CENTRAL MEDICAL SERVICES SOCIETY

Ministry of Health & Family Welfare, 2nd Floor, Vishwa Yuvak Kendra
Pandit Uma Shankar Dikshit Road, Chanakyapuri, New Delhi - 110021
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Dated 21.08.2024

AMENDMENT NO. 2

Tender No: CMSS/PROC/2024-26/UIP/004 for 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.	Representation	AMENDMENT
1	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 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.	Past Performance amended from Last two years to specifically 2021-22 & 2022-23 which restricts the participation of new entrants who have performed in 2023-24. This shows that CMSS is biased towards New and MSE. Requested to kindly make amendmends.	The Supplies made during the FY 2021-22 & 2022-23 OR 2022-23 & 2023-24, submitted along with GST invoice & e-way bill will be considered.

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2	Annexure-1A; Technical Specifications of Sterile Hypodermic Syringes-RUP	Product/Service specification Annexure-1A; Technical Specifications of Sterile Hypodermic Syringes-RUP: Since, the tender is for RUP Syringe, it is requested that only ISO 7886-4 may please be considered as this standard Part 4 is for Syringes with re-use prevention feature.	NO CHANGE Kindly Refer Amendment NO. 1.
3	General Characteristics of RUP Syringe 5ml	General Characteristics of RUP Syringe 5ml: 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."	NO CHANGE Kindly Refer Amendment NO. 1.
4	Annexure-1A; Technical Specification	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 Kindly Refer Amendment NO. 1.
5	Annexure-1A; Technical Specifications of Sterile Hypodermic Syringes-RUP	Annexure-1A; Technical Specifications of Sterile Hypodermic Syringes-RUP: Since, the tender is for RUP Syringe, it is requested that only ISO 7886-4 may please be considered as this standard Part 4 is for Syringes with re-use prevention feature.	NO CHANGE Kindly Refer Amendment NO. 1.
6	General Characteristics:	General Characteristics: 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	NO CHANGE Kindly Refer Amendment NO. 1.

		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."	
7	Annexure-1A; Technical Specification	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 Kindly Refer Amendment NO. 1.
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 tender quantity is reserved for MSE bidders, you are requested to kindly reduce the minimum quoted quantity to 25% since the tendered quantity is huge and MSE bidder shall be restricted from participation in the said tender. It is very difficult for a small MSE company to have previous orders for 40% of the quoted quantities i.e 50% of the tendered quantities.	NO CHANGE, however separate tender will be published as Development Order Tenders.
9	**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: - 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.	This condition seems to be restrictive where in it is mentioned that: For Sch I: Any AD Syringe For Sch II: Any AD/RUP Syringe. To give level playing field to all MSE suppliers also, it should be changed to "ANY SYRINGE" otherwise only bid player will be able to participate in this tender considering huge tender quantities. Moreover,	NO CHANGE

	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.		
10	**Clause 4 (h) & 6 (e)** The Supplies made during the FY 2021-22 & 2022-23, submitted along with GST invoice & e-way bill will be considered.	The Supplies made during the FY 2021-22 & 2022-23 OR 2022-23 & 2023-24, submitted along with GST invoice & e-way bill will be considered.	The Supplies made during the FY 2021-22 & 2022-23 OR 2022-23 & 2023-24, submitted along with GST invoice & e-way bill will be considered.
11	LOA & P.O Issues	Sir, usually LOA is issued immediately by CMSS wherein Delivery period starts with LOA date.And P.O is issued later on sometimes very late . As Delivery Period is linked to issue date of LOA, Inspection should be allowed as per LOA . If CMSS does not agree to this ,in case of delayed P,O Inspection Period, delivery period should be 45 days as Despatch will only start after receipt of Despatch Clerance . We request CMSS to be practical because Inspection & issue of Despatch itself will take one month as it is STERILE PRODUCT. We request you to give 45 days time for Inspection & delivery of the goods. Otherwise vendor will keep on giving L.D for no fault on his part . Hope CMSS accepts logical request.	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.
12	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 .The details of supplies along with E way bill duly certified by Chartered Accountant & have been uploaded on the portal with UID no may be accepted . We request you to accept this & you may verify from your portal / Logistic /Finance Division of CMSS.	NO CHANGE

