CENTRAL MEDICAL SERVICES SOCIETY
Ministry of Health & Family Welfare
(Autonomous Body under MoHFW, Govt. of India)
2nd Floor, Vishwa Yuvak Kendra, Pandit Uma Shankar Dikshit Road,
Chanakyapuri, New Delhi-110021 PHONE -:011-21410905/6, Fax -:011-21410849

Date: - 11.08.2023

Minutes of Pre-bid Meeting
For Procurement of Bivalent- RDT (Malaria) for NCVBDC
GeM Bid No.: GEM/2023/B/3659548, dated 07.07.2023
Pre-bid Meeting held on 12.07.2023 at 11:00 AM

1. Following officials were present during the Pre-bid meeting: -
   (i) Mr. P S Rahate, Research Officer (NCVBDC)
   (ii) Mr. Anil Kumar Mehta, CA (NCVBDC)
   (iii) Mr. D Mohapatra, GM (Finance), CMSS
   (iv) Ms. Anjana, GM (Procurement), CMSS
   (v) Mr. Lava Mishra, AGM (Procurement), CMSS
   (vi) Ms. Akanksha Jain, AGM (QA), CMSS

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

Sr. No.	Name of Representative	Name of firm
1	Mr. Sanjay Kumar Chawla, Mr. Rajesh Verma	M/s Medsource Ozone Biomedicals Pvt. Ltd.
2	Mr. Govind Khatri, Mr. Daan Singh	M/s Q-Line Biotech Pvt Ltd
3	Mr. Anil Kumar	M/s Vishat Diagnostics Pvt Ltd.
4	Mr. Rohit Bhatnagar	M/s Meril Diagnostics Pvt. Ltd.
5	Mr. Mudit Gupta	M/s Angstrom Biotech Pvt Ltd
6	Mr. Naresh Pal Singh	M/s Oscar Medicare Pvt Ltd
7	Mr. Pawan Chopra	M/s Labgell Biotech

3. Queries from following prospective firms were received via email: -

Sr. No.	Name of the bidders	
1	M/s Medsource Ozone Biomedicals Pvt Ltd.	M/s Q-Line Biotech Pvt Ltd.
2	M/s Oscar Medicare Pvt Ltd	M/s Hetero Healthcare
3	M/s Vimek Bioconcept Pvt Ltd	M/s SD Biosensor Healthcare Pvt Ltd

