Date: - 31.07.2024

CENTRAL MEDICAL SERVICES SOCIETY
Ministry of Health & Family Welfare
(Autonomous Body under MoHFW, Govt. of India)
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Minutes of Pre-bid Meeting for Procurement of 0.5 ml AD Syringes & 5 ml Sterile Hypodermic Syringe (RUP Syringe) for UIP through TENDER No: CMSS/PROC/2024-26/UIP/004, Pre-bid Meeting held on 27th May 2024 at 11:00 AM

Table -A

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

SR. NO.	BIDDER	PG NO. & CLAUSE	QUERY/ CLARIFICATION ASKED	CLARIFICATION/AMENDMENT
1	Bidder-1	**Clause No. 9** EMD shall remain valid for 45 days beyond the validity period for the bid and will be extended accordingly beyond any extension subsequently requested by purchaser.	As per Clause 9.1 b for EMD should be 150+45 days from the tender opening date, which is not fixed as tender may be extended for N number of times for various reasons. To avoid any confusion or misunderstandings, we recommend that CMSS clearly define the Earnest Money Deposit (EMD) validity as follows: The EMD is valid from the date the tender is floated. The EMD has a specific validity period in days, set by CMSS. CMSS has the option to extend the EMD's validity by a few additional days if necessary. By establishing these clear guidelines, CMSS can prevent issues related to the EMD's validity and potential extensions.	Please note that CMSS always provide 7 days time after uploading pre-bid MOM or any other amendments. The EMD is as per DOE guidelines 195 days from TOD. Hence, NO Change
		Clause No. 4 (h) & 6 (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	Page 11 para 4 h) reads as under: "The tenderer must have supplied at least 40% of the "Tentative quantity likely to be procured during the Rate Contract period" as stipulated in Schedule of Requirement (SOR) of the same or similar item during the last three financial years. In support of above, the tenderer shall submit details of past purchase orders executed by them in the proforma annexed at Annexure- Section VIII Form 4.1. The details shall be duly certified by the practicing Chartered	The Supplies made during the FY 2021-22 & 2022-23, submitted along with GST invoice & e-way bill will be considered.

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		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 items means For Sch I : Any AD Syringes For Sch II: Any AD/RUP Syringes 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.	Accountant. The certifying Chartered Accountant must indicate the details along with its UDIN. The copies of purchase orders and e-way bills (maximum 05 for each Purchase Order – the ones pertaining to for large consignments) shall be submitted, as documentary evidence in support of Performance Statement". In this regard, our submission is that if a supplier is having an LTA / Orders from the previous financial year 2020-2021 issued in November 2020 & December 2020 and the supply was made in the next financial years respectively and last supply schedule was completed in November 2023, the same LTA / Orders should be considered as the supply schedule was for the next 2 financial years as supplies were made in 2021-22 & 2022-2023.	
		Clause No. 4 (h) & 6 (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 items means For Sch I : Any AD Syringes	Regarding requirement for performance you have asked for Purchase order copy, GST Invoices and Eway bill against proof of execution of order for every submitted purchase order. Our submission in this regard is that we are facing significant challenges with the space provided by the GEM for uploading tender documents. The current limitations make it extremely difficult for us to upload all necessary documents in a timely and efficient manner. This is particularly problematic when it comes to providing copies of Purchase Orders, GST Invoices and Eway Bills , which are critical components of the tender process. These documents, which include vital details such as quantity and value, are typically certified by a chartered accountant or statutory auditor to ensure their accuracy and	CMSS has no role in the limit set out by GeM, however, As per provisions of GeM, the limit of uploading document in tender is about 10MB which should be sufficient.

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		For Sch II: Any AD/RUP Syringes 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.	compliance with relevant regulations. Given the constraints of the GEM's upload space, we respectfully request that you consider accepting these certified copies of Purchase Orders and Statements of Sales along with the quantity and value as part of our initial tender submission. We want to assure you that we are fully committed to transparency and compliance throughout this process. While we may not be able to upload every required document initially due to the space limitations, we are completely willing and able to produce any additional required documents as soon as they are requested. Our goal is to provide all necessary information in a manner that is as smooth and convenient as possible for the evaluation committee.	
		GeM	As you already know the Tender is floated through the GEM portal and the gem charges is applicable on us from the date of LOA /LTA on entire contract value including GST. As an MSME unit, we face unique challenges when participating in the bidding process on the Government e-Marketplace (GeM) platform. We have to bid a very competitive price in order to secure contracts, which can be financially risky for our business. Then, we have to provide a Performance Bank Guarantee (PBG) within the stipulated time frame, which requires additional financial resources and documentation. At the same time, we have to pay the GeM administration charge, which is 0.5% of the total order value. This fee can add up quickly and is very difficult for MSME units like ours to absorb.	NO CHANGE, you may contact GeM for their provisions.
2	**Bidder-2**	**Clause No. 4 (b)** The invitation to bid is opened to domestic manufacturers only.	We request your office to allow the Authorised representatives to participate in the bid as per the guidelines of Central vigilance commission followed by Department of Expenditure , Ministry of Finance.[Pl find enclosed Page of	**For Manufacturer:** Tenderer should furnish the Manufacturing License from the State Drug Licensing Authority as syringes fall under Class B category of

