15 November 2021
EMA/679405/2021
Veterinary Medicines Division

> It is strongly recommended to refer to the VGPV module on collection and recording of
> suspected adverse events for veterinary medicinal products and the relevant documents
> listed in the VGVP module Appendix, for guidance.
> To be noted that EVV is currently under development and further training will be
> provided in January 2022.

List of Q&As received during the webinar training on 10 November 2021: VGVP module on collection and recording of suspected adverse events for veterinary medicinal products & EVV system functionalities

Session 1: Regulatory framework and topics to highlight

1. **What are the species for animals managed as a group?**
   If a suspected adverse event in animals involves more than one species, a separate suspected adverse event report should be recorded in EVV for each species involved. These reports should then be linked.

2. **Do we still follow the EMA Q&A Non-Fatal Serious Guideline to decide if serious or not?**
   The VICH definition of a "serious adverse event" should be followed (please refer to VICH guideline GL24).

3. **Are you intending to provide MAHs with a list of the existing EMA Guidelines/Q&As/Reflection papers/Recommendation papers that remain applicable after 28Jan2022, and which should be considered obsolete?**
   Documentation will be published on EMA website in due course and all documents and guidelines will clearly state their applicability status.

4. **What does "Other" mean for Type of Information in a report (residual violation? environmental problem?)**
   Environmental incidents and residual violation should be recorded under "Other" in the "Type of information" field.

5. **In the LEE report example (30 pigs total), 20 had 2 adverse events and 3 out of 20 also had LEE. Are the 2 adverse events included in the 20, or in the other 10?**
   The 2 adverse events from the example (diarrhoea and vomiting) are related to the 20 animals (please refer to slide 11).

6. **In the example for both LEE and safety, the animals which experienced LEE were not included in the number of animals reacted? When it is only LEE how do you type number of animals reacted?**
   The number of animals can be indicated against each relevant VEDDRA term entered, so they can be differentiated.

7. **For AEs in animals treated with products for human use, how do I select the correct product if products for human use are not in the UPD?**
   Please use the free text option and report the name of the product as exact as possible. There is currently no link to the database for products for human use.

8. **So, the number of animals affected can be higher than the number of animals treated?**
   Yes, for some cases of parent-offspring this would apply.

9. **If signs of anaphylaxis or hypersensitivity are present (vomiting, diarrhoea, dyspnoea etc), but this term was not used in the case narrative, do we still include it in the VeDDRA list?**
   The current published guidance document on the use of VeDDRA terminology (EMA/CVMP/PhVWP/288284/2007-Rev.12) refers to clinical signs for anaphylaxis and anaphylactoid reactions and provides relevant guidance.

10. **The 22 offspring are not taken into account?**
    The 22 aborted offspring should be stated in the case narrative.

11. **Slide 21: 22 offspring to be coded as stillbirth?**
    The 22 offspring are aborted offspring.

12. **Are the scenarios described in slides 24 & 25 only available for EVWEB users, not for Gateway users?**
    The principles on product recording are also applicable to Gateway organisations.

13. **Is there a free text to register the dosage data?**
    No. Please refer to VICH guideline GL42.

14. **The routing ID should be both in the structured field and in the free text?**
    No. The structured part must be 8 characters and some Routing IDs are longer.

15. **Using propofol, the SPC indicates the dose at 1-2 mg/kg, the veterinarian loads the full dose into the syringe but administers it at dose-effect without administering the full amount. Is this situation also considered off-label use?**
    Yes.

16. **What about the cases already registered with the current format of Worldwide case number: will it be possible to submit them after 28/01/2022 in the system? It concerns non serious cases not yet presented in a PSUR.**
    No. New cases submitted as from 28 January 2022 must comply with the new AERID format.

17. **Is it not possible to link the Country of occurrence code with the login, so that it is automatically given?**
    The login country and the country of occurrence are not always the same, therefore this is not possible for MAHs. For NCAs, it is already implemented.

18. **Could you please explain again how to obtain the ROUTINGID?**
    ROUNTINGID is the ID assigned to the organisation when registering to EVV. For the generation of the MAH ID from the ROUNTINGID please refer to the EU AER VICH Implementation Guide, section 3.4.

