24 January 2017
EMA/CVMP/IWP/661057/2016
Committee for medicinal products for veterinary use (CVMP) / CVMP Immunologicals working party

Agenda – Stakeholder focus group meeting on availability of Lumpy Skin Disease (LSD) vaccines authorised to EU standards

31 January 2017, 9:00–16:15(17:30), European Medicines Agency, Room 3F

Chair: Jean-Claude Rouby

	Preliminary draft agenda	Presenter
	Health and safety information	
9:00	Opening of the meeting	F. Westerholm, EMA
9:05	Welcome, tour de table and adoption of draft agenda	Chair - J.-C. Rouby, CVMP member, ANSES, France
	Background and aims of the meeting	M. Ilott, EMA
9:25	LSD current situation - immunology, epidemiology and field experience in the EU:	
	• Capripox virology and immunology The epidemiology and immunology of Lumpy Skin Disease, goat and sheep pox viruses – 50 min	P. Beard, J. Flannery Pirbright, Ref. Laboratory, UK
	• Lumpy Skin Disease experience in Greece – 20 min	S.-E. Antoniou, Ministry of Rural Development and Food, Greece
	• Lumpy Skin Disease experience in Bulgaria – 20 min	G. Chobanov, Food Safety Agency, Bulgaria
11:00	Coffee break	
11:30	LSD current situation field experience in the EU (continued):	
	• European Union Lumpy Skin Disease and other exotic diseases antigen/vaccine banks - Current status, policy and future considerations – 30 min	A. Gavinelli, D. Dilaveris, European Commission

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	Preliminary draft agenda	Presenter

	• In vivo evaluation of Lumpy Skin Disease vaccine efficacy in controlled environment – 15 min
	  o Lumpy Skin Disease current situation – challenge models for efficacy and quality control tests on final vaccines
	• Quality control testing of LSD vaccines – 15 min
	  o Approaches for evaluating the quality (sterility, absence of extraneous agents and potency)
	  o Role of OMCLs for control of emergency vaccines
		K. De Clercq,
		A. De Vleeschauwer,
		J. Baré,
		CODA-CERVA, Ref. Laboratory, Belgium

12:30	Panel discussion and conclusions	J.-C. Rouby, J. Flannery, S.-E. Antoniou, G. Chobanov, A. Gavinelli, K. De Clercq
12:45	Lunch break	
13:45	Lessons learnt from authorisations under exceptional circumstances at National Competent Authorities (NCAs) and EMA level:	
	• Lessons learnt by EU regulators from the authorisation of Foot-and-Mouth Disease, Avian Influenza, Bluetongue and Schmallenberg vaccines in the EU – 30 min	E. Werner, IWP Chair, Paul-Ehrlich-Institut, Germany
	• Industry challenges for supplying emergency vaccines in Europe (regulatory issues) – 15 min • Industry challenges for supplying emergency vaccines in Europe (technical issues) – 15 min • Industry challenges for supplying emergency vaccines in Africa – 15 min	D. John, IFAH-Europe A. King, MSD-AH B. Nthangeni, OBP
15:00	Panel discussion and conclusions	J.-C. Rouby, E. Werner, D. John
15:15	Coffee break	
15:45	Open session – conclusions and recommendation to CVMP	M. Ilott, EMA
16:00	Summary and closure of the open part of the meeting	Chair - J.-C. Rouby
16:15 – 17:15	*16:15 Closed session – 30 min* *16:45 Closed session – 30 min*	Industry