



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Union Pharmacovigilance Database

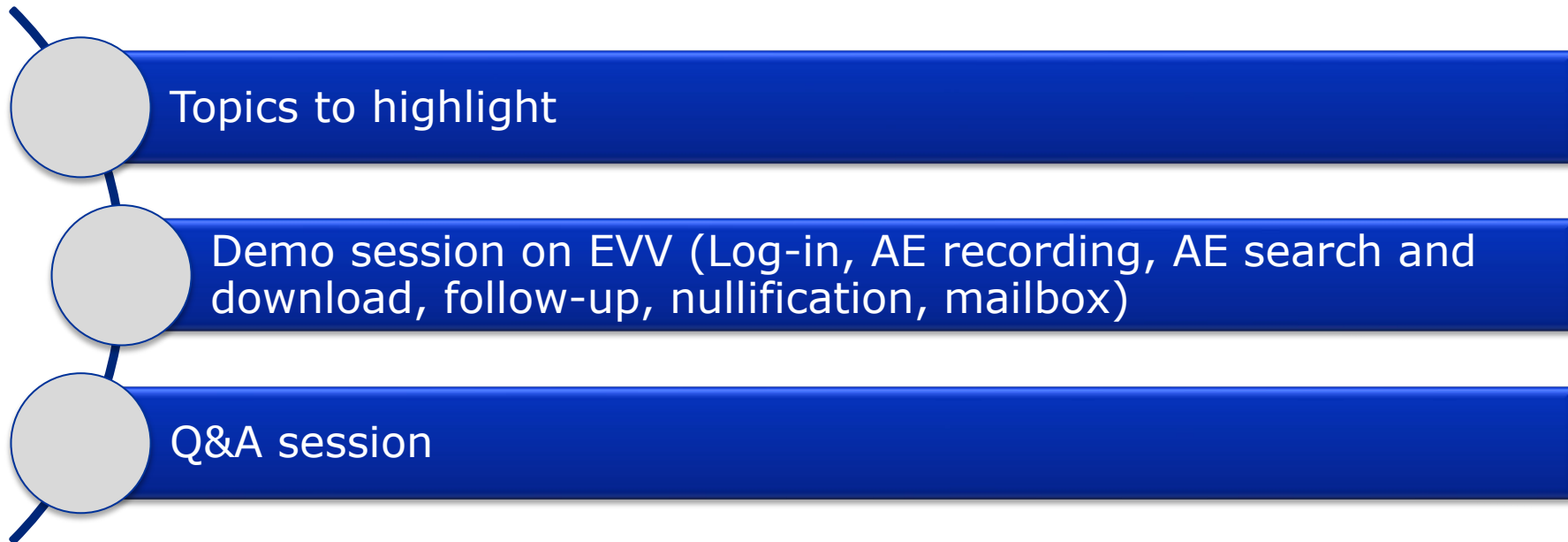
Follow up webinar on collection and recording of suspected adverse events for veterinary medicinal products

Presented by Laura Descalzo on 18 January 2022
Veterinary Risk and Surveillance





Content Summary





Topics to highlight



Unique Adverse Event Report Identification Number (AERID) Regulatory Authority (RA)

- Country of occurrence can only be stated in 1st part of the Unique Adverse Event Report ID Number (AERID). No separate field is available on VICH format.
- The value should follow the format below:

Country of occurrence code (3 digits)–VICH RA Identifier code (8 digits)– Internal case reference code

Example for Danish Agency:

DNK–DNKMEDAG-12345678

VICH RA Identifier Code	RA Name
CZEUSKVB	Uskvbl
DNKMEDAG	Danish Medicines Agency
ESTSAMVP	State Agency Of Medicines
FINAMVET	National Agency For Medicines

<https://www.vichsec.org/en/guidelines/pharmacovigilance/vich-gl30.html>



Unique Adverse Event Report Identification Number (AERID) Marketing Authorisation Holder (MAH)

- Country of occurrence: Same rule as for NCA
- The MAH AERID should follow the format below:

Country of occurrence code (3 digits)-MAHORGID (8 digits)-ROUTINGID + remaining text (up to 47 digits)

MAHs currently registered in EVVET, with an existing Routing(sender) ID that is longer or shorter than 8 digits (and they have not yet been provided a MAHORGID by a different region), will not be able to use it as their MAHORGID, and will need to generate a unique 8-digit MAHORGID from their Routing(sender) ID.

The use of an algorithm (CRC32 Hash Generator) is advised. Various tools are available online. When generating the MAHORGID from the Routing(sender) ID, it is advised to enter the Routing(sender) ID in CAPS. The MAHORGID and the Routing(sender) ID obtained should be used for all AERs.

Example:

For a MAH with the existing Routing(sender) ID "ROUTINGID", following the use of the algorithm to generate the MAHORGID, the AERID for an event that occurred in Germany is as follows:

DEU-A715DE58-ROUTINGIDxxxxx

Further guidance is provided in the EVV Best Practice guide.



