ANIMAL PHARM

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June 2015

VMD making headway with 3Rs concept

POLICY & REGULATION

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Historically, challenge tests with lethal endpoints have been used to assess batch potency testing for some vaccines such as rabies, leptospira, clostridial and various fish vaccines. Serological and/or in vitro alternative methods have been developed and implemented for some vaccines. However, some vaccines in these categories still rely on the challenge test. The London-based Veterinary Medicines Directorate (VMD) has questioned why this is the case.

At the VMD's Biologicals Information Day in London, one of the organisation's biologicals assessors, Ralph Woodland, explained that challenge tests are easier, cheaper and faster to develop compared to *in vitro* alternatives. The challenge test method will therefore naturally be leaned towards for development of emergency vaccines, for example.

He said it takes a long time to change methods due to validation work and costs, and sourcing suitable reagents, thus the VMD is not seeing variations coming through for replacement tests. Although alternative methods have been developed and implemented for some vaccines, the animal health industry's feedback during a Q&A session was that the authorised alternative methods are proprietary information, making it difficult for other marketing authorisation holders to change methods for similar existing products.

Anne-Marie Brady, the head of the VMD's biologicals team, commented that companies can submit a request to the European Pharmacopoeia for inclusion of accepted alternative methods in monographs. Therefore, the process relies on industry willingness to release proprietary information.

Dr Woodland explained there is little incentive for marketing authorisation holders to modify testing for already authorised vaccines. However, industry feedback from the Q&A session was that stakeholders are focusing on getting new products to market, rather than modifying old ones. The regulatory budget for older products is virtually zero, unless there is an emergency situation, and companies are reluctant to open up very old dossiers due to potential issues with efficacy studies. It was emphasised that the regulatory costs of modifying older products was cost-prohibitive, especially for multi-component clostridial vaccines which have multiple national licenses.

The VMD aims to increase the adoption of the 3Rs concept – to reduce, replace and refine the use of animals for scientific purposes – and will continue to focus on clostridial vaccines and will write to firms to encourage the three principles. The VMD will also liase with other national organisations responsible for animal testing e.g. the Home Office who authorise testing, and participate in European Medicines Agency working groups.

While the VMD said some progress has been made on implementing the 3Rs, a more rigorous focus is required. This includes: encouraging alternative methods; strong justification required from marketing authorisation applicants on why alternative methods were not selected; and enhanced liaison between regulators and industry.

Regulators encourage industry to inform them about their ongoing method development and validation. The VMD said there will likely be a hardening on assessor approach to new products because they can have a greater influence at that stage.

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