# COMMISSION DECISION

## of 18 December 2008

## establishing Community reserves of vaccines against African horse sickness

(2009/3/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field [1], and in particular Articles 6(2) and 8 thereof,

Having regard to Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness [2], and in particular Article 12 thereof,

Whereas:

(1) African horse sickness (AHS) is an arthropod-borne disease of equidae primarily of sub-Saharan Africa. Occasionally the disease has spread outside Africa as far as India but also into northern Africa and onto the Iberian Peninsula, and between the latter. The disease is caused by an *Orbivirus* similar to the causative virus of bluetongue. However, unlike bluetongue in sheep and cattle, AHS is almost always fatal for horses.

(2) Nine antigenically distinct serotypes of the AHS-virus have been identified by virus neutralisation but some cross-reaction has been observed between serotypes 1 and 2, 3 and 7, 5 and 8, and 6 and 9, which is used in vaccine manufacturing.

(3) The persistent circulation of bluetongue virus in certain Member States is sufficient proof for the almost uninterrupted presence of competent vectors in the affected areas. The AHS-virus and bluetongue virus are transmitted by the same vector Culicoides and therefore the risk of virus introduction into Member States is higher than negligible. The bluetongue affected parts of the Community are also core breeding grounds for valuable horse populations that are thus particularly threatened by AHS.

(4) The early use of vaccines in case of an outbreak of AHS is provided for in Article 6(1)(d) of Directive 92/35/EEC. In accordance with Article 9(2) of that Directive, the Commission may take a decision to carry out systematic vaccination of equidae against AHS, however, no vaccine against AHS is currently produced by the pharmaceutical industry based in the Member States or registered in Europe by an international manufacturer.

(5) With substantial Community support to Spain, Portugal and later also Morocco, the 1987-91 outbreak in that ecosystem was extinct, and since 1993 all Member States of the European Union comply with the conditions for an AHS free country according to the criteria set up by Community legislation.

(6) Chapter 12.1 of the Terrestrial Animal Health Code (the Code) of the World Organisation for Animal Health (OIE) [3] sets, inter alia, the standards for movements of vaccinated or seropositive equidae and provides for the guidelines to be followed in order to maintain or recover the free status following an outbreak.

(7) In the absence of a specific monograph for vaccines against AHS in the European Pharmacopoeia, the description in Chapter 2.5.1 of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals [4] of the vaccine produced by Onderstepoort Biological Products Ltd (OBP) in South Africa is the only available and authentic standard for live attenuated vaccines against AHS.

(8) In the light of the experience with vaccination against bluetongue in Member States, in order to prevent the introduction of previously undetected serotypes in an ecosystem, it is necessary to establish the capacity for resorting in case of emergency to monovalent vaccines containing only the serotype already prevalent or directly threatening the region. The OBP has the technology to produce suitable monovalent attenuated vaccines from the seven serotypes included in the routinely produced tri- and tetravalent attenuated live vaccines for combined subsequent use in endemic settings that is effective against all nine AHS-virus serotypes.

(9) OBP is thus the only potential contractor with the required capacities to provide effective vaccines for AHS that meet internationally accepted standards, within the meaning of Article 123(3) of Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002, laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities [5].

[1] OJ L 224, 18.8.1990, p. 19.
[2] OJ L 157, 10.6.1992, p. 19.
[3] http://www.oie.int/eng/normes/mcode/en_chapitre_1.12.1.htm
[4] http://www.oie.int/eng/normes/mmanual/2008/pdf/2.05.01_AHS.pdf
[5] OJ L 357, 31.12.2002, p. 1.

(10) The OIE Manual indicates an extended period of stability when the lyophilised vaccine is stored at 4-8 °C; however the commercially guaranteed shelf life is set at two years. A decision on the renewal of the vaccine stocks should therefore be taken in due course before the expiry of the shelf life and in the light of the epidemiological situation and the possible development of new vaccines.

(11) Based on experience with other Community vaccine reserves and taking into account that in case of AHS a complete primary course of vaccination consists of a first administration of the vaccine followed by a second booster vaccination, a total number of 100 000 doses of each of the seven attenuated serotypes would be sufficient for a first emergency response.

(12) For the protection of susceptible equidae it is therefore appropriate to establish Community reserves of vaccines against AHS and to make them available for emergency use in Member States or in epidemiologically relevant neighbouring third countries representing a particular AHS risk to them.

(13) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS DECIDED AS FOLLOWS:

*Article 1*

1. For emergency use the Community shall make arrangements for the purchase of 100 000 doses of lyophilised monovalent attenuated live vaccines, including the necessary diluents, against African horse sickness of each of the serotypes 1, 2, 3, 4, 6, 7 and 8.

2. The arrangements referred to in paragraph 1 shall include the supply and storage of the total of 700 000 doses of lyophilised vaccines and the shipment without delay of the specified vaccines to a place in the European Union, or its epidemiologically relevant direct neighbourhood, designated in case of emergency by the Commission.

*Article 2*

The maximum cost of the measures referred to in Article 1 shall be up to EUR 500 000 for a period of two years.

*Article 3*

To meet the objectives of Articles 1 and 2 the Commission shall conclude for the years 2009 and 2010 a supply contract with Onderstepoort Biological Products Ltd (OBP) in South Africa on:

— the supply and storage of the vaccines described in Article 1(1),

— the delivery of the vaccines together with the diluents as described in Article 1(2), and

— the details of disposal of expired vaccines.

Done at Brussels, 18 December 2008.

*For the Commission*
Androulla VASSILIOU
*Member of the Commission*