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Guidance for Industry

Pharmacovigilance of Veterinary Medicinal Products

Data Elements for Submission of Adverse Event Reports

VICH GL42

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only

The objective of this guidance document is to standardize the data for submission of adverse events relating to veterinary medicinal products (VMPs). A consistent set of data will contribute to a harmonised approach for the detection and investigation of adverse effects of marketed VMPs and thus help to increase public and animal health.

Comments and suggestions regarding the document should be submitted to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov/. All comments should be identified with the Docket No. 2006D-0170.

For questions regarding this document, contact Margarita Brown, Center for Veterinary Medicine, (HFV-214), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9048, e-mail: margarita.brown@fda.hhs.gov.

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PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS – DATA ELEMENTS FOR SUBMISSION OF ADVERSE EVENT REPORTS

Recommended for Consultation

at Step 4 of the VICH Process

on 2 November 2005

by the VICH Steering Committee

This Guidance has been developed by the appropriate VICH Expert Working Group and is subject to consultation by the parties, in accordance with the VICH Process. At Step 7 of the Process the final draft will be recommended for adoption to the regulatory bodies of the European Union, Japan and USA.

PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS
Data Elements for Submission of Adverse Event Reports

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

Pharmacovigilance of veterinary medicinal products (VMPs) is important for the continued safety and efficacy of VMPs in use. The objective of this guidance document is to standardize the data for submission of adverse events relating to VMPs. A consistent set of data will contribute to a harmonized approach for the detection and investigation of adverse effects of marketed VMPs and thus help to increase public and animal health.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.[1]

II. Scope

The scope of this guidance document is to describe the specific data elements to be used for the submission and exchange of spontaneous adverse event reports (AER) between marketing authorization holders (MAH) and regulatory authorities (RA). For the purpose of this guidance document, refer to the definitions given in VICH GL 24 (Management of Adverse Event

[1]Under 21 CFR 10.115(i)(3), when issuing draft guidance documents that are the product of international negotiations, FDA need not apply 21 CFR 10.115(i)(2), which states that guidance documents must not include mandatory language such as "shall," "must," "required," or "requirement," unless FDA is using these words to describe a statutory or regulatory requirement. However, any final guidance document issued according to 21 CFR 10.115(i) must contain the elements in 21 CFR 10.115(i)(2). In this draft guidance, any language that is mandatory under U.S. laws and/or regulations is followed by a citation to the appropriate statutory or regulatory provision. In accordance with 21 CFR 10.115(i)(3), any mandatory language in this draft guidance that does not describe a statutory or regulatory requirement will be revised in the final guidance document to comply with 21 CFR 10.115(i)(2).

Reports) under III. For the purpose of electronic reporting, this document should be read together with other relevant VICH guidances.

This guidance document applies also to the minimum information for the collection of the AER information. The mandatory data elements described in this guidance document are required to meet the reporting requirements of 21 C.F.R. 514.80. The MAH will strive to collect the information necessary to complete all the data elements in this guidance document. The submission of unstructured data not described in this guidance document, such as clinical records or images, is outside the scope of this guidance.

III. Format and Description of Data Elements

The data elements are sufficiently comprehensive to cover complex reports from most sources, different sets and transmission situations or requirements. (See 21 CFR 514.80.) Structured data are strongly recommended to facilitate consistent data input, submission, and analysis. Controlled vocabularies and lists of terms have been developed for this purpose (see draft guidance entitled "Pharmacovigilance of Veterinary Medicinal Products: Controlled List of Terms," VICH GL 30). In certain instances, there are provisions for the submission of some unstructured free text items.

Data elements, as defined in this document, should also be translated for electronic transmission of AER information. These issues will be addressed in other separate VICH guidances.

The specific data elements are described below. User guidances are presented *in italics* and notes for the transmission format are included as SMALL CAPITALS. To fill an AER related to human exposure to VMP(s), refer to Appendix 1 entitled *User Guidance for Submission of Human AERs*.

