**PSUR CHECKLIST & OPTIONAL TEMPLATE**

*This template is designed to be used as a guide to compiling a PSUR, and can be edited to suit local formatting; the content should remain the same.*

**Company name:**

**Product name(s):**

*National/CAP – name in that country*

*MRP/DCP – name in RMS (other names should be included in the table of MA* *numbers.*

**Procedure number:** *(if applicable)*

**EBD/Start date of PSUR cycle:**

*National – date of authorisation*

*MRP/DCP – Day 90*

**Period covered by this PSUR:**

**Chronological order of PSUR:**

*e.g. First six-monthly PSUR*

**Date of initial placing on market:**

**Author:**

**Reviewer:** *This is not necessary if you have an internal system for QC of the document*

**MA number(s) :**

|  |  |
| --- | --- |
| Country | MA numbers |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**Update on regulatory actions taken for safety reasons**

*This need only be included if required.*

**SPC**

*This should be included as an appendix*

**Sales**

*Information should only be included that is pertinent to the procedure involved.*

*An EEA total must be provided in addition to the worldwide total.*

*In combined PSUR it must be clear which product and product strength the sales are related to.*

*Sales data can be presented in a table (examples are provided in Volume 9B and in appendix i)*

*For all products authorised in the UK, the PSURs should include the volume of the product sold in each year covered by the report, calculated on an annual basis, beginning 1st January.*

**Number of Animals treated**

*If there is more than one species this should be worked out based on a justified* *species split.*

*Maximum recommended exposure should be used unless otherwise justified.*

*Standard weights should be used where practical; however it is acceptable to use a* *more appropriate animal weight if justified*

*Data can be presented in a table (examples are provided in Volume 9B and in* *appendix i)*

**Incidence**

*The incidence should be based on EEA data; a worldwide figure may be included for comparison. It is best practice to provide an incidence per species if applicable.*

*If there are lack of efficacy reports an incidence of lack of efficacy should be provided.*

**Data Review**

1.1 Adverse events in target species (*including lack of expected efficacy and events after off-label use in the target species)*

1.1.1 After recommended use

1.1.2 After non-recommended use (off-label, including overdose)

1.2 Adverse events in humans

1.3 Other pharmacovigilance fields

*1.3.1 Adverse events in non-target species*

*1.3.2 Potential environmental problems*

*1.3.3 Investigations of the validity of withdrawal periods*

*1.3.4* Transmission *of infectious agents*

1.4 Non-spontaneous reports (overview of available data from other sources e.g. pre-authorisation studies, post authorisation studies, published adverse event reports)

1.5 Other information (adverse events arising from prescription errors or medication errors)

*Adverse event reports should be analysed and discussed in relation to the benefit risk balance of the product. Any changes in the frequency of adverse events should be discussed in relation to possible changes to the product literature.*

**Important information received after the DLP**

*This should include, but is not limited to, SPC changes and adverse events which affect the benefit risk*

**Action from previous assessment recommendations**

**Overall safety evaluation/Conclusions**

*This section should include (lack of significant new information should be mentioned for each):*

* information on any previous action taken by either regulatory authorities or the MAH as a result of safety issues, and any new important information on the following (which has not been discussed in the data review):*

*i) evidence of previously unidentified toxicity or safety concerns*

*ii) increased frequency of known toxicity or expected undesirable effects*

*iii) drug interactions*

*iv) adverse events in animals associated with off-label use, including overdose and its treatment*

*v) human adverse reactions related to the use of the product*

*vi) lack of efficacy*

* prescription errors/medication errors, including those associated with invented names or with the presentation of the VMPs, that have safety implications, if available.*

* information on investigation regarding the validity of withdrawal periods arising from the use of the VMP*

* any environmental issues, caused by the VMP under normal conditions of use*

* any urgent safety issues that occurred during the period covered.*

*Conclusion should include reference to*

* *whether the safety information remain in line with the cumulative experience to date and the SPC or whether changes should be made to the SPC or other product information;*
* *ascertain whether further investigations need to be carried out, and*
* *specify any action recommended and the reasons why*

**Line Listings**

*Only need to be included if there are any reports received*

*A template is available (appendix i) for the PDF document, however it is preferable that Excel line listings are provided, especially for more than 20 reports. For searching and sorting it is useful to differentiate between EEA and third country reports.*

*For ease of assessment it is best practice to ensure that the line listings are presented by safety (serious and non-serious) and lack of efficacy (serious and non-serious).*

*Note: It is acceptable to use your own table providing the headings are adhered to.*

**Appendix i – optional tables**

Table 1: Comparison over time of the ratio of animals reported for <SARs, lack of expected efficacy> during a period to the amount of product sold by period <and by year, if data is available>

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Period | PSUR 1 | | | PSUR 2 | | |
|  | *<Year* | *Year* | *Year* | *Year* | *Year* | *Year>* |
| Number of animals <*reacting, experiencing lack of efficacy*> during the period |  |  |  |  |  |  |
| <*Number of doses sold during period, sales volume*\*> (<*insert sort e.g. Litres, Doses*>) |  |  |  |  |  |  |
| Ratio (number of animals : number of doses) |  |  |  |  |  |  |

\* Sales volume only where it is not feasible to estimate the number of doses. Every attempt should be made to estimate the doses sold.

