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RESPONSE TO PRE-BID QUERIES

PERTAINING TO
"Request for Proposal
for
Empanelment of FMD Vaccine Manufacturers"

Issued on 06.04.2022

Department of Animal Husbandry & Dairying (DAHD),
Ministry of Fisheries, Animal Husbandry & Dairying (MoFAHD)
Government of India
New Delhi

14.06.22
एम. के. दिवाकर
M.K. DIWAKER
अवर सचिव / Under Secretary
भारत सरकार/Govt. of India
मत्स्यपालन, पशुपालन एवं डेयरी मंत्रालय
Ministry of Fisheries, Animal Husbandry & Dairying
पशुपालन और डेयरी विभाग
Department of Animal Husbandry & Dairying
कृषि भवन, नई दिल्ली/Krishi Bhawan, New Delhi-110001

RESPONSE TO PRE-BID QUERIES

A pre-bid meeting through video conference was held on 21st April 2022 pertaining to "REQUEST FOR PROPOSAL FOR EMPANELMENT OF FMD VACCINE MANUFACTURER(s) FOR SUPPLY OF FMD VACCINE UNDER LHDCP SCHEME OF DAHD". The following response is provided to the queries received from various industry representatives and potential bidders:

Queries received from Indian Immunologicals Limited (IIL)				
S. No.	**Clause No.**	**Clause Details**	**Query/Suggestion**	**Response to the queries**
1	Chapter I A Clause 2.3 Page 9	DAHD intends to on-board FMD vaccine manufacturers (the manufacturers) for a period two (2) years or four rounds of vaccine supply, whichever is later to assist and support DAHD and State Governments /UT Administrations in the implementation of LHDCP and thereafter the tenure may be extended every year up to a maximum of additional 36 months on the same terms and conditions upon mutual consent.	Kindly clarify whether this tender is for 2+1 years (36 months) or 2 years + 36 months (5 years) 14.06.22 एम. के. दिवाकर M.K. DIWAKER अवर सचिव / Under Secretary भारत सरकार/Govt. of India मत्स्यपालन, पशुपालन एवं डेयरी मंत्रालय Ministry of Fisheries, Animal Husbandry & Dairying पशुपालन और डेयरी विभाग Department of Animal Husbandry & Dairying कृषि भवन, नई दिल्ली/Krishi Bhawan, New Delhi-110001	Clarification: 2+1 years (36 months) **Corrigendum:** DAHD intends to on-board FMD vaccine manufacturers (the manufacturers) for a period two (2) years or four rounds of vaccine supply, whichever is later to assist and support DAHD and State Governments /UT Administrations in the implementation of LHDCP and thereafter the tenure may be extended up to a maximum of additional 12 months on the same terms and conditions upon mutual consent (for a total period of 36 months).
2	Chapter I A Clause 7.3 Clause 8.2 (c) Clause 8.3 Page 10-11	The contract would be signed between the "Purchaser" and the "empanelled manufacturer" for supply of goods as per the terms and conditions of the contract	Requested to provide a "Model Contract Copy" to be signed with the Procurement Agency. This is to understand the conditions of the contract with the procurement agency. In case of any dispute with procurement agency, we suggest that an arbitrator may be designated for this purpose.	The terms and conditions will be mentioned in the "Manufacturer – Purchaser Contract (MPC)" in line with the RfP. As mentioned in Chapter XII – Integrity Pact (Page 34) of the RfP.
3	Chapter I A Clause 8.3 (d)	The purchaser shall reserve the right to determine the payment instalments as well as related conditions in consultation with DAHD,	Since vaccine production is hugely capital intensive and required longer lead time, we urge that 40% of the contract value should be given to the manufacturer in advance to ensure uninterrupted manufacturing.	No change from what is mentioned in RfP.