A. Administrative and Identification Information

A.1 Regulatory Authority (RA)

RA name

Street address

City

State/county

Mail/zip code

Country (2 character country codes ISO 3166)

User guidance: Mandatory.[2] *RA where the AER was initially submitted.*

NOTE CONCERNING SUBMISSION: TEXT

A.2 Marketing Authorisation Holder (MAH)

A.2.1 MAH Information

Business name

Street address

City

State/county

Mail/zip code

Country (2 character country codes ISO 3166)

User guidance: Mandatory.[3] *MAH where the AER has occurred*

NOTE CONCERNING SUBMISSION: TEXT

A.2.2 Person Acting on Behalf of MAH

Title

First name

Last name

Telephone

Fax

e-mail

User guidance: Optional.[4] *The person acting on behalf of the MAH is the contact person for this AER and its contents.*

NOTE CONCERNING SUBMISSION: TEXT

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[2] See 21 C.F.R. 514.80.

[3] See 21 C.F.R. 514.80.

[4] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the name and title of the individual responsible for accuracy of reported information.

A.3 Persons Involved in the AER

A.3.1 Attending Veterinarian

First name

Last name

Business name

Street address

City

State/county

Mail/zip code

Country (2 character country codes ISO 3166)

Telephone

Fax

e-mail

User guidance: Optional.[5] *Veterinarian or other health professional. If no attending veterinarian then enter "NONE" in the "First name" field. If attending veterinarian requests not to be identified, then enter "WITHHELD" in the "First name" field. If "WITHHELD" submit veterinarian's geographic information as privacy legislation allows.*

NOTE CONCERNING SUBMISSION: TEXT

A.3.2 Animal Owner

First name

Last name

Business name

Street address

City

State/county

Mail/zip code

Country (2 character country codes ISO 3166)

[5] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the name, address, and phone number of the attending veterinarian.

Telephone

Fax

e-mail

User guidance: Optional.[6] *Animal owner, owner's agent or tender of the animal(s). If animal owner requests not to be identified, then enter "WITHHELD" in the "First name" field. If "WITHHELD" submit animal owner's geographic information as privacy legislation allows.*

NOTE CONCERNING SUBMISSION: TEXT

A.3.3 Primary Reporter Category

User guidance: Mandatory.[7] *The individual/organization providing the primary information for the AER. An Agent acting for the owner will be entered as the animal owner (A.3.2).*

NOTE CONCERNING SUBMISSION: LIST: VETERINARIAN, ANIMAL OWNER, PHYSICIAN, PATIENT, OTHER HEALTH PROFESSIONAL, OTHER

A.4 AER Information

A.4.1 Unique AER Identification Number

User guidance: Mandatory. Globally unique identifier for the AER, designated by the MAH or RA, to be referred to in future follow-ups. Two character country code-MAH or RA initials-unique number (e.g. US-MER-xxxxx, US-FDA-xxxxx)

NOTE CONCERNING SUBMISSION: TEXT

A.4.2 Date AER Received by MAH

User guidance: Mandatory.[8] *Date AER received by MAH.*

NOTE CONCERNING SUBMISSION: DATE FORMAT: DAY, MONTH, YEAR

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[6] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the name or case identification of the owner.

[7] 21 C.F.R. 514.80, through Form FDA 1932, requires the reporter to identify the source and address.

[8] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the date the report was received.

A.4.3 Date of Current Submission

User guidance: Mandatory.[9] *Date current AER submitted by MAH to RA.*

NOTE CONCERNING SUBMISSION: DATE FORMAT: DAY, MONTH, YEAR

A.4.4 Type of Report

A.4.4.1 Type of Submission

User guidance: Mandatory.[10]

NOTE CONCERNING SUBMISSION: LIST: EXPEDITED, PERIODIC, FOLLOWUP, NULLIFICATION

A 4.4.2 Reason for Nullification Report *User guidance: Mandatory if nullification is checked in A.4.4.1.*[11]

NOTE CONCERNING SUBMISSION: TEXT

A.4.4.3 Type of Information in Report

User guidance: Optional.[12]

NOTE CONCERNING SUBMISSION: LIST: SAFETY ISSUE, LACK OF EXPECTED EFFICACY, BOTH, OR OTHER

B. Description of the AE

B.1 Animal Data

User guidance: Except for B.1.1, data relates to the affected animals only.

B.1.1 Number of Animals Treated

User guidance: Optional.[13] *(Estimated) number of animals treated.*

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[9] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the date the report was sent to FDA.

[10] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the type of report.

[11] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the type of report.

[12] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of a description of the adverse reaction.

