Specification for procurement of Lumpy Skin Vaccine

S No	**Specification**	
1	**Vaccine Manufacture**	
i	Manufacture Shall have global references and experience in manufacturing, Selling, exporting and delivering LSD vaccines An official certificate from the country of manufacture certifying that no material contaminated with BSE Agent has been used in the manufacture of vaccine has to be submitted. .	
ii	Vaccine production facilities and quality control must comply with WOAH international standards & others(Chapter 1..1.8 of WOAH Manual of Diagnostic Tests & vaccines for Terrestrials Animals 2022	
iii	Must be in possession of a valid Official Certificate of Good Manufacturing Practices provided by a relevant national authorities for all plants producing the vacancies to be provided	
iv	Must comply with the relevant quality assurance control programmes and procedures based on international standards for all vaccine to be provided	
	Proof of compliance for above must be provided by supplying relevant supporting documentation	
2	**LSD Vaccine**	
i	For prophylactic immunization of cattle and buffaloes against all the circulating strains of LSDV. Each 1ml dose of reconstituted vaccine contains at least 10^4 TCID50 (Tissue culture Infectious dose 50 %) of freeze-dried, live, attenuated LSDV (Neethling type and strains or equivalent)	
	Manufacture should provide vaccine matching data certification from World Reference Lab	
ii	The vaccines that supplied should be of high potency. Vaccine manufacture will need to demonstrate proof of compliance by providing relevant documentation	
iii	Shall confer the immunity for minimum 12 months post vaccination	

iv	Easy to use in parenteral (injectable) vaccine for cattle and buffaloes provide protection from lumpy Skin disease	
v	There should not be any adverse reaction or in case if there are should be very minimal and need to be indicated clearly.	
vi	Shall describe the characteristics of the vaccine in full detail including the vaccine strain, the efficacy, potency and safety, the administration procedure, the volume per dose and the possible secondary effects identified	
vii	Should comply with the WOAH international standards of the quality of Vaccines referred to in chapters 1.1.8 and 3.8.6 of the WOAH Manual of Diagnostic Tests & vaccines for Terrestrials Animals 2019. Vaccine production and quality assurance procedures should be indicated	
vii	Vaccine has to be in ready-to-use form with specific description on the color, texture and any other relevant characteristic(s).	
viii	Recommended vaccination schedule needs to be provided	
ix	Shelf-Life upon release from the factory should be indicated and minimum of 12 months of self-life from the date of supply. The storage temperature at different levels to be stated clearly and the handling instruction leaflet to be submitted with each bottle / batch of vaccine).	
x	The preferable pack is 20 doses	
xi	Vaccine should have a valid Registration Certificate in the country of the origin and the registration number to be indicated clearly. (a copy of the government registration certificate to be submitted).	
xii	The supplier should submit detailed dossiers required to be registered under the Veterinary Drug Control Authority of Department of Animal Production and Health at the time of submission of bids for future registration. The dossier needs to be supported by studies/experimental results wherever necessary	
3	**Delivery**	
i	The consignment of vaccine should be delivered within 60 days after awa rding the contactor	
ii	Delivery of vaccine at the vaccine bank to be informed to the Director Animal Health, Department of Animal Production and Health at least 48 hour prior to the delivery	

iii	Vaccine consignment has to be supplied at Vaccine Bank, Getambe, Peradeniya and the required temperature to be maintained from the Manufacturing plant up to the Vaccine Bank. The total quantity of vaccine dosses assured in front of the authorized DAPH staff at Vaccine Bank	
iv	The storage condition the vaccines must be specified (temperature range in ^{0} C) and possible measures to measures to monitor the temperature during transportation and storage should be with the vaccine supply	