Date: - 09.10.2024

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

AMENDMENT NO. 1

Tender No: CMSS/PROC/2024-26/UIP/024 for Developmental tender Procurement of 0.5 ml AD Syringes & 5 ml Sterile Hypodermic Syringe (RUP Syringe) for UIP

1. The following amendment in the subject bid document is made:

SR. NO.	CLAUSE No.	EXISTING CLAUSE	AMENDMENT
1	**Section V** **List of Quoted Items and Technical Specification**	However, upon reviewing the bid specifications, we noticed that the requirement for the syringe's needle characteristic includes a "fixed cap needle." We seek clarification on whether the term "fixed cap needle" implies that the needle should be permanently attached to the syringe, or if a detachable needle design is permissible under the given specifications. We would like to bring to your kind attention that several manufacturers currently offer 0.5 ml and 5 ml Auto-Disable Syringes with detachable needles, which comply with safety and performance standards while maintaining the intended functionality. In light of this, we respectfully request your intervention to provide clarification on this specification, allowing us to align our product offering accordingly. This clarification is crucial to ensuring that we, along with other manufacturers, can participate in the bidding process without ambiguity. Your prompt response and guidance on this matter would be highly appreciated, as it will enable us to move forward with the bid submission. We look forward to your favourable response.	Both fixed/integrated needle may be accepted only for 5 ml RUP Syringes.
	The invitation to bid is opened to domestic manufacturers only.	The invitation to bid is opened to domestic manufacturers only. We request your office to allow the Authorized 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 CVC, Page No 96,64 [CVC(CTE)No 12-02-06 dated 13.01.12.& Page No 206 In the previous tenders CMSS has allowed Authorised Representative to quote & supply.	**For Manufacturer:** Tenderer should furnish the Manufacturing License from the State Drug Licensing Authority as syringes fall under Class B category of 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

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			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.
	Annexure-1A; Technical Specifications of Sterile Hypodermic Syringes-RUP	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.	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.
	ITB 9.2.1.3	Additional Clause in Bid Data Sheet	This developmental tender is only for those manufacturers / authorised agents who are not able to meet prescribed eligibility criteria of corresponding regular tender but have credentials / meet requirements for development tender. Hence, bidders who are technically qualified and whose price bids are opened for regular tender schedule, will not eligible for corresponding developmental tender schedules. However, if a bidder is not eligible for a regular tender schedule for a particular manufacturing site (but qualifies for other manufacturing site), it can bid for developmental tender for the manufacturing site for which it is not eligible for regular tender.

2. **The Tender opening date is amended as:**

Sr. No.	Reference	Existing	Modified
1	Bid Submission End Date and Time	11.10.2024 at 3 p.m.	16.10.2024 till 3 PM
2	Last date of submission of original documents	11.10.2024 at 3 p.m.	16.10.2024 till 3 PM
3	Bid Opening Date and Time	11.10.2024 at 3 :30 p.m.	16.10.2024 till 3:30 PM

All other terms and conditions of the bid document shall remain unchanged.

GM (Procurement)

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Minutes of Pre-bid Meeting for Developmental tender 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/024, Pre-bid Meeting held on 19th Sep 2024 at 12:00 noon

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

SR. NO.	BIDDER	PG NO. & CLAUSE	QUERY/ CLARIFICATION ASKED	CLARIFICATION/AMENDMENT
1	M/s Iscon Surgical Limited	**Omitted clause**	Performance Clause Evaluation: We have observed that the performance clause from the previous tender seems to be omitted in this new tender. As this product is intended for infant immunization, the performance criteria play a crucial role in ensuring safety and efficacy. Therefore, we kindly request you to inform us on what basis the technical bid will be evaluated. Will CMSS request samples from participating bidders, or will there be an alternative evaluation process? Your clarification on this matter will greatly assist us in preparing our submission.	This is developmental tender for development of new sources of supply for the tendered items. As such, Performance clause has not been incorporated in the tender documents. Bids shall be evaluated based upon documents stipulated in the bid document.
		List of quoted item	Quantity Clarification: We would like to understand whether the quantity mentioned in this new tender is additional to the quantity mentioned in the previous tender CMSS/PROC/2024-26/UIP/004 (dated 20/05/2024), or if it has been reduced from the aforementioned tender.	As clarified above, this is a developmental tender to develop new sources of supply for tendered item. Bare minimum quantities considered essential for development of new sources have been specified here. Bids for both the schedule i.e. regular as well as developmental order shall be evaluated independently based upon criteria indicated in bid document.
		Price Bid Evaluation:	Since the products listed in both tenders appear to be identical, could you please clarify how the price bids will be evaluated if there is a significant difference in the prices of the respective L1 bidders for both tenders?	As clarified above, this is a developmental tender to develop new sources of supply for tendered item. The L1 for this tender will not be compared with other tenders.