NOTE CONCERNING SUBMISSION: INTEGER

B.1.2 Number of Animals Affected

User guidance: Mandatory.[14] *(Estimated) number of animals affected in the AER which will also include indirectly exposed animals, e.g. treated during pregnancy or lactation, co-mingled, infectious spread, et cetera.*

NOTE CONCERNING SUBMISSION: INTEGER

B.1.3 Species

User guidance: Mandatory.[15] *In case of human AE, species is "human".*

NOTE CONCERNING SUBMISSION: LIST (TO BE DETERMINED) (INCLUDES HUMAN)

B.1.4 Breed

User guidance: Optional.[16]

NOTE CONCERNING SUBMISSION: LIST (TO BE DETERMINED)

B.1.5 Gender

User guidance: Optional.[17]

NOTE CONCERNING SUBMISSION: LIST: FEMALE, MALE, FEMALE NEUTERED, MALE NEUTERED, MIXED, UNKNOWN

B.1.6 Physiological Status

User guidance: Optional: For male animals select "Not Applicable".[18]

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[13] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the number of animals treated.

[14] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the number of animals that reacted to the drug.

[15] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the species.

[16] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the breed.

[17] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the sex.

[18] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of information about the physiological status.

NOTE CONCERNING SUBMISSION: LIST: PREGNANT-LACTATING, NONPREGNANT - LACTATING, PREGNANT - NONLACTATING, NONPREGNANT - NONLACTATING, MIXED, NOT APPLICABLE, UNKNOWN

B.1.7 Weight

B.1.7.1 Minimum Weight

User guidance: Optional.[19] *For groups of animals, estimated minimum weight of an individual in kilos of the animals affected. For a single animal the weight goes in the minimum weight field.*

NOTE CONCERNING SUBMISSION: NUMBER (2 DECIMALS)

B.1.7.2 Maximum Weight

User guidance: Optional. For groups of animals, estimated maximum weight of an individual.

NOTE CONCERNING SUBMISSION: NUMBER (2 DECIMALS)

B.1.7.3 Exact, Approximate, Unknown Weights

User guidance: Mandatory if minimum or maximum weight is specified.

NOTE CONCERNING SUBMISSION: TEXT LIST: EXACT, APPROXIMATE, UNKNOWN

B.1.8 Age

B.1.8.1 Minimum Age

User guidance: Optional.[20] *(Estimated) Age of the animal(s) affected. For a single animal the age goes in the minimum age field.*

NOTE CONCERNING SUBMISSION: NUMBER

B.1.8.2 Maximum Age

[19] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the weight.

[20] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the age.

User guidance: Optional. For groups of animals, estimated maximum age of an individual.

NOTE CONCERNING SUBMISSION: NUMBER

B.1.8.3 Age Units

User guidance: Mandatory if minimum or maximum age is specified.

NOTE CONCERNING SUBMISSION: LIST: MINUTES, HOURS, DAYS, WEEKS, MONTHS, YEARS

B.1.8.4 Exact, Approximate, Unknown Age

User guidance: Mandatory if minimum or maximum age is specified.

NOTE CONCERNING SUBMISSION: LIST: EXACT, APPROXIMATE, UNKNOWN

B.1.9 Purpose for Use of VMP(s)

User guidance: Mandatory.[21] *The actual reason for use should be noted, not by default the registered indication(s). "Unknown" may be entered if unknown. Single field per AER.*

NOTE CONCERNING SUBMISSION: TEXT

B.2 VMP(s) Data and Usage

User guidance: The set of fields in B.2.1 – B.2.16.2 should be repeated for each VMP involved in the AE with as much information as is available.

B.2.1 Registered or Brand Name

User guidance: Mandatory for MAH's product(s).[22] *For all other non-MAH products, provide brand name(s) in B.2.1, or active ingredient(s) in B.2.3. Registered or Brand name of the VMP involved in the AE.*

NOTE CONCERNING SUBMISSION: TEXT

B.2.2 Registration Identifier

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[21] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the illness/reason for use of the drug.

[22] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the trade name.

User guidance: Mandatory for MAH's product(s) unless cannot be determined due to insufficient information from reporter, then "Cannot Be Determined" is entered. Optional for other MAHs' VMP(s). Registration number of the VMP involved in the AE.

