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VICH GL42: Pharmacovigilance: data elements for submission of adverse event reports (AERs)

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VICH GL42 (PHARMACOVIGILANCE: AERS)
June 2010
For implementation at Step 7 - Final

PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS: DATA ELEMENTS FOR SUBMISSION OF ADVERSE EVENT REPORTS (AERS)

Adopted at Step 7 of the VICH Process by the VICH Steering Committee
in June 2010
for implementation by 31st December 2015

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

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I. Introduction

Pharmacovigilance of veterinary medicinal products (VMPs) is important to guarantee the continued safety and efficacy of VMPs in use. The objective of this guidance document is to standardise the data for submission of adverse events relating to 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.

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 authorisation holders (MAH) and regulatory authorities (RA). For the purpose of this guidance document, refer to the definitions given in VICH GL24 (Management of Adverse Event Reports). For the purpose of electronic reporting, this document should be read together with GL30 (Controlled Lists of Terms), GL35 (Electronic Standards for Transfer of Data), and other relevant VICH guidelines.

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 submit the AER. The optional data elements described in this guidance document are required to be submitted if the data elements have been reported to the MAH. The MAH will strive to collect the information necessary to complete all the data elements in this guidance document. The submission of unstructured data, such as clinical records or images, not described in this guidance document will not be required unless specifically requested by the RA.

For the data fields that use controlled lists of terms (GL30), user systems can, to facilitate reporting or inputting, use a subset of terms listed in GL30 that are considered relevant to the region and to the products involved. However, when receiving reports electronically, that are compliant with the relevant VICH guidelines, all systems must be capable of importing and storing the full report including all standard terms and codes, without loss of information.

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. 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 GL 30). In certain instances, there are provisions for the submission of some unstructured free text items.

Data elements, as defined in this document, will be used for electronic transmission of AER information, as well as additional transmission information (e.g. sender and receiver identifiers). These issues are addressed in GL30 and GL35.

The specific data elements are described below. User guidance is presented *in italics* and notes for the submission format are included as SMALL CAPITALS. To fill an AER related to human exposure to VMP(s), refer to Appendix 1 entitled *User Guideline 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 (3 character country codes ISO 3166)

User guidance: Mandatory. RA where the AER was initially submitted.

A.2 Marketing Authorisation Holder (MAH)

A.2.1 MAH Information

Business name
Street address
City
State/county
Mail/zip code
Country (3 character country codes ISO 3166)

User guidance: Mandatory only for the MAH submitting this AER.

A.2.2 Person Acting on Behalf of MAH

Title
First name
Last name
Telephone
Fax
e-mail

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

NOTE CONCERNING SUBMISSION: TEXT

A.3 Person(s) Involved in the AER

A.3.1 Primary Reporter

Last name
First name
Telephone
Fax
e-mail
Business name
Street address
City
State/county
Mail/zip code
Country (3 character country codes ISO 3166)

User guidance: Last name and country code are mandatory. Other fields are optional. If the reporter requests not to be identified, then enter "WITHHELD" in the "Last name" field. If "WITHHELD" submit reporter's geographic information as privacy legislation allows. The Primary Reporter is determined by the MAH as the person/organization which holds/provides the most pertinent information related to the AER case.

NOTE CONCERNING SUBMISSION: TEXT

A.3.1.1 Primary Reporter Category

User guidance: Mandatory. An Agent acting for the owner will be entered as the animal owner (A.3.1.1).

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *REPORTER CATEGORIES.*

A.3.2 Other Reporter

Last name
First name
Telephone
Fax
e-mail
Business name
Street address
City
State/county
Mail/zip code
Country (3 character country codes ISO 3166)

User guidance: Optional. If reporter requests not to be identified, then enter "WITHHELD" in the "Last name" field. If "WITHHELD" submit reporter's geographic information as privacy legislation allows. The individual/organization providing information for the AER.

NOTE CONCERNING SUBMISSION: TEXT

A.3.2.1 Other Reporter Category

User guidance: Mandatory if Other Reporter given in A.3.2. An Agent acting for the owner will be entered as the animal owner (A.3.2.1).