		Still we will try to scan & upload on GEM & what ever quantities are uploaded on GEM may please be accepted OR Pl accept the hard copies of Invoices & e-way bills , we will submit to CMSS along with EMD .	
13	Short Closure of Contract	Gem says ,it is the responsibility of purchaser. In case of short closure CMSS should return GEM charges for the short closured amount & similarly Bank guarantee charges for short closured amount shall be returned to the vendor.	NO CHANGE
14	Performance Statement to establish 2 years market standing as per format given in Annexure-IV	It may please be clarified that if a company is authorizing a distributor to participate on their behalf, can the distributor utilise the orders of the manufacturer for fulfilments of the performance clause. A similar change in the performance criteria was made in GeM Bid Reference No: GEM/2021/B/1260831 dated 25.05.2021 for 5ml RUP Syringes wherein it was clarified that ***"Non-Manufacturer bidders can utilize the past performance criteria of the manufacturer firm."***	Please refer Annexure-A.
15	**Delivery Period**	Please note that as per the tender document, deliveries for 5ml RUP Syringe had to start July 2024 onwards. Since the tender is being extended, it is requested that clarity as regards to the delivery schedule may please be provided.	Revised Delivery Schedule mentioned at Annexure – B.
16	**Delivery Period, PDI & Testing**	Given the complexities involved in supplying to UIP, particularly for new companies, the production of the first tranche is expected to take long. The process will take at least 90 days, encompassing raw material procurement, printing of shippers and labels (following artwork approval), manufacturing, in-house testing, and PDI (Pre-Delivery Inspection) clearance. It is also pertinent to mention that final dispatch clearance post PDI typically takes around a month after PDI. ***Consequently, we request approval of the delivery period for Tranche I to 120 days from the date of award of LOA . For subsequent tranches, we request that supplies may please be accepted on a bi-monthly basis.***	Revised Delivery Schedule mentioned at Annexure – B.
17	**Local Content Certificate**	For local content certificate, it may please be clarified whether a distributor participating on behalf of its principal manufacturer can submit a local content certificate issued by the statutory auditor of the principal manufacturer.	Please refer Annexure-A.
18	**Annexure-1A; Technical Specifications of Sterile Hypodermic Syringes-RUP**	Since, the tender is for RUP Syringe, it is requested that only ISO 7886-4 may please be considered as this standard Part 4 is for	NO CHANGE Kindly Refer Amendment NO.1.

		Syringes with re-use prevention feature.	
19	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 feature is 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 Kindly Refer Amendment NO. 1.
20	Annexure A; List of Quoted	We write to draw your kind attention to Schedule II, specifically concerning the 5ml Sterile Hypodermic Syringe (RUP) mentioned in the subject tender. As per the technical specifications outlined in the tender documents, both the 5ml Sterile Hypodermic Syringe (Re-Use Preventive)	NO CHANGE. 1. The tender was published in 2 schedules i.e 0.5 ml AD & 5ml RUP as per requirement of programme division.

		and the 5ml AD (Auto-Disable) Syringe share the same technical characteristics, particularly their re-use preventive features. In light of this, we respectfully request that the category of the 5ml Sterile Hypodermic Syringe (RUP) be amended to fall under the AD Syringe category. Alternatively, we kindly urge you to instruct the GeM to approve the category (5ml Sterile Hypodermic Syringe - RUP) based on the AD Syringe manufacturing license. Your prompt action in this regard would be greatly appreciated. Further you are also requested to kindly extend the due date of the said tender accordingly.	2. For creation of any category and approval of supplier of that category is purely linked with GeM authority. CMSS has no role in the same. You are requested to bid as per the schedules mentioned in GeM.

NOTE: If Authorized Distributor is the bidder, it should have executed atleast 1(One) purchase order for the same quoted product in the last 2 Financial Year (FY).

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

Sr. No.	Reference	Existing	Modified
1	Bid Submission End Date and Time	23.08.2024 till 3 PM	27.08.2024 till 3 PM
2	Last date of submission of original documents	23.08.2024 till 3 PM	27.08.2024 till 3 PM
3	Bid Opening Date and Time	23.08.2024 till 4 PM	27.08.2024 till 4 PM

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

21/8/24

GM(Procurement)

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Annexure-A

All the bidders may please note that the documents to be submitted for manufacturer and authorized distributor as per eligibility criteria is bifurcated for better understanding & submission. The documents tick (✔) to be submitted as per the list below:

