CENTRAL MEDICAL SERVICES SOCIETY
Ministry of Health and Family Welfare (Government of India)
2nd floor, Vishwa Yuvak Kendra, Pt. Uma Shankar Dikshit Marg, Teen Murti Road,
Opposite Police Station Chanakya Puri, New Delhi-110021
Telephones: 011-21410905, 21410906,

Dated: - 20.10.2023

Minutes of Pre-bid Meeting for PROCUREMENT OF Hepatitis-B & Hepatitis-C Kits for NVHCP

TENDER No: CMSS/PROC/2023-24/NVHCP/022

Pre-bid conference held on 10.08.2023

1. Following officials were present during the Pre-bid meeting: -
   - (i) Mr. Partha Rakshit, NVHCP
   - (ii) Dr. Preeti Madan, NVHCP
   - (iii) Ms. Anjana, GM (Procurement) CMSS
   - (iv) Mr. D. Mahapatra, GM (Finance)CMSS
   - (v) Ms. Sakshi Juneja, AGM (Procurement)CMSS
   - (vi) Ms. Akanksha Jain, AGM (QA)CMSS

2. Following representatives from prospective bidders were present during the Pre-bid meeting:-

Sl. No.	Name of Representative	Name of Firm
1.	Mr. Ashish Hasija & Mr. Rohit	M/s Meril Diagnostics.
2.	Mr. Abinash Kumar Mishra	M/s. Medsource
3.	Mr. Govind Khatri	M/s. Q-Line Biotech
4.	Mr. Bhuwan Puri & Mr. Deepak Agarwal	M/s. Trans Asia

3. Points raised by representatives of prospective bidders were discussed. After due consideration of the queries, the remarks are enclosed.

Sr. No	Bidder	Pg No. & Clause	Query/ Classification Asked	Amendments/Clarifications
1.	M/s Q-Line Biotech	**Refer Page No. 15 Clause No. 6.2 (e)** Tenderer should have supplied 40% of the quoted quantity of same or similar items during the last two financial years. Bidder should submit Purchase order copies and certificate duly issued by statutory auditor of the company on his letter head by certifying the quantities manufactured and marketed in trade, export, open market, sold to government institutions, private bodies etc. and the marketed quantities are not less than at least 40% of the quoted/ similar items. Similar Items here relate to the following: - Similar item means quoted/AnyHepatitis B or C kits. Supply/Sale/Service order under loan license arrangement shall not be considered.	The tenderer must have supplied at least 20% or more of the tentative quantity of the same or similar item during the last two or more financial years. Bidder should submit Purchase order copies and certificate duly issued by statutory auditor of the company on his letter head by certifying the quantities manufactured and marketed in trade, export, open market, sold to government institutions, private bodies etc. and the marketed quantities are not less than at least 20% of the quoted/ similar items. Similar Items here relate to the following: - Similar item means Rapid Diagnostic Test Kits of any infectious marker. As the bid desired quantity is very high and very rarely such high quantity bids are floated, in such case the general eligibility standards of meeting 40% of the bid quantity is a major challenge and currently hardly 1 or 2 bidder can fulfill the criteria hence the clause should be diluted so that maximum indigenous manufacturers can participate and better competition could be seen	**Clause amended as:-** Tenderer should have supplied 40% of the quoted quantity of same or similar items during the last two financial years. Bidder should submit Purchase order copies and certificate duly issued by statutory auditor of the company on his letter head by certifying the quantities manufactured and marketed in trade, export, open market, sold to government institutions, private bodies etc. and the marketed quantities are not less than at least 40% of the quoted/ similar items. Similar Items here relate to the following: - **Similar item means quoted/Any Hepatitis B or C Kits/Rapid diagnostic test kits (lateral flow) of any infectious marker (antigen or antibody)** Supply/Sale/Service order under loan license arrangement shall not be considered. **Note:** Bidder should submit Purchase order copies along with the copy of GST invoice and E-way bill against the proof of execution of order for every submitted Purchase Order. If GST invoice is not applicable for any Purchase Order, the affidavit to that effect on stamp paper of Rs. 100/- should be submitted
		Refer Page No. 16 Clause No. 6.2 (f) Manufacturing and Market Standing Certificate/Market Standing Certificate issued by the Licensing Authority as a manufacturer for each	Manufacturing and Market Standing Certificate/Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted from any of the last 3 years i.e. 2020-21, 2021-22 or 2022-23 for	**Clause amended as:-** Manufacturing and Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted/any Hepatitis B or C kits/Rapid Diagnostic Test (lateral