19. **Nullified duplicates? What if there is additional data in one report not presented in the other?**
    The additional data should be recorded in the report to be kept.

20. **Please could you clarify regarding MAHs existing ROUTINGID - are you referring to the company specific identifier that populates the <messagesenderidentifer> field of an EU-XML generated by the MAH?**
    Yes, which is the one given to the organisation when registering in EVV.

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21. Who will be in charge of the duplicate detection in EVV? And when this research will have to be done?
Once the system goes live on 28 January 2022 there is no duplicate management. The interim procedure stated in the implementation guideline should be followed by all parties. The future solution is still under discussion.

22. WWN has died?
WWN has been renamed to Unique Adverse Event Report Identification number.

23. We use PV Works and will be reporting via the Gateway to EVV. Kindly advise if we will receive reports from the EMA which were reported by other MAHs onto the EVV database that involve one or more of our products?
No. MAHs will need to download these reports from EVWeb.

24. For the case scenario below, what administration start date should be entered for the concerned product? The vet reports that the patient is a dog that was adopted 2 years ago (2019) and since then it has been receiving the same antiparasitic in line with the SPC (continuous treatment). The vet reports that after one administration on 8 Nov 2020 the dog showed diarrhoea for a few days. The dog recovered without treatment. However, after the last dose, which was administered on 9 Feb 2021 the dog showed ataxia.
The administration date recorded in the field "Date of first exposure" should be that of the last dose. The previous administrations and reactions can be recorded under "Previous exposure to the VMP" and "Previous AE to the VMP".

25. What kind of access will have a local country that is not the MAH of the product involved in the AE, but is the legal representative of the HQ (product MAH)?
The question is not entirely clear. Further guidance can be requested through Ask EMA. Please also refer to the guidance documents "EVVET Access policy" and "EMA Eudravigilance Veterinary Registration manual".

26. If an initial case was recorded in EVVET2 and a follow-up is made in EVVET3, do we need to change the AERID/WWCN (from 2 digits to 3 digits?)
The AERID should never be changed, the 2-digit country code will be accepted as from 28 January 2022 (for cases that already exist in EVVet).

27. If an initial case was recorded in EVVET2 (CVMP XML) and a follow-up is made in EVVET3, are we allowed to submit the FU either under CVMP XML format or VICH XML format?
Correct.

28. If an initial case was recorded in EVVET2 (CVMP XML) and a follow-up is made in EVVET3 using the same CVMP XML format, do we have at least to re-code the species and breed values from the VICH list?
No. The current species list can be used.

29. Is it possible to enter a third country registered product in the EVVet3 in case of concomitant use with an EU registered product?
Yes. Please refer to slides 24-26.

30. Are there any time frames for follow-up reports?
The same timeframe (30 days) applies for initial and follow-up reports.

31. Are adverse events observed in Clinical trials to be reported in EVVet3?
AERs originating from clinical studies for authorised VMPs & post-marketing surveillance studies for VMPs should be recorded in EVV within 30 days from the date of the closure of the final study report (please refer to slide 7).

32. If adverse events observed in clinical trials are to be reported in EVVet3, that may initiate a tremendous additional workload since both non-serious and serious adverse events are to be reported. Will any guidelines related to reporting of adverse events in clinical studies be available?

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Please refer to slide 7.

33. **Can you please clarify regarding slide 31. Are you advising that the MAH should assign use of anaesthetic Product A as off-label, if the conditions of use of Product A do not comply with the SPC for Product A and regardless of whether the combination protocol used by the vet is recognised as clinically acceptable?**
Yes, this will be considered off-label use.

34. **If you have been provided with an MAHORGID by a different region; how should you interpret the sentence on slide 33**
If you have been provided with an 8-digit MAH ID by a different region, you can use it.

Session 2: EVV demo

35. **If one is not having access yet to the PV database. how to get new access?**
We will provide further information on this at a later stage.

36. **How to change password?**
We will provide further information on this at a later stage.

