ANIMAL PHARM
www.animalpharmnews.com
May 2015

Reduction in use of animals for immunological quality control

BY DR TAMSIN DAWSON

According to Anna Tout, biologicals assessor at the UK's Veterinary Medicines Directorate (VMD), the use of animals in quality control testing for immunological veterinary medicinal products has fallen. Dr Tamsin Dawson attended the VMD's Biologicals Information Day 2015 in London.

In 1986, the EU adopted the '3Rs' concept to reduce, replace and refine the use of animals for scientific purposes.

This stance was reinforced by Directive 2010/63/EU, which aims to protect animals used for scientific purposes. This directive was adopted on September 22, 2010, and came into full effect in January 2013.

More recently, the VMD conducted a review of the number of animals used in the quality control of Immunological Veterinary Medicinal Product (IVMP) batches released by the VMD from 2007 to 2012. The aim of this review was to determine if the use of animals in testing had changed over time.

Dr Tout said, over the six-year period, an average of 60,297 animals were used per annum for the quality control testing for IVMP batches.

Over the same period, there was a 26% reduction in the number of animals used in IVMP testing (or an 18% drop in the average number of animals used per batch).

She said the number of animals used peaked from 2009-2010. However, this was due to an increased release of clostridial vaccines. Incidentally, clostridial vaccines account for 7% of biological products registered in the UK and appear to account for a disproportionate use of animals used for quality control testing. However, these vaccines tend to contain a higher number of active components, therefore if each component was considered independently, animal use in clostridial vaccine testing would be similar to a monovalent vaccine.

Dr Tout also said leptospira and rabies vaccines account for 6% and 1% of biological products on the UK market respectively – both product monographs now provide a serological test as an alternative method. She said this has resulted in a 32% and 18% drop in the total number of animals required in the quality control testing of these types of products, respectively.

Chicken vaccines and fish vaccines account for 20% and 1% of batches released to the UK market, respectively. The numbers of animals used in the testing of chicken vaccines has increased by 10%, whereas the numbers have decreased by 19% for fish vaccines.

A breakdown of tests requiring animal models for testing was provided at the VMD Information Day:

Quality control test requiring animals	Proportion	
Toxicity and toxoid content	49.80%	Mostly clostridial vaccines.
Potency	36.60%	50% of UK authorised IVMPs base the release potency specification on animal testing.
		Animal use has reduced by around 23% since 2007 in this category.
		Potency tests based on serology, as opposed to challenge, has increased from 29% in 2007 to 42% in 2012. The potency test in the European Pharmacopoeia monograph for tetanus vaccine for example is now a serological method.
Safety	10.70%	Required over 5000 animals per year.
		It has been removed as a test from European Pharmacopoeia since October 2012. All UK authorised products have successfully removed target animal batch safety tests, therefore animal use in this category should reduce to 0.
Extraneous Agents	2.20%	Animal use down 40% from 2007 in this category due to egg and cell-based method alternatives.
Other	0.70%	-

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