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# Reflection paper on pharmacovigilance communication concerning veterinary medicinal products

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# 1. Introduction

The experience gained by regulatory authorities has demonstrated the need and the benefits of streamlining and coordinating the communication process effectively within the European Union (EU) regulatory network which is of particular relevance when it refers to pharmacovigilance communication. This document will provide an overview of different types of communication tools used by national competent authorities (NCAs), the European Medicines Agency (EMA or the 'Agency') and marketing authorisation holders (MAHs) with specific focus on direct veterinary medicine communication (DVMC). In addition, principles on how to communicate and coordinate pharmacovigilance information for veterinary medicinal products (authorised via prescription only or available over the counter) in the EU/European Economic Area (EEA) will be described. These principles may also be useful for MAHs to apply as part of good pharmacovigilance practice. Such communication is warranted when an emerging pharmacovigilance concern could modify the benefit-risk balance of a veterinary medicinal product and possibly require risk minimisation activities. Volume 9B of The Rules Governing Medicinal Products in the European Union includes principles for communication to the public and for the benefit of veterinarians and other health-care professionals, in particular. Volume 9B Part II: Guidelines for competent authorities and the Agency also includes the following: The Agency and NCAs should ensure that veterinarians and other health-care professionals and the general public are informed, where appropriate, of any significant pharmacovigilance issues, including significant changes in the product information (summary of product characteristics (SPC) and package leaflet), of suspension or withdrawal of a marketing authorisation (MA) due to pharmacovigilance data and of any suspected or confirmed concerns requiring vigilance. Effective coordinated communication is the cornerstone for management of potential incidents and/or crises. In addition, independent of pharmacovigilance communication, NCAs and the Agency have an ongoing responsibility to encourage reporting of adverse events by veterinarians and other health-care professionals and to encourage animal owners or users of the veterinary medicinal products to communicate any adverse events to veterinarians and to other health-care professionals, the MAH or to the NCAs.

Volume 9B Part IV: Guideline on public communication on medicinal products for veterinary use contains key principles which will be further reflected on in this paper. The objective of effective pharmacovigilance communication is to provide timely evidence- and causality-based information on the safe and effective use of veterinary medicinal products, which allows each party to modify their animal health practices for the benefit of animals and ultimately to protect and promote animal and public health. As a general principle consultation between the MAH and the NCAs or the Agency (and other partners as appropriate) is advisable on the format and content of the information to be communicated, the recipients and timetable before publishing to ensure harmonised and consistent information. However, the legal requirements should be respected by all concerned parties.

# 2. Terminology

Pharmacovigilance communication is an interactive process of exchange of information and may support veterinarians and other health-care professionals to prevent and respond to any concerns arising from pharmacovigilance. Communication to veterinarians and other health-care professionals, animal owners or users of veterinary medicinal products is defined as transmission of information aimed at ensuring safe and effective use of veterinary medicinal products.

Direct veterinary medicine communication (DVMC) is defined as information aimed at ensuring safe and effective use of veterinary medicinal products which is delivered directly (e.g. by post or email) to

individual veterinarians, other health-care professionals and/or animal owners or users by a MAH or by a competent authority.

Non urgent information (NUI) refers to pharmacovigilance data which do not require immediate or urgent action.

Urgent information describes pharmacovigilance data which require immediate action and could require major changes in the status of the marketing authorisation.

Signal refers to information arising from one or multiple sources, including observations and experiments, which suggests a new potentially causal association, or a new aspect of a known association between an intervention and an event or set of related events, either adverse or beneficial, that is judged to be of sufficient likelihood to justify verificatory action.

Risk refers to any risk relating to the quality, safety or efficacy of the veterinary medicinal product as regards animal health or public health and any risk of undesirable effects on the environment.

Benefit-risk balance refers to an evaluation of the positive therapeutic effects of the veterinary medicinal product in relation to the risks described above.

Benefit-risk management is the process, distinct from benefit-risk assessment of weighing policy alternatives. It includes the establishment of a benefit-risk assessment policy, the evaluation of benefit-risk management options and the monitoring and review of decisions taken.

# 3. Scope and objectives

This paper aims to develop principles for ensuring transparent and effective transfer of pharmacovigilance information to veterinarians and other health-care professionals, animal owners or users of the veterinary medicinal products in an objective and clear manner to optimise the safe and effective use of the products.

This paper will provide an overview of the different types of pharmacovigilance communication tools and methods used by NCAs and the Agency (see Section 5.4). This may also promote and facilitate optimal use of resources across Member States, where and when appropriate, to encourage veterinary pharmacovigilance communication in a harmonised manner.