37. **How can the MAH obtain the new password?**
We will provide further information on this at a later stage.

38. **EVVet3 will be compatible with Chrome or only with Explorer as EVV2?**
Officially we will support Chrome. We will make our best effort to make it work also on other modern browsers like Edge and Firefox.

39. **Are the technical requirements (e.g. list of compatible web-browers, etc.) described anywhere?**
Officially we will support Chrome. We will make our best effort to make it work also on other modern browsers like Edge and Firefox.

40. **What are the animal's details in case of mother + offspring?**
The number of animals treated should always be the parent. Regarding the number of animals affected, it would depend on whether only the offspring reacted, or on whether the mother also experienced any adverse events.

41. **What is the difference between VICH Batch number and medicine batch number?**
These are not related. The VICH batch is a way of grouping AER messages in one file. The medicinal product batch number is the Lot number.

42. **What about data protection, as lab reports do always contain personal data of the owner?**
No personal data should be included in the AE reports. Any personal data should be anonymised.

43. **Could you go through VICH batch please?**
Please refer to the relevant VICH guideline.

44. **What does VICH Batch Number mean?**
Please refer to the relevant VICH guideline.

45. **Can the message number and batch number be the same?**
Only if the batch only contains one message, therefore we do not recommend this.

46. **If only one AE report is sent, can the VICH batch number be the same as the message number?**
We do not recommend this.

47. **How to create the batch and also the message number? Which guidance we should follow?**

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Please review the VICH guidelines. No specific requirements other than the maximum length.

48. **If only one AE report is sent, can the VICH batch number be the same as the message number?**
    We do not recommend this.

49. **Why do you need to put the start of the postcode in the last name section when it is also going in the address section?**
    It is not necessary to complete the address section, only the country, as it is mandatory.

50. So, **a batch is just like a kind of drawer with several AEs?**
    Yes. we normally refer to it as a bucket or set.

51. **Are the Batch number and Message number something like an internal number, from an organization registry with released documents?**
    Yes. It can be used to manage the message exchange by the organisation.

52. **What is meant by "expedited" in this case?**
    This is per the VICH guidelines. This list, like many others, is defined in VICH guideline GL30.

53. **Why is there an expedited sending possibility if all AERs should be sent within 30 days?**
    This is per the VICH guidelines. This list, like many others, is defined in VICH guideline GL30.

54. **When should periodic report be selected?**
    When reporting to EVV, periodic reports should never be selected.

55. **Do the reports of the VICH batch have to be linked or not necessarily?**
    Not necessarily. The only requirement is that the sender and receiver of the batch must be the same as the sender and receiver of all the messages.

56. **Do I have to save the data in between or is there an automatic saving of entered data?**
    The data is available while the session is active. If you need to stop, you can export the data and re-import it later on and continue with the report.

57. **According to past discussions with EMA and NCAs we have established extrapolation rules internally in order to select a precise presentation (based on animal size, or on sales volumes). What is the recommendation now: keep the extrapolation rules for selecting the product strength or select an imprecise data?**
    The recommendation is not to extrapolate it. Please only record the information that you know.

58. **Time to onset is no longer captured for the different symptoms?**
    Please refer to VICH guideline GL42, section B.3.4.

59. **How can a MAH be sure to identify all cases for an own product, which were sent to EVV by another MAH, when the other MAH has registered the product e.g. under a name with a spelling mistake?**
    Products with spelling mistakes will be manually linked to correct entries in the UPD.

60. **Will there be an export functionality e.g. rtf or pdf that can be used for internal or QC purposes?**
    HTML export will be available and from that users can generate PDFs or copy and paste in a Word file.

61. **After sending a batch, is the system going to send us ack?**
    Yes.

62. **I was entering in Eudravigilance Veterinary, and I got to the old version and not to this new version. The old version only works in internet explorer and the one that we are seeing is in Microsoft edge. Can you please inform what is the correct internet address to Eudravigilance Veterinary.**

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Officially we will support Chrome. We will make our best effort to make it work also on other modern browsers like Edge and Firefox.