<table>
<tr><th>Sr. No.</th><th>Eligibility Criteria</th><th>Manufacturer</th><th>Authorized Distributor</th></tr>
<tr><td>1</td><td>Only Class-1 and Class-2 local supplier shall be eligible for participation. Bids from supplier (MSE/Non MSE) as defined in Department of Pharmaceuticals under Ministry of Chemicals and Fertilizers order no F.No 31026/36/2016-MD dated 16.02.2021 shall be accepted. Bids from firms/vendors other than Class-1 and Class-2 local supplier (MSE/Non MSE) shall be summarily rejected.</td><td>(✔)</td><td>-</td></tr>
<tr><td>2</td><td>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.</td><td>(✔)</td><td>-</td></tr>
<tr><td>3</td><td>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.</td><td>(✔)
If distributor</td><td>(✔)</td></tr>
<tr><td>4</td><td>For all regulated products, the bidder should have at least two years i.e. 2021-22 and 2022-23 OR 2022-23 and 2023-24 of manufacturing and marketing experience of the particular items as a manufacturer for each regulated product quoted in the tender. However, this would not apply to regulated products which have been licensed by DCG (I) in less than two years ago. A permission from DCG (I) shall be required for all new regulated products to this effect.
Note- For Authorized Agencies (non-manufacturers), the bidders can utilise the financial and past supply credentials of the principal.</td><td>(✔)</td><td>-</td></tr>
<tr><td>5</td><td>Average Annual turnover for Tenderers in the last three years i.e., 2020-21, 2021-22 and 2022-23OR 2021-22, 2022-23 and 2023-24 shall not be less than the following: -
<table>
<tr><td>Schedule</td><td>Amount (in Rs.) for 100% quantity quoted</td><td>Amount (in Rs.) for 50% Quantity quoted</td></tr>
<tr><td>I</td><td>56,25,25,376</td><td>28,12,62,688</td></tr>
<tr><td>II</td><td>4,91,36,208</td><td>2,45,68,104</td></tr>
</table></td><td>(✔)</td><td>-</td></tr>
<tr><td>6</td><td>The bidder should not be blacklisted/ banned/ debarred (as whole) or for the tendered goods by CMSS, MoHFW and Department of Expenditure on the date of tender opening. Aforesaid debarred/banned/blacklisted bidders are not eligible to bid in the tender.</td><td>(✔)</td><td>(✔)</td></tr>
<tr><td>7</td><td>Conformance to ISO Certification as per technical specifications.</td><td>(✔)</td><td>-</td></tr>
<tr><td>8</td><td>Tender Forwarding letter as per Annexure-II.</td><td>-</td><td>(✔)</td></tr>
<tr><td>9</td><td>Duly notarized general power of Attorney (on non-judicial stamp paper of worth Rs. 50/-) in favour of authorized signatory in case of partnership firm (to be signed by all</td><td>-</td><td>(✔)</td></tr>
</table>

	partners)/ proprietorship firm or board resolution in case of a company to sign the bid and bind the bidder. The signature of authorized signatory should be duly attested. In case of proprietorship on its letter head of firm declares himself as proprietor with specimen signature.		
10	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.	(✔)	-
11	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.	(✔)	-
12	Capacity certificate issued by Licensing authority should be submitted.	(✔)	-
13	Performance Statement to establish 2 years market standing as per format given in Annexure-IV.	(✔)	(✔)
14	Annual turnover statement for 3 years i.e. 2020-21, 2021-22 and 2022-23 OR 2021-22, 2022-23 and 2023-24 should be furnished in the format given in Annexure-V duly certified by the Chartered Accountant.	(✔)	(✔)
15	Copies of the audited Annual reports including the Balance Sheet and Profit and Loss Account along with all the annexure for the last three years i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 duly certified by a practicing Chartered Accountant.	(✔)	(✔)
16	Certificate of Incorporation along with MOA (Memorandum of Association) & AOA (Articles of Association) in case of Companies or Copy of partnership deed in case of partnership firm or Declaration in case of being a proprietary firm.	(✔)	(✔)
17	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.	(✔)	-
18	Tenderer should submit a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content at the time of submission of bid as per Annexure-XVII.	(✔)	-
19	Para wise compliance of technical specification of the quoted items.	(✔)	-
20	The bidders are requested to submit an undertaking on their letterhead for compliance to the Artwork enclosed for the items quoted by them. No further approval for Artwork would be provided by CMSS to any bidder.	(✔)	-

Note: All documents submitted by the manufacturer should be duly signed & stamped (Counter sign) by the bidder (Non-Manufacturer).

Annexure- B

Delivery Schedule of 0.5 ml AD syringes

Sr. NO.	Month-Year	Quantity required (Pieces in Lakh)
1	Nov-24	351.5
2	Dec-24	351.5
3	Jan-25	410
4	Mar-25	703
5	May-25	703
6	Jul-25	409.5
7	Scp-25	703
8	Nov-25	703
9	Jan-26	703
10	Mar-26	351.5
Total		**5389**

Delivery Schedule of 5 ml RUP syringes

Sr. No.	Month-Year	Quantity required (Pieces in Lakh)
1	Nov-24	50
2	Jan-25	50
3	Mar-25	50
4	May-25	50
5	Jul-25	48
6	Sep-25	50
7	Nov-25	50
Total		**348**