13 July 2017
EMA/CVMP/PhVWP/390033/2014-Rev.1
Committee for Medicinal Products for Veterinary Use (CVMP)

Reflection paper on promotion of pharmacovigilance reporting

Draft agreed by CVMP Pharmacovigilance Working Party (PhVWP-V)	January 2015
Adopted by CVMP	12 March 2015
Revised draft agreed by CVMP PhVWP-V	May 2017
Adopted by CVMP	13 July 2017

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Reflection paper on promotion of pharmacovigilance reporting

Table of contents

1. Introduction

Experience to date within the regulatory network suggests that there may be an issue relating to under-reporting of adverse events associated with the use of veterinary medicinal products (VMPs) particularly with regard to use in food producing animals.

In relation to centrally authorised products (CAPs) alone, approximately 47% of the products currently authorised are authorised for use in food producing species[1]. However adverse event reports in food producing species accounted for only 13% of all adverse event reports received in 2013 in relation to CAPs when this reflection paper was first drafted; with the revision of this paper in 2016, this figure increased marginally to 18%.

This document will provide an overview of the different tools used by national competent authorities (NCAs) and the European Medicines Agency (EMA or the 'Agency') to date to promote pharmacovigilance (PhV) reporting. In addition, further activities that may be beneficial in increasing PhV reporting in general and particularly with regard to food producing animals will be examined.

A focus group meeting on promotion of PhV in food producing animals was held on 23 November 2016 and was attended by a number of practising veterinarians specialised in the food producing sector. These individuals shared valuable insights with the meeting that have been used as a basis to revise this reflection paper and further examine issues that may be important to the PhV promotion strategy of the European network going forward.

2. Legal basis

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

3. Current situation

The Committee for Medicinal Products for Veterinary Use (CVMP) Pharmacovigilance Working Party (PhVWP-V) has previously led initiatives aimed at increasing PhV reporting across the European Union (EU). For example, in 2006 A Simple Guide to Reporting Adverse Reactions template was developed by the PhVWP-V and adopted by the CVMP and subsequently translated and distributed by the majority of NCAs in their respective countries.

The PhVWP-V also contributes to ongoing public communication in respect of the safety of VMPs, particularly with regard to the compilation of an annual public bulletin on veterinary PhV.

At national level, a number of Member States currently employ one or more of the following methods to increase PhV awareness and promote reporting:

- Publication of annual PhV reports;
- Publication of PhV articles and other safety related literature, e.g. product safety notices, information on prudent use of VMPs etc.;
- Dedicated online reporting form for veterinarians/healthcare professionals/animal owners;
- Provision of feedback to reporters;

[1] Species classified as food producing include cattle, chicken, goats, horses, pigs, rabbits, sheep and ducks.

- Provision of PhV training to veterinary students;
- Participation in seminars/conferences/workshops/exhibitions aimed at the veterinary profession or animal owners; and
- Organisation of PhV information days/seminars or incorporation of PhV elements into other seminars related to VMPs.

Additionally it is noted that national legislation is in place in various Member States requiring veterinarians to report adverse events that come to their attention. Where applicable Member States should remind veterinarians of their obligations to report through one or more of the various promotional activities listed above.

4. Possible tools for promotion of PhV and reporting of adverse events

4.1. Feedback to reporters

The time commitment invested by individual reporters is much appreciated and it is acknowledged that the overall time required to submit an adverse event report is one of the factors contributing to under-reporting. Concerns have also been expressed from the veterinary profession that the consequences of reporting were unclear and within some sectors there is a fear that reporting may result in increased scrutiny of a veterinarian's individual practice by authorities or withdrawal of products thereby decreasing the availability of VMPs. The NCAs wish to assure reporters that information provided is used solely for the purposes of PhV, in accordance with the legislation on personal data protection and regulatory action on products is rarely taken on the basis of single reports. Regulators wish to maximise the availability of safe and effective medicines to the veterinary profession. While an individual reporter's experience with adverse events may be limited, it is important that all suspected adverse events (including lack of expected efficacy) are reported to ensure that as much as possible is known about product safety and efficacy profiles and that information available to prescribers and users of VMPs remains current.