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	Page 12	depending on the outstanding liabilities (if any) of the manufacturers (bidders) under LHDCP (which includes NADCP)		
4	Chapter I A Clause 8.1 (b) Page 11	DAHD shall evaluate the bids and empanel the FMD vaccine manufacturer(s) at the L1 rate based on the bids received from the bidders	Only prices of serious bidders should be considered. Any bidder offering less than 50 mio doses per year should not be considered as serious bidder.	No change from what is mentioned in RfP.
5	Chapter I B Clause 12.1 Page 15	The Bid price of the goods shall comprise of the rate per vial of vaccines inclusive of all taxes, duties and transport to district headquarters pan India	1. Only at District HQ and NOT multiple locations in a district 2. Odd terrains, hills, flood affected areas, islands, NE states may be exempted from the delivery guidelines. This is subject to situation and transport available on ground on case-to-case basis and direct supplies. 3. Acknowledgement on any document while delivery / online acceptance by PLA should be used and digital certification through on-line medium may be developed by PLA	No change from what is mentioned in RfP.
6	Chapter I B Clause 14.1 Page 15	Bids shall remain valid for a period of minimum of 2 years from date of submission of bid or fulfilment of supply commitment of four rounds, whichever is later. A bid valid for a shorter period shall be treated non- responsive and rejected. The validity of the bid shall be extendable subject to decisions of the issuer.	Extension should be mutually agreed 14.06.22 एम. के. दिवाकर M.K. DIWAKER अवर सचिव / Under Secretary भारत सरकार/Govt. of India मत्स्यपालन, पशुपालन एवं डेयरी मंत्रालय Ministry of Fisheries, Animal Husbandry & Dairying पशुपालन और डेयरी विभाग Department of Animal Husbandry & Dairying कृषि भवन, नई दिल्ली/Krishi Bhawan, New Delhi-110001	Please refer to corrigendum to Chapter I B, Clause 14.1 (point 1 of the corrigendum to RFP).
7	Chapter I B Clause 16.1 Page 16	Bid security of Rs. 4 crores (Rs Four crores only) shall be provided by the interested bidder to the Issuer. A scanned copy of the bid security will be uploaded at the CPP portal at time of	1. Bid Security, EMD may be reduced to Rs.1 Cr from Rs. 4 Cr, since we will have to submit performance Bank guarantee while signing the contract 2. The EMD should be immediately returned upon signing the contract with MPC and hence validity of the EMD need not exceed 3 months.	No change from what is mentioned in RfP.

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		bidding. However, bid security in hard copy will be deposited to the issuer before opening of Bid.		
8	Chapter I D Clause 27 Page 19	Any amount of penalty outstanding against any bidder towards supply of FMD vaccine or vaccination on field by FMD vaccine which did not comply with stipulated quality parameters in any earlier procurement (vide E Tender Enquiry No. NAFED / HO/ NADCP/ 2019-20/ 1 dated 27/11/2019) by DAHD (or its procurement agency viz. NAFED) if not paid / not recovered prior to procurement, would be adjusted against payment for future supply(ies) of FMD vaccine, against this Tender.	Two different legal contracts may not be combined.	No change from what is mentioned in RfP. The objective behind this clause is to ensure supply of quality vaccines.
9	Chapter-III Clause IA Sr. No. 5 Page 21	FMD vaccines should satisfy the quality parameters of safety and sterility as per IP in vogue and generate a minimum of 1:64 SNT titre for serotype „O" and 1:45 for serotype „Asia-1" and1:45 for serotype „A" in cattle or correlated serum titre in guinea pigs following the protocol finalised by DAHD.	• We recommend that for "O" strain the titre should be 1:32 as per the recent recommendations of WRL for FMD, Pirbright Institute, UK. • We accept 1:32 for A and 1:36 for Asia-1 as SN_{50} titre Please refer to the recommendation by Pirbright Institute, UK, titled as - "Recommendation to Ag Results on using serological indicators ("valency testing") of cross protection for FMD vaccines", recommending 1:32 dilution, expressed as 1.5 cut-off value. (https://www.wrlfmd.org/sites/world/files/quick_media/Cross-neutralisation%20measure%20AgResults%20Final%20v2.1.pdf) 1. Kindly refer to the Video Conference dated 16.2.2022 with DADF and industry, wherein it was suggested for Geomean and use of 8 animals for testing. All such specs are not mentioned in the tender document. Kindly let us know the testing procedures and pass criteria. 2. How the SNT titres of serotypes O, A and Asia-1 will be	The FMD vaccine specifications have since been revised. Refer Corrigendum to Chapter-III Clause IA Sr. No. 5 (point 6 of the corrigendum to RFP). 14.06.22 एम. के. दिवाकर M.K. DIWAKER अवर सचिव / Under Secretary भारत सरकार/Govt. of India मत्स्यपालन, पशुपालन एवं डेयरी मंत्रालय Ministry of Fisheries, Animal Husbandry & Dairying पशुपालन और डेयरी विभाग Department of Animal Husbandry & Dairying कृषि भवन, नई दिल्ली/Krishi Bhawan, New Delhi-110001

