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The VGVP draft modules are released for consultation and may change further, pending the finalisation and publication of the Implementing Regulation laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products.

3 Guideline on veterinary good pharmacovigilance practices 4 (VGVP)

5 Module: Veterinary pharmacovigilance communication

6 Draft

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7

Comments should be provided using this template. The completed comments form should be sent to Vet-Guidelines@ema.europa.eu

8

Keywords	***Communication plan; public announcement; direct animal healthcare professional communication ('Dear Dr' letter); veterinary pharmacovigilance alert; non-urgent information***

9

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Table of contents

1. Introduction

Communication is a fundamental part of veterinary pharmacovigilance for promoting rational, safe and effective use of medicines for safeguarding animal and public health and the environment. In this module of the guideline on veterinary good pharmacovigilance practice (VGVP), communication refers to the active dissemination of veterinary pharmacovigilance information for an intended audience, particularly in the public domain, from marketing authorisation holders, competent authorities and the Agency with specific focus towards veterinarians.

This module describes the principles for best practice on communication on veterinary pharmacovigilance in the Union for marketing authorisation holders, competent authorities, the Agency and the Commission for safeguarding animal and public health and the environment. The principles for best practice on veterinary pharmacovigilance communication described in this module underpin the components of the overarching communication plan which is a legal requirement for marketing authorisation holders under the draft Commission Implementing Regulation (EU) …/... of XXX laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products [Article 20 of the Draft Commission Implementing Regulation]. This module also recommends that competent authorities and the Agency have an overarching communication plan. This should comprise the procedures and information required for communicating on veterinary pharmacovigilance issues in a timely manner to relevant stakeholders in the Union.

This module uses the term 'topic-specific communication plan' to describe how the overarching communication plan is applied in an individual situation when communication is required, specific to the circumstances. It provides a template (see Annex II of this module) for preparing a topic-specific communication plan. While this document is particularly relevant for communication in the event of potential need for urgent regulatory or other action, the principles and recommendations outlined should be considered best practice for communication under other circumstances.

Communication will be the principal mechanism used by competent authorities or the Agency when making recommendations or highlighting concerns on medicinal products for human use administered to animals, which is within the scope of the veterinary pharmacovigilance reporting requirements (Article 73(2)(g) of Regulation (EU) 2019/6).

This guidance will be reviewed and updated at regular intervals, or as required, on the basis of experience gained.

Routine communication, for example, update of product information to include new adverse events, is addressed as part of general pharmacovigilance procedures in place for marketing authorisation holders and competent authorities and the Agency, alike, and is not the subject of this module. Also out of scope of this module are responses to individual requests for information on pharmacovigilance issues received by marketing authorisation holders, competent authorities or the Agency; or communication with individuals about the treatment or management of adverse events e.g. veterinarian or client queries received by marketing authorisation holders and competent authorities. Promotion of veterinary medicinal products (as described in Article 119 of Regulation (EU) 2019/6) is also out of scope of this module. Furthermore, communication, in this context, is distinct from transparency, which aims to provide public access to information related to data assessment, decision-making and safety monitoring performed by competent authorities.

This module must be read in conjunction with Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive

2001/82/EC and Commission Implementing Regulation (EU) …/... of XXX laying down rules for the application of Regulation (EU) 2019/6 of the European Parliament and of the Council as regards good pharmacovigilance practice and on the format, content and summary of the pharmacovigilance system master file for veterinary medicinal products (reference to be updated when available).

2. Principles for good veterinary pharmacovigilance communication

The principles described in this section under points 2.1.1-2.1.7 should be considered throughout the process of communicating on veterinary pharmacovigilance and applied as part of veterinary good pharmacovigilance practice. This entire process includes the preparation, dissemination, and follow-up of communication. Where necessary, based on sound judgement and experience, the principles may be adapted as required to address the specific needs for communicating on a particular veterinary pharmacovigilance issue.

The overriding principle of pharmacovigilance communication is to deliver relevant, clear, accurate, consistent, and timely messages to the right audience so they can take appropriate action. Effective veterinary pharmacovigilance communication can strengthen and support public confidence in the regulatory system and is in line with the principles of transparency on veterinary medicinal products.

There should be consultation, collaboration and coordination between the marketing authorisation holder(s) and the regulatory authorities (and other partners as appropriate) while preparing communication, as this is considered beneficial to all parties involved and crucial for delivering consistent information through the Union.