NOTE CONCERNING SUBMISSION: TEXT

B.2.3 Active Ingredient(s)

User guidance: Mandatory for MAH product(s).[23] *For all other non-MAH products, provide brand name(s) in B.2.1, or active ingredient(s) in B.2.3.*

NOTE CONCERNING SUBMISSION: REPEATABLE TEXT FIELD

B.2.4 Anatomical Therapeutic Chemical Vet (ATCvet) Code *User guidance: Mandatory for MAH product(s). To be used for RA searching purposes. For purposes of AER submission this is not to be used to define "same" or "similar" VMPs. If not readily available, then "Unknown" may be entered.*

NOTE CONCERNING SUBMISSION: TEXT

B.2.5 Strength

B.2.5.1 Strength

User guidance: Mandatory for MAH's product(s) unless cannot be determined due to insufficient information from reporter, then "Cannot be determined" is entered.[24] *Optional for all other non-MAH products. Concentration of the active pharmaceutical ingredient of the VMP involved in the AE.*

NOTE CONCERNING SUBMISSION: REPEATABLE NUMERIC FIELD

B.2.5.2 Strength Unit

User guidance: Mandatory if strength specified.

NOTE CONCERNING SUBMISSION: LIST (TO BE DETERMINED)

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[23] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the generic name(s) of active ingredient(s).

[24] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the strength,

B.2.6 Dosage Form

User guidance: Optional.[25] *Dosage form of the VMP involved in the AE.*

NOTE CONCERNING SUBMISSION: LIST (TO BE DETERMINED)

B.2.7 Company or MAH

User guidance: Optional. Company or MAH involved with the VMP(s) involved in the AE.

NOTE CONCERNING SUBMISSION: TEXT

B.2.8 Lot Number

User guidance: Optional.[26] *Lot number of the VMP involved in the AE.*

NOTE CONCERNING SUBMISSION: TEXT

B.2.9 Expiry Date

User guidance: Optional.

NOTE CONCERNING SUBMISSION: DATE FORMAT: DAY, MONTH, YEAR

B.2.10 Route of Exposure

User guidance: Optional.[27] *Route of exposure/administration of the VMP involved in the AE.*

NOTE CONCERNING SUBMISSION: LIST (TO BE DETERMINED)

B.2.11 Dose per Administration

User guidance: Optional.[28] *Dose administered, not by default the dosage as registered.*

NOTE CONCERNING SUBMISSION: TEXT

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[25] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the dosage form.

[26] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the lot number.

[27] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the route of administration.

[28] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the dosage administered.

B.2.12 Interval of Administration

User guidance: Optional.[29] *Interval of administration or frequency of administration of the VMP involved in the AE.*

NOTE CONCERNING SUBMISSION: LIST (TO BE DETERMINED)

B.2.13 Date of First Exposure

User guidance: Optional. (Approximate) date of first exposure/treatment with VMP involved in the AE.

NOTE CONCERNING SUBMISSION: DATE FORMAT: DAY, MONTH, YEAR

B.2.14 Date of Last Exposure

User guidance: Optional. (Approximate) date of last exposure/treatment with VMP involved in the AE.

NOTE CONCERNING SUBMISSION: DATE FORMAT: DAY, MONTH, YEAR

B.2.15 Who Administered the VMP

User guidance: Optional.[30] *Category of the person who administered the VMP involved in the AE. An Agent acting for the owner will be entered as the owner.*

NOTE CONCERNING SUBMISSION: LIST: VETERINARIAN, ANIMAL OWNER, PHYSICIAN, PATIENT, OTHER HEALTH PROFESSIONAL; UNKNOWN

B.2.16 Use According to Label

B.2.16.1 Use According to Label

User guidance: Optional.[31] *Information on whether the VMP was used according to its label recommendations.*

NOTE CONCERNING SUBMISSION: LIST: YES, NO, UNKNOWN

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[29] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the dosage administered.

[30] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of information about who administered the drug.

[31] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of information about whether there was extralabel use involved.