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			CVC,Page No 96,64 [CVC(CTE)No 12-02-06 dated 13.01.12.& Page No 206 In the bid document you had given Authorised Representative format . In the previous tenders CMSS has allowed Authorised representatives to participate .	Medical Devices valid on 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. **For Non Manufacturer Bidder:** The bidder should be duly authorized (as per authorization Form Annexure XXII) by the manufacturer of the goods. Information as asked for manufacturer shall be submitted with the bid.
		Clause No 4(g) Tenderer should quote at least for 50% of the tender quantity of each items quoted and the tenderer shall have an annual production capacity not less than one and half times the quantity quoted for each schedule.	As per CMSS requirement ,the production capacity for 100% Quantity should be Monthly Production Capacity : 5,05,21,875 Pcs Per Day Production Capacity : 20,20,875 Pcs ,And for 50% quantity Monthly Production Capacity : 2,52,60,938 Pcs Per Day Production Capacity : 10,10,438 Pcs	NO CHANGE Please see clause 4 (g). The quoted quantity should be as per clause 4(g) Tenderer should quote at least for 50% of the tender quantity of each items quoted and the tenderer shall have an annual production capacity not less than one and half times the quantity quoted for each schedule.
		Clause No 4(h) Capacity certificate issued by Licensing authority should be submitted	We would like to inform you that certificate issued by Licensing authority should be verified by Independent Third party. The production capacity is assessed by Production Engineers / Chartered Engineers after taking several factors in consideration like No of machines, No of Moulds etc . The capacity of the every bidder should be verified by the independent third party like QCI/	No Change as per clause 4(h) of tender document.

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			RITES etc etc. **We request that financial bids should be opened only after CMSS gets the Actual Production capacity of 0.5ml A.D Syringes verified by the Independent Third party.**	
		Submission of Purchase order copies	We are supplying these products to CMSS ,in 21-22 we have submitted 765 invoices along with E way bills to CMSS for one year it would be 1500 papers to be uploaded on the portal & the portal may not allow due to space constraints . We request you to accept the Undertaking of the summaries of the bills raised to CMSS for the quoted product & you may verify from your portal / Logistic /Finance Division of CMSS.	CMSS has no role in the limit set out by GeM, however, As per provisions of GeM, the limit of uploading document in tender is about 10MB which should be sufficient.
		Order Distribution criteria	Kindly clarify whether it would be 70:30 as per Annexure 1 **OR** 50;50 **OR** 50;30;20 as per clause 13.3 & 13.5 Pl refer to page no 3 of GEM document wherein it is mentioned that maximum no of Bidders amongst order will be split are 02 in the ratio of 70:30 We request you to clarify -which clause will prevail. ?	The criteria is as per Annexure-A (70:30). Also, please refer tender document instruction on pg 3 which states that: "*As per directives of GOI, the custom bid/BOQ bid is published on GEM platform. In case of any contradiction in terms and conditions of GEM bid, the clauses of the tender document (uploaded in Technical Specifications-Buyer Specification Documents) shall prevail.*"
		Annexure I Delivery Schedule & Performance Security.	You have spread Delivery schedule in 10 Slots starting from Oct 24 to Jan 26. Suppose we get 20% share ,& this quantity we will be completing within 03 months , our delivery schedule should be considered 90 days + 3 years warranty +60 days (extension) = 1245 days & accordingly we will submit our performance security which may please be accepted . Hence we request you to accept performance Bank Guarantee keeping in view the delivery schedule period.	The delivery schedule will be strictly as per the requirement of programme division in the lots specified in the tender. The quantity of tranches & percentage of award will be equally distributed among the total tranches. Hence, no change in Performance Security Deposit.