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			calculated? Which statistical tool (Geo-mean/Median/Average) will be used in the test to arrive at the pass criteria of SN values? 3. How many animals will be used to test a batch for serology potency? What will be the acceptance criteria for declaring a pass batch from the number of animals included in test? Protocol for FMD potency in Guinea pig to be shared, finalized by DAHD. Also please share the correlation for cattle and guinea pig potency.	
10	Chapter-III Clause II Sr. No. 1 Page 21	Vaccine will be tested prior to supply to the field.	1. Harmonization of Guinea pig potency and correlation to cattle potency methods to be done between the Government labs and manufacturers. 2. Post harmonization of test methods, training need to be provided to manufacturers to ensure consistent implementation of Guinea pig potency test. 3. This is required before commercial batches to be produced. This has to be arranged by DADF. Parallel testing of FMD vaccine batches may be continued	No change from what is mentioned in RfP.
11	Chapter-III Clause II Sr. No. 5 Page 21	Any information regarding the vaccine, if necessary, shall be made available to the Purchaser/ DAHD. Reference sera for homologous vaccine strains to use as reference standards in serological tests for Post Vaccination Monitoring will be made available to the Purchaser/ DAHD, when requested	1. Final QC testing SOP before tender finalization to be shared with all manufacturers. 2. Reference standards (anti-sera and virus pools) to be provided 3. Validation data for basis of establishing test procedure and acceptance criteria should be shared with manufacturers.	No change from what is mentioned in RfP. 14.06.22 एम. के. दिवाकर M.K. DIWAKER अवर सचिव / Under Secretary भारत सरकार/Govt. of India मत्स्यपालन, पशुपालन एवं डेयरी मंत्रालय Ministry of Fisheries, Animal Husbandry & Dairying पशुपालन और डेयरी विभाग Department of Animal Husbandry & Dairying कृषि भवन, नई दिल्ली/Krishi Bhawan, New Delhi-110001
12	Chapter-III Clause II Sr. No. 6 Page 21	QC testing of the FMD vaccine will be done as per the mechanism and SOP communicated by DAHD from time to time.	Any change in SOP in the course of the tender (once harmonization is done) should be mutually agreed. Post changes in SOP, fresh harmonization exercise has to be carried out and till then, manufacturing of FMD vaccine will be paused.	No change from what is mentioned in RfP.
13	Chapter-III Clause II	Self-certification by the manufacturer regarding NSP-freedom: Manufacturer shall	Batch release of FMD vaccine on Potency, Sterility, and Safety should be done upfront and to be used as parameters for clearance of the batch.	No change from what is mentioned in RfP.

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	Sr. No. 7 Page 21	self-certify for NSP-freedom. However, DAHD reserves the right to test the vaccines for purity as per extant SOP, whenever desires, through the designated laboratories.	There is no requirement for NSP Free testing	
14	Chapter-III Clause III Sr. No. 1.2 Page 22	The designated laboratories will complete the testing of vaccine batches for different parameters as per the extant SOP after receipt of the samples. The results shall be communicated to DAHD by the designated laboratories and subsequently to the Purchaser	1. Please specify if every batch to be tested prior to release to the field by DAHD. If yes, how many samples from each batch to be earmarked for this.? 2. Sampling of vaccines has to be done within 5 days from the date of notification from the manufacturer, once batch is ready. 3. Test report for clearance of batch should be made available within 45 days from the date of sampling.	No change from what is mentioned in RfP.
15	Chapter-III Clause III Sr. No. 1.4 Page 22	DAHD reserves the right to conduct the random sampling and testing of the vaccine doses supplied to the field as per the approved SOP at the designated laboratories	After batch/es is/are cleared by the testing agencies and supplied to LHDCP/DAHD, manufacturer should not be held responsible in case field samples do not meet the acceptance criteria as IIL will not have any control on storage/usage of vaccine in field conditions.	No change from what is mentioned in RfP.
16	Chapter-III Clause III Sr. No. 4 Page 22	The maximum delivery time for the supply of vaccines will be 60 days from the date of placing the order.	Once the vaccine batch is cleared by the authorised lab, then we should be given 45 days for delivery.	No change from what is mentioned in RfP. The supply order is placed only once clearance is received from the authorized laboratories. As per RFP, the vaccines need to be supplied on-ground within 60 days of placing the supply order.
17	Chapter III Clause III Sr. No. 8.1.2 Page 23	Submission of duly signed certificate / letter of receipt of vaccine by the consignee	We suggest that, once the procurement agency gets on-line acceptance / physical verification of the stocks in the manufacturer / district level, then "letter of receipt" should be exempted from manufacturer and should be considered as received. This process is amounting to duplication of the same work. Hence PAC should be abolished. An on-line receipt mechanism may be developed which can be easily downloaded. Allocation for delivery of released batches should be given at the time of batch release. If not, payment for the entire quantity of the batch made should be given to the manufacturer within 7	Payment to vaccine manufacturer would be made basis submission of duly signed certificate/letter of receipt of vaccines by the consignee and uploaded by PLA on its portal. Please refer to corrigendum to Chapter III Clause III, Sr. No. 8.1.2 (point 5 of the Corrigendum to RFP).