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *REPORTER CATEGORIES.*

A.4 AER Information

A.4.1 Unique Adverse Event Report Identification Number

User guidance: Mandatory. Globally unique identifier for the adverse event report, designated by the MAH or RA, to be referred to in future follow-ups. Three character country code-8 character MAH or 8 character RA identifier code-unique number (e.g. USA-MERIALLT-xxxxx, USA-USFDACVM-xxxxx). The country code-MAH or RA is for the country where the AE occurred. Use the 3 character country codes from ISO 3166.

NOTE CONCERNING SUBMISSION: TEXT. CHOOSE FROM THE CONTROLLED LIST OF *RA IDENTIFIER CODES.*

A.4.2 Original Receive Date

User guidance: Mandatory. This is the date of first communication of an AER from the primary reporter to the MAH or RA. This date is fixed and cannot be changed in future submissions.

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

A.4.3 Date of Current Submission

User guidance: Mandatory. Date current AER submitted 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.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *TYPE OF SUBMISSION* CATEGORIES.

A 4.4.2 Reason for Nullification Report

User guidance: Mandatory if nullification is checked in A.4.4.1.

NOTE CONCERNING SUBMISSION: TEXT

A.4.4.3 Type of Information in Report

User guidance: Optional.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *TYPE OF INFORMATION IN REPORT* CATEGORIES.

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. (Estimated) number of animals treated.

NOTE CONCERNING SUBMISSION: INTEGER

B.1.2 Number of Animals Affected

User guidance: Mandatory. (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.1.2.1 Attending Veterinarian's Assessment of the Animal(s) Health Status Prior to VMP Use

User guidance: Optional. This is the attending Veterinarian's assessment of the health status of the animal(s) involved in the AE prior to their exposure to the VMP. The MAH should choose from the list the Attending Veterinarian's assessment of animal health status prior to treatment with the VMP(s). The definitions of these values will be left to the veterinarian's medical opinion. The MAH should select "Unknown" if the attending veterinarian does not provide the information.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *ATTENDING VETERINARIAN'S HEALTH STATUS ASSESSMENT* CATEGORIES.

B.1.3 Species

User guidance: Mandatory. In case of human AE, species is "human".

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *SPECIES* (includes human).

B.1.4 Breed

User guidance: Optional. B.1.4.1.1 and B.1.4.2.1 are repeatable fields.

For reports involving a single purebred animal, place the breed in B.1.4.1.1. For reports involving a single crossbred animal and the breeds in the cross are known, up to 3 breeds can be listed in B.1.4.2.1. If the breed makeup of this single crossbred animal is unknown then use the term "Crossbred/[Species]" in B.1.4.2.1.

For groups of purebred animals, list the breeds of the affected animals in B.1.4.1.1. For groups of both purebred and crossbred affected animals B.1.4.1.1 and B.1.4.2.1 should be populated respectively. When affected animals include various crossbreds and their breed makeup is known, use B.1.4.2.1 as a repeatable field to capture each breed. When affected animals include various crossbreds and the breed makeup of some of the crossbreds is unknown, then also include the term "Crossbred/[Species]" in B.1.4.2.1. The breeds of treated but not affected animals may be entered in the narrative, if relevant.

B.1.4.1 PUREBRED

User guidance: This field is for purebred animal(s).

B.1.4.1.1 BREED

User guidance: This is the breed of the animal(s).

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *BREEDS*.

B.1.4.2 CROSSBRED

User guidance: This field is for crossbred animal(s).

B.1.4.2.1 BREED

User guidance: If the actual breed makeup is unknown then choose the appropriate "Crossbred/[Species]".

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *BREEDS*.

B.1.5 Gender

User guidance: Optional. "Mixed" is used for groups of male and female animals. "Unknown" only should be used for animal events where the gender is not known.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *GENDER* CATEGORIES.

B.1.6 Reproductive Status

User guidance: Optional

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *REPRODUCTIVE STATUS* CATEGORIES.

B.1.7 Female Physiological Status

User guidance: Optional: For cases where there are only male animal(s) and(or) neutered female animal(s), the appropriate term from the list would be "Not Applicable". If there is a mixed group of male and female animals then select the physiological status appropriate for the female animals. Select "MIXED" if the group has multiple different physiological statuses. If the physiological status of the animal(s) is not known then the appropriate term from the list would be "Unknown".

