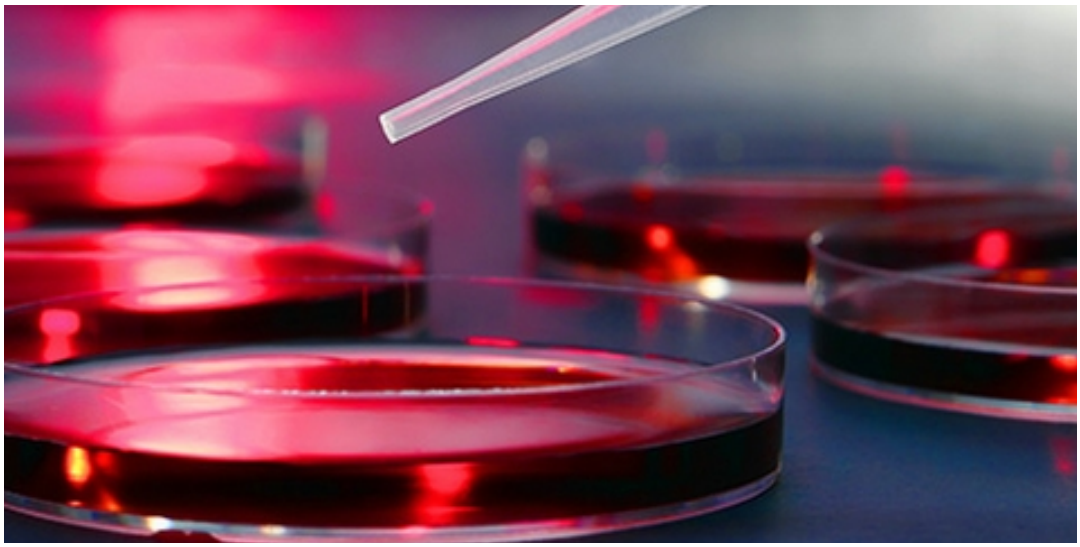
ANIMAL PHARM
www.animalpharmnews.com
May 2015

Balance required between regulation and innovation for novel vet meds

BY DR TAMSIN DAWSON



Dr Noemi Garcia del Blanco, head of assessment at the UK's Veterinary Medicines Directorate (VMD), spoke at the VMD's Biologicals Information Day 2015 in London on the regulation of innovative/novel veterinary medicines, writes Dr Tamsin Dawson.

Dr Garcia del Blanco said in order to encourage innovation in such a specialised field, there needs to be constructive collaboration between regulators and stakeholders.

Regulators need to continuously evolve their knowledge of emerging technology because biological developers need greater clarity on regulatory requirements for novel products. Whilst regulators need to maintain assurance of quality, safety and efficacy of the products, they have identified that there is also a need for specific risk identification and mitigation.

Novel veterinary therapies have a high level of complexity linked to their composition, development, manufacture, characterisation and administration, and are frequently produced by research institutes and small-medium enterprises which have limited experience of veterinary regulations.

EU directive 2001/82/EC as amended (as well as several guidance documents) provides a definition and framework for development of conventional biological veterinary medicinal products. However, they do not offer appropriate framework and guidance for the regulation of emerging novel therapies, such as stem cells, monoclonal antibodies, tumour vaccines, bacteriophages and cytokines.

Dr Garcia del Blanco noted there is a definition for advanced human therapies (Regulation 1394/2007), but no equivalent for veterinary products.

Therefore, companies developing these types of products have problems meeting the existing requirements, and it is likely the first products successful in authorisation will set a precedent for others.

Currently there are a number of European Medicines Agency working committees that provide support in this particular area:

AP - PATENT ARCHIVE

Global patent approvals for the animal health industry

- Committee for Advanced Therapies (CAT) – responsible for preparing scientific guidelines in the field of gene and cell therapies and tissue engineered products, and for issuing scientific recommendations on product classification and scientific advice for novel products.;
- Innovation Task Force (ITF) – responsible for identifying the need for specialised expertise at an early stage, provide advice to applicants (in conjunction with CHMP/CVMP), review regulatory and scientific implications in relation to emerging therapies/technologies, and increase the EMA's awareness of these emerging product developments;
- Scientific Advice (SA) – provide specific advice to applicants on the development and authorisation of a particular product
- Committee for Medicinal Products for Veterinary Use Ad Hoc Group on Veterinary Novel Therapies (ADVENT) – provide general guidance on the requirements for authorisation of novel veterinary medicines, and not specific advice to a particular application or product.

Over recent years, the Agency has received an increasing number of requests for SA relating to therapies entirely new to the veterinary domain. Through experience of providing advice on these novel therapies, it has highlighted the need for additional sources of guidance for future applications based on the same technology. Advice frequently requested has related to:

- Quality (standards of manufacture, quality control of starting materials, extraneous agent testing);
- Safety (target animal safety study, selection of safety parameters/measurements);
- Efficacy (study design, statistical power).

ADVENT's Guideline/Q&A on novel therapies is anticipated.

Informa UK, Christchurch Court, London EC1A 7AZ, UK
Telephone: +44 20 7551 9000

Editor **Joseph Harvey**
Tel: +44 (0) 20 7017 7392
Email: joseph.harvey@informa.com

Asia Editor **Malcolm Flanagan**
Tel: +44 (0) 20 7017 7547
Email: malcolm.flanagan@informa.com

Analyst **Sian Lazell**
Tel: +44 (0) 20 7017 4682
Email: sian.lazell@informa.com

Advertising sales **Ben Watkins**
Tel: +44 (0) 20 3377 3911
Email: ben.watkins@informa.com

Marketing executive **Rory Brown**
Tel: +44 (0) 20 7017 7334
Email: rory.brown@informa.com

Subscriptions **Shouvik Sen**
Tel: +44 (0) 20 7551 9541
Email: shouvik.sen@informa.com

Subscriptions hotline:
Tel: +44 (0) 20 7017 0000
Fax: +44 (0) 20 7017 7599
Email: marketing@agra-net.com

Customer services:
Tel: +44 (0) 20 7551 9201
Fax: +44 (0) 870 136 1073
Email: agrahelp@informa.com