

Global experts join forces to improve animal health

By Mark Ross
Chief Executive, Agcarm

Animal health and wellbeing requires greater global cooperation than ever before and New Zealand has the rare opportunity to participate in discussions which will contribute to the health of farm animals and pets around the world.

Delays in urgently-needed treatments for diseases are often caused by a mismatch in global regulatory regimes. This increases costs and often leads to the duplication of studies needed for registering veterinary medicines.

Bringing a veterinary medicine to market is expensive and time-consuming. The research and development programmes needed to take a new product from its development to the market can cost up to \$500 million and take between five to 11 years to complete. To be efficient, the process needs greater transparency as well as an increase of internationally-accepted standards amongst regulators.

One way of doing this is by simplifying the regulatory process to create a universal framework for researchers and developers, allowing faster, more efficient approval of beneficial medicines.

New Zealand is a global partner in the regulation of veterinary drugs and for this reason Agcarm is considering an industry observer status role on the VICH (the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products) steering committee.

VICH was conceived in 1996 as a fall out from the human medicines forum, the International Council of Harmonisation, and is a programme of collaboration between governments and animal health industry groups. Full members include the United States, the European Union and Japan, with secretarial support provided by the Brussels-based Health for Animals.

New Zealand takes an observer role via the Ministry for Primary Industries, along with Canada, South Africa and Australia. Due to the significance of regulatory harmonisation VICH is also reaching out to a number of developing countries.

Since the start of VICH, more than 100 of the world's leading experts have negotiated and prepared a number of draft and final guidelines in the different fields of drug product safety, quality and efficacy. A number of guidelines have already been adopted and for the most part implemented in the regions. Others are at the end of the consultation period, or are under consultation. Agcarm's role on VICH would be to represent our industries views at the global decision table.

With greater emphasis on the quality, safety and efficacy of veterinary medicines, VICH is becoming more important today than ever before as a coordinated means to facilitate the global registration of veterinary medicinal products, while establishing and maintaining consumer confidence. As recent news has shown, consumer safety and animal welfare are of paramount importance to modern society.

The principal goal of VICH is to harmonise technical data requirements of participating regulatory authorities before granting drug marketing authorisation or registration. The majority of the technical work is completed by expert working groups, who are guided by the

steering committee. Current outputs aim to reduce animal testing, reduce the costs of development, increase availability of new veterinary medicine products, and accelerate the development and review process.

There are few industries in New Zealand that have the opportunity to engage with and influence global regulators, and meet with fellow international industry groups. With the current strong drive for greater cooperation when it comes to animal health, playing our part is more important than ever. Although complex, the VICH framework is allowing this to happen, with global coordination driving the way forward.

With VICH representation, Agcarm will contribute to the health of our farm animals and pets, making for a safer and more vibrant economy.

- Mark Ross is chief executive of Agcarm, the industry association for companies which manufacture and distribute crop protection and animal health products.