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *FEMALE PHYSIOLOGICAL STATUS* CATEGORIES.

B.1.8 Weight

B.1.8.1 Measured, Estimated, Unknown Weights

User guidance: Mandatory if minimum or maximum weight is specified. "UNKNOWN" means that the information was not available from the reporter. If "UNKNOWN" is selected then B.1.8.2 and B.1.8.3 will not be completed.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *PRECISION CATEGORIES*

B.1.8.2 Minimum Weight

User guidance: Optional. 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.1.8.3 Maximum Weight

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

NOTE CONCERNING SUBMISSION: NUMBER (2 DECIMALS)

B.1.9 Age

B.1.9.1 Measured, Estimated, Unknown Age

User guidance: Mandatory if minimum or maximum age is specified. "UNKNOWN" means that the information was not available from the reporter. If "UNKNOWN" is selected then B.1.9.2 and B.1.9.2.1; and B.1.9.3 and B.1.9.3.1 will not be completed.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *PRECISION CATEGORIES*

B.1.9.2 Minimum Age

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

NOTE CONCERNING SUBMISSION: NUMBER

B.1.9.2.1 Minimum Age Units

User guidance: Mandatory if minimum age is specified.

NOTE CONCERNING SUBMISSION: CHOOSE THE TIME UNITS FROM THE CONTROLLED LIST OF *UNITS OF MEASUREMENT*.

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B.1.9.3 Maximum Age

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

NOTE CONCERNING SUBMISSION: NUMBER

B.1.9.3.1 Maximum Age Units

User guidance: Mandatory if maximum age is specified.

NOTE CONCERNING SUBMISSION: CHOOSE THE TIME UNITS FROM THE CONTROLLED LIST OF *UNITS OF MEASUREMENT*.

B.2 VMP(s) Data and Usage

User guidance: The set of fields in B.2.1 – B.2.5.1 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). For all other non-MAH products, provide brand name(s) in B.2.1, or active ingredient(s) in B.2.2. Registered or Brand name of the VMP involved in the AE.

NOTE CONCERNING SUBMISSION: TEXT FIELD(S)

B.2.1.1 Product Code

User guidance: Optional

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE LIST TO BE DEVELOPED.
THE AVAILABILITY OF SUCH CODES SOLELY DEPENDS ON THE DEVELOPMENT OF A GLOBAL VETERINARY PRODUCT DICTIONARY BY THE REGULATORY AUTHORITIES.

B.2.1.2 Registration Identifier

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). The Registration Identifier consists of the (3 character county code)-(8 character RA Identifier Code)-(registration number of the VMP involved in the AE). The country code is for the country where the product is approved. Use the 3 character country codes from ISO 3166. {For EU centrally authorized products use GBR for the character country code and EUEMA000 for the 8 character RA Identifier Code.}

Note: Use the 8 character RA identifier codes. For example, FDA CVM approved products, the registration identifier could be the [3 character country code]-[8 character RA Identifier Code]-[FDA CVM NADA/ANADA Number] (e.g. USA-USFDACVM-xxxxxx for FDA CVM). An example of a registration identifier for an USDA approved biologic product could be USA-APHISCVB-xxxxxx. For other than USA USDA or FDA CVM products, use the country code where the product is approved and the registration number associated with that country's approval. For Japan approved products, the registration identifier would be JPN- JPNJMAFF -xxxxxxxxxxxxxx.

NOTE CONCERNING SUBMISSION: TEXT

B.2.1.3 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 cannot be determined, then "Unknown" may be entered. More information is available about the ATCvet Code at the following website: http://www.whocc.no/atcvet.

NOTE CONCERNING SUBMISSION: ATCVET CODE (FROM WHO LIST)

B.2.1.4 Company or MAH

User guidance: Optional. MAH associated with the VMP identified in B.2.1 involved in the AE.

NOTE CONCERNING SUBMISSION: TEXT

B.2.1.5 MAH Assessment

User guidance: In those regions where required, assessment by the MAH of the association between the use of the VMP and the AE based on a hierarchical system. For the purposes of 3rd country reports of an AE, the assessment originally conducted by the MAH will be sufficient for subsequent RAs.