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			Pl make 10 Schedules or how many schedules -you make & performance Security to be asked schedule wise , And the same should be submitted 15 days before the start of Delivery Period . And request you not to spread say 20% quantity in all slots forcing the bidder to accept delivery period of 487 days. Kindly make the delivery terms keeping in view the problems being faced by vendors by submitting Performance Security for such a long period [487 + 365X5 +60 = 79 months / 6 & half years – just think & show any example wherein this Performance Security for such a long time has been asked. In fact by doing this , it is violative of spirits of the Performance security guidelines of DOE / Ministry Of Finance . Hence it is requested to ask Performance Security of 60+3X365+60 days. irrespective of the shelf life.	
		LOA & P.O & **Performance guarantee**	Sir, usually LOA is issued by CMSS wherein Delivery period starts with LOA date. We start manufacturing & invite Quality Wing to come & Inspect .The quality Wing says that Inspection will be carried only when we have P.O . P.O is not issued in time the reasons best known to CMSS. After receiving P.O ,then we again call Quality Wing to come for inspection .After Inspection the goods are sent for testing & after 03 weeks we get dispatch Clerance & after receipt of Despatch Clearance we dispatch the goods to the consignees which is a process of 10 days ,in toto 15 days are required for Inspection, Testing & Despatch & in the mean time Delivery period as per LOA ceases & we come under Penalty zone & in the end we cough up the penalty amount as requests to waive off the L.D are	NO CHANGE, however, if for any reason there is delay in release of purchase order, minimum 30 days will be provided for inspection & delivery from the date of release of purchase order. NO CHANGE, Please submit Performance Bank Guarantee as per clause no. 12 of tender document.

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			not entertained in CMSS. We file & then wait -nothing happens, the vendor gets frustrated & stops follow up the L.D issue. **Hence it is requested to issue the P.O & Delivery period should start from the date of issue of P.O** Sir, we may or may not get, in case we get that would be part quantity & as per our capacity we will execute the complete order within 90 days .Delivery Period of the quantity that we get would be 90 days & not 487 days & The performance bank Guarantee shall be valid from the date of commencement of our P.O & we will submit Performance Security 15 days before the P.O date . We request CMSS not to force upon the Bidder to submit the bank guarantee in the beginning & when delivery period to supply that slots starts after six months/ seven months/eight months/ nine months For Sch 1 Last date of delivery would be 90 days Or the pro rata quantity that CMSS places @ 351.5 lacs per month [as mentioned in Delivery schedule in Bid document] + 365X3 [shelf life] +60 days [B.G Extension] For sch II Last date of delivery would be 90 days Or the pro rata quantity that CMSS places @ 50 lacs per month [as mentioned in Delivery schedule in Bid document] + 365X3 [shelf life] +60 days [B.G Extension]	
		Clause No. 12.2 **Performance Security** **If the bidder offers more than shelf life against the requirement of 3 years, the PBG would also be required for the offered shelf life.**	As per the DOE guidelines, Performance Security is meant to safeguard the interests of the purchaser that the vendor executes the contract in all aspects . Now you had put warranty for 03 years & you had mentioned that the vendor who supplies the product for shelf life of 05 years , he should	NO CHANGE, Please submit the Performance Bank Guarantee as per clause no.12 of tender document.

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			submit PBG of 05 years . Instead of appreciating better products , you are penalizing the better product .The enhanced bank guarantee period requires additional fund which affects the bidder financially. **Hence we request that every bidder should be brought to on the equitable platform ,either 03 years or 05 years**. [page no 109]	
		Purchase preference	We request your office to give Purchase preference of 10% in case CMSS is asking Performance security of 05 years from the company who is supplying better stable products by giving shelf life of 05 years in comparison to the companies who are giving shelf life of 03 years	NO CHANGE
		Letter from MOH & FW	Sir, we are facing problems in getting our Performance securities released .We have executed order in 2020 & after this order we have executed 05 orders & are requesting CMSS to release our expired bank Guarantees . CMSS is pressing us to bring letter from Programme division stating that the syringes supplied in 2020 , its stocks have been consumed , then only CMSS will release our performance securities. We therefore request Programme Division to find out the solution so that performance securities are released .	This query does not pertain to the current tender. However, CMSS is committed to release the PBG once all contractual obligation are fulfilled.
		Pl refer to para (a) & (f) on page No 34	Sir, It takes long time to issue the Amendment & sometimes one & half month & if the goods are not delivered during this period ,L.D will keep on increasing . In fact what happens in the critical delivery period of 60 days ,some times test report comes on edge & you can only dispatch after receipt of dispatch Clerance & then only you may start dispatch, receiving dispatch Clearances on Friday evening or on Saturday , the cycle of dispatch	NO CHANGE

