Global Veterinary Product Regulators Converge at VICH 5 Conference

The VICH 5 Public Conference, with the theme *Reaching Out to the World*, was held in Tokyo on 28-29 October 2015. The Conference was successfully organised by the Japanese Veterinary Pharmaceutical Association (JVPA) to bring together veterinary product regulators and others. It was attended by 189 participants from 23 countries, who broadly reviewed and discussed the benefits of VICH outreach to non-VICH countries.

VICH is an international cooperation programme aimed at harmonising technical requirements for veterinary product registration between the EU, Japan and the USA, with Australia, New Zealand, Canada and South Africa as observers. Its full title is the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products. VICH was launched in April 1996 under the auspices of OIE, the World Organisation for Animal Health.

VICH's role is to harmonise technical requirements of data necessary for the marketing authorisation (or "registration") of a veterinary medicinal product. This is achieved by developing harmonised guidelines on the studies to be submitted in a marketing authorisation application.

During the VICH 5 Conference, debate focussed on the benefits of VICH guidelines for non-VICH member countries, the needs and priorities of non-VICH countries regarding the technical requirements for the registration of veterinary medicinal products, and the contribution of VICH to the global One Health approach to food security and to animal welfare.

Dr Donald Prater, Director of the US FDA Europe Office, pointed out that the benefits of VICH to VICH member countries/regions, as well as observers, emerging countries, industry and consumers will accrue through the continued development of new guidelines and maintenance of existing guidelines. Trends in research, One Health, evolution of the livestock sector and other factors will provide new opportunities and challenges.

Dr Sasi Jaroenpioj, representing the Thai FDA and the 10 nations of ASEAN, explained that the primary benefits of the use of the VICH internationally harmonised guidelines include the assurance of product quality, safety and efficacy, the reduction of animal testing and costs of development and the increased availability of new veterinary medicinal products. He recognised that VICH represents a unique opportunity for discussion of regulatory data requirements between worldwide scientific experts from regulators and industry. Speakers highlighted how the VICH guidelines are used in VICH member and observer countries and regions, but also the perspectives and possible regulatory obstacles encountered by VICH Outreach Forum countries/regions in adopting VICH guidelines.

Dr Nicholas Jarrett, European Medicines Agency (EMA) and VICH EU coordinator, confirmed that one of the major objectives of VICH is to minimise the use of animals for regulatory testing in establishing and implementing harmonised technical requirements based on the "3Rs" – replacement, refinement, reduction; whilst ensuring high quality, safety and efficacy standards for the registration of veterinary medicinal products. The conference provided up-to-date information on new VICH topics under development which are of particular interest for the non-VICH countries, such as a guideline on stability studies to address climatic zones III and IV (hot and dry/humid conditions) and new VICH guidelines on residue studies in aquatic species as well as in honey.

Samuel Thevasagayam, from the Bill and Melinda Gates Foundation, explained the importance of regulatory convergence to make quality veterinary medicines and vaccines available, accessible and affordable to the developed world, as well as to developing countries. In these countries, reducing mortality and morbidity is a critical lever to maximise livestock productivity and production by reducing avoidable losses, maximising production, improving income and consequently decreasing poverty, improving food security, assuring nutritional security, reducing impact on climate and realising export aspirations. Dr Steve Vaughn, head of new animal drug evaluation at the Centre for Veterinary Medicine of US FDA set out the vigorous efforts VICH would be undertaking to train regulators around the world about VICH and its guidances.

Edna Massay Kallon from the World Bank Group gave insights into the large global survey the Bank was finalising. The study is part of the World Bank's "Enabling the Business of Agriculture" programme and aims at identifying global obstacles, including in disease prevention and control.

Stefan Lange from Boehringer Ingelheim reminded participants of the rapidly rising need for safe and secure animal food sources, and how that goal needs to be balanced with care for the environment, good animal welfare and societal preferences. The conference concluded that more predictability in the local regulatory environment would be beneficial to all. Harmonised guidelines are seen as useful instruments to set clear and technically well-defined requirements as well as to orient future investments. The VICH countries welcomed increased collaboration with non-VICH countries, in order to improve both human and animal health by providing the VICH standards and knowledge to the world.

The 30 Conference presentations will be made available on the VICH website (www.vichsec.org).

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