NOTE CONCERNING SUBMISSION: TEXT AND/OR CODE

B.2.1.6 RA Assessment

User guidance: Assessment of the association between the use of the VMP and the AE(s). Each VMP is evaluated and assigned to one of the categories as defined within regions.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *RA ASSESSMENT* CATEGORIES.

B.2.1.6.1 Explanation Relating to Assessment

NOTE CONCERNING SUBMISSION: TEXT

B.2.1.7 Route of Exposure

User guidance: Optional. Route(s) of exposure/administration of the VMP involved in the AE. For a VMP given through multiple routes of exposure, this field B.2.1.7 and subfields are repeated. The MAH should choose from the list the routes of exposure (administration) for the VMP(s).

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *ROUTE OF EXPOSURE*.

B.2.1.7.1 Dose Administration per Unit

User guidance: Optional. Dose administered, not by default the dosage as registered. Field B.2.1.7.1 and associated subfields are repeatable if different doses of the VMP are given over time.

Numerator: This is the quantity/volume of the actual dose given, e.g., number of tablets, number of boluses, amount of feed, quantity of solution, etc

Denominator: This describes the recipient of the dose by individual animal, weight, volume, etc.

Complex situations, such as premixes for multiple animals, should be described in the narrative.
Examples:

The owners give 3 tablets to their dog.
Numeric value numerator 3
Unit for numeric value numerator tablets
Numeric value denominator 1
Unit for numeric value denominator animal

The veterinarian gives each animal in the herd 10 ml of the VMP per kg of body weight.
Numeric value numerator 10
Unit for numeric value numerator ml
Numeric value denominator 1
Unit for numeric value denominator kg

The flock of 10,000 birds in an enclosure is administered a vaccine by spray at the labeled dose
Numeric value numerator 1
Unit for numeric value numerator dose
Numeric value denominator 1
Unit for numeric value denominator animal

The pond of 100,000 fish is administered a one litre container of a 100 mg/L strength liquid tetracycline at a dose of 100 mg/1000 L .
Numeric value numerator 1

Unit for numeric value numerator container
Numeric value denominator 1000
Unit for numeric value denominator L

Or

Numeric value numerator 1
Unit for numeric value numerator L
Numeric value denominator 100,000
Unit for numeric value denominator animals

A cow is infused with 1 tube of VMP in her right front quarter.
Numeric value numerator 1
Unit for numeric value numerator tube
Numeric value denominator 1
Unit for numeric value denominator quarter

A goat is infused with 1 tube of VMP in her left mammary gland.
Numeric value numerator 1
Unit for numeric value numerator tube
Numeric value denominator 1
Unit for numeric value denominator teat

B.2.1.7.1.1 Numeric Value for Dose (Numerator)

NOTE CONCERNING SUBMISSION: NUMERIC FIELD

B.2.1.7.1.1.1 Units of Value for Dose (Numerator)

User guidance: These are the units that qualify the numeric value for numerator dose.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *UNITS OF MEASUREMENT* (EXCLUDING ALL TIME UNITS) OR *UNITS OF PRESENTATION*.

B.2.1.7.1.2 Numeric Value for Dose (Denominator)

NOTE CONCERNING SUBMISSION: NUMERIC FIELD

B.2.1.7.1.2.1 Units of Value for Dose (Denominator)

User guidance: These are the units that qualify the numeric value for denominator dose.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *UNITS OF MEASUREMENT* (EXCLUDING ALL TIME UNITS), *UNITS OF PRESENTATION*, OR *DOSE DENOMINATOR QUALIFIERS*.

B.2.1.7.1.3 Interval of Administration

User guidance: Optional. This is the interval of administration or frequency of administration of the VMP involved in the AE. If there are multiple intervals of

administration or frequency of administrations the same given dose per administration then B.2.1.7.1.3.1 - B.2.1.7.1.3.3 and B.2.1.7.1.3.1.1 are repeatable.

B.2.1.7.1.3.1 Numeric Value for Interval of Administration

NOTE CONCERNING SUBMISSION: INTEGER

B.2.1.7.1.3.1.1 Units of Value for the Interval of Administration

User guidance: Mandatory if interval of administration specified.