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			gets disturbed .Hence it is requested to allow for 10 days to dispatch after receipt of the test report so that goods reach to the consignee & programme will not suffer due to Amendments coming late.	
		Clause No. 12.1 (a) Liquidity damage/ Interest payment Delivery of the goods and performance of services shall be made by the supplier in accordance with the time schedule specified by the purchaser in its LOA/purchase order. In case the supply is not completed in the stipulated delivery period, as indicated in the LOA/purchase order or in case of non-submission of Security Deposit within the stipulated time, purchaser reserves the right either to short-close/cancel this LOA/purchase order and/or recover liquidated damage charges. The cancellation/short-closing of the LOA/Purchase order shall be at the risk and responsibility of the supplier and purchaser reserves the right to purchase balance-unsupplied quantity at the risk and cost of the defaulting vendor. This purchase at the risk and cost of the defaulting vendor can be at the same L1 cost of the tender or at higher cost and can be met through other vendors available in the present tender/contract or through any vendor from the open market. Any additional cost towards this risk purchase will be entirely borne/adjusted from running bills/demanded from the defaulting vendor.	Insertion of interest Clause : Pl refer to clause 9.5.3 [Page no 151enclosed] of Manual for Procurement of Goods [updated June 22] issued by Department of Expenditure , Ministry of Finance, Govt of India, pl put provision for payment of Interest in case of delayed payments of bills of Supplier ,rate of Interest should be rate of interest of GPF.	The amended LD Clause is as follows: *"If the contractor fails to deliver any or all of the Goods or fails to perform the incidental Works/ Services within the time frame(s) incorporated in the contract, the Procuring Entity shall, without prejudice to other rights and remedies available to the Procuring Entity under the contract, deduct from the contract price, as agreed liquidated damages, but not as a penalty, a sum equivalent to the ½ % (half percent) of the delivered price (including elements of GST & freight) of the delayed Goods and/ or incidental Works/ Services for each week of delay to be applied proportionately on per day basis for first four weeks of delay. For subsequent delays, a sum equivalent to 2.5% (two and half percent), instead of 0.5%, for each week of delay to be applied proportionately on per day basis of delivered price shall be deducted as liquidated damages. The maximum deduction on account of LD shall not exceed 10% of the delayed goods or incidental works/service contract price(s)."*
		Clause No. 14.7 All the Tenderers are required to supply the product(s) with	Pl delete NACO SUPPLIES NOT FOR SALE	DELETED

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		printed text "NACO SUPPLIES – NOT FOR SALE" in red-colour on the strips, blisters, vials, ampoules & bottles and also on the external packings. The type/thickness of packing materials used in Blister packs may also be specified. Goods received without this print will not be accepted by CMSS/Consignee. Affixing of rubber stamp shall not be accepted. However, the approved art work will prevail.		
		Annexure XXI	Pl delete zero point 1ml AD Syringe which seems to be clerical error.	Amended as " zero point 5ml AD Syringe"
		Short closure of contract	Sir, GEM takes its charges in the beginning itself & due to any reason ,the purchaser short closes the contract , in that case CMSS should pay us the amount for the quantity got short closed.	The bidder are advised to appropriately follow up with GeM.
3	**Bidder-3**	Clause No. 6(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 should be submitted.	Please note that we expanded our manufacturing unit and started manufacturing 0.5 ml Auto Disable Syringes with fixed needle owing to the requirement of Government of India during COVID vaccination drive. We further wish to submit that we have supplied more than 7 Crore 0.5 ml AD Syringes to UIP during FY 2021-22, 2022-23 & 2023-24 and have received no complaints or adverse reports regarding the quality of our syringes. Bearing in mind that we expanded our manufacturing unit to assist the Government and that our products meet the required standard, we request you to relax the long term stability data clause and accept accelerated stability data along with ongoing stability data for 03 batches & COAs. It is therefore that the clause may please be amended as follows: ***"Accelerated Stability Data along with available Long Term (Real Time) Stability Data of the quoted product in specified packaging for***	NO CHANGE, please provide the data as per tender terms & conditions.

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			atleast for 3 batches, to support shelf life and certificate of Analysis of one batch of the quoted product should be submitted."	
		Clause No. 4(g) Tenderer should quote at least for 50% of the tender quantity of each items quoted and the tenderer shall have an annual production capacity not less than one and half times the quantity quoted for each schedule	As per tender terms, the order quantity that can be awarded to a successful bidder can be as low as 20% of the total tender quantity. Further as per tender terms, a bidder should quote atleast 50% of the total tendered quantity. Please note that the tendered quantities are extremely huge and it is therefore requested that minimum quoting quantity may please be reduced to 25% of the total tender quantity to enable more companies to participate in the tender enquiry. It is therefore that the clause may please be amended as follows: "*Tenderer should quote at least for 25% of the tender quantity of each items quoted and the tenderer shall have an annual production capacity not less than one and half times the quantity quoted for each schedule"*	NO CHANGE
4	**Bidder-4**	**Clause No. 4 (b)** The invitation to bid is opened to domestic manufacturers only.	This is to inform that we will be supplying the above goods through our authorized distributor and will be submitting manufacture's Authorization (Annexure-XXII). We will be submitting all the relevant data, as desired by the Tendering Authority. We request you to kindly do a 3rd party audit for the purchase, sales data & the installed production capacity for the items provided by our manufacturers against the above mentioned tender. This must be done before opening of the financial bid. As this will help the Tendering Authority to award the tender to the Bonafide manufacturer, who really has a capacity to supply the items, mentioned in the tender, so that Govt. of India's immunization programme is not hampered. Sir, we are Bonafide manufacturers of A.D. Syringes for the last 02 decades & supplying to MOH&FW,	**For Manufacturer:** Tenderer shall be a manufacturer of the quoted product and having valid own manufacturing license from the state Drug Licensing Authority as syringes fall under Class B category of Medical Devices in the indicate pharmacopeia (in technical specification at Annexure IA) The manufacturing license should be valid on the date of tender opening packet 1. In case of failure to submit the same, the bid shall not be considered any further. **For Non Manufacturer Bidder:** The bidder should be duly authorized (as per authorization Form Annexure XXII) by the manufacturer of