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			days from release of the batch.	
18	Chapter-IV Page 24	1.The bidder may be domestic / international manufacturer. 2. Should have drug license issued by DCGI for commercial manufacturing and supply of FMD Vaccine of the required strain in the country.	2 years Market Standing Certificate should be obtained from manufacturers	No change from what is mentioned in RfP. This is to ensure adequate availability of quality FMD vaccines.
19	Chapter I B Clause 12.1 Page 15 Chapter V Page 25	The Bid price of the goods shall comprise of the rate per vial of vaccines inclusive of all taxes, duties and transport to district headquarters pan India	In 12.1, it is mentioned that price to be submitted per vial. However, in Chapter V, it is mentioned per dose and vial. Kindly clarify whether prices to be submitted in dose / vial?	**The appropriate amendments have been made in the RfP.** Please refer to corrigendum to Chapter I B Clause 12.1 and Chapter V (point 3 of the Corrigendum to RFP).

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S. No.	**Clause No.**	**Clause Details**	**Query/Suggestion**	**Response to the queries**
1	2.3 Page 9	DAHD intends to on-board FMD vaccine manufacturers (the manufacturers) for a period **two (2) years or four rounds of vaccine supply, whichever is later** to assist and support DAHD and State Governments /UT Administrations in the implementation of LHDCP and thereafter the tenure may be extended every year up to a	Does this means, the empanelment for the price fixation is valid for 24 months + 36 months i.e. 60 months (5 Years). As defined in the tender, it should be fixed for 24 months or 4 rounds of vaccination whichever is later. Any extension needs to be in consultation with empaneled manufacturer and the purchaser with mutual consent only for 3 or 6 months as it would be difficult at this stage to predict inflation beyond 2 years.	The price fixation would be as mentioned in the corrigendum. **Corrigendum:** DAHD intends to on-board FMD vaccine manufacturers (the manufacturers) for a period two (2) years or four rounds of vaccine supply, whichever is later to assist and support DAHD and State Governments /UT Administrations in the implementation of LHDCP and thereafter the tenure may be extended up to a maximum of additional 12 months on the same terms and

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		maximum of additional 36 months on the same terms and conditions upon mutual consent.		conditions upon mutual consent (for a total period of 36 months).
2	7.2 Page 10 8.2.c Page 11	Upon empanelment of successful bidders, the FMD vaccine manufacturers will have to sign the contract with the Procurement Agency for supply of vaccine doses as per mutually agreed terms and conditions Tender along with the mutually agreed conditions outlined in the "Manufacturer – Purchaser Contract (MPC)	Does this means the terms and conditions will be discussed with empaneled manufacturers before finalization of the same. We opine that the model contract document (MPC) should be given now and is subject to discussion.	No change from what is mentioned in RfP.
3	8.2.e Page 11 25.5 Page 18 25.6 Page 18	Empanelment will be done to the evaluated bidder (s) whose bid has been found to be technically responsive and who is qualified to perform satisfactorily as per the terms and conditions incorporated in the tender document at the uniform L1 rate (discovered through this process) Based on the L1 rate so discovered, DAHD will invite the remaining technically qualified eligible bidders to agree to supply the FMD vaccine at the discovered L1 rate Successful technically qualified bidders who have agreed to supply FMD vaccine at the discovered L1 rate shall	1. The cost of production differs from manufacturer to manufacturer as the same depends on investment made for the land, manufacturing plant, technology, financial institution loan and interest there on, percentage of dependence on the product FMD alone which is the integral part of cost of production. Hence, **dual pricing structure** is requested. Also suggest that unrealistic low price should not be accepted.	No change from what is mentioned in RfP. 14.06.22 एम. के. दिवाकर M.K. DIWAKER अवर सचिव / Under Secretary भारत सरकार/Govt. of India मत्स्यपालन, पशुपालन एवं डेयरी मंत्रालय Ministry of Fisheries, Animal Husbandry & Dairying पशुपालन और डेयरी विभाग Department of Animal Husbandry & Dairying कृषि भवन, नई दिल्ली/Krishi Bhawan, New Delhi-110001