# 4. Legal basis

Article 51 of Regulation (EC) No 726/2004 includes recommendations concerning the communication of information on adverse events relevant to veterinary medicinal products, in particular for the benefit of healthcare professionals, are also outlined in Part IV of Volume 9B.

Article 57 of Regulation (EC) 726/2004 contains, in particular, the following reference: "the Agency, acting particularly through its committees, shall undertake the following tasks:

> (e) assist Member States with the rapid communication of information concerning pharmacovigilance to health-care professionals.
>
> (f) distribute appropriate pharmacovigilance information to the general public."

Additionally, Article 47 of Regulation (EC) 726/2004, respectively Article 87 of Directive 2001/82/EC, refers to the responsibility for encouraging veterinarians and other health-care professionals, animal owners and breeders to report adverse events.

Finally Article 49 (5) of Regulation (EC) 726/2004, respectively Article 75 (8) of Directive 2001/82/EC, state the following: "The holder of a marketing authorisation may not communicate information relating to pharmacovigilance concerns to the general public in relation to its authorised medicinal product without giving prior or simultaneous notification to the Agency/competent authority. In any case, the marketing authorisation holder shall ensure that such information is presented objectively and is not misleading."

# 5. Structures and processes

## *5.1. Principles of pharmacovigilance communication*

The following principles should be considered for pharmacovigilance communication on veterinary medicinal products:

- The overriding principle should be to ensure that the right message is delivered to the right audience at the right time. Consideration should therefore be given to what to communicate (using appropriate terminology and taking into account the different levels of knowledge) in addition to how to communicate, when and to whom, based on an appropriate benefit-risk evaluation.
- The provision of information about safe and effective use of veterinary medicinal products is an essential element of pharmacovigilance activities and should be considered an animal and public health responsibility.
- The description of the risk should always be placed in the context of the overall benefit of the veterinary medicinal product.
- Communication between MAHs and NCAs or the Agency is considered to be an essential part of pharmacovigilance. As a general principle consultation between the MAH and the NCAs or the Agency (and other partners as appropriate) is advisable regarding a communication as this is considered to be beneficial to all parties involved.
- Communication of pharmacovigilance information needs to be considered throughout the benefit-risk management process.
- It is essential that such relevant information is communicated to veterinarians, other health-care professionals, animal owners or users of the veterinary medicinal product and concerned partners including professional organisations, learned societies, authorities for food safety and pharmaceutical wholesalers depending on local regulations or conventions.
- In principle, significant new or emerging information should be brought to the attention of veterinarians and other health-care 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. In the case of an over the counter product, communication to animal owners or users of significant new information should preferably be simultaneous with communication to veterinarians and other health-care professionals. The important function of veterinarians and other health-care professionals in disseminating such information to animal owners or users of the veterinary medicinal product should be recognised and supported.
- Effective pharmacovigilance communication in the EU/EEA entails adequate coordination by all partners involved (and, when appropriate, outside the EU/EEA as detailed in Volume 9B Part II) and a strategy which meets the requirements resulting from the urgency to communicate and from the expected impact of the information on animal or public health in different Member States. It is therefore important that other NCAs and, where applicable, the Agency are informed of potential

communication in case of media questions on such issues and to have consistent answers from the regulatory network to queries (so-called 'lines to take'). Where necessary it may be useful that MAHs are also informed to ensure a consistent message is given.

- Communication should not usually take place before the corresponding regulatory procedure has been completed, however, exceptionally (e.g. in the case of an urgent safety restriction) there may be a need to disseminate information prior to completion of a procedure. For centrally authorised products (CAPs) the appropriate point in time for dissemination of information is usually once the CVMP opinion has been adopted.
- A consultation between the MAH and the NCAs or, in the case of CAPs, the Agency (and other partners as appropriate) is advisable on the format and content of the information, intended recipients and the timetable. If a timetable is agreed for release of the information it should be fully respected by all partners. For all communication on pharmacovigilance issues either to veterinarians, other health care professionals or the general public it is advisable to ensure concerned parties are informed in a timely manner.
- In order to verify or invalidate a potential signal NCAs might need to request further information and stimulate reporting concerning a certain veterinary medicinal product or a class of products. If such a situation arises, it must be emphasised that at that time there is not enough information available to conclude on any potential causal relationship between the product/product class and emerging concern.
- For general encouragement of reporting of adverse events direct contact with veterinarians and other health-care professionals, as well as organisations representing these individuals is advocated. Further encouragement of reporting can be achieved by providing transparent feedback and accessible pharmacovigilance review of reports; ensuring veterinarians and other health-care professionals can see the benefit of reporting, which is foreseen as part of the Eudra-Vigilance Veterinary (EVVet) access policy. Other means of encouragement are also useful, such as the publication of articles in relevant journals, the participation in discussions at veterinary colleges particularly with new graduates and the stimulation of research in the area of veterinary pharmacovigilance. The importance of providing good quality data should be stressed and information on what defines good quality data should be provided to all partners concerned. Ongoing encouragement of reporting is necessary and annual reporting of the experience of the Agency or the NCAs to the concerned veterinarians and other health-care professionals is desirable.