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			We have enhanced our production capacities to cater to the needs of MOH&FW and international agencies e.g. UNICEF etc. in our other plants. We request CMSS to accept the goods manufactured in our other plants also, where we have increased the production capacity and we have Drug license for the same. We will be providing market standing certificate for our main plant, where we are manufacturing the said items from last 2 decades.	the goods. Information as asked for manufacturer shall be submitted with the bid.
5	**Bidder-5**	Performance Bank Guarantee Clause	The tender quantity is substantial, indicating a significant contract value, yet the delivery timeline is spread over an extensive period of approximately eighteen months. Requiring bidders to furnish a 3% performance security, in the form of a bank guarantee upon receipt of the Letter of Award (LOA), entails immobilizing considerable funds in the bank as security deposit well before production commences, for a long period. To ensure smoother cash flow and mitigate financial strain on the bidders, we propose a reduction in the security deposit against the LOA from 3% to 1%.	NO CHANGE
		Clause No. 13.5 CMSS will counter offer the lowest rate (L1 rate) to other Tenderers in the order of their ranking i.e. L2, L3 and so on will be asked to match the L1 price.	As per the schedule, the requirement stands at 53 Crores for 0.5ml AD syringes, with Clause 13.5 (i) outlining the methodology for placing orders, specifying allocation to a minimum of two suppliers – 70% to the L1 supplier and the remaining 30% to the subsequent lowest tenderer. However, reflecting on past experiences, it was noted that the preferred methodology for placing orders was in a ratio of 50:30:20, involving a minimum of three suppliers. Given the significance of this tender within the prestigious immunization program of the Ministry of Health and Family Welfare, Government of India, and in alignment with the national imperative of promoting 'Make in India' and 'Atmanirbhar Bharat', we strongly advocate for retaining the	NO CHANGE

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			50:30:20 methodology for placing orders. This approach not only fosters a competitive landscape but also ensures a smooth and timely supply of 0.5ml AD syringes for the immunization program, thereby averting the challenges currently encountered with non-supply or delayed supply, similar to those faced with the 0.1ml AD syringe contract, where only two suppliers were engaged. We, therefore, urge CMSS to consider engaging a minimum of three suppliers for the forthcoming National Program, adhering to the 50:30:20 distribution ratio."	
		Clause No. 4 (h) 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.	In Clause 4 (h) of the Eligibility Criteria, there's a provision regarding past performance, wherein during the pre-bid meeting, a request was made to consider any syringe (Disposable or AD) under a similar product category for evaluating past performance. This request stems from the fact that the manufacturing process for both normal disposable syringes and AD syringes remains largely identical, with the primary distinction lying in the mold and design aspects. In essence, the molding, printing, assembly, and packing processes for both types of syringes are typically carried out using the same machinery. Furthermore, it's important to note that currently in India, AD syringes are not widely available in the open market or procured through tenders by State Governments. The sole significant demand for AD syringes is from the Ministry of Health and Family Welfare, Government of India, for their immunization programs. Consequently, establishing a track record of performance specifically for AD syringes poses a considerable challenge for many Small and Medium-sized Enterprises (SMEs). If this condition remains unchanged, it could disproportionately favor one or two large manufacturers, thereby	NO CHANGE

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			depriving SMEs, despite possessing ISO and CE approved infrastructure and production capacity, of a level playing field in bidding processes. Therefore, we earnestly request that the performance evaluation criterion for AD syringes under a similar item be broadened to encompass all types of syringes (normal as well as AD), ensuring fair opportunities for participation from all stakeholders."	
		GeM	We have a proven track record of supplying 2ml AD and 3ml AD syringes to CMSS in the past, successfully delivering over 3 Crore syringes for their vaccination programs. Notably, our supply encompassed both AD syringes and normal disposable syringes to the Government of India (GOI), with no complaints registered regarding the quality or packaging of the syringes provided through CMSS. We are confident in our ability to execute the supply of 0.5ml and 5ml AD syringes in accordance with the terms of the Letter of Award (LOA) Currently registered under the Q3 category on the Government e-Marketplace (GeM) portal, we have applied for registration under the Q2 category in alignment with the tender requirements. However, as the ongoing bid on the GeM portal is designated under the Q2 category, and registration as an Original Equipment Manufacturer (OEM) panel on GeM is a time-consuming process, we kindly request that the bid/tender be categorized under the Q3 category. By accommodating this adjustment, all newly registered vendors as well as manufacturers would have the opportunity to participate, fostering healthier competitiveness in the bidding process. We believe that these minor changes/amendments will not only incentivize greater participation in the bid but also ensure that CMSS receives the most	NO CHANGE