B.2.16.2 Explanation for Off-Label Use

User guidance: Optional.[32] *Explanation on why the VMP was not used according to its label recommendations. To be filled only if 'no' was selected in B.2.16.1*NOTE CONCERNING SUBMISSION: LIST OF TERMS (TO BE DETERMINED)

B.3 Adverse Event Data

B.3.1 Date of Onset of AE

User guidance: Mandatory.[33] *(Approximate) date of onset of the AE.*

NOTE CONCERNING SUBMISSION: DATE FORMAT: DAY, MONTH, YEAR

B.3.2 Length of Time Between Exposure to Primarily Suspect VMP(s) and Onset of AE

User guidance: Optional.[34] *Length of time refers to the difference between B.2.13 and B.3.1. Suggested intervals may include <2 minutes, <1 hour, <12 hours, <48 hours, <7 days, <14 days, <30 days.*

NOTE CONCERNING SUBMISSION: LIST: TO BE DETERMINED

B.3.3 Duration of AE

User guidance: Approximate length of time the AE lasted.

B.3.3.1 Duration

User guidance: Optional.[35]

NOTE CONCERNING SUBMISSION: INTEGER

B.3.3.2. Time Unit

User guidance: Optional. NOTE CONCERNING SUBMISSION: LIST: MINUTES, HOURS, DAYS

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[32] 21 C.F.R. 514.80, through Form FDA 1932, requires an explanation for any extralabel use.

[33] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the date of onset.

[34] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the length of time between the last administration of the suspect drug and the adverse reaction.

[35] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of the duration of the reaction.

B.3.4 Serious AER

User guidance: Mandatory. To be completed (Yes/No) by MAH.

NOTE CONCERNING SUBMISSION: LIST: YES, NO

B.3.5 Narrative of AE

User guidance: Mandatory.[36] *Describe the sequence of events including:*

- *administration of VMP(s)*
- *all clinical signs*
- *sites of reaction*
- *severity*
- *pertinent laboratory test results*
- *necropsy results*
- *possible contributing factors*
- *treatment of AE*
- *relevant medical history*
- *reason for use of VMP*
- *comment on assessment (veterinarian's or MAH's)*

NOTE CONCERNING SUBMISSION: TEXT

B.3.6 Adverse Clinical Manifestations

User guidance: Mandatory.[37] *Adverse clinical manifestations observed in the AE.*

NOTE CONCERNING SUBMISSION: LIST (TO BE DETERMINED)

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[36] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of a description of the adverse reaction, including all signs, results of pertinent lab tests, necropsy results, possible contributing factors, etc. Also, Form FDA 1932 requires the inclusion in this section of product ineffectiveness and product defects such as cracled tablets, cloudy solution, etc.

[37] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of a description of the adverse reaction, including all signs.

NOTE: The intention of Pharmacovigilance Expert Working Group is to capture clinically significant diagnostic results in a systematic/standardized format.

B.3.7 Treatment of AE

User guidance: Optional.[38] *If the AE was treated, description of the treatment should be done in the narrative B.3.5.*

NOTE CONCERNING SUBMISSION: LIST: YES, NO, UNKNOWN

B.3.8 Outcome to Date

B.3.8.1 Ongoing

B.3.8.2 Recovered

B.3.8.3 Alive with Sequelae

B.3.8.4 Died

B.3.8.5 Euthanized

B.3.8.6 Unknown

User guidance: Optional.[39] *The number of animal(s) in each category should be given. Sequelae mean irreversible effects. The total number from B.3.8.1 to B.3.8.6 should be equal to B.1.2.*

NOTE CONCERNING SUBMISSION: INTEGER

B.4 Dechallenge-Rechallenge Information

User guidance: The information in this section relates to affected animal(s).

B.4.1 Previous Exposure to the Primarily Suspect VMP(s)

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[38] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of information about whether the adverse reaction was treated.

[39] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of information about the outcome of the reaction.

User guidance: Optional.[40] *Only exposures outside the dates mentioned in B.2.13 and B.2.14. If yes is selected, put the dates of previous exposure in the narrative B.3.5.*

NOTE CONCERNING SUBMISSION: LIST: YES, NO, UNKNOWN

B.4.2 Previous AE to the Primarily Suspect VMP(s)

User guidance: Optional.[41] *Only clinical manifestations outside those mentioned in B.3.6. If yes is selected, put the clinical signs in the narrative B.3.5.*

NOTE CONCERNING SUBMISSION: LIST: YES, NO, UNKNOWN

B.4.3 Did AE Abate After Stopping the Primarily Suspect VMP(s)

User guidance: Optional.[42] *'Not applicable' is used when there is no repeated dose or long-lasting signs.*