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		be selected and empaneled		
4	8.3.d Page 12	The purchaser shall reserve the right to determine the payment instalments as well as related conditions in consultation with DAHD, depending on the outstanding liabilities (if any) of the manufacturers (bidders) under LHDCP (which includes NADCP)	The outstanding liabilities i.e payment received from NAFED, if any, can be adjusted against the fresh supplies to the extent of 20% on every supplies.	No change from what is mentioned in RfP.
5	27 Page 19	Any amount of penalty outstanding against any bidder towards supply of FMD vaccine or vaccination on field by FMD vaccine which did not comply with stipulated quality parameters in any earlier procurement (vide E Tender Enquiry No. NAFED / HO/ NADCP/ 2019-20/ 1 dtd 27/11/2019) by DAHD (or its procurement agency viz. NAFED) if not paid / not recovered prior to procurement, would be adjusted against payment for future supply(ies) of FMD vaccine, against this Tender.	In the same way, penalty outstanding of Rs.6/- each per dose of NAFED, if any, also should be adjusted against the fresh supplies.	No change from what is mentioned in RfP. 14.06.22 एम. के. दिवाकर M.K. DIWAKER अवर सचिव / Under Secretary भारत सरकार/Govt. of India मत्स्यपालन, पशुपालन एवं डेयरी मंत्रालय Ministry of Fisheries, Animal Husbandry & Dairying पशुपालन और डेयरी विभाग Department of Animal Husbandry & Dairying कृषि भवन, नई दिल्ली/Krishi Bhawan, New Delhi-110001
6	12.1 Page 15	The Bid price of the goods shall comprise of the rate per vial of vaccines inclusive of all taxes, duties and transport to district headquarters pan India	In the BOQ the price asked for per dose. Please clarify whether per dose price or per vial price to be quoted.	The appropriate amendments have been made in the RfP. Please refer to corrigendum to Chapter I B Clause 12.1 and Chapter V (point 3 of the Corrigendum to RFP).
7	14.1 Page 15	Bids shall remain valid for a period of minimum of 2 years from date of submission of bid or fulfilment of supply commitment of four rounds, whichever is later. A bid valid	It is proposed to amend the same to "extensible with mutual consent of manufacturer and purchaser". Any difference of opinion, the same should be taken up with the Arbitrator.	Please refer to corrigendum to Chapter I B, Clause 14.1 (point 1 of the corrigendum to RFP). In case of any difference, please refer to Chapter XII – Integrity Pact (Page 34) of the RFP.

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		for a shorter period shall be treated non- responsive and rejected. The validity of the bid shall be extendable subject to decisions of the issuer.		
8	16.1 Page 16 & 16.4 Page 16 And Chapter-IX Page 30	Bid security of Rs. 4 crores (Rs Four crores only) shall be provided by the interested bidder to the Issuer. A scanned copy of the bid security will be uploaded at the CPP portal at time of bidding. However, bid security in hard copy will be deposited to the issuer before opening of Bid. The earnest money shall be valid for a period of forty-five (45) days beyond the validity period of the tender. This guarantee will remain in force for a period of forty-five days after the period of tender validity	1. It is requested that the same should be reduced to Rs.1 Crore as it is only the empanelment of manufacturer and it should be for 90days or 120 days only. As such the empaneled manufacturer has to sign MPC and separate BG has to be given in their favor as Security Deposit. 2. It is also proposed that DAHD being the Nodal Agency for this program and the funding also being done by them, the Security Deposit also should be parked with them. It is also proposed that the Security Deposit already given to NAFED for the same program, should be kept up to the extent of replacement to be given and the balance can be returned.	No change from what is mentioned in RfP.
9	28 Page 19	The comparison of the responsive tenders shall be carried out on FOR rate for delivery at State Head Quarters / Focal Points.	It is proposed to restrict supplies up to State HQ/Dist. HQ only. Anything extra will be at an additional cost of 2% of cost of products to absorb additional expenditure on transportation in reefer van.	No change from what is mentioned in RfP.
10	30 Page 19	INTRODUCTION OF NEW MANUFACTURER FOR SUPPLY OF FMD VACCINE The issuer reserves the right to introduce a new manufacturer (not participating in the current bid) during the Programme implementation upon the arising need of the	Does this means that any new manufacturers of FMD vaccine without any experience is allowed without any Market Standing Certificate for the products?	No change from what is mentioned in RfP.