How to handle “Unique Adverse Event Report Identification Number” (AERID) when recording AERs in DEG format (1)

- For **NEW** initial AERs recorded in DEG format:
 - the new rules for the creation of the AERID also apply to new AERs recorded in DEG format.
- Example for Danish Agency: **DNK-DNKMEDAG-12345678**



How to handle “Unique Adverse Event Report Identification Number” (AERID) when recording AERs in DEG format (2)

- For **FOLLOW-UPS** to AERs previously recorded in DEG format:
 - It will be allowed for a limited time for the AERID not to fully comply with the VICH format.
- Only requirement: The AERID needs to contain the 2 or 3 letters country code of the country of occurrence at the beginning of the DEG ID. AERs not conforming with this rule should be nullified and a new AER should be created and sent as follow-up.



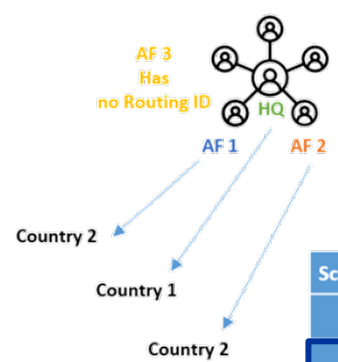
Adverse Event Report (AER): Initial **vs** Follow-up

The AERID from the initial AER should NOT be changed when recording a follow-up AER.

- **Initial AER**
 - Original receive date = Date of receipt of **initial** info from primary source
 - Type of report: Initial
 - Allows calculation of 30 day compliance (calculated from “Message received date”).
- **Follow-up AER**
 - Original receive date should not be changed when recording follow-up reports
 - Type of report: Follow-up

Date of current submission (Most recent info date) for Initial AERs and Follow-up AERs: This is the date when the AER is recorded in EVV.

Access Policy



Scenario	Organisation that logs in EVWEB	Report Sender	Users that want to retrieve data						
	Sender organisation	Reported product	HQ	AF 1	AF 2	NCA C1	NCA C2	External	
1	HQ	Report Product A	L3	L1	L1	L3	L3	L1	
2	HQ	Report Product B	L3	L2	L1	L3	L3	L1	Case 2
3	AF 1	Report Product B	L3	L3	L1	L3	L3	L1	Case 1
4	NCA1	Report Product A	L2	L1	L1	L3	L3	L1	Case 3
5	NCA2	Report Product B	L2	L2	L1	L3	L3	L1	
7	External (To Hierarchy)	Report Product A	L2	L1	L1	L3	L3	L3	
8	External (To Hierarchy)	Report Product B	L2	L2	L1	L3	L3	L3	
9	AF 2	Report Product B	L3	L2	L3	L3	L3	L1	

*HQ will have the highest Access Level of the affiliates

HQ: Actrevo GmbH (ORG-10005776)
AF1: Biomet JSC (ORG-100014159)
AF2: Chemvet dk (ORG-100014420)



Access Policy – Level 2

Who?

- **MAH** - HQ organisations from the hierarchy of the Sender.
- **MAH** – AF organisation from the sender’s hierarchy and owner of the reported product.

Restricted information:

- Following fields are restricted for Level 2 (EXAMPLE):

VICH	Data Element	Accessible
A.1.	Regulatory Authority (RA)	
A.1.1	RA Name	Y
A.1.2	Street address	N
A.1.3	City	N
A.1.4	State/County	N
A.1.5	Mail/Zip code	N
A.1.6	Country	Y
A.2.1	MAH Information	
A.2.1.1	Business Name	Y
A.2.1.2	Street address	N
A.2.1.3	City	N
A.2.1.4	State/County	N
A.2.1.5	Mail/Zip code	N
A.2.1.6	Country	N
A.2.2	Person Acting on Behalf of MAH	N

VICH	Data Element	Accessible
A.3.1	Primary Reporter	
A.3.1	Other Reporter	
A.3.1.1	Primary Reporter Category	Y
A.3.1.2	Last Name	N
A.3.1.3	First Name	N
A.3.1.4	Telephone	N
A.3.1.5	Fax	N
A.3.1.6	e-mail	N
A.3.1.7	Business Name	N
A.3.1.8	Street address	N
A.3.1.9	City	N
A.3.1.10	State/County	N
A.3.1.11	Mail/Zip code	N
A.3.1.12	Country	Y
A.4.4	Type of report	
A.4.4.1	Type of submission	N
A.4.4.2	Reason for Nullification	N
A.4.4.3	Type of information in Report	Y
B.7	Supplemental Documents	N



Access Policy – Level 3

WHO?