The importance of providing feedback to reporters is widely recognised and a number of Member States already provide feedback to individual reporters via email or letters. Sending of the same or similar feedback to each reporter and perhaps multiple times to the same reporter, has been questioned amongst the Member States as it is unlikely to have an impact on increasing reporting. However providing extensive feedback to individual reporters is not always possible due to resourcing issues in NCAs.

Member States could however examine the possibility of sending an overview of reports received or a link to any PhV annual reports/bulletins that may be published by the NCA, to all reporters at year end. Overviews could also be tailored to individual reporters or products where capacity for undertaking such feedback exercises exists. Marketing authorisation holders (MAHs) are also encouraged to promote reporting through the provision of feedback to reporters.

4.2. General ideas to encourage/promote reporting in the future

The following ideas should be considered by the Member States in developing any future PhV promotion strategy:

- Simplify the reporting process, e.g. develop a reporting tool integrated with veterinary practice management software and examine how existing systems in place in different Member States relating to data capture on the use of VMPs could be integrated with existing electronic

reporting systems. It is recognised that this may be difficult to achieve in the short term due to the diversity of available practice management software packages, however the idea shouldn't be discounted and should be revisited as technology progresses into the future;

- Examine how veterinary medical journal software could be adapted to integrate with the PhV systems of NCAs and incorporate a facility for reporting of adverse events via this software;
- Develop an adverse event reporting application for smart phones/tablets;
- Collaborate with veterinary professional regulatory bodies/veterinary societies to promote reporting;
- Use communication tools (e.g. social media) to inform health care professionals more directly in relation to PhV and ensure that they are aware of relevant information that is published by or available from NCAs;
- Consider updating and re-publishing 'A Simple Guide to Reporting Adverse Events' template or alternative multimedia promotional material;
- Collaborate with university veterinary clinics to promote reporting and engage with undergraduate and postgraduate veterinary students to raise the profile of veterinary PhV and educate on the full scope of veterinary PhV (i.e. adverse reactions, lack of expected efficacy, investigations into the validity of the withdrawal period and environmental issues, not just adverse reactions) the importance of reporting suspected adverse events and methods of reporting;
- Organise a network of voluntary veterinarians acting as contact points for NCAs on PhV issues;
- In some Member States veterinarians are obliged to maintain professional knowledge by means of ongoing training/learning. Systems already exist in these countries whereby veterinarians must attain a certain number of points in a given time period and points are awarded for time spent learning or training for the purposes of maintaining professional knowledge. A system could be introduced for awarding points for continuing professional development (CPD) or continuing veterinary education (CVE) to veterinarians for PhV reporting or attending PhV related seminars/workshops (in countries where CPD or CVE is a requirement);
- Promote PhV to other health care professionals in addition to veterinarians, e.g. pharmacists, veterinary nurses;
- Develop a European PhV bulletin with input from MSs and make available online or provide links to national PhV bulletins/annual reports from the webpage containing the CVMP annual public bulletin on veterinary PhV;
- Issue communications on specific PhV topics that may be of current interest to veterinarians/animal owners on the basis of emerging issues reported in the media or elsewhere; and
- Discuss with industry, strategies for promotion of PhV reporting by MAHs to users of their VMPs. For example, specialist training could be provided for product technical managers to ensure that differences between complaints and AE reports are clearly understood and that potential PhV information is not being missed.

4.3. Ideas to encourage further reporting of adverse events, particularly regarding food producing animals in the future

Feedback was received from specialised veterinarians working with food producing species that in relation to these species, the value of submitting reports on individual or limited numbers of animals and known reactions was limited, considering expected levels of morbidity in these species. While this point is acknowledged, it is considered that it is still important to report known reactions and increased levels of morbidity in food producing species so that the most up to date information is available and practitioners that may have less experience with these species can access all available information and make informed clinical judgements regarding use of VMPs.