Table 2: Sales volume, estimated number of treated animals, number of animals reacting (animal count) and incidence of suspected adverse reactions during the reporting period by country and region

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Country\* | Total sales volume | Number of animals treated \*\* | Number of animals reacted in SARs assessed A, B or O | Incidence\*\*\* |
| Austria |  |  |  |  |
| Belgium |  |  |  |  |
| Bulgaria |  |  |  |  |
| Croatia |  |  |  |  |
| Cyprus |  |  |  |  |
| Czech Republic |  |  |  |  |
| Denmark |  |  |  |  |
| Estonia |  |  |  |  |
| Finland |  |  |  |  |
| France |  |  |  |  |
| Germany |  |  |  |  |
| Greece |  |  |  |  |
| Hungary |  |  |  |  |
| Ireland |  |  |  |  |
| Italy |  |  |  |  |
| Latvia |  |  |  |  |
| Lithuania |  |  |  |  |
| Luxembourg |  |  |  |  |
| Malta |  |  |  |  |
| Netherlands |  |  |  |  |
| Poland |  |  |  |  |
| Portugal |  |  |  |  |
| Romania |  |  |  |  |
| Slovakia |  |  |  |  |
| Slovenia |  |  |  |  |
| Spain |  |  |  |  |
| Sweden |  |  |  |  |
| United Kingdom |  |  |  |  |
|  |  |  |  |  |
| Iceland |  |  |  |  |
| Liechtenstein |  |  |  |  |
| Norway |  |  |  |  |
|  |  |  |  |  |
| **Total EU/EEA** |  |  |  |  |
|  |  |  |  |  |
| Third countries |  |  |  |  |
|  |  |  |  |  |
| Total |  |  |  |  |
| \* This table includes details only on those countries of the EU/EEA where the product has been sold during the reporting period. Countries with zero (0) sales have been deleted.  \*\* <please explain here assumptions underlying the estimated number of treated animals > | | | | | |
| \*\*\* <please explain here the assumptions underlying the incidence calculation– see also Volume 9 of the Rules governing medicinal products in the European Union, Part II. 1. Pharmacovigilance of Veterinary Medicinal Products – Notice to Marketing Authorisation Holders (to be replaced by Volume 9B, when available)> | | | | | |

Table 3: Report, animal and mortality count for all reports received on any suspected adverse reaction during the reporting period in any species, including human beings. All causality categories (A,B,O,N) are included.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Reports | Community (EU/EEA) | | | Third Countries (Non EU/EEA) | | |
|  | Reports (N) | Number of reported animals (N) | Deaths (N) | Reports (N) | Number of reported animals (N) | Deaths (N) |
| Target species |  |  |  |  |  |  |
| Non-target species |  |  |  |  |  |  |
| Human |  |  |  |  |  |  |
| Total |  |  |  |  |  |  |

Table 4. Report count of serious and non-serious suspected adverse reactions reports received during the period. All causality categories (A, B, O, N) are included. This table excludes reports of lack of expected efficacy

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Use of product | Category of species | Number of reports | | |
|  |  | Serious | Non-serious | Total |
| As recommended in SPC | <Insert Target species> |  |  |  |
| Off label use | <Insert Target species> |  |  |  |
| <Insert Non-Target species. |  |  |  |
| Unknown | <Insert Target species> |  |  |  |
| Total | All |  |  |  |

Table 5: Number of animals affected and nature of reports by causality category in <non->target species received during the reporting period (animal count)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Reports | A (probable) + B (possible) +  O (unclassifiable) | | N (unlikely) | |
|  | Number of reported animals (N) | Deaths  (N) | Number of reported animals (N) | Deaths  (N) |
| Suspected adverse reactions |  |  |  |  |
| Lack of expected efficacy |  |  |  |  |
| Total |  |  |  |  |

Table 6: Number and nature of suspected adverse reactions in any species received during the PSUR period (report, animal and mortality count)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Reports | Community (EU/EEA) | | | Third Countries (Non EU/EEA) | | |
|  | Reports (N) | Number of reported animals (N) | Deaths (N) | Reports (N) | Number of reported animals (N) | Deaths (N) |
| Target species |  |  |  |  |  |  |
| Used as recommended |  |  |  |  |  |  |
| Off label use |  |  |  |  |  |  |
| Unknown |  |  |  |  |  |  |
| Non-target species |  |  |  |  |  |  |
| Total |  |  |  |  |  |  |

Table 7: Event count of clinical signs reported as <Serious, Serious unexpected, Non-serious unexpected (unlisted)> adverse reactions (animal count) by species and VeDDRA terminology

|  |  |  |
| --- | --- | --- |
| Species | Clinical sign  VeDDRA terms, <SOC, HLT, PT > level | Number of events\* |
|  |  |  |

\* Number of times the clinical sign was reported (i.e. occurrences, citations, occasions etc.)