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		Programme for meeting the desired quantity and quality parameters, applicable as per this tender condition. However, the new manufacturer shall be empaneled at the same bid price (discovered L1 price) as well as terms and conditions for the offered good and services as per this tender and its subsequent corrigendum, if any.		14.06.22 एम. के. दिवाकर M.K. DIWAKER अवर सचिव / Under Secretary भारत सरकार/Govt. of India मत्स्यपालन, पशुपालन एवं डेयरी मंत्रालय Ministry of Fisheries, Animal Husbandry & Dairying पशुपालन और डेयरी विभाग Department of Animal Husbandry & Dairying कृषि भवन, नई दिल्ली/Krishi Bhawan, New Delhi-110001
11	Chapter-III- II. 1 Page 21	Vaccine will be tested prior to supply to the field.	Whether all batches of vaccine will be tested before supplies. Please elaborate.	No change from what is mentioned in RfP.
12	Chapter-III- II. 5 Page 21	Any information regarding the vaccine, if necessary, shall be made available to the Purchaser/ DAHD. Reference sera for homologous vaccine strains to use as reference standards in serological tests for Post Vaccination Monitoring will be made available to the Purchaser/ DAHD, when requested	Whether the reference sera for homologous Strains will be provided by DAHD. Further virus pool also should be shared with manufacturer.	No change from what is mentioned in RfP.
13	Chapter-III- II. 7 Page 21	**Self-certification by the manufacturer regarding NSP-freedom:** Manufacturer shall self-certify for NSP-freedom. However, DAHD reserves the right to test the vaccines for purity as per extant SOP, whenever desires, through the designated laboratories.	The process of manufacturing adopted by the company comply for NSP free vaccine. Hence only self-certification should be accepted.	No change from what is mentioned in RfP.
14	Chapter-III- 1.2	The designated laboratories will complete the testing of	1. It is proposed that the SOP of QC testing should be discussed, harmonized with the manufacturer prior to the	No change from what is mentioned in RfP.

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	Page 22	vaccine batches for different parameters as per the extant SOP after receipt of the samples. The results shall be communicated to DAHD by the designated laboratories and subsequently to the Purchaser.	signing the MPC. 2. The Test Result should be communicated to manufacturer within a time frame, say, within 45 days on receipt of Samples at the Designated Lab. If it is delayed beyond this period, the Purchaser should accept the corresponding stocks as passed so that the vaccine can be utilized at the field without any delay.	
15	Payment 8.1.1 Page 23 8.1.2 Page 23	Receipt of written request for release of payment; with the copy of the original invoice/s, approved unit price and consolidated statement of due amount Submission of duly signed certificate / letter of receipt of vaccine by the consignee	It is proposed to accept electronic receipt of confirmation of stocks at the consignee end i.e. the scanning of code would directly confirm the Purchaser about the receipt. This will help timely updating the stocks and would be more authentic. This practice is observed many institutions in India (Ex: TNMSC).	Payment to vaccine manufacturer would be made basis submission of duly signed certificate/letter of receipt of vaccines by the consignee and uploaded by PLA on its portal. Please refer to corrigendum to Chapter III Clause III, Sr. No. 8.1.2 (point 5 of the Corrigendum to RFP).
16	Chapter IV Page 24	The bidder may be domestic / international manufacturer.	As it is meant for domestic manufacturer, the word international should be removed.	No change from what is mentioned in RfP.
17	Chapter VIII Page 29	Authority for submission of Bid Document at DAHD for supply of *FMD* Vaccine for financial years2021-2022 and 2022-2023.	Understand this must be a typographical error as it should be 2022-23 and 2023-24. Please confirm.	The appropriate amendments have been made in the RfP. Please refer to corrigendum to Chapter VIII (point 4 of the Corrigendum to RFP).
18	Chapter III A.5 Page 29	FMD vaccines should satisfy the quality parameters of safety and sterility as per IP in vogue and generate a minimum of 1:64 SNT titre for serotype "O" and 1:45 for serotype "Asia-1" and 1:45 for serotype "A" in cattle or correlated serum titre in guinea pigs following the protocol finalized by DAHD.	1. Further to the discussions in VC on 16th Feb'22 and subsequent discussion with the Consultant Dr. Danny on 14th & 15th Mar'22 at Hyderabad, we have been given to understand that the parameter for Serotype "O" as 1:32 and serotype "A" and "Asia 1" as 1:22 is more than enough which will elicit protection in the field. Understand that this is also supported by the studies done by IVRI as well as Intervet. This would also ensure required production quantity to fulfill the country's requirement. The guinea pigs testing protocol should be discussed, Harmonized with the manufacturer before implementing the same for the testing.	The FMD vaccine specifications have since been revised. Refer Corrigendum to Chapter-III Clause IA Sr. No. 5 (point 6 of the corrigendum to RFP). 14.06.22 एम. के. दिवाकर M.K. DIWAKER अवर सचिव / Under Secretary भारत सरकार/Govt. of India मत्स्यपालन, पशुपालन एवं डेयरी मंत्रालय Ministry of Fisheries, Animal Husbandry & Dairying पशुपालन और डेयरी विभाग Department of Animal Husbandry & Dairying कृषि भवन, नई दिल्ली/Krishi Bhawan, New Delhi-110001