NOTE CONCERNING SUBMISSION: LIST: YES, NO, UNKNOWN, NOT APPLICABLE

B.4.4 Did AE Reappear After Re-introduction of the Primarily Suspect VMP(s)

User guidance: Optional.[43] *'Not applicable' is used when the primarily suspect VMP(s) is not stopped or not re-introduced.*

NOTE CONCERNING SUBMISSION: LIST: YES, NO, UNKNOWN, NOT APPLICABLE

B.5 Assessment of AE

B.5.1 Attending Veterinarian's Assessment

User guidance: Optional.[44] *Assessment of the attending veterinarian on the association between the VMP(s) and the AE (other than human).*

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[40] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of information about whether the animal was previously exposed to the drug.

[41] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of information about whether the animal previously reacted to this drug.

[42] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of information about whether the reaction continued or stopped after treatment with the drug was discontinued.

[43] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of information about the reaction after the drug was re-introduced.

[44] 21 C.F.R. 514.80, through Form FDA 1932, requires the submission of information about the attending veterinarian's suspicion that the drug caused the reaction.

NOTE CONCERNING SUBMISSION: LIST: PROBABLE, POSSIBLE, UNKNOWN, UNLIKELY, NO ASSESSMENT, NO ATTENDING VET

B.5.2 MAH Assessment

User guidance: Optional. Assessment of the MAH on the association between the primarily suspect VMP(s) and the AE. Description of the categories in the list is provided in Appendix 2.

NOTE CONCERNING SUBMISSION: LIST: PROBABLE, POSSIBLE, UNKNOWN, UNLIKELY, NO ASSESSMENT

B.6 RA Use Only

B.6.1 RA Assessment

This field is for RA use only – is not required for MAH to complete/transmit/maintain this field.

Assessment of the Regulator on the association between the primary suspect VMP(s) and the AE. Description of the categories in the list is provided in Appendix 2.

NOTE CONCERNING SUBMISSION: LIST: PROBABLE, POSSIBLE, UNKNOWN, UNLIKELY, NO ASSESSMENT

B.6.2 Report Number(s) of Linked Report(s)

This field is for RA use only. This section should be used to identify reports that warrant being evaluated together.

NOTE CONCERNING SUBMISSION: TEXT

B.6.3 Explanation Relating to Assessment

This field is for RA use only.

NOTE CONCERNING SUBMISSION: TEXT

Appendix 1

User Guidance for Submission of Human AERs

To fill an AER related to human exposure to VMP(s), the following user guidance should be considered:

A.3.1 Enter the information on the 'attending physician'

A.3.2 Enter the information on the person exposed to the VMP(s)

B.1 Relates to the person exposed to the VMP(s)

B.1.3 Select 'human'

B.1.4 Not applicable for humans

B.1.6 Not applicable for humans

B.1.9 For most report 'accidental exposure' will be entered

B.2.10 Indicate the route of exposure

B.2.11 Indicate the dose to which the person was exposed

B.2.12 For most reports 'once' will be entered

B.2.14 For most reports there will be no date entered

B.2.15 Not applicable

B.2.16.1 Not applicable

B.2.16.2 Not applicable

B.5.1 Assessment of attending physician

Appendix 2

Assessment Categories

MAH and RA may comment on whether they consider that there is an association between the VMP(s) and the AE reported. Four categories indicating the assessment of the likelihood of this association can be made.

PROBABLE: For inclusion in the category 'probable', all of the following minimum criteria should be met:

- There should be a reasonable association in time between the administration of the VMP and onset and duration of the reported AE.
- The description of the clinical phenomena should be consistent with, or at least plausible, given the known pharmacology and toxicology of the VMP.
- There should be no other equally plausible explanations for the AE.

When any of the above criteria cannot be satisfied (due to lack of sufficient information or conflicting data) then the association should not be assessed as 'probable'.

POSSIBLE: For inclusion in the category 'possible', association of the AE with administration of the primarily suspect VMP(s) may be one of other possible and equally plausible explanations for the described event.

UNLIKELY: Where sufficient information exists to establish that the described event was not likely to have been associated with administration of the VMP(s), or other more plausible explanations exist, the assessment should be categorized as 'unlikely'.

UNKNOWN: All events where reliable data is either unavailable or is insufficient to make an assessment should be categorized as 'unknown.'