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		item quoted for the last 2 years i.e. 2020-21 & 2021-22 OR 2021-22 & 2022-23 for compliance of tender clause no. 4 (d). Note: 1. Unless otherwise stipulated in the Market standing certificate, the said certificate issued on a particular date shall be treated valid certificate for the financial year in which it has been issued. For example, Market Standing Certificate issued on 15.07.2022 for the period 15.07.2022 to 14.07.2023 shall be treated as Market Standing Certificate for the FY 22-23 only.	compliance of tender clause no. 4(d). The restriction for the years involved in the market standing of the product and non-conviction of the firm should be diluted. As yourself is well aware that during the high-time of Covid-19 pandemic, the supply chain of any organization is affected and many manufacturing organization were not in a state to supply their manufactured products in the Covid-19 pandemic tenure. Hence, for the market standing of the product and non-conviction of the firm the restriction for the years should be removed.	flow) of any infectious marker (Antigen or antibody).
		Refer Page No. 16 Clause No. 6.2 (g) Non-Conviction Certificate issued by the FDA/ Drugs Controller of the State certifying that the firm/company (as well as the manufacturer firm in case of nonmanufacturer bidders) has not been convicted and the products quoted have not been cancelled during last two years i.e. 2020-21 and 2021-22 OR 2021-22 and 2022-23. Note: 1.Unless otherwise stipulated in the Non-Conviction Certificate, the	Non-Conviction Certificate issued by the FDA/ Drugs Controller of the State certifying that the firm/company has not been convicted and the products quoted have not been cancelled	**Refer Page No. 16 Clause No. 6.2 (g)** Non-Conviction Certificate issued by the FDA/ Drugs Controller of the State certifying that the firm/company has not been convicted and the products quoted have not been cancelled during last two years i.e. 2020-21 and 2021-22 OR 2021-22 and 2022-23. Note: 1.Unless otherwise stipulated in the Non-Conviction Certificate, the said certificate issued on a particular date shall be treated valid certificate for the financial year in which it is issued. For example, Non-Conviction Certificate issued on 15.07.2022 for the period 15.07.2022 to 14.07.2023

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		said certificate issued on a particular date shall be treated valid certificate for the financial year in which it is issued. For example, Non-Conviction Certificate issued on 15.07.2022 for the period 15.07.2022 to 14.07.2023 shall be treated as Non-Conviction Certificate for the FY 22-23 only.		shall be treated as Non-Conviction Certificate for the FY 22-23 only. 2. Non Conviction certificate should be for the same manufacturing premises for which quoted goods have been offered for supply.
		Refer Page No. 17 Clause No. 6.2 (n) Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life and Certificate of Analysis of one batch of the quoted product and Stability data/ performance data up to 45 degrees Celsius in reference to technical specification clause no D, G (iii) should be submitted.	Long Term (Real Time) stability Data available for the quoted products shall be submitted by using any type of specimen like serum/plasma/whole blood Generally Long Term (Real Time) stability data available for the quoted products not available related to whole blood testing by any company. so this clause should be diluted for other specimens too like-serum/plasma/whole blood which ensure maximum bidder participation	**Long Term data clause amended as:-** **For Sch-I** **a) Long term stability data of the quoted product on any type of specimen like serum/ plasma/whole blood in** specified packing for at least for 3 batches, to support shelf life and Certificate of Analysis of one batch of the quoted product and Stability data/ performance data should be submitted. b) Accelerated studies for HBsAg i.e., for Sch-I is also to be submitted. **For Sch-II:- No Change**
		Technical specification Point No. 42- HBsAg (Rapid Test) Whole Blood & Point No. 43-Anti HCV Antibody kits (Rapid Test) Whole Blood: The Assay component should include positive & Negative control sufficient for conducting 20% of the tests (10% Negative & 10%	Clause should be removed The Assay procedure does not require positive & Negative control for conducting the tests and its result it will unnecessary increase the price In spite of these kits do not require temperature indicator & stable at 30 degree C temp ormore, only controls will require the 2 to 8 degree C temp. So there is no need of temperature indicatortechnology for kits, It will be an extra burden on	No Change

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		Positive control) which may be provided along with the kits if not part of the kit. General specification: Point No. 1: The Manufacturer/authorized agent should insure maintenance of cold chain during storage & Transport of kits at 2 to 8 degree C. The cumulative time temperature indicator technology should be used on each kit & pre- qualified by WHO.	the company & the firms who is supplying these kits by which quoted prices will be very high. Therefore, for better competition among bidders this clause should be removed.	
		Refer Page No. 42 & 43 **General specification: Pont No. 3** 8 Kit should be supplied along with the procurement lot of which four kits willbe used for Validation, subjects to which the kits of each batch No. and lot No. will be supplied to programme and four kits will be retained for evaluation close to the expiry of Kit	Kindly specify the No. of Test to be submitted as sample as per your requirement It will be very helpful for any bidder to assume the total no. of samples for submission, as different pack sizes from different manufacturer are available in market, Therefore, sample submission will vary in quantity and it will affect your requirement.	**Provision of General Specifications Pt. No.3 Deleted.**
2.	**M/s Mylan Pharmaceuticals.**	We refer to your Tender. CMSS/PROC/2023-23/NVHCP/022 - Dt. 04.08.2023 for the items – Whole Blood Finger prick based Hepatitis B (HBsAg) test Kits and Whole Blood Finger prick based Hepatitis (Anti HCV) test Kits.	In this regard, we came to know that you have only allowed manufacturers to participate in the tender. M/s. Mylan Pharmaceuticals Pvt Ltd, registered office: Plot No. 564/A/22, Road No. 92, Jubilee Hills, Hyderabad- 500 096, have an exclusive authorization in India from M/s. Mylab Discovery Solution Pvt Ltd, Pune for participating in the tenders for cited products. With this, we intend to participate	No Change

