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Veterinary Medicines Division

## Summary Record of Focus group on promotion of pharmacovigilance for food producing animals

23 November 2016, 11.00-17.00, Room 3F, European Medicines Agency, London – chaired by Peter Ekström

The focus group was held with participants from the Committee for Medicinal Products for Veterinary Use (CVMP) Pharmacovigilance Working Party (PhVWP-V) and interested parties<sup>1</sup> in the context of the ongoing revision of the Reflection paper on promotion of pharmacovigilance reporting (EMA/CVMP/PhVWP/390033/2014) Practising veterinarians specialised in the following food producing species: cattle, pigs, poultry, fish and horses were specifically invited to share with the audience their experience and reflections on the pharmacovigilance system and ways of improving reporting of adverse events in food producing species.

The main objectives of the meeting included discussing and developing approaches to encourage reporting on food producing animals as well as providing feedback to reporters. In addition it was considered whether and how a future collaborative network could be established for veterinary pharmacovigilance of food producing animals.

From the presentations on field experience on pharmacovigilance reporting in the different species and the subsequent discussions, the following elements were highlighted:

1. Reports in cattle comprise the majority of reports for food producing animals.
2. The following were highlighted as factors contributing to under-reporting: The overall time required to submit a report e.g. background investigations, paperwork required etc.); Incomplete information to confirm whether the observed signs were due to an adverse event; the consequences of reporting were unclear and within some sectors, there was potential fear that reporting may result in withdrawal of the product and decrease availability of VMPs.
3. There are examples of reversion to virulence of certain vaccines which were difficult to detect because of delayed time of emergence but have been highly disruptive. Considering the nature of treatment, i.e. preventative medicines administered to large groups of food producing animals, the risk of reversion to virulence remains real even with the newest vaccine techniques. Therefore it was considered that pharmacovigilance (or 'vaccine vigilance') should be optimised for food

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<sup>1</sup> Association of Veterinary Consultants (AVC), European Group for Generic Veterinary Products (EGGVP), Federation of Veterinarians of Europe (FVE) and International Federation for Animal Health (IFAH) Europe



producing animals across the EU to better capture similar future situations in future to allow timely investigation and potential regulatory action.

4. Practitioners considered that in relation to poultry, pigs and fish; reporting on individual animals and reporting of already known reactions, e.g. certain level of lack of efficacy or expected/accepted levels of morbidity would be of limited value. However it was also recognised that this type of know-how, while common to specialised vets would not necessarily be available in published information (SPC), hence would not be available or known to the “EU general practitioner”.
5. While there were improvements mentioned in raising awareness of of pharmacovigilance through education at undergraduate level and through continuing professional development there were still concerns that the importance of reporting is not sufficiently emphasised or understood by veterinarians. Veterinarians often accept that there may be problems with medicinal (e.g. vaccine failures/lack of expected efficacy or adverse reactions) but they do not recognise the need and the benefit of sharing their experiences with regulatory authorities.
6. Improvements are needed to raise the profile of veterinary pharmacovigilance and emphasise the importance of communicating basic pharmacovigilance information and rudimentary training on when and how to report adverse events targeted at veterinarians and non-veterinary professionals responsible for animal husbandry. This should comprise the following elements: identification and recognition of adverse reactions and lack of expected efficacy i.e. to distinguish these from the normal course of disease; raising awareness of reporting routes for adverse events. Basic education would be beneficial both at undergraduate and post-graduate level (as part of the curricula and potential examination criteria for gaining qualifications e.g. European Diplomat) and as part of continued professional development.
7. While there are great efforts in some Member States to provide individual feedback to reporting veterinarians, notably in France, overall there is still concern that insufficient and often no direct feedback is provided to veterinarians. Providing veterinarians with access to pharmacovigilance data may be a useful way of providing feedback on adverse events reported. This would, in turn, enable veterinarians to identify if similar adverse events have been observed.
8. Despite technological advances and increasing use of smart devices, there is still a need for user-friendly electronic reporting tool integrated with practice management systems and the EU pharmacovigilance reporting network. The available practice management software packages used by [specialised] veterinarians are diverse, even within one Member State, and are not yet facilitating pharmacovigilance reporting.
9. Specialised veterinarians highlighted that it is very difficult to find regulatory information on regulator’s websites that is targeted to their species. It was considered that a way to query EU pharmacovigilance data for a particular product of interest for a particular species would potentially be very useful to veterinarians, particularly to identify when particular adverse events may have already been reported.
10. It was recognised that reporting in food producing animals is not only limited to the veterinarians but should also consider the animal owners/carers however a first screening of the information by the veterinarians was still considered preferable. For fish in particular and in certain Member States treatments are provided by non-veterinary professionals e.g. qualified biologists which are also considered important first line reporters of pharmacovigilance data.

11. It was highlighted that for the main food producing animals and in particular for poultry, swine and fish, that specialised veterinarians are increasingly organised at EU level through species groups. Such groups may also be considered as the contact point for potential future collaborative network on pharmacovigilance. The value of national veterinarian associations was highlighted for ensuring continued training and coordinating communication to all veterinarians e.g. by organising specific species specific meetings for veterinarians
12. It was recognised that a pharmacovigilance system that ensures proper and comprehensive feedback to the veterinary community, as individual practitioners as well as specialised group practices remains an important element to animal and public health within the EU.
13. It was highlighted that for the interpretation of adverse events it is often necessary to fully understand the husbandry and animal management conditions of the different food producing species and that this 'know how' is increasingly available from the specialised veterinarians and, for certain species in particular, e.g. fish, non-veterinary professionals, e.g. biologists. Hence regulators may lack this specialised knowledge and also increasingly depend on the input of the specialised veterinarians for the interpretation of pharmacovigilance data
14. It was highlighted that pharmacovigilance is predominantly considered as collecting adverse event data and rarely includes potential lack of efficacy data.
15. It was highlighted that the potential liability and perceived threat of increased scrutiny of a veterinarian's individual practice by the authorities also hinders reporting. Similarly the fear that reporting adverse events may lead to the withdrawal of a particular product from the market was considered to be of particular concern for some species and therefore also hinder reporting on that product, for example, for fish.
16. Some specialised veterinarians proposed that reporting should pre-dominantly occur directly to the authorities instead of the corresponding marketing authorisation holders.
17. It was highlighted that there is very little pharmacovigilance reporting from Academia/ University clinics. However it was also considered that a relatively low proportion of food production animals are treated at veterinary universities.

The Chair concluded the meeting commending the open discussions and feedback provided in particular from the point of view of day to day veterinary practice with food producing animals. The above recommendations will be considered by the CVMP and the PhVWP-V to be taken into account in the revision of the Reflection on paper promotion of pharmacovigilance reporting. In addition there will be further consideration towards future network collaboration to allow for direct exchange of expertise in particular in the field of veterinary medicines for food producing animals.