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

TABLE-A

Pre-bid queries raised by the prospective bidders & remarks by CMSS

Sr. No.	As per tender	Tender clause no. & Pg No.	Bidder's Representation	Bidder's Name	Response
1.	Tenderer should submit a scientific study report of product testing at designated ICMR laboratory in support of their claim of performance of the offered product, mentioning the panel detection score, false positivity rate, invalid rate, ease of use, thermal stability data etc. in reference to technical specification clause G (ii).	6.2 (z) & Pg No. 18	Request you to please amend it as "Tenderer should submit a scientific study report of product testing at designated **ICMR laboratory/ WHO FIND/ NIMR** in support of their claim of performance of the offered product, mentioning the panel detection score, false positivity rate, invalid rate, ease of use, thermal stability data etc. in reference to technical specification clause G (ii)". **Since ICMR gives sensitivity and specificity report only.**	M/s Medsource Ozone Biomedicals Pvt. Ltd.	**Clarified as:** As per response from ICMR-NIMR: ICMR-NIMR provides testing report of the test performance in terms of sensitivity and specificity. The data related to thermal stability is innate part of product development which is not tested as WHO FIND has not mentioned the same to be tested at labs so it may be only the claim by vendors during the development of product.
2.	The supplier shall supply the ordered quantity within minimum required period of 60 days (or as mentioned in LOA/PO) from the date of award at the destinations mentioned.	14.3 (a) & Pg No. 27	As per Annexure 1 40% supply to be completed in 90 days from the LOA date. Please clarify which clause to follow. **Since this is a PDI item we request you to please extend the delivery period up to 150 days.**	M/s Medsource Ozone Biomedicals Pvt. Ltd.	**Clarified as:** Delivery schedule mentioned in Annexure-I at Pg No. 40 will be applicable.
3.	With the prior approval of CMSS, the supplier may continue to supply the unexecuted quantity after 60th day or after the delivery dates/schedule as mentioned in order with Liquidated Damages as specified in Clause 18 of the tender conditions on the delayed supplies.	14.3 (b) & Pg No. 27	Request you to please amend it as "With the prior approval of CMSS, the supplier may continue to supply the unexecuted quantity after 150th day with Liquidated Damages as specified in Clause 18 of the tender conditions on the delayed supplies".	M/s Medsource Ozone Biomedicals Pvt. Ltd.	**Clarified as:** As per tender terms & conditions.
4.	The supplier will not dispatch/supply stocks/goods after the last date of scheduled delivery of the Lot/Tranche without PO amendment issued by procurement wing.	18.4 (a) & Pg No. 35	Request you to please amend it as "The supplier shall continue to dispatch/supply stocks/goods after the last date of scheduled delivery of the Lot/Tranche. Additionally need to request for delivery extension and PO amendment from procurement wing".	M/s Medsource Ozone Biomedicals Pvt. Ltd.	**Clarified as:** As per tender terms & conditions.
5.	Lot 1 (40%) - To be delivered between 90 days from the date of issue of LOA Lot 2 (30%) - To be delivered between 91-	Annexure-I & Pg No.-40	Request you to please amend it as "Lot 1 (40%) - To be delivered between 1-150 days from the date of issue of PO Lot 2 (30%) - To be delivered between 151-240 days from the date of issue of PO Lot 3 (30%) - To be delivered between	M/s Medsource Ozone Biomedicals Pvt. Ltd.	No changes.

	180 days from the date of issue of LOA Lot 3 (30%) - To be delivered between 181-270 days from the date of issue of LOA		241-330 days from the date of issue of PO **OR** "Lot 1 (30%) - To be delivered between 1-120 days from the date of issue of PO Lot 2 (30%) - To be delivered between 121-210 days from the date of issue of PO Lot 3 (40%) - To be delivered between 211-300 days from the date of issue of PO		
			LOT 1: To be delivered between 120 days from the date of issue of LOA LOT 2: To be delivered between 121-211 days from the date of issue of LOA LOT 3: To be delivered between 182-301 days from the date of issue of LOA	M/s Meril Diagnostics Ltd	
			The delivery time for the 1st lot to be increased from 90 days to 120 days from the date of LOA.	M/s Vimek Bioconcept Pvt Ltd	
6.	Each kit should contain all the material required for performing the test including individually packed sterile lancets for pricking, heparinized capillary tubes (diameter-1mm) with relevant markings and reaction tubes with stand/ wells as required.	Annexure-I & Pg No.-41	Please amend it as "Each kit should contain all the material …… **capillary or sample loop or inverted sample cup** convenient to perform test can be provided.	M/s Medsource Ozone Biomedicals Pvt. Ltd.	**No changes.** Test Kit material should be as per technical specifications only.
7.	**B. Content of Kit and Packaging:** Storage conditions, expiry dates and limitations of the test should be provided. The small box should be packed in bigger cardboard carton containing 10 such small boxes. The cartoon should be sealed with a sealing sealing tape.	Annexure-I & Pg No.-41	Request you to please keep the pack size as - The small box should be packed in bigger cardboard carton containing **5 such small boxes** in line with existing ongoing contracts.	M/s Medsource Ozone Biomedicals Pvt. Ltd.	**Clarified as:** States getting 5 x 10 test in current supply. We may agree.
8.	**D. Stability requirements at temperatures of indented storage, transport and use:** RDTs should have high thermal stability for use in areas with very high ambient temperatures as per evaluation by ICMR against a single cultured P. falciparum isolate at 200 parasites/µl at baseline and after 60 days of incubation at room temperature, 35℃ and 45℃.	Annexure-I & Pg No.-42	Request you to please amend it as "Tenderer should submit a in-house scientific study report for use in areas with very high ambient temperature at base line ans after 60 days at room temperature 35℃C and 45℃. " **Since ICMR gives sensitivity and specificity report only and not at very high temperature of 35℃ and 45℃.**	M/s Medsource Ozone Biomedicals Pvt. Ltd.	**Clarified as:** As per response from ICMR-NIMR: The thermal stability of the RDTs is supposed to tested in house and may be validated further from any organization as part of scientific study. Currently ICMR-NIMR provide the test performance in terms of sensitivity and specificity in span of 5 working days.
			RDT Should have high thermal stability for use in areas with very high ambient temperatures as per evaluation by ICMR/Inhouse report at baseline and after 60 days of incubation at room temperature, 35*C and 45*C. **Justification** Referring to the new WHO SOP effective from Feb-2020, **"METHODS MANUAL FOR LABORATORY QUALITY CONTROL TESTING OF MALARIA RAPID DIAGNOSTIC TESTS-V. 9 Chapter 2, SOP 2.01 to SOP 2.05,** The long-term temperature stability study has been removed from the protocol and	M/s Q-Line Biotech Pvt Ltd	