When making a public announcement (i.e. public communication) on pharmacovigilance marketing authorisation holders shall notify the relevant competent authorities or the Agency of their intention to do so, preferably in advance, however, at least simultaneously to the announcement (Article 77(11) of Regulation (EU) 2019/6). Similarly, competent authorities and the Agency shall notify respective marketing authorisation holders in a timely manner when they communicate publicly on veterinary pharmacovigilance, preferably in advance of, however, at least simultaneously to the public communication (Article 79(3) of Regulation (EU) 2019/6).

All pharmacovigilance communication should comply with relevant requirements relating to individual data protection and confidentiality.

In accordance with the quality system requirements in the VGVP module on pharmacovigilance systems and their pharmacovigilance system master files and quality management systems (EMA/257136/2021), procedures should be in place to ensure that veterinary pharmacovigilance communication complies with the guidance in this section, as appropriate. Veterinary pharmacovigilance communication should be subject to quality controls to ensure this.

2.1.1. Clear objectives of communication

Veterinary pharmacovigilance communication aims to:

- provide timely information to, and raise awareness within, the targeted audience about the safe and effective use of veterinary medicinal products used in animals;
- enable informed decisions to be taken on the rational use of veterinary medicinal products (or medicinal products for human use) in animals;
- support risk management throughout the continuous benefit-risk evaluation process; and
- enhance collection of information from the targeted audience(s).

2.1.2. Determining timing for communication

The need for communicating veterinary pharmacovigilance information should be considered throughout pharmacovigilance and benefit-risk evaluation processes.

As a general principle, communication on the basis of evaluation of pharmacovigilance data should be considered when there is new important information to be conveyed on adverse events relating to the veterinary medicinal products (or medicinal products for human use administered to animals) affecting exposed animals or humans or the environment which needs to be communicated more urgently than through a routine update to the product information.

Communication should generally be coordinated in a timely manner with the corresponding recommendation from the pharmacovigilance (e.g. signal management, see VGVP module on signal management (EMA/307620/2021)) or regulatory procedure. However, exceptionally (e.g. in the case of an urgent safety issue, i.e. in the event of a risk to public or animal health or to the environment that requires urgent action (Article 129(1) of Regulation (EU) 2019/6)) it may be necessary to disseminate information before completion of the regulatory procedure.

A competent authority or the Agency may disseminate or request the marketing authorisation holder to disseminate communication in any situation where considered necessary for safe and effective use of the veterinary medicinal product(s).

In principle, significant new or emerging information should be brought to the attention of veterinarians and other animal healthcare professionals before animal owners or other users of the veterinary medicinal product, in order to enable them to take action and respond adequately and promptly.

Veterinary and other animal healthcare professionals (see VGVP Glossary (EMA/118227/2021)) in clinical practice and those involved in clinical trials should be provided with appropriate veterinary pharmacovigilance information at the same time.

2.1.3. Clarity of communication (content and presentation)

2.1.3.1. Content

The information should not be misleading or contain any material or statement considered to be promotional or commercial. The following should be taken into account concerning the content of veterinary pharmacovigilance communication:

- The reason for initiating the communication should be explained, for example:
  - Important new veterinary pharmacovigilance information which impacts the benefit-risk balance of a veterinary medicinal product for animal or public health, user safety or the environment.
  - Important new veterinary pharmacovigilance information concerning medicinal products for human use administered to animals.
  - Information on the important changes to the product information of a veterinary medicinal product on the basis of pharmacovigilance.
  - Regulatory action, for example, suspension, withdrawal, revocation of the marketing authorisation based on the changes to the benefit-risk balance of the veterinary medicinal product, restriction in availability or discontinuation of a medicine with potential detrimental effects on animal or public health or the environment.

