

## **Strasbourg, 20/09/2006**

*Note for the Editors*

Is it necessary to define the quality requirements of avian influenza (AI) vaccines at European Pharmacopoeia level? And if yes, what are they?

These questions are particularly important in the context of the preventive vaccination campaigns, targeted at protecting poultry against highly pathogenic AI because of the potential impact on public health. Highly pathogenic AI causes enormous economic losses in the poultry industry and there are reasons to believe that lack of control of the disease in birds could favour the arrival of a new human influenza pandemic via mutation and reassortment of the avian virus. Effective AI vaccines therefore contribute to both animal and human public health.

The EDQM, a Directorate of the Council of Europe, can be considered as the 'facilitating European body' for the adaptation and extension of European regulations on the quality of medicines. Since 1964 the European Pharmacopoeia, and later the EDQM, has developed close links with the other European bodies. Its networks collaborate on a daily basis with all the authorities involved in the standardisation, regulation and control of medicines for human and veterinary use. The organisation of such a large consultation and communication, involving all parties, is one of the channels used by the EDQM to receive feedback.

## **INTERNATIONAL SYMPOSIUM ON 'REQUIREMENTS FOR PRODUCTION AND CONTROL OF AVIAN INFLUENZA VACCINES', 19-20 OCTOBER 2006, STRASBOURG, FRANCE**

The main aims of the symposium organised by the European Directorate for the Quality of Medicines (EDQM, Council of Europe) were:

- to discuss within existing regulations (a number of new AI vaccines are in the process or have already been received their marketing authorisation), if it is necessary to regulate via the European Pharmacopoeia AI vaccines so that their quality will be controlled and assured in the same way throughout Europe?,
- to take into consideration the views and expectations of all parties involved, such as European authorities and national authorities, manufacturers, inspectors and assessors from all over the world, and
- to discuss future regulatory provisions, and in particular those regarding the demonstration of immunogenicity and routine potency testing.

Round-table discussions took place at the end of each session and these were aimed at exploring all the issues concerning production of quality control further and to open up the debate in order to share scientific knowledge and expertise.

The conclusions of this symposium will be published later on the EDQM's internet site ([www.pheur.org](http://www.pheur.org)).

This symposium was attended by almost 80 scientific experts from throughout the world, vaccine manufacturers and national European laboratories from 21 different countries on 19 - 20 October 2006.

**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 46 member states.**

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