## *5.2. Audiences*

The main target audiences of pharmacovigilance communication consist of veterinarians, other health-care professionals or users of the veterinary medicinal product who prescribe, handle, dispense or administer the products that are the subject of the concern. Animal owners or users of the veterinary medicinal product are also a target audience for pharmacovigilance communication, as a high level of interest from the public is anticipated around the safe and effective use of veterinary medicinal products and it is most important that clear and consistent messages are provided across the EU/EEA, which will also result in increased trust in the regulatory system.

It is also important to consider other specific audiences and parties in the EU/EEA acting as information multipliers such as health ministries, public and animal health agencies and authorities for food safety. Agricultural associations can also play a role in spreading important urgent information through their channels to strengthen the message.

Close relations with other third parties (such as the scientific community, learned societies and scientific journals) are encouraged so that any new information or upcoming publication which may relate to the "safety" of veterinary medicinal products reaches quickly the competent authorities and MAH for prompt action.

## *5.3. Situations requiring communication, the timetable and content of pharmacovigilance communication*

A well balanced and efficient system is sought which ensures that the EU regulatory network is made aware of all relevant safety information which becomes publicly available while minimising workload. The following criteria could be used to select the information which should be communicated in a coordinated manner in relation to veterinary medicinal products authorised in more than one Member State:

- suspension, withdrawal or revocation of a MA for safety reasons;
- start or finalisation of an Article 78 of Directive 2001/82/EC or community referral procedure for safety reasons;
- restrictions of indications (changes to 4.2 of the SPC);
- whenever a DVMC is agreed by the PhVWP-V/CVMP which contains specific new information and/or recommendations for veterinarians and other health-care professionals on the safe and effective use of veterinary medicinal products (e.g. potential for medication errors, supply shortages, quality defect, etc.);
- in case of any other emerging safety concern that may give rise to media interest (e.g. publication in a scientific journal); and
- stimulation of reporting for emerging pharmacovigilance issues.

There may be cases where sharing of information via established routes (e.g. the NUI system) concerning veterinary medicinal products authorised in only one Member State may be relevant for other Member States where the product may not be authorised but used under the conditions outlined in the prescribing cascade, for example.

In addition to the principles for pharmacovigilance communication, the following key points should be considered for communication on veterinary medicinal products by means of DVMCs in particular:

- Communication should describe in a clear and concise way any new important information on an authorised veterinary medicinal product.
- The reason for initiating the pharmacovigilance communication should be clearly explained.
- Recommendations to veterinarians and other health-care professionals on how to deal with the information should be provided if known, for risk minimisation or for provision of alternative treatment.
- The information should not be misleading and should be presented objectively by placing the risk in the context of the benefit and should not contain any material or statement which is considered to be promotional or commercial.
- A list of contact points for further information, including websites, telephone numbers and a postal address to write to should be provided at the end of the communication.
- A list of literature references should be annexed, when relevant.

- The information should include a reminder of the need to report adverse events in accordance with the established reporting systems.
- Upon receipt of a notification from a MAH of its intention to communicate information to veterinarians, other health-care professionals, animal owners or users of the veterinary medicinal product relating to pharmacovigilance concerns, the Agency or the NCA should review the information and provide the MAH with comments, if necessary, to ensure that the information is presented objectively and is not misleading. As a general principle consultation between all partners involved is advisable on the format and content of the information, recipients. If a timetable has been agreed for release of the information, it should be fully respected by all partners.