			WHO/ICMR does not provide this kind of study as of now. Hence requested to accept in-house temperature study for the high temperature stability		
9.	**F. Marking/ Labelling:** The large carton (containing 10 small boxes) and small box (containing 10 test) should have the following markings:	Annexure-I & Pg No.-42	Request you to please keep the pack size as - The small box should be packed in bigger cardboard carton containing **5 such small boxes.**	M/s Medsource Ozone Biomedicals Pvt. Ltd.	**Clarified as:** Kindly refer reply of Sr. No. 7 above.
10.	**G. Details regarding approval of license** – (ii) The bidder must submit scientific study report of product testing at designated ICMR laboratory in support of their claim of performance of the offered product, mentioning the panel detection score, false positivity rate, invalid rate, ease of use, thermal stability data etc.	Annexure-I & Pg No.-43	Request you to please amend it as "Tenderer should submit a scientific study report of product testing at designated **ICMR laboratory/ WHO FIND/ NIMR** in support of their claim of performance of the offered product, mentioning the panel detection score, false positivity rate, invalid rate, ease of use, thermal stability data etc. in reference to technical specification clause G (ii)" **Since ICMR gives sensitivity and specificity report only and not thermal stability data.**	M/s Medsource Ozone Biomedicals Pvt. Ltd.	**Clarified as:** Kindly refer reply of Sr. No. 1 above.
			Tenderer should submit a scientific study report of product testing at designated ICMR laboratory in support of their claim of performance of the offered product, mentioning the panel detection score, false positivity rate, invalid rate, ease of use, etc. in reference to technical specification clause G (ii). **Justification:** Referring to the new WHO SOP effective from Feb-2020, **"METHODS MANUAL FOR LABORATORY QUALITY CONTROL TESTING OF MALARIA RAPID DIAGNOSTIC TESTS-V. 9 Chapter 2, SOP 2.01 to SOP 2.05,** The long-term temperature stability study has been removed from the protocol and WHO/ICMR does not provide this kind of study as of now. Hence requested to accept WHO collaborated centre ICMR/NIMR study without temperature stability study.	M/s Q-Line Biotech Pvt Ltd	
11.	**RDT Performance criteria:** Each Lot of RDT should be tested at a designated ICMR laboratory at the time of delivery.	Annexure-I & Pg No.-41	We request you kindly allow the In-house Test Report or NABL Accelerated Report of Each Batch.	M/s Oscar Medicare Pvt Ltd	No changes.
12.	Vide Gazette no. CG-DL-E26062020-220191 dt. 26.06.2020, Ministry of MSME have revised criteria for classifying the enterprises as Micro, small and medium enterprises with effect from 1st July 2020 therefore following firms will be exempted from submission of EMD.	9.2 (ii) & Pg no. 21	We request you kindly confirm that Medium Enterprises are exempted from EMD.	M/s Oscar Medicare Pvt Ltd	**Clarified as:** As per tender terms & conditions.