NOTE CONCERNING SUBMISSION: CHOOSE THE TIME UNITS FROM THE CONTROLLED LIST OF *UNITS OF MEASUREMENT*.

B.2.1.7.1.3.2 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.2.1.7.1.3.3 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.2.2 Active Ingredient(s)

User guidance: For all biologic products involved in the case, as long as the registration identifier is provided in B.2.1.2, the active ingredients field (B.2.2.1) and strength fields (B.2.2.1.1 and B.2.2.1.1.1) are not required.

In cases where the user has altered the physical characteristics of the VMP prior to administration (example-mixed VMPs together or diluted a VMP) the fields B.2.2.1 are to be filled in with the characteristics of the VMP as sold. In addition, fields for dose per administration B.2.1.7.1 should be ignored and a description of the dose administered should be accurately described in narrative B.3.1.

B.2.2.1 Active Ingredient(s)

User guidance: Mandatory for MAH product(s). For all other non-MAH products, provide brand name(s) in B.2.1, or active ingredient(s) in B.2.2.1. For VMP(s) with multiple active ingredient(s), fields B.2.2.1 and subfields are repeated.

User guidance: Mandatory for MAH's product(s) unless cannot be determined due to insufficient information from reporter, then "Cannot be determined" is entered. Strength is optional for all other non-MAH products. Strength with its associated strength unit should be reported for both the numerator and the denominator for each Active Ingredient in the VMP. For a VMP with multiple active ingredients these fields are repeated. Strength of the active pharmaceutical ingredient of the VMP involved in the AE.

NOTE CONCERNING SUBMISSION: REPEATABLE TEXT FIELD(S)

B.2.2.1.1 Numeric Value for Strength (Numerator)

NOTE CONCERNING SUBMISSION: NUMERIC FIELD

B.2.2.1.1.1 Units for Numeric Value for Strength (Numerator)

User guidance: Mandatory if strength is specified.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LISTS OF *UNITS OF MEASUREMENT* (EXCLUDING ALL TIME UNITS).

B.2.2.1.2 Numeric Value for Strength (Denominator)

NOTE CONCERNING SUBMISSION: NUMERIC FIELD

B.2.2.1.2.1 Units for Numeric Value for Strength (Denominator)

User guidance: Mandatory if strength is specified.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LISTS OF *UNITS OF MEASUREMENT* (EXCLUDING ALL TIME UNITS); OR *UNITS OF PRESENTATION*

B.2.2.1.3 Active Ingredient Code

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE LIST TO BE DEVELOPED.
THE AVAILABILITY OF SUCH CODES SOLELY DEPENDS ON THE DEVELOPMENT OF A GLOBAL VETERINARY PRODUCT DICTIONARY BY THE RAS

B.2.2.2 Dosage Form

User guidance: Optional. This is the dosage form of the VMP involved in the AE. The MAH should choose from the list the labeled dosage form of the VMP(s).

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *DOSAGE FORMS*.

B.2.3 Lot Number

User guidance: Optional. Lot number of the VMP involved in the AE.

NOTE CONCERNING SUBMISSION: REPEATABLE TEXT

B.2.3.1 Expiration Date

User guidance: Optional.

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

B.2.4 Who Administered the VMP

User guidance: Optional. 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: CHOOSE FROM THE CONTROLLED LIST OF *ADMINISTRATORS OF THE VMP*.

B.2.5 Use According to Label

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

NOTE CONCERNING SUBMISSION: CHOOSE FROM THIS LIST: YES, NO, UNKNOWN

B.2.5.1 Explanation for Off-Label Use

User guidance: Optional. Explanation on why the VMP was not used according to its label recommendations. To be filled only if 'no' was selected in B.2.5.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *OFF-LABEL USE CODING SYSTEM*.

B.3 Adverse Event Data

B.3.1 Narrative of AE

User Guidance: Mandatory.