## *5.4. How to communicate: tools and channels*

A variety of methods for pharmacovigilance communication is already used. An overview of the tools used is provided in Figure 1 below.

| | | **Veterinarian and other health-care professionals** | **Animal owners or users of the veterinary medicinal product** |
|---|---|---|---|
| **Urgent** | **Tools:** | DVMC<br>Press release | Press release<br>Press conference<br>Q&A |
| | **Via:** | Medical-scientific press<br>Post<br>Fax<br>Email<br>Rapid Alert System (NCAs)<br>Veterinary clinic/pharmacists warning<br>MAH communication (letter/webpage | TV- press: press agency/print-audio-visual press<br>Lay press<br>Free telephone number<br>Websites of NCAs, veterinarians and other health-care professional–networks<br>Animal health insurance providers<br>MAH communication (webpage) |
| | | **Cooperate:** Associations, societies professional boards, veterinarians and other health-care professionals | **Cooperate:** Associations, societies professional boards, veterinarians and other health-care professionals |
| **Non urgent** | **Tools:** | DVMC<br>Poster<br>Publication<br>**Educational Material:**<br>Veterinarians guide<br>Pharmacists guide<br>Checklist: how to prescribe and dispense | Poster<br>Article<br>**Educational Material:**<br>Animal owner card<br>Animal owner booklet<br>Animal owner guide |
| | **Via:** | Medical-scientific press<br>Assistance software<br>Training courses<br>Website (mailing list)<br>MAH communication (letter/webpage)<br>**Cooperate:** Associations, societies professional boards, veterinarians and other health-care professionals | Website<br>Animal health networks<br>Animal health-insurance providers<br>MAH communication (webpage)<br>**Cooperate:** Associations, societies professional boards, veterinarian and other health-care professionals |
| **Promotion of reporting adverse events** | **Tools:** | DVMC<br>Poster<br>Publication | Poster<br>Article |
| | **Via:** | Medical-scientific press<br>Assistance software<br>Training courses<br>MAH communication (letter/webpage)<br>**Cooperate:** Associations, societies professional boards, veterinarians and other health-care professionals | Website<br>Animal health networks<br>Animal health-insurance providers<br>MAH communication (webpage)<br>**Cooperate:** Associations, societies professional boards, veterinarians and other health-care professionals |

Figure 1 Overview of types of communication and methods used for veterinarians and other health-care professionals and the general public.

Communication tools have become increasingly numerous, varied and powerful. Animal and public health topics, including those related to veterinary medicinal products, are of high general interest. This is likely to significantly influence perceptions of the safety and efficacy of veterinary medicinal products. New communication technologies and growing public interest in animal and public health increase the importance of communication from NCA and MAHs responsible for veterinary medicinal products. Herewith an overview of the possibilities.

Websites of regulatory agencies

The websites of regulatory agencies are important tools for communication to members of the public actively searching for specific information. Documents on the websites should also be reached via search engines as well as by navigating from the home page. Examples of documents published on NCA websites include yearly summaries of adverse event reports and DVMCs approved by the NCA.

Direct veterinary medicine communications (DVMC) (*or 'Dear Dr/DVM letters'*)

A DVMC is defined as information aimed at ensuring safe and effective use of veterinary medicinal products which is delivered directly (e.g. via post or email) to individual veterinarians and other health-care professionals by a MAH or by a competent authority. This excludes replies to requests for information from individual veterinarians and other health-care professionals. DVMCs should not include any material or statement which might constitute advertising or which is considered to be promotional or commercial by the competent authority.

DVMCs are sent out when veterinarians and other health-care professionals need specific advice, recommendations or information regarding the pharmacovigilance concern of a product. DVMCs sent by MAHs should generally have the agreement of the relevant regulatory agency on any recommendations on a safety issue.

Press communication

Press communication by regulatory authorities involves tools such as press releases that are primarily intended for journalists. They are normally prepared by the communication department/press office of the NCA in cases of media interest and should give details of the main safety concern, clearly expressing the recommendations of the regulatory authority.

Lay language communication

Regulatory authorities may need to produce communication material in lay language to help animal owners or users of the veterinary medicinal product understand the scientific and regulatory facts relating to a pharmacovigilance concern, as well as to enable them understand what recommendations have been made. Lay language communication should generally be aimed at members of the public who have an interest in the subject but do not have a scientific, regulatory or media background.

Inter-agency communication tools

The rapid alert (RA) and NUI system has been established for exchange of pharmacovigilance information within the regulatory network. Use of the RA/NUI system is particularly important when one competent authority has concerns about a change in the balance between the benefits and risks of a veterinary medicinal product that could require major changes in the status of the MA such as the need to inform veterinarians and other health-care professionals about an identified risk without delay or takes regulatory action on a particular pharmacovigilance issue, to share information rapidly to enable other authorities to respond to enquiries or communicate on the same issue. Intra-agency communication material, such as lines-to-take documents, are specifically prepared by one regulatory

authority to assist other regulators in answering enquires or communicating on a specific pharmacovigilance issue especially as part of management of incidents or potential crises.