- The information should objectively describe the risks in the context of the overall benefits of the medicinal product
  - relevant information on adverse events may include the severity, frequency, risk factors, time to onset, reversibility (including potential treatment of clinical signs) and expected time for recovery;
  - use appropriate quantitative measures when describing and comparing risks e.g. simple descriptive statistics, such as frequencies, the use of absolute risks and not just relative risks;
  - present denominators (i.e. estimated number of animals treated), where available, and when comparing risks, ensure denominators are comparable;
  - consider using visual and graphical forms of reporting, including statistical presentation of the risks and/or the benefit-risk balance;
  - acknowledge uncertainties related to a pharmacovigilance concern including whether there is insufficient information currently available to conclude on potential causal relationships with the product(s)/product class.
- Recommendations on how to deal with the information should be provided, if possible and appropriate, e.g. actions to be taken to minimise risks:
  - Information on competing risks, such as the risk of non-treatment or off-label use, and whether alternative products may or may not be available.
  - Specify whether the treatment course should be completed to avoid causing possible harm to the animal if treatment is not continued.
  - Information on any proposed change to the product information.
- Where relevant, a reminder to report adverse events in accordance with national requirements.
- Contact points (e.g. websites, telephone numbers et cetera) should be provided at the end of the communication, when relevant, for:
  - pharmacovigilance/adverse event reporting; and
  - further information, if different from the pharmacovigilance contact point.
- Any other additional information about the issue or use of the medicinal product or other data that may be relevant for tailoring the message to the targeted audience. If relevant, literature references should be annexed or linked.

2.1.3.2. Presentation of information

- Communication should be as clear and concise as possible to ensure the key messages are delivered effectively.
- Language should be tailored appropriately to the audience (e.g. veterinarians and other animal healthcare professionals, animal owners/carers etc.) taking account of the different levels of knowledge and information needs whilst maintaining the accuracy and consistency of the information conveyed (EMA medical terms simplifier (europa.eu)).
- Other editorial considerations include the following:
  - It may be useful to refer at least once to the recommended international non-proprietary name (rINN) or other active substance name as well as the medicinal product brand name.

- Use active sentences rather than passive (e.g. change "veterinarians were requested to complete a questionnaire" to "veterinarians completed a questionnaire").
- Avoid abbreviations that may be unfamiliar to veterinarians and other animal healthcare professionals; if they are necessary, spell them out first time and include the abbreviation in brackets after.
- Avoid over-use of bold and italics for emphasis, which can be difficult to read.

2.1.4. Identifying the target audience and stakeholders facilitating information dissemination

The main target audience for veterinary pharmacovigilance communication comprises veterinarians and other animal healthcare professionals, including people who handle, dispense or administer the veterinary medicinal product (or medicinal products for human use administered to animals).

Animal owners, carers or keepers are also a target audience for pharmacovigilance communication, as they have a vested interest in the safe and effective use of veterinary medicinal products. This audience is particularly important when communication concerns non-prescription, over-the counter products.

Other organisational bodies can act as information multipliers, by disseminating important information to the target audiences. These include, for example, Veterinary Statutory Bodies (VSBs), professional veterinary associations or federations; veterinary colleges; health ministries; public and animal health agencies; authorities for food safety; agricultural associations; breeder associations and animal welfare organisations.

The media may also be a target audience for communication. The capacity of the media to reach the general public in particular, in addition to veterinarians and other animal healthcare professionals, is a critical element for amplifying new and important veterinary pharmacovigilance information, in particular where there may be animal and public health implications. The way veterinary pharmacovigilance information is communicated through the media impacts public perception and it is therefore vital that the media receives information directly from regulatory authorities in addition to the information they receive from other sources.

2.1.5. Selecting appropriate communication tools and channels

Consideration should be given to the most effective tools for communication of veterinary pharmacovigilance issues to reach the intended target audience.

The variety of tools used for communication continues to evolve and it is important to be aware of new developments in communication technologies and how audiences access information (for example, particular media channels or publications, such as open access journals, may be more frequently accessed by veterinarians). Liaison with communication or stakeholder departments within organisations may be helpful for this purpose.

Some examples of communication are provided here, however, particular focus is given to direct animal healthcare professional communication since this is one area in particular where Union-level guidance has been needed for some time, whilst acknowledging that direct animal healthcare professional communications are not foreseen to be used frequently.

2.1.5.1. Direct animal healthcare professional communication or 'Dear Dr/DVM letters'

Direct animal healthcare professional communication is a risk minimisation tool for communication of important, and potentially new, veterinary pharmacovigilance information directly to individual veterinarians and other animal healthcare professionals by a marketing authorisation holder, a competent authority or the Agency. Annex I of this module provides a template for use when preparing a direct animal healthcare professional communication.