1. PSUR line listing template - PSUR Line listing for suspected adverse events in animals

**VETERINARY PHARMACOVIGILANCE SCHEME - PERIODIC SAFETY UPDATE REPORT**

**MARKETING AUTHORISATION HOLDER FORM FOR REPORTS OF**

***ANIMAL ADVERSE EVENTS***

**TO A VETERINARY MEDICINAL PRODUCT**

**PRODUCT:**

**MARKETING AUTHORISATION HOLDER:**

**Marketing AUTHORISATION NO:**

**PERIOD OF REPORT FROM .../.../... TO .../.../....**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| MAH  *(Please ensure these  sections are completed)*  CASE REF | CA Case Ref | DATE OF  TREATMENT/VACCINATION | DATE OF  EVENT | NO.  TREATED | SPECIES  AND AGE  (Juv/Adult) | NO.  REACTED  (a) | NO.  DIED  (b) | WAS PRODUCT  USED AS  RECOMMENDED  YES/NO | OTHER  PRODUCTS USED  CONCURRENTLY | VeDDRA | PRESENTING  SIGNS/DIAGNOSIS | BRIEF INFORMATIVE NARRATIVE AND MAH CONCLUSION | CAUSALITY  (ABON  CODE) |
| EEA  REPORTS  (COUNTRY CODE -ORGANISATION ID -CASE NUMBERREF + NAME & COUNTRY) |  |  |  | *(Please ensure that this total is put in)* |  | *(Please ensure that this total is put in)* |  |  |  |  |  |  |  |
| OVERALL TOTAL OF ALL (EEA) PAGES  Total no of (reports): Total no of animal reactions (a): Total no of animals died (b): | | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| MAH  *(Please ensure these  sections are completed)*  CASE REF | CA Case Ref | DATE OF  TREATMENT/VACCINATION | DATE OF  EVENT | NO.  TREATED | SPECIES  AND AGE  (Juv/Adult) | NO.  REACTED  (a) | NO.  DIED  (b) | | WAS PRODUCT  USED AS  RECOMMENDED  YES/NO | OTHER  PRODUCTS USED  CONCURRENTLY | VeDDRA | PRESENTING  SIGNS/DIAGNOSIS | BRIEF INFORMATIVE NARRATIVE AND MAH CONCLUSION | CAUSALITY  (ABON  CODE) |
| THIRD COUNTRY REPORTS  (COUNTRY CODE -ORGANISATION ID -CASE NUMBER) |  |  |  | *(Please ensure that this total is put in)* |  | *(Please ensure that this total is put in)* |  | |  |  |  |  |  |  |
| OVERALL TOTAL OF ALL (3rd country) PAGES | | | | | | | | Total no of (reports): Total no of animal reactions (a): Total no of animals died (b): | | | | | | |

**FOR Competent Authority USE ONLY:** **REFERENCE: DATE OF RECEIPT**

1. PSUR line listing template - PSUR line listing for suspected human adverse events

**VETERINARY PHARMACOVIGILANCE SCHEME – PERIODIC SAFETY UPDATE REPORT**

**MARKETING AUTHORISATION HOLDER FORM FOR REPORTS OF**

***HUMAN ADVERSE EVENTS in HUMANS***

**INVOLVING A VETERINARY MEDICINAL PRODUCT**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **PRODUCT:**  **Marketing AUTHORISATION HOLDER** | | | | | | | | | | |
| **MARKETING AUTHORISATION NO:** | | | | | | | | | | |
| **Period OF REPORT FROM -----/-----/----- TO -----/-----/-----** | | | | | | | | | | |
| MAH CASE REF | CA CASE REF | NAME(S) OR UNIQUE PATIENT(S) IDENTIFICATION [[1]](#footnote-1) | OCCUPATION | Date of Exposure | DATE OF EVENT | NATURE OF ACCIDENT/ EXPOSURE | VeDDRA | NATURE OF REACTION/ SYMPTOMS | OUTCOME OF EVENT | BRIEF INFORMATIVE NARRATIVE AND MAH CONCLUSION |
|  |  |  |  |  |  |  |  |  |  |  |
| (COUNTRY CODE -ORGANISATION ID -CASE NUMBERREF + NAME & COUNTrY) |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

**FOR COMPETENT AUTHORITY USE ONLY: REFERENCE**: **DATE OF RECEIPT**: **Number of Incidents:**

1. As appropriate according to national laws [↑](#footnote-ref-1)