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			competitive prices We respectfully urge you to consider our request, recognizing the potential benefits it holds for all stakeholders involved.	
6	Bidder-6	Annexure-1A; Technical Specifications of Sterile Hypodermic Syringes-RUP: General Characteristics Sterile & Single-use; Including a mechanism to prevent reuse. The syringe and needle shall be passively and automatically rendered unusable by the delivery of the intended fixed dose. And/or The auto- disable featureis automatically activated and remains effective from the time that the injection is commenced. And/or The auto - disable feature is automatically activated on completion of the injection	The ISO 7886:4 standard governing RUP Syringes stipulates the following specifications as General: "Re-use Prevention Feature: feature that either automatically activates upon or during administration of the intended dose or is activated by the user to prevent subsequent re-use of the syringe. The reuse prevention feature may be categorized as follows: Type 1: Operates automatically during or upon completion of intended single use. Type 2: Required elective activation upon completion of intended single use. The intended use / application shall be categorized as follows: Type A: Single Aspiration & Injection Type B: Multiple Plunger Aspirations prior to the final intended single use." It is also worth mentioning that at Point 2 of the technical specifications, the syringe so desired is Type 1B i.e. the desired should have the following specification: The reuse prevention feature may be categorized as follows: Type 1: Operates automatically during or upon completion of intended single use. The intended use / application shall be categorized as follows: Type B: Multiple Plunger Aspirations prior to the final intended single use. It is therefore requested that the general definition of the Syringe may be amended as per the laid down standard for RUP Syringes (refer to Point 4 of the enclosed standard).	NO CHANGE (As per technical specification)
		Annexure-1A; Technical Specifications of Sterile Hypodermic Syringes-RUP:	It is submitted that RUP Syringes are not manufactured with permanently fixed needles. It is also submitted that our RUP Syringe with safety feature have an integrated needle that	Both fixed/integrated needle may be accepted only for 5ml RUP Syringes

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		Type & Application Non pre-filled, Type 1B To reconstitute lyophilized vaccines with the diluent Syringes with permanently fixed needles.	cannot be removed with minimum force as detailed in ISO 7864 & is thus manufactured in accordance with the standard (refer to Point 11.1 of the enclosed standard). It is therefore requested that the said clause may be amended to needle with luer-lock feature (which is comparable to fixed needle) as per the laid down standard.	
		Annexure-1A; Technical Specifications of Sterile Hypodermic Syringes-RUP: Syringe size with pre-set volume and marking 5 ml for reconstitution of lyophilized vaccine with diluents (+20% to allow for removal of air)	The said clause has now been removed from ISO 7886. It is clarified that the standard stipulated the following specification for removal of air: With reference to ISO 7886-4:2018(E) (Second Edition) - barrel dimension - the additional 20 % capacity should be removed. The same may be amended as below and as per ISO 7886-4 (refer to Point 9.1 of the enclosed standard): "Point No. 9.1, Dimensions: The length of the barrel and the design of the re-use prevention feature shall be such that the syringe has a recommended maximum capacity that is determined by risk assessment with consideration of, for example, removal of air bubbles or risk of overdose"	As per ISO 7886-3 or as defined in ISO 7886-4
		Annexure-1A; Technical Specifications of Sterile Hypodermic Syringes-RUP: Needle Fixation Fixed capped needle. The union of the hub and needle tube shall not be broken by the minimum force given in Table 2 of ISO 7864: 1993/2016 or updated applied as push or pull in the direction of the needle axis. If accidental needle – stick protection devices are included in the design of the syringe or needle, the y should not compromise the ease of use or the performance of the syringe.	It is submitted that RUP Syringes are not manufactured with permanently fixed needles. It is also submitted that our RUP Syringe with safety feature have an integrated needle that cannot be removed with minimum force as detailed in ISO 7864 & is thus manufactured in accordance with the standard (refer to Point 11.1 of the enclosed standard). It is therefore requested that the said clause may be amended to needle with luer-lock feature (which is comparable to fixed needle) as per the laid down standard.	Both fixed/integrated needle may be accepted only for 5ml RUP Syringes
		Annexure-1A; Technical Specifications of Sterile Hypodermic Syringes-RUP: Leakage Freedom from air and liquid leakage as per ISO 7886-3/4:2005/2020 or updated	Since, the tender is for RUP Syringes, it is requested that only ISO 7886-4:2018-11 (Second Edition) may be considered for this syringes. It is also specified in the standard that this standard is not applicable to auto-disable syringes for fixed dose immunisation (refer to Point 1 of the enclosed standard). It is therefore requested that this clause	No Change suggested. The technical specifications refers to any update of ISO 7886-3/4.