Direct animal healthcare professional communications are sent out when veterinarians and other animal healthcare professionals need to be provided with specific advice, recommendations or information regarding a veterinary pharmacovigilance concern, in particular which may require them to take certain action or adapt their practices in relation to administration of a medicinal product for use in animals.

Direct animal healthcare professional communication preparation involves cooperation between marketing authorisation holders and competent authorities. Direct animal healthcare professional communications prepared by marketing authorisation holders, under their own initiative or upon request, should be agreed by the competent authorities or the Agency before dissemination. A statement on the agreement between the marketing authorisation holder and the competent authority on the information provided should be included in the direct animal healthcare professional communication.

In addition to dissemination to veterinarians and other animal healthcare professionals, direct animal healthcare professional communications should be published according to an agreed timetable on websites of the concerned competent authority and marketing authorisation holder(s), as applicable, and via any other communication tool which appears useful in the specific situation.

2.1.5.2. Bulletins and newsletters

Bulletins and newsletters provide useful summaries of veterinary pharmacovigilance information at regular intervals, in particular for veterinarians. They are suitable platforms for describing trends, reporting on new emerging safety issues, or highlighting information in a wider context of issues relating to veterinary medicinal products.

2.1.5.3. Websites

Websites should enable easy direct access to documents and information published on them, by navigation from the respective home page and also via internet search engines. The information published should be understandable by the public. When publishing veterinary pharmacovigilance information on websites, appropriate links, and/or contact details, should be provided to facilitate adverse event reporting. It is important to ensure information on websites is kept up to date.

Regulatory authority websites should serve as the authoritative reference point (or 'go-to') for information on veterinary pharmacovigilance. Examples of documents published on regulatory authority websites include regular summaries of adverse event reports and direct animal healthcare professional communications agreed by competent authorities. Direct animal healthcare professional communications agreed by the Agency will be published on the Agency website.

2.1.5.4. Online/digital communication including social media

Online platforms, including social media, and other digital tools may also be useful for disseminating veterinary pharmacovigilance communication. When using newer, more rapid communication channels, special attention should be paid to ensure that the accuracy of the information released is not

compromised and the language used is appropriate for the audience. Communication practices should take into account emerging digital communication tools used by the various target audiences.

2.1.5.5. Press communication

Press communication involves tools such as press releases and briefings primarily intended for journalists and the general public. Press releases prepared and published by marketing authorisation holders should make reference to the regulatory action taken by the competent authority or the Agency.

Since press releases will also be read by other audiences such as veterinarians and other animal healthcare professionals and the general public, reference should be made to related communication materials on the topic. In cases where direct animal healthcare professional communications are also prepared, veterinarians and animal healthcare professionals should ideally receive these communications prior to or around the same time of the publication or distribution of a press release so that they are prepared to respond to potential queries.

Press briefings and public meetings should be considered by competent authorities of the Agency for safety concerns or other matters relating to the safety of medicinal products that are of high media interest or when complex or animal or public health-sensitive messages need to be conveyed.

2.1.5.6. Coordinated inter-agency communication tools: 'Lines to take' documents

'Lines to take' documents are prepared when coordination of communication cross the Union is necessary. They are not intended for publication. Usually they are prepared by one regulatory authority to assist other regulators in answering enquires or communicating on a specific pharmacovigilance issue in a consistent manner, particularly where coordination is required within the regulatory network. This is particularly important for, but not limited to, management of incidents or potential crises[1]. Although not for publication, they should only contain information that can be released on request (i.e. not confidential information). 'Lines to take' should be prepared in a very short timeframe (usually a few hours) and circulated to the network promptly.

2.1.5.7. Other means of communication

In addition to those discussed above, other tools and channels include, for example, publications in scientific journals and journals of professional bodies, lectures at universities or professional bodies, scientific conferences.

2.1.6. Setting a timetable for communication

A timetable should be determined for each communication initiative. Timetables should detail all the relevant timelines required for preparation and management of the communication (e.g. including the internal review, quality control and approval process; approval by competent authorities and the Agency; translation of communication, as required; dissemination; and follow-up measures required to monitor effectiveness). The timetable should be agreed in advance between the marketing authorisation holder, the competent authority, and the Agency, as required, and should be respected by all partners. However, a proactive and pragmatic approach should be taken if, for example, delays occur, which should be communicated promptly to the concerned parties.

