16 March 2017
EMA/CVMP/119074/2017
Committee for Medicinal Products for Veterinary Use (CVMP)

Stakeholder focus group meeting on availability of Lumpy Skin Disease (LSD) vaccines authorised to EU standards held on 31 January 2017

Summary report

A Stakeholder focus group meeting on availability of Lumpy Skin Disease (LSD) vaccines authorised to EU standards was held at the European Medicines Agency (EMA). The Committee for Veterinary Medicinal Products for Veterinary Use (CVMP) had expressed concern that there were currently no approved vaccines to EU standards available for prevention of LSD despite incursion of the disease into some EU Member States since 2015. Under emergency procedures live homologous attenuated vaccines sourced from third regions had been used in some of those EU Member States to control outbreaks of the disease under the emergency provision of Article 8 of Directive 2001/82/EC on the Community code relating to veterinary medicinal products. Modelling of LSD outbreaks and field experience in Southeastern Europe has demonstrated that vaccination can have a significant impact in reducing LSD virus spread and thereby to reduce the extent of culling and to improve the situation for animal health and welfare.

The objectives of the meeting were to identify steps that could facilitate the authorisation of LSD vaccines to EU standards. The meeting concluded on an unequivocal preference by all stakeholders, notably national competent authorities, farmers and consumers, to have access to vaccines manufactured and tested to EU standards to guarantee the quality, safety and efficacy of products used on their territories.

It was recognised that the current EU regulatory framework for veterinary medicines required more flexibility to respond to emergency outbreaks of disease using legal, regulatory and financial incentives to develop appropriate medicinal products during disease-free periods to help ensure vaccines of the appropriate strain(s) and quantity were accessible during such disease emergencies. An effective pharmacovigilance system for emergency vaccines was also considered essential to identify any potential adverse events from use of unauthorised products. To identify the measures to achieve these aims, effective collaboration between EU competent authorities and stakeholders would be paramount. EU regulators and animal health risk managers would need to better understand product development challenges, manufacturing (particularly GMP requirements and capacity constraints), distribution and supply issues. To facilitate the development of antigen and vaccine banks to EU standards for use against emergency infectious disease a shared approach for the risks related to product development

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

would encourage manufacturers to invest in the development of products for which the potential need was uncertain and unpredictable.

Improved monitoring of disease threats with cooperation between EU bodies and national institutions would help achieve greater harmonisation and predictability for measures that would apply to a particular disease situation and the minimum standards that could be applied for authorising vaccines to EU standards.