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SR. NO.	BIDDER	PG NO. & CLAUSE	QUERY/ CLARIFICATION ASKED	CLARIFICATION/AMENDMENT
2	**M/s Noble Pharma**	**Section V** **List of Quoted Items and Technical Specification**	However, upon reviewing the bid specifications, we noticed that the requirement for the syringe's needle characteristic includes a "fixed cap needle." We seek clarification on whether the term "fixed cap needle" implies that the needle should be permanently attached to the syringe, or if a detachable needle design is permissible under the given specifications. We would like to bring to your kind attention that several manufacturers currently offer 0.5 ml and 5 ml Auto-Disable Syringes with detachable needles, which comply with safety and performance standards while maintaining the intended functionality. In light of this, we respectfully request your intervention to provide clarification on this specification, allowing us to align our product offering accordingly. This clarification is crucial to ensuring that we, along with other manufacturers, can participate in the bidding process without ambiguity. Your prompt response and guidance on this matter would be highly appreciated, as it will enable us to move forward with the bid submission. We look forward to your favourable response.	Both fixed/integrated needle may be accepted only for 5 ml RUP Syringes.
3	M/s ONE TOUCH Medical Products (P) Limited	Section V List of Quoted Items and Technical Specification	Please elaborate on technical specification of 0.5 ml and 5 ml (for reconstitution of lypophilized vaccines with dilutes +20% to allow for removal of air). Ref- Page no- 58 &65 (Technical specification) Point no- 4 Syringe size with pre set volume and marking.	No Change
4	M/s R R Medical Enterprises (P) Limited	EMD exemption	Is it mandatory to send all hard copies of uploaded documents or only specific documents is to be send.(for MSE with EMD exemption) Ref- Page no 50 , ITB -9.2.1 Sub Para-6	Please refer Section III: BDS at page no. 50.
		MSE Exemption	MSE exempted from EMD has to submit Bid securing declaration. Please elaborate. Ref – Page no- 10, Para 4.2 , point no 1	Please refer Section III: BDS at page no. 50.
		Technical Specification	When AD syringe and REUSE PREVENTION SYRINGE are	No Change

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			functionally same why AD is used for 0.5ml and RUP is used for 5ml (MP Govt. has approved that both are same) irrespective of fixed needle or integrated needle	
		Local Content Declaration	Local Content Declaration from CA (Statutory Auditor) for purchase above 10 crore Whose purchase tenderer or purchaser? Ref- Page no -27, para 9.2.1 point no – 2 c	This refers to the schedules of requirement, if the total value of procurement is more than 10 cr then certificate from statutory auditor is to be submitted, if less than 10 cr then certificate from practicing CA is to be submitted.
		Participation of tender	What if the bidder had participated in last tender 004 for 1 schedule out of 2 schedules (Item) and gets technically qualified . will he be able to participate for the schedule he did not participate in the previous tender? Ref- Page no- 3 NIT, Para-1 sub point - 2)	Refer NIT *"Manufacturer who gets technically qualified and those price bid is opened against CMSS regular tender no. CMSS/PROC/2024-26/UIP/004 dtd. 26.04.2024 will not be eligible to participate in this developmental tender. This developmental tender is only for those manufacturer who are not able meet prescribed eligibility criteria of aforesaid regular tender but have credential/ meet requirements for subject developmental tender."*
		NIT	Regarding Documents and instructions which will supersede GEM or CMSS tender documents.	As per directives of GOI, the tender is floated in GeM portal. However, in case of any contradiction in terms & conditions of GeM bid, the clauses of the tender document of CMSS tender document (uploaded in ATC) shall prevail.
5	**M/s Manchanda Medicos**	Participation in tender	We have our three plants , out of which CMSS does not accept 0.5ml/ 01ml A.D Syringes manufactured at Plant No. 99, Sector- 25, Ballabgarh- Faridabad because we do not have market standing certificate at B-99.Now you have relaxed the condition of Market Standing Certificate & wish to participate in this tender so that we can also develop our said plant for future supplies. Kindly clarify whether we are can participate.	Refer NIT *"Manufacturer who gets technically qualified and those price bid is opened against CMSS regular tender no. CMSS/PROC/2024-26/UIP/004 dtd. 26.04.2024 will not be eligible to participate in this developmental tender. This developmental tender is only for those manufacturers who are not able meet prescribed eligibility criteria of aforesaid regular tender but have credential/ meet requirements for subject developmental tender."* However, if bidder is not eligible for regular tender for a particular manufacturing plant but qualifies for other manufacturing sites, it can bid for development tender for the manufacturing site for which it is not eligible for regular tender.

