

INTERNATIONAL HARMONISATION IN THE FIELD OF PHARMACOVIGILANCE FROM AN OIE PERSPECTIVE

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The OIE (World Organisation for Animal Health) is an intergovernmental organization founded in 1924 which aims at improving animal health all around the world. It has 178 Members from all regions of the world and its headquarters, located in Paris, interact with four main entities: Specialists Commissions, Regional Commissions, Reference Laboratories and Collaborating Centres (the French Agency for Veterinary Medicinal Products is one of those). The involvement of the OIE in international harmonization regarding pharmacovigilance hinges on two specific activities which are explicitly mentioned in the OIE 5th strategic plan: the Performance of Veterinary Services (PVS tool) and the VICH - Veterinary International Cooperation on Harmonisation.

OIE tool for the evaluation of Performances of Veterinary Services (PVS tool) is a guide developed in the framework of "Good governance of veterinary services" concept in order to assist countries in their self-evaluation of national veterinary services. It is a three step-tool (evaluation - gap analysis - follow up) performed by independent experts, aiming at the promotion and improvement of veterinary services worldwide by achieving compliance with OIE standards. The existence of a regional and/or national

pharmacovigilance system is a criterion for the highest level of advancement in the critical competency related to the regulation of veterinary products.

The VICH is the Veterinary International Cooperation on Harmonisation on technical requirements for registration of medicinal products. It is an international program created under the auspices of the OIE, and for which OIE acts as an associated member. The objective of the VICH is to establish harmonised technical requirements for veterinary medicines in VICH regions, by developing guidelines. Amongst these guidelines, some are specifically related to pharmacovigilance activities, such as management of adverse events reporting and electronic standards for transfer of data.

In 2009, a questionnaire was sent to all OIE Member Countries in order to have a general view of the situation worldwide on public policy and its implementation (structures and procedures) dealing with veterinary products and to identify the needs and expectations of the OIE members regarding the international harmonization of technical requirements for veterinary medicinal products (VMPs). The responses revealed that amongst

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countries with a very high Human Development Index, all had legislation in place regarding veterinary products and 98% had a national pharmacovigilance system. Developing countries expressed their need for guidance from OIE and VICH for the implementation of basic guidelines, and guidelines in pharmacovigilance were identified as priority number two, after guidelines relating to the quality, safety and efficacy of VMPs. Since 2011, a dedicated VICH Outreach Forum has been constituted to allow better involvement of designated countries or regions other than VICH members in VICH activities.

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