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			with best competitive prices, if we are allowed to participate in above cited tender. Kindly consider our request and allow us to participate in this aforesaid tender.	
3.	**M/s Meril Diagnostics Pvt. Ltd.**	Product-HbsAg whole blood finger prick. Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life and Certificate of Analysis of one batch of the quoted product Page 17 point 6.2 n	The majorly available Product in the Market for HbsAg is based on Serum and Plasma specimen. The whole blood product is fairly new in the market; hence manufacturers won't be able to submit long-term real-time studies. Request you to please consider Long Term Stability data of HbsAg-Serum/Plasma kit. And, the accelerated studies as well as ongoing studies for HbsAg – Whole Blood kit can be asked for.	**Long Term data clause amended as:-** **For Sch-I** **c) Long term stability data of the quoted product on any type of specimen like serum/plasma/whole blood in** specified packing for at least for 3 batches, to support shelf life and Certificate of Analysis of one batch of the quoted product and Stability data/ performance data should be submitted. d) Accelerated studies for HBsAg i.e., for Sch-I is also to be submitted. **For Sch-II:- No Change**
		Product – HCV whole blood finger prick. Tenderer must submit Market standing certificate issued by the Licensing Authority, as a Manufacturer of the item quoted, for at least last two financial year i.e. 2020-21 and 2021-22 OR 2021-22 and 2022-23. However, this would not apply to products which have been licensed by DCG (I) less than two years ago. Page No.16-QUALIFICATION CRITERIA Sub point f)	Financial Year 2020-21 was under covid Pandemic and Govt. Authority floated tenders related to covid Test and didn't generated enquiries for other products for throughout the financial year 2020-21. Therefore, we Request you to please include/consider the financial Years 2018-19 and 2019-20 for HCV	**Clause amended as:-** Manufacturing and Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted/any Hepatitis B or C kits/Rapid Diagnostic Test (lateral flow) of any infectious marker (Antigen or antibody).

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		Product –HbsAg whole blood finger prick. Tenderer must submit Market standing certificate issued by the Licensing Authority, as a Manufacturer of the item quoted, for at least last two financial years i.e. 2020-21 and 2021-22 OR 2021-2022 and 2022-23. However, this would not apply to products which have been licensed by DCG (I) less than two years ago. Page No. 16- QUALIFICATION CRITERIA Sub point f)	The HbsAg whole blood product is fairly new in the market and the majority of manufacturers available for this product have received manufacturing licence (subjected to this product) in the recent past. Hence, recent past. Hence, none of the manufacturers have market standing for 2 years for this product. While, the same product with Serum/plasma as samples shall be considered for market standing as it would state the credibility and capability of the manufacturer. Therefore, we Request you to Please consider Market Standings of 2 years for Serum/Plasma HbsAg kit in place of HBsAg whole blood Kit.	**Clause amended as:-** Manufacturing and Market Standing Certificate issued by the Licensing Authority as a manufacturer for each item quoted/any Hepatitis B or C kits/Rapid Diagnostic Test (lateral flow) of any infectious marker (Antigen or antibody).
		Annexure-I Schedule of Requirement Purchase Order against the Rate contract for a qty. of 29, 29,500 (for Sch. I) and 14,00,200 (For Sch.II) is likely to be placed immediately after issuance of Rate Contract with a delivery schedule of 60 days B. Delivery Schedule:- Point 1 and 2	Supply period also includes the time period for PDI and hence a certain part of it (15-20 Days) is not in the manufacturer's control. Hence, request you to increase the delivery period for the initial delivery to 100-120 days.	**Delivery Schedule amended as:** **For SCH. I (Hepatitis-B Whole blood Rapid Diagnostic Test)** TRANCHE I- Quantity of 29,29,500(no. of tests) to be delivered within 90 days from the date of issue of LOA. TRANCHE II- Quantity of 29,20,500 to be delivered within 90-150 days from the date of issue of LOA. TRANCHE III- Quantity of 29,29,500(no. of tests) to be delivered within 150-210 days from the date of issue of LOA. TRANCHE IV- Quantity of 29,20,500(no. of tests) to be delivered within 210-270 days from the date of issue of LOA **For SCH. II (Hepatitis-C Whole blood Rapid Diagnostic Test)**

Sr. No	Bidder	Pg No. & Clause	Query/ Classification Asked	Amendments/Clarifications
				TRANCHE I- Quantity of 14,00,200 (no. of tests) to be delivered within 90 days from the date of issue of LOA. TRANCHE II- Quantity of 13,99,800 to be delivered within 90-150 days from the date of issue of LOA. TRANCHE III- Quantity of 14,00,200 (no. of tests) to be delivered within 150-210 days from the date of issue of LOA. TRANCHE IV- Quantity of 13,99,800 (no. of tests) to be delivered within 210-270 days from the date of issue of LOA
All Certificates issued by Charted Accountant shall mandatorily include UDIN No.				