SR. NO.	BIDDER	PG NO. & CLAUSE	QUERY/ CLARIFICATION ASKED	CLARIFICATION/AMENDMENT
		Participation in tender	If CMSS does not allow us to participate in the said tender, in that situation pl allow to accept the supply of A.D syringes from our plant at Plant No. 99, Sector- 25, Ballabgarh- Faridabad. We request you to accept the A.D syringes manufactured from the plant at Plant No. 99, Sector- 25, Ballabgarh-Faridabad Kindly clarify.	Refer NIT *"Manufacturer who gets technically qualified and those price bid is opened against CMSS regular tender no. CMSS/PROC/2024-26/UIP/004 dtd. 26.04.2024 will not be eligible to participate in this developmental tender. This developmental tender is only for those manufacturer who are not able meet prescribed eligibility criteria of aforesaid regular tender but have credential/ meet requirements for subject developmental tender."*
		Long Term Stability	Long term Stability data should be for complete shelf life i.e for 03 years as asked in the tender. Pl clarify that there will not be any dilution on this. Real time Stability data should be for complete shelf life i.e for 03 years as asked in the tender. Pl clarify that there will not be any dilution on this.	Please refer page no. 28 of tender document and submit your bid accordingly.
		Price Evaluation	There is one tender of the same items which is under evaluation vide No CMSS/PROC/2024-26/UIP/004.Now you have floated another tender of the same items while the previous tender is under evaluation .Now there is chance that one of the bidder may quote very less price because CMSS has deleted the prequalification criteria of Bid No 004 about the performance, its market standing & past performance. Under these circumstances will CMSS ask to match the price of Bid no 004 with the price of Bid No 04 [Development tender] Sir , it seems that someone is trying to sabotage this tender by putting low price ,thereby asking CMSS to match the price of Bid No 04 with the Development tender price [Bid No 024]. We request CMSS to clarify its stand on this issue i.e rates of Bid No 04 & Bid No 024 are separate identities because both the bids are not on same terms & conditions & CMSS should not ask to match the price with the Development	As clarified above, this is a developmental tender to develop new sources of supply for tendered item. The L1 for this tender will not be compared with other tenders.

SR. NO.	BIDDER	PG NO. & CLAUSE	QUERY/ CLARIFICATION ASKED	CLARIFICATION/AMENDMENT
			tender. In fact, this bid should have been floated after Bid No 04 is finalized .	
		The invitation to bid is opened to domestic manufacturers only.	The invitation to bid is opened to domestic manufacturers only. We request your office to allow the Authorized 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 CVC, Page No 96,64 [CVC(CTE)No 12-02-06 dated 13.01.12.& Page No 206 In the previous tenders CMSS has allowed Authorised Representative to quote & supply.	**For Manufacturer:** Tenderer should furnish the Manufacturing License from the State Drug Licensing Authority as syringes fall under Class B category of 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.
6	**M/s Novex Healthcare Pvt Ltd**	Price Justification	We are concerned that in such a case any mischievous element may quote a low rate because he has to give very small quantities and can jeopardise the whole program. Also, kindly confirm whether any price difference is acceptable in both the tenders and if yes up to what extent. (Mention in %). The same should be clearly mentioned before closing of the tender.	As clarified above, this is a developmental tender to develop new sources of supply for tendered item. The L1 for this tender will not be compared with other tenders.
		Eligibility Condition	Could you please confirm if this is correct and if so, what is the rationale behind this decision? Additionally, we would like to know if the department can call for the 2nd tender before the 1st tender is finalized and the price bid is not opened.	As clarified above, this is a developmental tender to develop new sources of supply for tendered item.
		Tender participation	It has been observed that distributors are allowed to participate in the 1st big volume tender, but they are not allowed to participate in the 2nd small tender. We would like to know the reason behind this discrepancy. Is there a specific reason why distributors are not allowed to participate in the smaller tender?	**For Manufacturer:** Tenderer should furnish the Manufacturing License from the State Drug Licensing Authority as syringes fall under Class B category of Medical Devices valid on tender opening for each items quoted been duly renewed up to date and the items quoted shall be

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				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.
		Eligibility Condition	We are worried that this could lead to undue discretionary power to the department, which may result in corrupt practices. Allowing multiple tenders for the same item at the same time could create an unfair advantage for certain bidders, leading to a lack of transparency and accountability in the tendering process. This could undermine the integrity of the process and lead to unfair outcomes.	As clarified above, this is a developmental tender to develop new sources of supply for tendered item.
		Price Evaluation	If there is any price difference between these two tenders of the same item, whose prices will prevail. whether the department would negotiate, if yes then what is the price sanctity of 1st tender.	As clarified above, this is a developmental tender to develop new sources of supply for tendered item. The L1 for this tender will not be compared with other tenders.
		Participation in Tender	Other Queries: · Can a person who has participated in the last tender through one of his firms can participate in this tender with another firm? · Can a company who has participated in the last tender participate in this tender with another plant of the same company? Kindly Confirm	Refer NIT *"Manufacturer who gets technically qualified and those price bid is opened against CMSS regular tender no. CMSS/PROC/2024-26/UIP/004 dtd. 26.04.2024 will not be eligible to participate in this developmental tender. This developmental tender is only for those manufacturers who are not able meet prescribed eligibility criteria of aforesaid regular tender but have credential/ meet requirements for subject developmental tender."* However, if bidder is not eligible for regular tender for a particular manufacturing plant but qualifies for other manufacturing sites, it can bid for development tender for the manufacturing site for which it is not eligible for regular tender.

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