63. Is there also a field to show whether it is a safety report from a spontaneous or a non-spontaneous source?
No.

64. Can we search by active substance?
Yes.

65. Is this the interface to use for signal detection?
The signal detection activities are not performed in EVWeb, but in a separate system, the Data Warehouse (DWH). A webinar training showing the function of the DWH will be held on 23-24 November 2021.

66. Please enter also an option to export files as rtf or pdf.
HTML export will be available and from that users can generate PDFs or copy and paste in a Word file.

67. Just xml document? non RTF archive?
HTML export will be available and from that users can generate PDFs or copy and paste in a Word file

68. If we search cases using the field "MAH", are we sure that we will recover reports sent by other MAH as their case may have not documented who is the MAH of our product?
Yes, provided that the product is recoded.

69. From their submission, how long are AEs retained in EVV database?
For ever.

70. When will the test be available for the MAH?
To be defined.

71. When will the System be available for MAHs to enter and practice in it?
To be defined.

72. Is there a standardisation of MAH naming, e.g. due to alignment with UPD? Also, when a brand without strength is chosen from drip-down (as UPD may not contain such an entry?). Otherwise MAH may miss cases.
The MAH names listed when selecting a full product entry from the drop-down list are standardised. If a partial entry has been selected from the drop-down list, the relevant MAH will still be able to retrieve their cases.

73. How does the Mailbox work?
This will be addressed during the webinar training in January 2022.

74. What can we do with the Mailbox in the system?
Check messages that where sent or receive by the organisation as well as Acknowledgements.

75. Day zero is not included to be completed?
Please refer to VICH guideline GL42, A.4.2 Original receive date.

76. Is it possible to transfer XML versions without an own pharmacovigilance database?
This will be addressed during the webinar training in January 2022.

77. Won't there be for example RTF or PDF formats?
HTML export will be available and from that users can generate PDFs or copy and paste in a Word file.

78. What is the definition for a Batch? Which series of reports go into the one batch number?

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Please review the VICH guidelines.

79. In which tab will MAHs perform the signal activities?
The signal detection activities are not performed in EVWeb, but in a separate system, the Data Warehouse (DWH). A webinar training showing the function of the DWH will be held on 23-24 November 2021.

80. Which is the criteria for including several AER in the same VICH batch?
None, the sender and receiver of the batch must be the same as the sender and receiver of all the messages.

81. Are the cases sent by other MAHs sent automatically to Gateway users or should they be searched from EVV?
MAHs will need to download the cases from EVWeb.

82. The MAH will receive a message when another organization sends an AER from one of its VMP?
MAHs will need to actively search and download the cases from EVWeb.

83. Is it possible to use the system with something other than internet explorer?
Officially we will support Chrome. We will make our best effort to make it work also on other modern browsers like Edge and Firefox.

84. Regarding searching for XML reports which may contain our own products (e.g. submitted by other MAH): will we be able to build and maintain a query to identify such reports based on all our global brand names / active ingredients / names of marketing authorisation holders? Else it is not clear how this will work under practical conditions for larger multinational MAHs.
This feature will not be available at the initial release in January 2022. It is possible to search using a MAH filter.

85. Will RTF format be available in addition of xml?
HTML export will be available and from that users can generate PDFs or copy and paste in a Word file.

86. When making the search for cases involving our products, can we select in the search module only the reports that have not been recorded by us, but only the reports recorded by other organisations?
This feature will not be available at the initial release in January 2022. However, it is possible to sort by Sender Organisation.

87. I am also interested to know if we will have RTF format available.
HTML export will be available and from that users can generate PDFs or copy and paste in a Word file.

88. What happens if we use xml import to submit a case report? Do we need to include also a VICH batch number?
Assuming that this refers to the import of a DEG file (current format), the answer is yes, after import all information that is required to make a valid VICH report needs to be filled in.

89. So is every event from the one company, over say a year, to be sent as the same batch?
No. Batches should be kept small and there are documented limits of the size of each batch. Please refer to EU AER VICH Implementation guide.

