EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 March 2015
EMA/CVMP/PhVWP/390033/2014
Committee for Medicinal Products for Veterinary Use (CVMP)

Reflection paper on promotion of pharmacovigilance reporting

Draft agreed by CVMP Pharmacovigilance Working Party	January 2015
Adopted by CVMP	12 March 2015

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 alone, approximately 52% of the products currently authorised are licensed for use in food producing species. However adverse event reports in food producing species accounted for only 13% of all adverse event reports received in 2013 in relation to centrally authorised products.

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.

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 veterinary medicinal products, 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 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 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 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;
- 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;
- Collaborate with university veterinary clinics to promote 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; 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

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.
- 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.
- 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.) to simplify the reporting process.
- 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 medicinal product is potentially an adverse event and that new knowledge of how a medicinal product 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.

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

1. Committee for Medicinal Products for Veterinary Use (CVMP) (2014) Veterinary pharmacovigilance 2014 Public bulletin http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/03/WC500183739.pdf