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VETERINARY PRODUCTS: VICH INITIATIVES

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The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products (VICH) is an effort to reach agreement on the studies and scientific data needed for demonstrating safety, efficacy, and quality of veterinary medicinal products in order to be registered or licensed by national regulatory agencies.

Regulatory authorities and industry representatives have participated in VICH from the following countries and regions: USA, EU, Japan, Australia, New Zealand and Canada. Recognising that the availability of safe and effective veterinary medicinal products is a key factor in controlling animal disease worldwide, OIE has been an observer and a strong supporter within VICH from its beginning in 1996.

Following an established VICH process, animal health and public health scientists from each of these regions participate in Expert Working Groups to draft guidances concerning the technical and scientific aspects of product registration. These guidances are then reviewed by the members of the VICH Steering Committee who address any relevant policy concerns. The VICH procedures provide for transparency and for opportunity for interested parties to appropriately modify the proposed guidelines. The final guidelines represent the consensus of all the parties involved. In addition, each regulatory authority participating in VICH has agreed to implement the final guidelines as its national standards. Along with the regulators, representatives of the veterinary pharmaceutical and biologics industries of each region participate on the Steering Committee and in the expert Working Groups.

To this date, VICH has produced over 45 guidelines have been considered and adopted in the fields of Safety, Quality, Ecotoxicity, Good Clinical Practices, Anthelmintics, Pharmacovigilance, Biologicals Quality Monitoring, Antimicrobial Resistance and Target Animal Safety. These guidelines have been implemented, for the most part, in all three VICH regions and in the observer countries. Additional guidelines are under consultation and established guidelines are under review.

As a result of interest by many countries that have not yet participated in VICH, OIE is helping to make others aware of the accomplishments of VICH. Some countries are interested in adopting VICH standards as part of their own licensing requirements. Other countries wish to have more information about the scientific basis for veterinary product approvals in countries currently using VICH guidance.

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