[1] Incident management plan for medicines for veterinary use (EMA/711053/2010-Rev.2) https://www.ema.europa.eu/en/documents/other/incident-management-plan-medicines-veterinary-use_en.pdf

2.1.7. Follow-up of communication and measuring its effectiveness

Communication is considered effective when the message transmitted is received and understood by the target audience in the way it was intended, and appropriate action is taken by the target audience. The effectiveness of the communication should be measured. However, it should be acknowledged that in practice such assessment is difficult to make, and to interpret, and to ascribe to the communication initiative. Therefore, methods for measuring effectiveness should be practicable and proportionate in relation to the urgency and importance of the subject communicated. Consideration should be given to investigating:

- whether, and which proportion of, the target audience was reached (i.e. is the list of recipients accurate and up to date?);
- the timeliness of receipt of the communication;
- whether the communication tools used were appropriate; and
- whether the key message was understood and, where necessary, acted on or attitudes or behaviour changed in line with the message.

Examples of approaches to measure communication effectiveness include the following:

- Receipt of responses to the communication, if expected, which would require subsequent analysis and consideration.
- Data analyses in the Union pharmacovigilance database to monitor the development of certain adverse events requiring action or other safety measures, e.g. decrease in frequency of human adverse events following recommendations to wear gloves; decrease in fatalities in cats after information campaigns on the risks of permethrin.
- In the case of direct animal health care professional communications, marketing authorisation holders should inform the relevant competent authorities of the total number of veterinarians and animal healthcare professionals or veterinary practices targeted and the number that received the direct animal health care professional communications, e.g. after a defined number of delivery attempts, if necessary.

Where relevant, communication should be complemented at a later stage with follow-up communication, e.g. on the resolution of a safety concern or updated recommendations.

The evaluation of the effectiveness of communication should also ensure that lessons learned are considered and acted on. This is important to identify difficulties encountered during the process and enable recommendations for improvement to be made to the overarching communication plan and procedures for its implementation.

2.1.8. Procedures for communication

It is important to ensure procedures are in place concerning communication on pharmacovigilance issues, in particular, but not limited to, public announcements on pharmacovigilance [(Article 20(2)(g) of Implementing Regulation (reference to be updated when available); see also VGVP Module on Pharmacovigilance systems, their quality management systems and pharmacovigilance system master files (EMA/257136/2021)].

3. Overarching and topic-specific communication plans

3.1. Overarching communication plan

Marketing authorisation holders shall have an overarching communication plan that identifies the relevant stakeholders in the Union, including veterinarians, other healthcare professionals, customers and the general public [Article 20(1) of Implementing Regulation (reference to be updated when available)]. In cases of urgent safety concerns, it shall outline the approach to be taken to communicate in a timely manner concerns arising from pharmacovigilance data or in relation to other relevant pharmacovigilance information. [Article 20(1) of Implementing Regulation (reference to be updated when available)]

In practice, this means that marketing authorisation holders are required to have an overarching communication plan as part of their pharmacovigilance system (see VGVP module on pharmacovigilance systems and their pharmacovigilance system master files and quality management systems (EMA/618404/2020); Article 20(1) of Implementing Regulation (reference to be updated when available)].

Competent authorities and the Agency should also have an overarching communication plan in place. The overarching communication plan comprises the information and procedures required for communicating on veterinary pharmacovigilance issues in a timely manner to relevant stakeholders in the Union. Stakeholders include, but are not limited to, veterinarians and animals healthcare professionals, pharmacists, animal owners and the general public. Although primarily intended for communication of urgent safety concerns or where potential regulatory action may be required, based on pharmacovigilance data, the overarching communication plan may also be useful for addressing communication of non-urgent veterinary pharmacovigilance information. Whilst it is acknowledged that every eventuality cannot be addressed in the overarching communication plan, it should however contain the relevant information 'ready for use' when needed.

3.2. Components of an overarching communication plan

The overarching communication plan includes information on how the following will be determined, and the procedures to follow, when communication is required e.g. for dissemination of a direct animal health care practitioner communication to veterinarians following suspension of the marketing authorisation of a product following pharmacovigilance concerns (see also Annex III of this module which provides an example of the components of an overarching communication plan). The overarching communication plan comprises the necessary procedures and information required to determine and address the following [Article 20(2) of Implementing Regulation (reference to be updated when available)] :

1. Objectives.
2. Target audience.
3. Additional stakeholders involved in:
    - 3.1. preparing and approving the communication (e.g. marketing authorisation holders, competent authorities and the Agency); and
    - 3.2. disseminating the communication (e.g. VSBs, veterinary associations etc.).
4. Tools for communication.
5. Means of dissemination.