Other web based communication

Many regulatory agencies publish pharmacovigilance articles, press releases or DVMCs on their own websites. In future regulatory agencies may also disseminate information via web tools. Regulatory agencies may also need to review their communication strategies regularly and keep up to date with emerging communication tools used by their target audiences.

Responding to external enquiries

Regulatory authorities should have a system in place for responding to external enquires (as part of the requirement to comply with legislation regarding public access to information and documents) and this is an important aspect of pharmacovigilance communication. Indeed frequently enquires received by regulatory authorities from the public relate to communication materials that have already been published and relate to the safe and effective use of veterinary medicinal products. Some NCAs publish responses to such requests for pharmacovigilance information from the general public on their websites.

MAH communication channels/activities

In addition to the methods listed above, MAHs may communicate to veterinarians and other health-care professionals and/or to animal owners or users of the veterinary medicinal product through the use of letters and webpages.

# 6. Key stakeholders responsible for pharmacovigilance communication

In the first instance, pharmacovigilance communication is the responsibility of the MAH, the NCAs or the Agency. Upon request, the CVMP's PhVWP-V provides advice on the use of veterinary medicinal products authorised in the EU and communication of risks to animal and/or public health at any phase in the product life cycle. Upon request of the Member States or CVMP, the PhVWP-V will advise on the content of the pharmacovigilance information and will collaborate in deciding the timing and the optimal level of coordination.

For CAPs, the CVMP and, where appropriate, the PhVWP-V deals with DVMCs on behalf of the European Commission. Where there is a need to inform veterinarians and other health-care professionals or the public about safety issues relevant to CAPs, the rapporteur or the MAH in cooperation with the rapporteur should propose the content of information for consideration by the PhVWP-V and subsequent discussion and adoption by the CVMP. The agreed information may be distributed in Member States, for example, by DVMC from the MAH. In some cases coordinated press releases, in addition to any CVMP public statements may be necessary. The text and timing for release of such information should be agreed by all parties prior to their dispatch.

For products authorised through the mutual recognition or decentralised procedure, the competent authorities are those of the Reference Member State (RMS) and the Concerned Member State(s) (CMS(s)). For practical reasons, the RMS usually takes the lead for coordination of consistent and synchronised DVMCs in the RMS and all CMSs. In such cases, the RMS should propose the content of the information to be provided and whenever possible this should be agreed by the CMSs and, where possible, consulted with the MAH; and, if necessary, referred to the PhVWP-V should there be a need for advice. There should be agreement whenever possible on the method and timing of distribution of

the information e.g. by letters from MAHs or NCAs, or through NCA bulletins. Agreement should also be reached on the need for and timing of public statements.

For purely nationally authorised products, the competent authorities are those of the Member States where the product is authorised, but it is suggested that one Member State may take the lead in co-ordinating the process with the MAH and apply synchronised timetables across the other Member States in which the product is authorised.

For products subject to Article 78 (of Directive 2001/82/EC) or other community referral procedures, the Agency in relation to CVMP opinions and Commission Decisions and otherwise the RMS, as appropriate, should provide veterinarians and other health-care professionals with consistent information about safety issues. In some cases coordinated press releases, in addition to any CVMP/European Commission public statement, may be necessary. The text and timing for release of such information should be agreed by all parties prior to their dispatch.

Where the MAH proposes or is requested by the NCA or the Agency to disseminate a DVMC, the relevant NCA(s)/the Agency should be provided with the content of the information and the communication plan. A consultation between MAH and the NCAs or the Agency (and other partners as appropriate) is advisable on the format and content of the information, recipients and the timetable. If a timetable is agreed for release of the information it should be fully respected by all partners.

# 7. Conclusion

Communication tools have become increasingly numerous, varied and powerful. Public and animal health topics, including those related to veterinary medicinal products, are of high general interest. This is likely to significantly influence perceptions of the safety and efficacy of veterinary medicinal products. Transparency of the pharmacovigilance communication processes in place would help the public understand the decision-making by competent authorities and MAHs.

Communication to veterinarians and other health-care professionals and animal owners or users of the veterinary medicinal product should be harmonised. Veterinary medicinal product users need unbiased information for safe and effective use of veterinary medicinal products.

Experience with veterinary pharmacovigilance communication should be evaluated and taken into account for further development and refinement of the principles outlined in this document for harmonising the approach to pharmacovigilance communication across the EU. The need for developing guidance on pharmacovigilance communication in future may be considered in light of experience gained applying the principles outlined in this reflection paper.

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