08 March 2013, Strasbourg, France

The European Pharmacopoeia and Bluetongue Vaccines (BTV): opportunity and feasibility for a BTV inactivated vaccines monograph.

Bluetongue disease, which affects ruminants, creates issues in a number of different areas. Bluetongue epidemics have a direct impact on birth and death rates among sheep and cattle, and on milk and meat production. They also affect domestic and trade movements; some 5 million cattle (7% of the EU's livestock) cross national borders every year. The main lessons learned from the last few years have been that bluetongue has become a reality in Europe and is likely to persist, and that vaccination is the only control tool.

Bluetongue disease has triggered emergency situations in Europe. From 1998 up to 2006, when the first outbreaks occurred, there were significant efforts by industry and European and national authorities to jointly develop safe and efficacious vaccines. An emergency vaccination and surveillance campaign was carried out in 2007-2009, with the aim of controlling and ultimately eradicating bluetongue disease in Europe. A total of 26 different serotypes are known and which serotype might lead to the next outbreak cannot be predicted. Fortunately, the stakeholders involved now know more about the disease and have gained useful experience working with such vaccines.

The aim of the workshop on Bluetongue Vaccines, organised by the Council of Europe's European Directorate for the Quality of Medicines & HealthCare (EDQM) in February 2013, was to reflect on the lessons learned, the challenges that still remain, and on the opportunity and feasibility of drafting a monograph for BTV inactivated vaccines.

The workshop gave a very good global view of the complexity of the disease. Scientific aspects were discussed (*e.g.* inactivated vaccines versus live attenuated vaccines), regulators gave their expectations for future vaccines, and industry representatives spoke of the latest developments in vaccines (in particular, for specific strains BTV 1, 4 and 8). Until now, bluetongue vaccines were only authorised under exceptional circumstances. For BTV 1 and 8, several manufacturers are in the process of applying for a marketing authorisation application. The workshop also offered the opportunity to hear the views of the EU Commission on political aspects and how to make the best use of European taxpayers' money (*e.g.* costs of vaccination versus the benefits of disease control), and the perspective of individual member states such as Spain.

The recommendations from the workshop, including the advantages and disadvantages of drafting a European Pharmacopoeia monograph, will be discussed further by the relevant Group of Experts during their forthcoming meetings. Specific recommendations will then be made to the European Pharmacopoeia Commission.

The workshop was attended by 35 participants, including officials and experts from 15 countries, as well as representatives from the EU Commission, World Organization for Animal Health (OIE) – Reference Laboratory for Bluetongue, Committee for Medicinal Products for Veterinary Use (CVMP/EMA), European licensing authorities, Official Medicines Control Laboratories (OMCL) and European manufacturers of bluetongue vaccines.

Bluetongue disease, in short:
Bluetongue disease or catarrhal fever is a non-contagious, insect-borne, viral disease of ruminants, which is caused by the Bluetongue virus (BTV). The virus is transmitted by the midge *Culicoides imicola* and other culicoids. In sheep, BTV causes an acute disease with high morbidity and mortality. Major signs are high fever, excessive salivation, swelling of the face and tongue and cyanosis of the tongue. Swelling of the tongue results in its blue appearance, though this symptom is confined to a minority of animals. Not all animals develop symptoms, but all those that do lose condition rapidly and the sickest die within a week. For the affected animals that do not die, recovery is very slow, lasting several months.
From 2002 to 2006, bluetongue was mainly present in the Mediterranean area (serotypes 1, 2, 4, 9, 16).
In autumn 2006, northern Europe was rapidly contaminated; a BTV 8 epidemic started in the Netherlands, Luxembourg, Belgium and Germany. There has been an improvement in the situation in 2009-2012 due to successful vaccination campaigns. The BTV 8 strain has disappeared and the BTV 1 strain has only been sporadically active in Spain and Portugal. Today, localised circulation of BTV strains 1, 2, 4, 9 and 16 is seen in Italy, Greece and Cyprus.

Contact: Caroline Larsen Le Tarnec, Public Relations Division, EDQM, Council of Europe
Tel.: +33 (0) 3 88 41 28 15 - E-mail: caroline.letarnec@edqm.eu

Note for the Editor: Further information is available on the internet site **www.edqm.eu**
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 is legally-binding in European Member States. Similarly, the EDQM develops guidance and standards in the areas of blood transfusion, organ transplantation and consumer health issues.

[1]There are now thirty-eight 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, Ukraine, United Kingdom and the European Union.* There are twenty-four observers: *the World Health Organization (WHO); 5 member states of the Council of Europe - Albania, Armenia, Georgia, Moldova and the Russian Federation; and 18 other countries in the world - Algeria, Argentina, Australia, Brazil, Canada, China, Israel, Madagascar, Malaysia, Morocco, Republic of Belarus, Republic of Guinea, Republic of Kazakhstan, Republic of Singapore, Senegal, Syria, Tunisia, United States of America*.

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.