The narrative should describe the sequence of events, where information is available, including:

- *administration of VMP(s)*
- *clinical signs*
- *sites of responses*
- *severity*
- *pertinent laboratory test results*
- *necropsy results (accurate description of gross pathology and accurate description of histopathologic findings including a pathologists assessment)*
- *possible contributing factors*
- *treatment of AE*
- *relevant medical history*
- *reason for use of VMP*
- *comment on assessment (veterinarian's or MAH's)*
- *chronological sequence of events*

NOTE CONCERNING SUBMISSION: TEXT

B.3.2 Adverse Clinical Manifestations

User guidance: Mandatory. Adverse clinical manifestations observed in the AE.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *VEDDRA TERMS*. The MAH should use the VeDDRA medical terminology to describe the adverse clinical manifestations. The lowest level term from VeDDRA should be transmitted.

NOTE CONCERNING SUBMISSION: REPEATABLE

B.3.2.1 Number of Animals

User guidance: Optional. Number of animals associated with VeDDRA term selected in B.3.2. As the number of animals affected within an AER increases, the willingness and ability of the reporter to know the exact number of animals displaying each clinical sign is expected to decrease. When animals are kept as a herd, one may only observe a small number of animals and then make estimates about the rate and seriousness of events within the remainder of the herd. Regardless, collecting the number of animals affected per clinical sign can have value to pharmacovigilance. Therefore, the MAH will make a reasonable attempt to collect the number of animals affected per clinical sign. When only percentages have been made available, the MAH will convert this percentage into an integer and insert this value into B.3.2.1. The way in which the MAH arrives at the integer should be provided in the narrative. If the reporting party cannot or will not provide an integer value or a percentage estimate then the MAH should provide an explanation in the narrative.

NOTE CONCERNING SUBMISSION: Integer

B.3.2.1.1 Accuracy of the Number of Animals

User guidance: Optional. If a value is entered in the Number of Animals field, please indicate whether the integer provided under B.3.2.1 is an actual or estimated number.

NOTE CONCERNING SUBMISSION: Choose from the controlled List of *Accuracy of No. of Animals* categories.

B.3.3 Date of Onset of AE

User guidance: Mandatory. (Approximate) date on onset of the AE.

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

B.3.4 Length of Time Between Exposure to VMP(s) and Onset of AE

User guidance: Optional. Length of time refers to the difference between the exposure in B.2.1.7.1.3.2 and onset of AE in B.3.3. This field will be used for cases where there is a clear time relationship between the VMP and onset of AE(s). Generally, this field would be for single VMP cases or when multiple VMPs are given at the same time. When a clear time picture is difficult to ascertain or not coded easily, particularly in cases where multiple VMPs are involved; or, in single/multiple VMP cases where more explanation is necessary, the time relationship should be described in the narrative to the best detail possible.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *EXPOSURE AND ONSET TIME*.

B.3.5 Duration of AE

User guidance: Approximate length of time the AE lasted.

B.3.5.1 Duration

User guidance: Optional.

NOTE CONCERNING SUBMISSION: INTEGER

B.3.5.1.1 Duration Time Unit

User guidance: Mandatory if duration is specified.

NOTE CONCERNING SUBMISSION: CHOOSE THE TIME UNITS FROM THE CONTROLLED LIST OF *UNITS OF MEASUREMENT*.

B.3.6 Serious AE

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

NOTE CONCERNING SUBMISSION: CHOOSE FROM THIS LIST: YES, NO

B.3.7 Treatment of AE

User guidance: Optional. If the AE was treated, description of the treatment should be included in the Narrative of AE (B.3.1).

NOTE CONCERNING SUBMISSION: CHOOSE FROM THIS LIST: YES, NO, UNKNOWN

B.3.8 Outcome to Date

B.3.8.1 Ongoing
B.3.8.2 Recovered/Normal
B.3.8.3 Recovered with Sequela
B.3.8.4 Died
B.3.8.5 Euthanized
B.3.8.6 Unknown

User guidance: Optional. The number of animal(s) in each category should be given. The total number from B.3.8.1 to B.3.8.6 should be equal to the Number of Animals Affected in B.1.2.

NOTE CONCERNING SUBMISSION: INTEGER.

