order to avoid some the aforementioned issues, we strongly recommend to read the Chapter 7 from the Vet EU IG

UPD – webinar on VoS for MAHs

Join at <u>slido.com</u> #3024 790

### Most frequently asked questions by users





1 Accepted **browsers for UPD** (Chrome and Edge)

Reported VoS for packages that were deleted in UPD because were created in error

3 Submission of zero sales

## Takeaway messages (1/2)



The Volume of sales value	for each mont	n MUST	be the same	(do not split the
total sales for a month by the	e different spec	ies)		

	E	K	N	0	Р	Q	R
1	Package Identifier	Country Identifier	Year-Month	Volume of sales	Species Identifier	Species %	Dose Factor
2	5963e6b9-54ad-44c8-abdc-1d3da4402dee	100000000478	2022-01	100	200000000219	70	0.5
3	5963e6b9-54ad-44c8-abdc-1d3da4402dee	10000000478	2022-01	100	200000000232	30	1

#### **Species**

- Species field shall be filled in with one term from the SPOR RMS Species list (20000000019) and **not from** the RMS Target Species list.
- For each of the Species in a package there must be a row in the CSV file except for those species for which no sales were made.
- Species percentage (Species %) for each species for EEA sales should be a number (4 decimal places are allowed between 0 and 100 (do not try and format as a %)
- **No** specific **naming convention is required** for the VoS CSV file
- When submitting the VOS 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 (or even tomorrow).

## Takeaway messages (2/2)



- 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.
- For users developing systems to submit VoS, 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 (package identifier, country identifier and all VoS columns except the optional comments column): 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.

4	r	IV.	N.I.	0	D	0	D		
4	Ė	K	IN	U	Р	Q	K	<b></b>	Mandatory
1	Package Identifier	Country Identifier	Year-Month	Volume of sales	Species Identifier	Species %	Dose Factor		1-4-
2	5963e6b9-54ad-44c8-abdc-1d3da4402dee	100000000478	2022-01	100	200000000219	70	0.5	'	data
3	5963e6b9-54ad-44c8-abdc-1d3da4402dee	100000000478	2022-01	100	200000000232	30	1		

You do not need data in the columns which are not mandatory – but also you may find it useful.

.1 UPD – webinar on VoS for MAHs Join at slido.com #3024 790



## **Q&A Session**

14:40 - 14:55

12 Join at <u>slido.com</u> #3024 790



### How to find information and User support

Beyhan Mustafov, UPD Product Owner, EMA

#### Industry supporting materials





- Bite size videos published on the <u>EMA</u> website
- UPD Introduction webinar for industry



- UPD Release notes
- UPD Implementation Guide VET EU IG
- UPD Implementation Guide revised Chapter 7 (v.1.4) will be published within the next couple of days



- UPD industry Q&As (under update)
- Variations not requiring assessment Q&As
- Variations requiring assessment Q&As
- Worksharing of variations requiring assessment Q&As



- Best practice guides from CMDv
- List of contacts per NCA published on the CMDv website

Please share this information within your network

## Industry support channels



#### UPD provides dedicated User support

Issue Type	Channel			
System-related and product/procedure specific issues	<u>EMA Service Desk for UPD</u> ! Very soon to be replaced by <u>EMA ServiceNow</u> !			
General queries	<u>AskEMA</u>			
! On 1 July 2023 vetchange.programme@ema.europa.eu will be discontinued!				

15 UPD – webinar on VoS for MAHs

Join at slido.com #3024 790



## Thank you!

#### Further information

Union Product Database | European Medicines Agency (europa.eu)

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands Send us a question Go to www.ema.europa.eu/contact
Telephone +31 (0)88 781 6000



Classified as public by the European Medicines Ag