13 February 2012, Strasbourg, France

EDQM WORKSHOP ON ALTERNATIVES TO THE LEPTOSPIROSIS BATCH POTENCY TEST, 26-27 January 2012, Strasbourg, France

As part of the on-going efforts of the European Pharmacopoeia Commission to replace *in vivo* with *in vitro* methods and further to significant efforts to develop alternative methods for the batch potency test for leptospirosis vaccines, a workshop targeted to leptospirosis manufacturers took place at the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe in Strasbourg.

This workshop was attended by 36 participants, which included officials and experts from 11 countries, as well as representatives from European licensing authorities, Official Medicines Control Laboratories (OMCL), the World Organisation for Animal Health (OIE) - Reference Laboratory for Leptospirosis and manufacturers of veterinary and human Leptospirosis vaccines. The workshop was dedicated to discussing the current alternative methods being used or under development to the hamster potency test for leptospirosis vaccines and to define a clear strategy for its replacement.

Development of alternative methods is a key step toward implementing the 3Rs (replacement, reduction and refinement) in animal testing. The aim of the workshop was to share information and experiences on the recent advances that have been made with regard to alternative methods for the leptospirosis batch potency test. The workshop provided the opportunity for an in-depth discussion of alternative methods and their practical implementation.

The scientific programme was composed of presentations on alternative methods, both from industry and control laboratories, and discussions on how to help manufacturers to implement them. Participants agreed that a single, universal alternative method could not be developed, due to the complexity of the vaccines (relevance of specific antigens as protective agents, number of serotypes, number of serovars, combinations, presence/absence of adjuvants). However, the workshop showed that there had already been a successful implementation of an alternative method in Europe, approved by a Competent Authority, with a further example from the US. These methods use lipopolysaccharide (LPS)-based antigen quantification by ELISA.

There was unanimous agreement among all participants present that moving towards complete *in vitro* testing for leptospirosis vaccine is possible and should be promoted. As a consequence, the European Pharmacopoeia (Ph. Eur.) monographs should be revised in order to provide some suggestions as to the use of alternative methods.

It was recognised that replacement of the batch potency test by *in vitro* testing was an exercise that took companies almost 10 years to complete, using the conventional validation approach of comparing the alternative method to the compendial method. Not all companies were ready to undertake such replacement. Suggestions were made as to how an easier way to replace this test could be found, and how the Ph. Eur. could promote the replacement of the batch potency test for leptospirosis vaccines. The discussions were very constructive, and many good ideas were put forward. The European Pharmacopoeia Commission would be informed about the outcome of the workshop and would decide on future developments.

The abstracts and presentations are available on the EDQM's internet site: www.edqm.eu.

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Note for the editor: The EDQM is a leading organisation that protects public health by enabling development, supporting implementation, and monitoring the application of quality standards for safe medicines and their safe use. Our standards are recognised as a scientific benchmark world-wide. The European Pharmacopeia[1] is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantations and consumer health issues.

A political organisation set up in 1949, the Council of Europe works to promote democracy and human rights continent-wide. It also develops common responses to social, cultural and legal challenges in its 47 member states.

[1] There are currently thirty-seven members of the European Pharmacopoeia Commission: *Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Montenegro, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, United Kingdom and the European Union* and twenty three observers: *The World Health Organisation (WHO); 6 member states of the Council of Europe: Albania, Armenia, Georgia, Moldova, Russian Federation and Ukraine; 16 other countries in the world: Algeria, Argentina, Australia, Brazil, Canada, China, Israel, Madagascar, Malaysia, Morocco, Republic of Belarus, Republic of Kazakhstan, Senegal, Syria, Tunisia, United States of America*.