13.	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 kit of NCVBDC **Supply/Sale/Service order under loan license arrangement shall not be considered.**	4 (i) and 6.2 (e) & Pg No. 11 and 15	Tenderer should have supplied 10-20% of the quoted quantity of same or similar items during the last two financial years. **Justification:** As you are aware in last three to four years, malaria cases are gone down drastically i.e. also evident from the NVBDC website, and new manufacturers which got their marketing license within three years, might not have supplied such a huge quantity to any institutions. Considering the above, we request you to amend it as requested to make room for other new manufacturers to BID in the tender. Which will make wider options for CMS.	M/s Q-Line Biotech Pvt Ltd	No changes.
14.	**A. Description of the Test Kit** Each test kit should contain all the materials required for performing the test including individually packed sterile lancets for pricking, heparinised capillary tubes (diameter-1mm) with relevant markings and reaction tubes with stand/wells as required.	Annexure-I & Pg No.-41	Each test kit should contain all the materials required for performing the test including individually packed sterile lancets for pricking, heparinised capillary/loop/dropper with relevant markings and reaction tubes with stands/well as required. **Justification:** As the capillary tubes are available with limited vendors and prone to damage, and so the existing vendor is struggling to provide. Now a days, better solutions are available for sample transfer such as the sample loop (inverted as well as vertical) and droppers. these are easy to use and more robust with good availability. Amendment to this will facilitate a better options of sample transfer solutions in point of care testing.	M/s Q-Line Biotech Pvt Ltd	**Clarified as:** Kindly refer reply of Sr. No. 6 above.
15.	**G. Details regarding approval of license** (iii). Reports of proven performance of the offered product in conditions similar to the Indian field conditions (Room Temperature up to 45°C) with certification of no adverse report for the offered product from the end users during the last **five years** must be submitted with the bid.	Annexure-I & Pg No.-43	Reports of proven performance of the offered product in conditions similar to the Indian field conditions (Room Temperature up to 45*C) with certification of no adverse report for the offered product from the end users during the last Two years must be submitted with the bid. **Justification:** As past performance/market standing/nonconvention certificates are asked for last two years and also the new manufacturers providing good quality products might not have their license for last five years, you are requested to amend it for	M/s Q-Line Biotech Pvt Ltd	No changes.

			last two years to make more participation.		
16.	Manufacturing and Market Standing Certificate / Market Standing Certificate issued by the Licensing Authority as a manufacturer for each 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).	6.2 (f) & Pg No. 15	Manufacturing and Market Standing Certificate / Market Standing Certificate issued by the Licensing Authority as a manufacturer for each 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). 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 & FY 21-22. **Justification:** Market Standing Certificate duration should be count from the date of Manufacturing licence issued till now. For example, if it is issued in 15.07.2022 and date of Manufacturing licence is July 2020 so Market Standing of OEM should be count from the date of Manufacturing licence.	M/s Q-Line Biotech Pvt Ltd	No changes.
17.	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 non-manufacturer 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.	6.2 (g) & Pg No. 16	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 non-manufacturer 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 2023. 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 & FY 21-22. **Justification:** Non-Conviction Certificate duration should be count from the date of Manufacturing licence issued till now. For example If it is issued in 15.07.2022 and date of Manufacturing licence is July 2020 so Market Standing of OEM should be count from the date of Manufacturing licence.	M/s Q-Line Biotech Pvt Ltd	No changes.
18.	Only for the drugs introduced in Indian Pharmacopoeia in the recent past (last 2yrs), Market standing certificate for previously approved Pharmacopoeia or Inhouse Standards (Export/ Domestic) shall be accepted.	Page No. 16	Confirmation and clarification required about Pharmacopoeia.	M/s Q-Line Biotech Pvt Ltd	**Clarified as:** This is related to drugs and tendered item is not under the category of drugs.
19.	e-tenderer should furnish the Manufacturing License valid on the date of tender opening for each items quoted been duly renewed up to date and the items quoted shall be clearly highlighted in the license. Original documents should be	Page No. 15	e-tenderer should furnish the Manufacturing License valid on the date of tender opening for each items quoted been duly renewed up to date and the items quoted shall be clearly highlighted in the license. Original documents should be produced for verification when demanded. If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only.	M/s Q-Line Biotech Pvt Ltd	**Clarified as:** Indian Pharmacopoeia is related to drugs and tendered item is not under the category of drugs.