Queries received from Biovet Pvt. Ltd.				
S. No.	**Clause No.**	**Clause Details**	**Query/Suggestion**	**Response to the queries**
1	Clause I.5 Page no. 21	FMD vaccines should satisfy the quality parameters of safety and sterility as per IP in vogue and generate a minimum of 1:64 SNT titre for serotype 'O' and 1:45 for serotype 'Asia-1' and 1:45 for serotype 'A' in cattle or correlated serum titre in guinea pigs following the protocol finalized by DAHD.	During Various meetings with DAHD and their International Consultant, it was discussed and felt necessity of revision in SNT titre values. Based on realistic data the SNT titre values should be revised to 'O'- 1:22, 'Asia-1 - 1:22, 'A' - 1:16.	The FMD vaccine specifications have since been revised. Refer Corrigendum to Chapter-III Clause IA Sr. No. 5 (~~point 6~~ of the corrigendum to RFP).
2	Clause II.2 Page no. 21	Vaccine will be tested prior to supply to the field.	**Testing Methodology: To consider implementing as per FMD-CP in Vogue.** It's understood each batch will be tested by the designated laboratory prior to supply that results in block in our Working Capital, accumulation of stocks and constraint of cold storage space.	No change from what is mentioned in RfP.
3	Clause II.6 Page no. 21	QC testing of the FMD vaccine will be done as per the mechanism and SOP communicated by DAHD from time to time.	SOP of QC testing by the designated laboratory should be shared to the manufacturers at the earliest.	No change from what is mentioned in RfP.
4	Clause II.7 Page no. 21	Manufacturer shall self-certify for NSP-freedom. However, DAHD reserves the right to test the vaccines for purity as per extant SOP, through the designated laboratories.	SOP and testing methodology is to be finalized in discussions with Manufacturers.	No change from what is mentioned in RfP.
5	Clause 1.3 Page no. 22	The supplier shall provide self-certified records and the details of production/testing to the purchaser or his representative, wh8enever required.	Production details are confidential and will be made available for onsite review only.	No change from what is mentioned in RfP.
6	Clause 1.4 Page no.	DAHD reserves the right to conduct the random sampling and testing of the vaccine doses supplied to the field as	Once prior testing is conducted by designated laboratories then random field samples testing is not recommenced, due to various uncertain factors prevailed in field.	No change from what is mentioned in RfP.

14.06.22
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	22	per the approved SOP at the designated laboratories.		
7	Clause 5 Page no. 22	LABELLING - Packing and Labelling..... label should contain as "SUPPLIED FOR LHDCP. GOI "NOT FOR SALE"	Since stock holding is maintained at six months consumption, request approval to utilize the labels with old "NADCP SUPPLY NOT FOR SALE"	No change from what is mentioned in RfP.
8	Clause 8.1.3 Page no. 22	Payment	50 % advance payment of the tender allotted quantity to be released. Release period of payment after submission of relevant documents needs to be specified.	No change from what is mentioned in RfP.
9	Clause 27 Page no. 19	Any amount of penalty outstanding against any bidder towards supply of FMD vaccine or vaccination on field by FMD vaccine which did not comply with stipulated quality parameters in any earlier procurement (vide E Tender Enquiry No. NAFED/HO/NADCP/2019-20/1 dated 27/11/2019) by DAHD (or its procurement agency viz MAFED) if not paid / not recovered prior to procurement, would be adjusted against payment for future supply(ies) of FMD vaccine, against this Tender.	Liability of replacement of stocks other than Non-compliance batches should be Waived. Re-Vaccination cost should be charged only for two non-compliance batches. Liability derived as above should be recovered from fresh supplies @30% of each payment is released. This should be considered keeping in view of huge losses incurred due to destruction of Re-called batches as well as the FMD vaccine manufacturers have suffered huge setback in last two years.	No change from what is mentioned in RfP.
10	Chapter-VIII Page 29	Authority for submission of Bid Document at DAHD for supply of FMD Vaccine for financial years 2021-2022 and 2022-2023. "Resolved that the consent of Board be and is hereby accorded for submission of Bid Documents at DAHD for empanelment for supply of FMD Vaccine for	In Authorization letter in financial year is mentioned as 2021-2022 and 2022-2023 we believe it should be finical year 2022-2023 and 2023-2024 kindly consider accordingly.	The appropriate amendments have been made in the RfP. Please refer to corrigendum to Chapter VIII (point 4 of the Corrigendum to RFP).