- **NCA**
- **MAH** – sender
- **MAH** – when it's the HQ from the sender organization

Restricted information:

- No restricted fields for this level permissions



Latest version of the Access policy Documentation can be found in the [EMA website](#)



Access Policy – Level 1

Who?

- **MAH** – external organisations to the hierarchy of the sender
- **MAH** – AF organization from the sender’s hierarchy and not owner of the reported product.

Restricted information:

VICH	Data Element	Accessible
A.1.	Regulatory Authority (RA)	
A.1.1	RA Name	Y
A.1.2	Street address	N
A.1.3	City	N
A.1.4	State/County	N
A.1.5	Mail/Zip code	N
A.1.6	Country	Y
A.2.1	MAH Information	
A.2.1.1	Business Name	Y
A.2.1.2	Street address	N
A.2.1.3	City	N
A.2.1.4	State/County	N
A.2.1.5	Mail/Zip code	N
A.2.1.6	Country	N
A.2.2	Person Acting on Behalf of MAH	N

VICH	Data Element	Accessible
A.3.1	Primary Reporter	
A.3.1	Other Reporter	
A.3.1.1	Primary Reporter Category	Y
A.3.1.2	Last Name	N
A.3.1.3	First Name	N
A.3.1.4	Telephone	N
A.3.1.5	Fax	N
A.3.1.6	e-mail	N
A.3.1.7	Business Name	N
A.3.1.8	Street address	N
A.3.1.9	City	N
A.3.1.10	State/County	N
A.3.1.11	Mail/Zip code	N
A.3.1.12	Country	Y
A.4.4	Type of report	
A.4.4.1	Type of submission	N
A.4.4.2	Reason for Nullification	N
A.4.4.3	Type of information in Report	Y



Who?

- **MAH** - External organizations to the hierarchy of the Sender.
- **MAH** – AF organization from the sender’s hierarchy and not owner of the reported product.

Restricted information:

VICH	Data Element	Accessible
B.2	VMP(s) Data and Usage	
B.2.1	Registered name or Brand Name	Y
B.2.1.2	Registration identifier	N
B.2.1.3	ATCvet Code	N
B.2.1.4	Company or MAH	N
B.2.1.5	MAH Assessment	N
B.2.1.6	RA Assessment	N
B.2.1.6.1	RA Assessment term	N
B.2.1.6.1.1	Explanation Relating to Assessment	N
B.2.1.7	Route of Exposure	Y
B.2.2	Active Ingredient(s)	
B.2.2.1	Active Ingredient(s)	Y
B.2.2.1.1	Numeric Value for Strength (Numerator)	N
B.2.2.1.1.1	Units for Numeric Value for Strength (Numerator)	N
B.2.2.1.2	Numeric Value for Strength (Denominator)	N
B.2.2.1.2.1	Units for Numeric Value for Strength (Denominator)	N
B.2.2.2	Dosage Form	Y
B.2.3	Lot Number	N
B.2.3.1	Expiry Date	N

VICH	Data Element	Accessible
B.3	Adverse Event Data	
B.3.1	Narrative of AE	N
	<i>Rest of fields in section</i>	Y
B.5	Assessment of AE	
B.5.1	Attending Veterinarian’s Assessment of AE	N
B.6	Report Number(s) of Linked Report(s)	
B.6.1	Unique Adverse Event Report Identification Number	N
B.6.2	Explanation for Linkage	N
B.7	Supplemental Documents	
B.7.1	Attached Document Filename	N
B.7.1.1	Attached Document Type	N



EVV Registration

- Updated guidance document will be published at the EMA website (EVV section) [“EMA Eudravigilance Veterinary Registration manual”](#);
- Registered users do not need to re-register;
- **Passwords will need to be reset;**
- The new passwords will need to be used for all other EMA applications;



Interim measures in case not all product data is available in UPD/Not recoded

- For product data not yet included in the UPD or not yet recoded, it **will not be possible to grant L2 access** to MAHs;
- NCAs will forward AERs to relevant MAHs;
- However, EVWEB MAHs will not be able to send follow-ups from their Mailbox;
- Due dates for signal management only for CAPs at least until June 2022;
- For urgent cases needing immediate regulatory action, **MAHs should contact relevant NCA/EMA** to request for the product to be added to the UPD;
- For urgent cases needing immediate regulatory action, if the product is already available in the UPD but the case narrative is not visible, **please contact EMA for recoding prioritisation.**



EVV Demo session



Items for the demo session

- Log-in/ select Organisation;
- Create an initial AER (data entry: number of animals, species and breeds (crossbred/purebred)), product entry (select one product from UPD, one as partial information and one manually typed);
- How to save a partial entry, import and complete it;
- Copy and send more than 1 AERs as a batch;
- Search for a specific AER or search for the batch, search for MAH AERs for a period of time (product level and MAH level);
- Create and send a follow-up AER & nullification;
- Mailbox (find acks).

Any questions?

Further information

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