The following ideas should be considered when attempting to address the issue of perceived under-reporting in relation to food producing animals:

- Implement national strategies in the Member States for developing contact with industry groups representing key areas within the food producing sector or groups representing specialist veterinarians dealing only with food producing animals. For example groups exist in some countries that represent farmers or larger groups of food producers in the dairy sector and many countries may have professional bodies representing veterinarians dealing only with large animals or large scale production such as cattle, pigs and poultry. Strategies to be developed will depend on the existence of such groups and the existing level of interaction with such groups. Furthermore it is noted that the Federation of Veterinarians of Europe is an umbrella organisation incorporating 38 European countries and may be of assistance in liaising between veterinarians and NCAs;
- Consider the need for developing contacts and consulting with specialised non-veterinary professionals e.g. biologists in relation to the interpretation/assessment of adverse events for particular food producing species such as fish. It is recognised that such groups can provide technical knowledge regarding husbandry/animal management conditions that is necessary for the assessment of such reports and that may be lacking amongst NCAs;
- Where veterinarians are not directly involved in the administration of VMPs to groups of food producing animals, they should be encouraged to promote reporting by regularly seeking feedback from clients in relation to their experiences with the administration of VMPs to groups of food producing animals treated by the client;
- Encourage practitioners/breeders/owners to report to the pharmacovigilance network when they call their professional/pet insurance; every practitioner/breeder/owner should have reported to the competent actors of the PhV network before the adverse event is considered by the insurance company (e.g. to pay for a compensation). It is recommended that this requirement be added to each veterinary professional liability insurance programme, breeder insurance or pet insurance policy;
- Collaborate with research institutions e.g. university veterinary clinics to encourage reporting of adverse events in general & from other non-spontaneous sources;
- Adapt existing reporting forms to account for animals treated as groups (poultry, pigs, rabbit etc.);
- Simplify the reporting process; and
- Provide information about how reported adverse events are dealt with. Information provided to prescribers/animal owners/animal carers should highlight that any unexpected clinical sign

observed in animals when treated with a VMP is potentially an adverse event and that new knowledge of how a VMP behaves in the field may form the basis for future updates to the summary of product characteristics.

5. Conclusion

It is evident that there have been varied efforts by the Member States to promote PhV reporting to date. Individual NCAs may wish to reflect on the material presented and examine national strategies for promotion of PhV in future. Following engagement with the veterinary profession, regulators are keen to work on simplifying the reporting process by optimising systems in order to maximise reporting to the NCAs thereby increasing the level of information regarding the use of VMPs that is available to product users. It would be beneficial to continue to ensure liaison/dialogue with veterinarians, in particular specialised veterinarians from the food production sector, both at national and EU level where possible. Experience with promotion of PhV should be evaluated and taken into account, and individual elements of this document could be selected for further development in an effort to harmonise the approach to PhV promotion across the EU.

6. References

- Committee for Medicinal Products for Veterinary Use (CVMP) Veterinary pharmacovigilance Public bulletins 2013 and 2016 (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000167.jsp&mid=WC0b01ac058002dea7)
- Committee for Medicinal Products for Veterinary Use (CVMP) (2006) Veterinary pharmacovigilance in the EU – a simple guide to reporting adverse reactions (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500004990.pdf)
- European Commission (2004) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (http://eur-lex.europa.eu/en/index.htm
- European Parliament and the Council (2001) Directive 2001/82/EC of 6 November 2001 on the Community Code Relating to Medicinal Products for Veterinary Use, as amended by Directives 2004/28 EC, 2009/9/EC and 2009/53/EC in European Commission: The Rules Governing Medicinal Products in the European Union – Volume 5 – EU pharmaceutical legislation for medicinal products for veterinary use (http://ec.europa.eu/health/documents/eudralex/index_en.htm)
- European Parliament and the Council (2006) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN)
- European Commission (2011) Volume 9B - Pharmacovigilance for Medicinal Products for Veterinary Use Guidelines on Pharmacovigilance for Medicinal Products for Veterinary (http://ec.europa.eu/health/documents/eudralex/vol-9/index_en.htm)