14.06.22

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Queries received from Biovet Pvt. Ltd.				
S. No.	**Clause No.**	**Clause Details**	**Query/Suggestion**	**Response to the queries**
		financial years 2021-2022 and 2022-2023.		
11	Clause 12.1 Page no. 15,25	The Bid price of goods shall comprise of the rate per vial of vaccine inclusive of all taxes duties and transport to District headquarters PAN India.	In BOQ rate to be quoted of DOSE or Vial.	The appropriate amendments have been made in the RfP. Please refer to corrigendum to Chapter I B Clause 12.1 and Chapter V (point 3 of the Corrigendum to RFP).
12	Clause 14.1 Page no. 15	Tender Validity is for two years extendable to 36 months on Mutual consent.	After two years price escalation of year on year needs to be specified.	No change from what is mentioned in RfP.
13		Ceiling of price is fixed as an essential product	Tender conditions don't mention any Ceiling price, should be considered minimum 25% above the last 2019 price i.e., 12.78. Three years inflation needs to be considered.	Not part of RfP
14	Clause 16.1 Page no. 16	Bid security of Rs. 4 crores (Rs Four crores only) shall be provided by the interested bidder to the Issuer. A scanned copy of the bid security will be uploaded at the CPP portal at time of bidding. However, bid security in hard copy will be deposited to the issuer before opening of Bid.	EMD amount should be reduced and should be adjusted against BG	No change from what is mentioned in RfP. 10.06.22 एम. के. दिवाकर M.K. DIWAKER अवर सचिव / Under Secretary भारत सरकार/Govt. of India मत्स्यपालन, पशुपालन एवं डेयरी मंत्रालय Ministry of Fisheries, Animal Husbandry & Dairying पशुपालन और डेयरी विभाग Department of Animal Husbandry & Dairying कृषि भवन, नई दिल्ली/Krishi Bhawan, New Delhi-110001
15	Clause 8.2.C Page no. 11	FMD vaccine manufacturer(s) shall be appointed as per the specifications mentioned in this Tender document for supply of FMD vaccine under LHDCP	Chapter of MPC, LOA, Conditions of Contract, Inspection authority etc, are not provided in the tender and should be part of the tender document.	As per RFP, as this is an empanelment tender.
16	Clause 8.2.C Page no. 11	b. The successful bidders shall be empaneled by DAHD for supply of vaccine doses as per the submitted bid	Chapter of MPC, LOA, Conditions of Contract, Inspection authority etc, are not provided in the tender and should be part of the tender document.	As per RFP, as this is an empanelment tender.
17	Clause 8.2.C	c. The FMD vaccine manufacturer(s) shall sign a	Chapter of MPC, LOA, Conditions of Contract, Inspection authority etc, are not provided in the tender and should be part	No change from what is mentioned in RfP.

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S. No.	**Clause No.**	**Clause Details**	**Query/Suggestion**	**Response to the queries**
	Page no. 11	contract with the Procurement Agency for supply of FMD vaccine doses as per the terms and conditions mentioned in the Tender along with the mutually agreed conditions outlined in the "Manufacturer – Purchaser Contract (MPC)"	of the tender document.	
18	Clause 8.2.C Page no. 11	d. The FMD vaccine manufacturer(s) shall adhere to all the necessary obligations of the Purchaser as mentioned in the "Manufacturer – Purchaser Contract (MPC)" and the Purchaser will have the rights to evoke necessary actions on non-fulfilment of the conditions of the said contract.	Chapter of MPC, LOA, Conditions of Contract, Inspection authority etc, are not provided in the tender and should be part of the tender document.	No change from what is mentioned in RfP.

14.06.22

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