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			may be amended as follows: "Freedom from air and liquid leakage as per ISO 7886-4:2018-11 (Second Edition)."	
		Annexure-1A; Technical Specifications of Sterile Hypodermic Syringes-RUP: Essential Requirement The technical specification of 5ml RUP Syringes should conform to ISO 7886 PART 3 and 4:1993/ 2018 or updated. Validation of sterilization process shall be carried out by ISO 11135- 2014/Amd. 1:2018 (E) or 11607-1:2019. The bidders should submit a copy of their ISO 13485:2016 certificate issued by the certifying body. The certificate should be valid on the date of tender opening. A certificate from the manufacturer certifying that the product meets the ISO 7886 - PART 3 and 4 product standard to be submitted along with the bid documents.	Please refer to our above submission. In view of the same it is requested that the said clause may be amended as follows: "The technical specification of 5 ml RUP Syringes should conform to ISO 7886 PART 4:2018 or updated. Validation of sterilization process shall be carried out by ISO 11135- 2014/Amd.1:2018 (E) or 11607-1:2019. The bidders should submit a copy of their ISO 13485:2016 certificate issued by the certifying body. The certificate should be valid on the date of tender opening. A certificate from the manufacturer certifying that the product meets the ISO 7886 - Part 4 product standard to be submitted along with the bid documents."	Amended as: " Annexure-1A; Technical Specifications of Sterile Hypodermic Syringes – RUP: Essential Requirement. The Technical specification of 5ml RUP Syringes should conform to ISO 7886 Part 3 and/or 4:1993/2018 or updated. Validation of Sterilization process shall be carried out by ISO 11135-2014/Amd. 1:2018 (E) or 11607-1:2019. The bidders should submit a copy of their ISO 13485:2016 certificate issued by the certifying body. The certificate should be valid on the date of tender opening. A certificate from the manufacturer certifying that the product meets the ISO 7886 – Part 3 and/or 4 product standard to be submitted along with the bid documents."
		Clause No. 4 (h) 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:	It is submitted that Disposable Syringes with Needle are similar and comparable to RUP Syringes as their intended use is similar. It is therefore requested that Disposable Syringes may also be considered for fulfillment of performance criteria.	NO CHANGE

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SR. NO.	BIDDER	PG NO. & CLAUSE	QUERY/ CLARIFICATION ASKED	CLARIFICATION/AMENDMENT
		Similar item means Page 6 of 6 For Sch. II: Any AD/RUP Syringes		
		Clause No.6.2 (a): RTGS/NEFT e-receipt or Bank Guarantee (if applicable) in respect of EMD asper Clause 9 of this Tender document or in case of MSE, a copy of their valid registration certificate in support of their being an MSE and a notarized undertaking given in Annexure VIII and, Clause at Page 3 of Tender Document: As per directives of GOI, the custom bid/BOQ bid is published on GEM platform. In casc of any contradiction in terms and conditions of GEM bid,the clauses of the tender document (uploaded in Technical Specifications- Buyer Specification Documents) shall prevail: It is submitted that as per GEM Terms & Conditions, we are exempted from payment of EMD as we are a Vendor Assessed Seller. The following clause is also mentioned in the GEM bid document: "The additional terms and conditions have been incorporated by the Buyer after approval of the Competent Authority in Buyer Organization, whereby Buyer organization is solely responsible for the impact of these clauses on the bidding process, its outcome, and consequences thereof including any eccentricity / restriction arising in the bidding process due to these ATCs and due to modification of technical specifications and / or terms and conditions governing the bid. If any clause(s) is / are incorporated by the Buyer regarding following, the bid and resultant contracts shall be treated as null and void and such bids may be cancelled by GeM at any stage of bidding process without any notice: 2. Seeking EMD submission from bidder(s), including via Additional Terms & Conditions,	In view thereof, it is requested that EMD Exemption as per GEM Terms & Conditions may be extended.	NO CHANGE