90. In Unique AER number, e.g. XXX-XXXXXXXX-1234567890, can we add in a last free section (1234567890) symbol like - if we want that last part to be like year and number of reports. Example would be XXX-XXXXXXXX-2022-0001.
Please refer to EU adverse event report VICH Implementation Guide.

91. Difference between VICH batch number and the Unique adverse event identification?
Please refer to the relevant VICH guideline.

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92. **Regarding new password as already registered EVVET user: at the moment you will get access to the EVVET with the EMA account - not only for EVVET also for other EMA applications so if I have to change the password what happens with my EMA account access?**
The access will be the same and you will need to use the new password also on the other applications, same as today in case you change your password.

93. **For Gateway user, will the submission be handled as presented in the "Create and Send" section, or will it be handled directly from the MAH database as currently?**
Similar to the current process. B2B connection via gateway.

94. **Where can we find the CRC32 hash generator? do MAHs have to use it in any case, if the org-id does not have 8 digits?**
The recommendation is to use any available CRC32 hash generator.

95. **Can we export an entered but not yet submitted case, like we can in the human EVWEB?**
Yes.

96. **Could we save entered data if we cannot get to the point of validating and sending?**
You need at least to fill in all mandatory field.

97. **Will there be an additional field in the future to record the fact that a medically Important term (MIE) has been entered as a VeDDRA Low Level Term?**
Not in the AE reporting form. The data analysis system will allow distinguishing the MIE terms.

98. **1. In section where we assign symptoms to number of animals experiencing them, in a case where 1 animal have e.g. recumbency and later died, we need to add 1 animal under recumbency and death or we add two symptoms under that 1 animal? 2. And how does total number of animals reacting calculates it?**
1. One animal per VeDDRA term. 2. The total number of animals reacting is calculated at report level. In some AERs there are also metrics that show the number of animals reacting per VeDDRA term.

99. **Will our current credentials be kept to enter new EVVET?**
Yes. Only the passwords will need to be reset. We will provide further details at a later stage.

100. **A report of an off-label use of a human medicine in a veterinary context, even without an adverse event, connect with information somehow with the human products databases? Would it not be important in PSUR context?**
PSURs will no longer apply as from 28 January 2022.

101. **If a MAH submitted a case that involved a product from other TAC, the other TAC will be notified somehow that they have a new report involving one of their products?**
MAHs will need to actively search and download the cases from EVWeb.

102. **Can we send amendments? As a follow-up?**
Any amendment can be submitted as a follow-up.

103. **For clarification: export of report in printable format required prior to submission?**
The printable format is only available after submission.

104. **How do we (as MAH) receive AE reports from national regulatory authorities? Via the Mailbox (Inbox)?**
MAHs will need to actively search and download the cases from EVWeb.

105. **Re-recoding of product names - will this be done for third country reports?**
Yes.

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106. Will the current EVVet xml format be able to be imported to the UPD? or is it the same format?
    The UPD provides the product data for EVV.

107. How long will the entered data under-Search AE reports-be visible? One month? A half a year? One year? Regarding signal detection periods.
    All reports will be permanently available.

108. Will all the reports already recorded in EVVET2 be re-mapped into VICH format?
    All reports in EVVET2 will be migrated and when accessed via EVWeb can be exported in VICH format.

109. Is it possible to save HTML prior to sending the ADR, to check the information entered?
    The printable format is only available after submission.

110. What is understood by day of first reporting?
    Day zero is the date of receipt of the minimum information for a valid report ("Original Receive Date") by a NCA or a MAH, including a third party (person or organisation) with which the MAH has set up a contractual arrangement, irrespective of whether the information is received during a weekend or public holiday.

111. Will EMA submit reports which have been received by another MAH that involve one or more of our products to us or will we be able to import these manually onto our database?
    MAHs will need to actively search and download the cases from EVWeb.

112. It is very important for MAHs to be able to record pre-defined queries, not only relating to large number of cases to query, but also for large product portfolio, with many different product names to enter for each separate query, to be run daily or weekly.
    This functionality will not be available in EVWeb in January 2022. We have plans to improve the export functionality after that.

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