B.3.9 Previous Exposure to the VMP

User guidance: Optional. This field applies only to exposures outside the dates mentioned in Date of First Exposure (B.2.1.7.1.3.2) and Date of Last Exposure (B.2.1.7.1.3.3). If there was a previous exposure to the VMP, choose "YES" and provide the dates of previous exposure in the Narrative of AE (B.3.1). Choose "NO" if there was no previous exposure. Choose "UNKNOWN" if the information was not available from the reporter.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THIS LIST: YES, NO, UNKNOWN

B.3.10 Previous AE to the VMP

User guidance: Optional. This field refers only to clinical manifestations that occurred during the previous exposure mentioned in B.3.9. Choose "YES"if there was previous AE(s) from an exposure to the VMP and "NO" if there was not a previous AE(s) to the VMP. If "YES" is chosen, describe the clinical

signs of in the Narrative of AE (B.3.1).. Choose "UNKNOWN" if the information is not available from the reporter.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THIS LIST: YES, NO, UNKNOWN

B.4 Dechallenge-Rechallenge Information

User guidance: The information in this section relates to affected animal(s). This set of fields will be used for cases where dechallenge or rechallenges occur in single VMP events. Dechallenge-Rechallenge information for multiple VMP events should be described in the narrative to the best detail possible.

B.4.1 Did AE Abate After Stopping the VMP

User guidance: Optional. Choose from the list whether or not the AE stopped or diminished after dechallenge. Dechallenge is the removal, withdrawal, or discontinuance of a VMP from the animal's therapeutic regimen. Dechallenge also includes a substantial dosage reduction. Choose "UNKNOWN" if the information is not available from the reporter.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THIS LIST: YES, NO, NOT APPLICABLE, UNKNOWN

B.4.2 Did AE Reappear After Re-introduction of the VMP

User guidance: Optional. . Choose from the list whether or not the AE reappeared after the rechallenge. Rechallenge is the reintroduction of a VMP after the occurrence of a positive dechallenge. It also includes a substantial increase in dosage following a previous reduction which produced improvement in the clinical manifestation. Choose "UNKNOWN" if the information is not available from the reporter.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THIS LIST: YES, NO, NOT APPLICABLE, UNKNOWN

B.5 Assessment of AE

B.5.1 Attending Veterinarian's Assessment

User guidance: Optional. Assessment by the attending veterinarian on the association between the VMP(s) and the AE (other than human). The MAH should choose from the list the Attending Veterinarian's assessment on the association between the VMP(s) and the AE. The definitions of these values will be left to the veterinarian's medical opinion.

NOTE CONCERNING SUBMISSION: CHOOSE FROM THE CONTROLLED LIST OF *ATTENDING VETERINARIAN'S CAUSALITY ASSESSMENT* CATEGORIES.

B.6 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.7 Supplemental Documents

User guidance: Utilized by MAH upon request from RA for additional information on a specific AER, or voluntarily by the MAH. This field is a file attachment to be used for pathology, radiology, clinical

chemistry reports, et cetera. The MAH should provide a description of the contents in the files and a listing of the files. This section is repeatable for each supplemental document. The description of the contents of the file should be given in the B.3.1 Narrative of AE.

NOTE CONCERNING SUBMISSION: OBJECT FIELD

B.7.1 Attached Document Filename (Text Field)

This field will specify the filename of the document.

NOTE CONCERNING SUBMISSION: TEXT

B.7.1.1 Attached Document Type (List)

The MAH will choose from the list of supplemental document types, e.g. necropsy, pathology, clinical chemistry reports, that describe the contents of the file.

NOTE CONCERNING SUBMISSION: REPEATABLE. CHOOSE FROM THE CONTROLLED LIST OF *DOCUMENT TYPES.*

Appendix 1
User Guideline 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	Primary Reporter	Enter the information on the 'attending physician'
A.3.2	Other Reporter	Enter the information on the person exposed to the VMP(s)
B.1	Animal Data	Relates to the person exposed to the VMP(s)
B.1.3	Species	Select 'human'
B.1.4	Breed	Not applicable for humans
B.2.1.7	Route of Exposure	Indicate the route of exposure
B.2.1.7.1	Dose per Administration	Indicate the dose to which the person was exposed
B.2.1.7.1.3.3	Date of Last Exposure	For most reports there will be no date entered
B.2.5.1	Explanation for Off-Label Use	Not applicable
B.5.1	Attending Veterinarian's Assessment	Assessment of attending Physician