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SR. NO.	BIDDER	PG NO. & CLAUSE	QUERY/ CLARIFICATION ASKED	CLARIFICATION/AMENDMENT
		incontravention to exemption provided to such sellers under GeM GTC."		
7	Bidder-7	**Clause No. 6 (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.	Tenderer should have supplied 40% of the quoted quantity of same or similar items in **any two/three financial years out of the last five 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. **Furthermore, Experience-Turnover Criteria for Startup India Manufacturers shall be included in terms and conditions of the NIT.** **Copy of Letter No-F.26/4/2016 PPD dated:20 Sept 2016 attached as per the issued order.**	The Supplies made during the FY 2021-22 & 2022-23, submitted along with GST invoice & e-way bill will be considered.
		Clause No. 6 (e) Similar Items here relate to the following: -Similar items means For Sch I : Any AD Syringes For Sch II: Any AD/RUP Syringes	Similar Items here relate to the following: -Similar items means **For Sch I : All types of Syringes** **For Sch II: All types of syringes**	NO CHANGE
		Clause No. 6 (f) 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. 2021-22 &2022-23 OR 2022-23 & 2023-24 for compliance of tender clause no. 4 (d). Note- For Authorized Agencies (non-manufacturers), the bidders can utilise the financial and past supply credentials of the principal.	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. 2021-22 &2022-23 OR **2022-23 & 2023-24/ 2024-25** for compliance of tender clause no. 4 (d). Note- For Authorized Agencies (non-manufacturers), the bidders can utilise the financial and past supply credentials of the principal.	NO CHANGE

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SR. NO.	BIDDER	PG NO. & CLAUSE	QUERY/ CLARIFICATION ASKED	CLARIFICATION/AMENDMENT
		Clause No. 6 (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 non-manufacturer bidders)has not been convicted and the products quoted have not been cancelled during last two years i.e. 2021-22 and 2022-23 OR 2022-23 and 2023-24.	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. 2021-22 and 2022-23 OR **2022-23 and 2023-24/ 2024-25**.	NO CHANGE
		Annexure 1 A :Technical Specification, Point 2 Non-prefilled. To reconstitute lyophilized vaccines with the diluent Syringes with permanently fixed needles	Non-prefilled. To reconstitute lyophilized vaccines with the diluent Syringes with permanently **fixed needles/ luer lock with detachable needles**	Both fixed/integrated needle may be accepted only for 5ml RUP Syringes
		Annexure 1 A :Technical Specification, Point 6 Diameter: 20 G to 22 G Length: 25 mm to 40 mm	Diameter: **20 G to 25 G** Length: 25 mm to 40 mm	No Change (As per technical Specification)
		Annexure 1 A :Technical Specification, 0.5 ml AD Syringe Syringes with permanently fixed needles	Syringes with permanently **fixed needles/ luer lock with detachable needles**	No Change (As per technical Specification)
		EMD	MSME traders/ MSME non manufacturer bidder shall be given benefits while giving the EMD	NO CHANGE
8	Bidder-8	**Clause No. 4 (g)** Tenderer should quote at least for 50% of the tender quantity of each items quoted and the tenderer shall have an annual production capacity not less than one and half times the quantity quoted for each schedule.	In view of clause 10.3 of the tender, where quantity of 25% order of the total tendered quantity is reserved for MSE bidders, you are requested to kindly reduce the minimum quoted qty to 25% since the tendered quantity is huge and MSE bidder shall be restricted from participating in the said tender.	NO CHANGE
		Clause No. 4 (h) Tenderer should have supplied 40% of the quoted quantity of	This condition seems to be restrictive where in it is mentioned that:	NO CHANGE

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SR. NO.	BIDDER	PG NO. & CLAUSE	QUERY/ CLARIFICATION ASKED	CLARIFICATION/AMENDMENT
		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.	For Sch I: Any AD Syringe For Sch II: Any AD/RUP Syringe. To give level playing field to all MSE manufacturers also, it should be changed to "ANY SERVICE" with 10-15% performance for any AD Syringe and rest for sterile Hypodermic Disposable syringes, otherwise only bid player will be able to participate in this tender considering huge tender quantities. However, in view of Circular No. 1 (2) (1)/ 2016-MA(attached herewith) of Ministry of Micro, Small & Medium Enterprise, you may please relax the prior experience criteria for MSE bidder to provide level playing field.	
		Annexure-I 0.5 ml AD Syringe/ 5 ml Sterile Hypodermic Syringe (RUP Syringe)	We request you to kindly note that AD Syringe (Auto-Disable syringe) is the same as RUP syringe (reuse preventation syringe) and reuse preventation feauture is a feature already present in all Auto-Disable syringes. Reuse Preventation(RUP) syringes are commonly known as Auto-Disable (AD)Syringes Manufacturing Licenses are generally In the name of Auto-Disable Syringes. Therefore, kindly amend and mention only Auto Disable (AD) Syringes. We are herewith submitting the Pre-brd Query Resolution for T-7/547/MPPHSCL/Surgical Consumable and Kits of Madhya Pradesh Public Health and Service Corporation Tender No T-547/MPPHSCL/Surgical Consumable and Kits/RC/2024. Kindly refer to the Row Number 16 of this document where MPPHSCL has I accepted that Auto-Disable Syringe (AD Syringe) and Reuse Prevention (RUP Syringe) are the same.	No Change (As per technical Specification)

GM (Procurement)

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