	produced for verification when demanded. If the tendered drug is in Indian Pharmacopoeia (IP), then the manufacturing license has to be submitted in IP only.				
20.			We noticed a discrepancy in the EMD amount mentioned in the GeM tender document and ATC document which is attached with the GeM Bid. As per the GeM tender document, the EMD payable for this tender is mentioned as Rs 7,39,789. However, upon reviewing the additional terms and conditions, specifically Annexure III, we found a different EMD amount stated for 100% quantity is Rs 14,79,576 & Amount of EMD Payable for 50% quantity is Rs. 7,39,789. This conflicting information has caused confusion regarding the appropriate EMD amount for quoting our bid. We are specifically interested in quoting for 100% quantity, and it is crucial for us to have clarity regarding the correct EMD amount to be deposited. Therefore, we kindly request your assistance in clarifying the exact EMD amount required for quoting on the 100% quantity.	M/s SD Biosensor Healthcare Pvt Ltd	**Clarified as:** Kindly submit the EMD as per Annexure-III of the tender document.
21.			Extension of tender due dates by 2 weeks.	M/s Vimek Bioconcept Pvt Ltd	No changes.
22.			We are a "Micro" company under MSME & therefore we request you to waive the criteria of manufacturing & marketing experience of 2 years. And also to waive the need of Market Standing Certificate.		
23.			We are a "Micro" company under MSME & therefore we request you to waive the performance criteria of having supplied 40% of quoted quantity & also to waive the requirement of PO copies.		
24.			Kindly permit us to provide Accelerated Data of 6 months in lieu of Long-Term Stability Data.		
25.			We are a Startup company & we can submit the production data for one Year only from the date of issue of License of Malaria Kit.		

Note: - Above changes will be part of the tender document.

-sd/-
GM (Procurement)

TABLE-B

Pursuant to the Pre-bid meeting discussion, following amendment in the subject tender enquiry is hereby authorized: -

Sr. No.	Tender Clause No. & Page No.	As per Tender	After Amendment
1.	8 & Pg No. 19		The technical evaluation of this tender consists of two stages: - 1. In the first stage, Evaluation of technical bids submitted by the bidder on GeM portal shall be done by the Committee. 2. In the second stage, the samples of the bidder (submitted by the bidder physically to CMSS office as per tender clause no. 6.2 (aa) of Pg No. 18) who have qualified in the first stage of evaluation shall be opened and evaluation of the samples shall be done. For the disqualified bidder in the first stage of technical evaluation, the samples of the bidder shall not be opened and not be evaluated and marked as "Technically Disqualified" Bidder. The samples submitted by the bidder should be: i. Strictly as per technical specification. ii. unlabelled, leaked poor quality samples shall be rejected. The bidder whose samples are rejected by the Committee, shall stand technically disqualified in the tender.

TABLE-C

REVISED CRITICAL DATE SHEET ARE AS UNDER:

Description	Scheduled date
Bid Submission End Date and Time	18.08.2023 till 03:00 PM
Last date of submission of original documents	18.08.2023 till 03:00 PM
Bid Opening Date and Time	18.08.2023 at 03:30 PM

Note: - Apart from above, all other terms & conditions of tender document will remain unchanged.

-sd/-
GM (Procurement)