6. Follow up and measuring effectiveness of communication.

7. Timetable.

8. Agreement on topic-specific communication plans prepared using the template in Annex II of this module, specific to the topic of communication.

9. Procedures in place for preparing and managing veterinary pharmacovigilance communication, should include, but not be limited to:

    9.1. ensuring the relevance and clarity of the information for the target audience, in line with the requirements of the overarching communication plan outlined in this section, and the principles in Section 2 of this module;

    9.2. ensuring timely notification of the intention to communicate on veterinary pharmacovigilance, in particular for public announcements, between marketing authorisation holders and competent authorities and the Agency, as applicable, and vice-versa; and

    9.3. for competent authorities and the Agency, ensuring coordination of communication at Union level, when appropriate.

3.3. Topic-specific communication plan

As referred to in the introduction of this module, a template (Annex II of this module) for a topic-specific communication plan has been developed for use to detail how the overarching communication plan is applied when communication is required for a specific situation. The template should be used to detail the steps required, including projected time-lines, for preparing, disseminating and evaluating follow-up of communication, documented in a transparent way, for a specific communication initiative e.g. dissemination of a direct animal healthcare practitioner communication to veterinarians following suspension of the marketing authorisation of a product following pharmacovigilance concerns. The principles described in Section 2 of this module should be considered, and judgement applied, for populating the template tailored to the specific situation. Deviations from the key principles described in this guidance should be documented for audit purposes and transparency. The topic-specific communication plan prepared using the template in Annex II of this module, specific to the particular initiative should be agreed with the relevant competent authority or the Agency prior to implementation and adhered to, as far as possible, by all parties. Where deviations from the agreed topic-specific communication plan occur, including delays, these should be communicated to all parties as soon as practicable.

3.4. Quality control including maintenance

Procedures should be in place to ensure that overarching communication plans address the relevant key principles in Section 2 of this module.

Overarching communication plans should be subject to quality controls to ensure this and review of topic-specific communication plans (prepared in accordance with Annex II of this module) can be used to ascertain how the principles in the overarching communication plan are applied and followed. For this purpose, review procedures with allocated tasks and responsibilities should be documented and followed to ensure the principles are applied, as necessary, and to ensure accuracy, relevance and clarity of communication [Article 20(2)(e) of Implementing Regulation (reference to be updated when available)].

It is essential that the information contained in the overarching communication plan is kept up to date and relevant and therefore reviewed periodically. Evidence should also be retained of how

communication is distributed, how communication procedures and materials are reviewed (e.g. to ensure they are up to date and remain relevant) and updated, as required, ensuring appropriate version control.

4. Future steps

It is foreseen that this guidance will be reviewed and updated at regular intervals, or as required, on the basis of experience gained.

Definitions

Please refer to the VGVP Glossary (EMA/118227/2021) for relevant definitions.

Appendix I: Template: Direct animal healthcare professional communication[2]

<Date>

<Active substance, name of medicinal product and main message *(e.g. introduction of a warning or a contraindication)*>

Dear Veterinarian <and animal healthcare professional – specify as required>

<Name of marketing authorisation holder> in agreement with <the European Medicines Agency> and the < Competent Authority > would like to inform you of the following:

Summary

Guidance: This section should be in bullet points.

- <Brief description of the safety concern in the context of the therapeutic indication, recommendations for risk minimisation (e.g. *contraindications, warnings, precautions of use)* and, if applicable, switch to alternative treatment>
- <Recall information, if applicable, including level (pharmacy) and date of recall>

Background on the issue/concern

Guidance: This section may include the following information:

<Brief description of the therapeutic indication of the veterinary medicinal product or administration of medicinal product for human use in animals>

<Important details about the safety concern (adverse event, severity, statement on the suspected causal relationship, and, if known, the pharmacodynamic mechanism, temporal relationship, positive re-challenge or de-challenge, risk factors)>

<An estimation of the frequency of the adverse event reporting with estimated animal exposure/denominator>

