Pharmacovigilance Expert Working Group

Chairperson: Lynn O. Post (US FDA)

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Introduction

Pharmacovigilance (PV) of veterinary medicinal products (VMPs) can be defined as the detection and investigation of the effects of the use of these products, mainly aimed at safety and efficacy in animals and safety in people exposed to the products.

Within all regions involved in the VICH process there are certain legal obligations for the marketing authorisation holders (MAHs) with regard to adverse events reported to them. Those legal obligations relate to the acceptance of adverse event reports (AERs) and the storage and submission of those reports to the authorities.

EWG Composition

Margarita Brown (US FDA, g) 	Erik De Ridder (IFAH-Europe, i) 	Kaoru Eguchi (JMAFF, g) 	Dave Hustead (AHI, i) 
Cornelia Ibrahim , (EU, g) 	Steven Karli (USDA, g) 	Michelle Nicholson (Canada, g) 	Marie-Odile Hendrickx (IFAH-Europe, i) 
Jos Olaerts (EU, g) 	Glenn Peterson (US FDA, g) Photo	Lynn Post – Chair (US FDA, g) 	Robert G. Rhorer , (AHI, i) 
Peter Scott (NZ-AUS, i) 	Scott Taylor (USDA, g) 	Koji Uchida (JVPA, i) 	

Government (g), Industry (i)

Key scientific issues resolved

GL 24 Management of Adverse Event Reports

Scope is the spontaneous reporting of suspected adverse effects of marketed VMPs, concerning the safety and effectiveness in animals and the safety of people exposed to any veterinary medicinal product with approved claims of protective, therapeutic or diagnostic effect or altering physiological functions.
'Same' and 'similar' were defined for biological and pharmaceutical products, where 'same' indicates the same manufacturing specifications (bio) or formulation (pharma). A 'similar pharmaceutical VMP' is defined as: originating from the same MAH, having the same active ingredients and having major excipients with the same or similar pharmaceutical function, and at least one common registered species.
3rd country expedited reporting requirements of AERs to other VICH regions were resolved.

GL 29 Management of Periodic Summary Update Reports (PSURs)

The frequency and all items to be submitted in the PSUR only for AERs were defined as well as the concept of the 'International Birth Date' (IBD) that provides a basis for harmonizing periodic reporting by the MAH.
A special focus is agreed on the Benefit/Risk analysis and opinion related to: new signals, changes in frequency of the adverse events, drug interactions and human adverse events.

GL 42 Data Elements

To allow comparison and analysis of global safety data and trends, a common definition of the data fields to be used in the description of the adverse event was agreed, as well the "required" status of each field.
The last difficulties sorted out were/are on set-up for fields describing crossbreds and the requirement to list the number of animals for each sign coded.

GL 30 Controlled Lists of Terms

Lists of terms for GL 42 Data Elements were developed to assure consistency and to allow comparison between products and product classes as well as electronic submission of AERs. As an example the clinical signs will all be described using the VEDDRA dictionary.
A task Force was set-up to finalise the lists and these will be maintained with 1 industry and 1 authority representative per region.

GL 35 Electronic Standards for Transfer of Data

This GL is very short and contains a recommendation to ensure transmission is possible, defining the electronic message structure. To this goal, it further defines relationships between the data elements and additional vocabularies as well as business and schema validation rules and field descriptors specifications for AER data and wrapper information.

Key benefits of the harmonized guidelines

It is of importance for all global stakeholders to develop harmonized and common systems, common definitions and standardized terminology within pharmacovigilance. Harmonization of those elements between the regions facilitates the reporting responsibilities for the MAHs, many with worldwide activities. At the same time harmonization of systems and requirements facilitates the inter-regional comparison of data and exchange of information, thereby increasing the general, global knowledge of a product`s general performance and safety profile. This is to the benefit of all stakeholders, including consumers, users, authorities and industry as well as the animals, whose welfare is best served with safe and efficacious VMPs. The global scale of pharmacovigilance will also allow to more readily detect trends that are very rare and therefore will only be detected on a large reporting scale.

Guidelines under development

Guidelines 30 and 35 were the last ones to be finalized by the EWG. Their resolution will lead to a full implementation of all Pharmacovigilance Guidelines. Indeed GL 24, 42 and 29 are all waiting for this moment to come into force simultaneously.

New topics

The next big task for the VICH community will be to ensure that the implementation of this package of five PhV GL will be run smoothly and that the defined lists and dictionaries are maintained.