<A statement indicating any association between the adverse event and off-label use, if applicable>

<If applicable, details on the recommendations for risk minimisation>

<A statement if the product information is to be or has been revised, including a description of the changes made or proposed> *Guidance: No need to include or attach the precise (translated) text of the product information which, at the time of dissemination of the direct animal health care professional communication may not be available as final approved translations)*

<Place the risk in the context of the benefit>

<The reason for disseminating the direct animal health care professional communication at this point in time>

<Any evidence supporting the recommendation (e.g. include citation(s) of key study/ies)>

<A statement on any previous direct animal health care professional communications related to the current safety concern that have recently been disseminated>

[2] This template should also be used for the preparation of a core Union direct animal healthcare professional communication .

<Any schedule for follow-up action(s) by the marketing authorisation holder/competent authority/the Agency, if applicable>

Call for reporting

<A reminder of the need and how to report adverse events in accordance with the national reporting system, including the details (e.g. preferably electronic links/website address, name, postal address) on how to access the national reporting system>

<For immunological/biological medicinal products, also include a reminder to report the product name and batch details>.

<Mention if product is subject to additional surveillance requirements and the reason why>

Company contact point

<Contact point details for access to further information, including relevant website address(es), telephone numbers and a postal address>

Annexes *(if applicable)*

<Link/reference to other available relevant information, such as information on the website of a competent authority/the Agency>

<Additional scientific information, if applicable>

<List of literature references, if applicable>

Appendix II: Template: Topic-specific communication plan

TOPIC-SPECIFIC COMMUNICATION PLAN FOR: <Direct animal health care professional communication or other communication tool (to be specified)> ON <*insert subject*>>	
Medicinal product(s)/active substance(s)	
Marketing authorisation holder(s)	*In cases where the communication concerns several marketing authorisation holders of the same active substance or is part of a class review, it is strongly encouraged that a single consistent message is sent to animal healthcare professionals in each Union Member State.* *All concerned marketing authorisation holders in each Member State are strongly encouraged to collaborate, so that a single communication is prepared and circulated in each Member State. The communication circulated in each Member State should cover all active substance-containing products authorised in that Member State.* *It is encouraged that the reference/originator marketing authorisation holder (where available) in each Member State acts as the contact point for the competent authority, on behalf of the other concerned marketing authorisation holders in the same Member State. If no reference product is marketed in the Member State, it is encouraged that one of the concerned generic companies acts as contact point for the competent authority.*
Issue and objectives of the communication	*Consider using the title of the communication to describe the concern*
Target audience (to be specified) <direct animal health care professional communication> recipients	*List all (groups of) recipients in this section, e.g. veterinarians, other animal healthcare professions, pharmacists, product wholesalers and distributers.*
Member States where the communication <to be specified> will be distributed	
Stakeholders to coordinate with	*Veterinary statutory bodies, specialist veterinary associations, associations of pharmacists, associations of veterinary medicinal product wholesalers or distributors.*
Means of dissemination	*Email, traditional post (e.g. via courier), publication in press, webpages. This may vary in different Member States*
Follow-up and measurement of effectiveness	*Specify measures for measuring effectiveness e.g. responses required, surveys to conduct, need for follow-up communication.*

513

Timetable *(Delete steps which are not applicable)*	**Date**
Preparation of draft <direct animal health care professional communication or other communication tool to be specified>	
Consultation on draft <communication tool to be specified> with involved partners (to be specified as necessary)	
Submission of draft <communication tool to be specified> and topic-specific communication plan to <the rapporteur, RMS or LMS, as applicable/competent authorities/Agency (to be specified)>	
Draft <communication tool to be specified> and topic-specific communication plan agreed by rapporteur, RMS or LMS, as applicable	
If coordinated communication required, draft <communication tool to be specified> and topic-specific communication plan (in English) agreed by PhVWP-V	
Submission of translations to the competent authorities for review	
Agreement of translations by competent authorities	
Dissemination of <communication tool to be specified>	
Evaluation of effectiveness (measure to be specified)	
Follow up required (measure to be specified)	
Lessons learned and recommendations (to be specified)	

514

Appendix III: Example of components of an overarching communication plan

Overarching communication plan component	Sub-categories or examples	Further details
1. **Objectives of communication**		Key messages (or core key messages) to be defined
	Urgent regulatory action proposed by marketing authorisation holder (MAH)	
	Urgent regulatory action intended by competent authority/Agency	
	Urgent safety concern possibly impacting benefit-risk balance	
	Other veterinary pharmacovigilance issue including non-urgent issues	
	Etc.	
2. **Target audience**		**How to contact (examples) N.B. Liaison and cooperation between competent authorities and MAHs is advisable (preferably in advance of communication) concerning the organisations below and particularly in case of any problems encountered**
	Veterinarians	Veterinary statutory bodies (VSBs) or other animal healthcare professional body (e.g. National College of Veterinary Surgeons); Association of different veterinarian specialists (e.g. on equine, bovine, etc.).
	Other (non-veterinarian) animal healthcare professionals authorised to prescribe and administer veterinary medicinal products (VMPs) to animals	Other (non-veterinarian) animal healthcare professional associations
	Pharmacists and other professionals responsible for dispensing VMPs	Professional pharmacist associations
	VMP wholesalers and distributors	Customer database client list

Overarching communication plan component	Sub-categories or examples	Further details
	Animal owners/keepers – production animals	Professional agricultural organisations; Customer database client list
	Animal owners/keepers – companion animals	National breeders' associations, kennel clubs etc.
	Etc.	
3. **Additional stakeholders**		
	Veterinary statutory bodies	See contact information of the associations' website
	Associations of veterinarian specialists	
	Associations of pharmacists	
	Etc.	
3.1. **Stakeholder coordination**		Coordination via:
	Union competent authorities	Union pharmacovigilance database (e.g. pharmacovigilance alert system)
	European Medicines Agency	
	European Commission	
	Other (to be specified)	
4. **Tools for communication**		
	Direct animal healthcare professional communication	
	Animal owner communication (e.g. pamphlet or leaflet)	Package leaflets, articles in non-scientific journals for animal keepers, microblogs (e.g. Twitter)
	Press release	
	Lectures	At universities, scientific conferences etc.
	etc	
5. **Means of dissemination**		
	Email	
	Traditional post (with confirmation of receipt which should be retained for audit purposes)	

Overarching communication plan component	Sub-categories or examples	Further details
	Publication in press	
	Webpages	
	Etc.	
6. **Follow-up and measurement of effectiveness**	Criteria & methods for measuring effectiveness	
	Responses to communication	Receipt of responses if requested in the communication
	Conduct surveys	Surveys among target audience on usefulness of the communication
	Receipt of feedback	Questions, comments from target audience
7. **Timetable**	Include steps required for preparation, approval, dissemination and follow-up of communication (for use/deletion as required)	All relevant steps for preparation and management of the communication should be determined. Deadlines to be inserted for the relevant steps for communication plan (allowing for sufficient time for review). The timetable should be agreed in advance. Compliance with the timetable should be respected by all partners.
	Preparation of draft communication	Deletion of one or more step(s) is acceptable if required, e.g. in case of urgent safety issues when rapid communication is considered of vital importance.
	Consultation on draft with involved partners	
	Submission of communication e.g. Direct animal healthcare professional communication and topic-specific communication plan to competent authorities/Agency as applicable	

Overarching communication plan component	Sub-categories or examples	Further details
	Communication e.g. Direct animal healthcare professional communication and topic-specific communication plan (in English) to be agreed by PhVWP-V (where coordinated communication required)	
	Submission of translated communication <e.g. Direct animal healthcare professional communication> to the competent authorities for review	
	Agreement of translations by competent authorities	
	Dissemination of e.g. <Direct animal healthcare professional communication to veterinarians>	
	Follow-up of communication	Measures to be specified e.g.
	Measurement and evaluation of effectiveness	
	Confirmation of completion of communication initiative and provision of evaluation of effectiveness to competent authority or the Agency, as required.	
8. **Agreement on topic-specific communication plan**		Agreement should be attained with the relevant competent authority or the Agency prior to implementation.
9. **Procedures in place for veterinary pharmacovigilance communication**	Insert references to procedures to be followed	Should be subject to quality controls and review and updated in consideration of lessons learned, if applicable
10. **Quality control and lessons learned**	Analysis of the specific communication initiative	If applicable recommendation of changes to the topic-specific communication plan
	Implementation of lessons learned and corrective actions	

516