

CENTRAL MEDICAL SERVICES SOCIETY

Ministry of Health & Family Welfare
2nd Floor, Vishwa Yuvak Kendra, Near Teen Murti Marg
Chanakya Puri, New Delhi – 110021, India

Dated: - 26.06.2024

Minutes of Pre-Bid Meeting for Procurement of Vaccines under Universal Immunization Program (UIP)

TENDER No: CMSS/PROC/2024-25/UIP/001
Pre-bid conference held on 31.05.2024

Table-A

(Pre Bid Queries Raised by the Bidder and Remarks by CMSS)

Sr. No.	Bidder	Query/ Classification Asked	Clarification/Amendment
1.	Bidder-1	<p>Waiver for WHO-GMP and COPP certificate.</p> <p>A) WHO-GMP and COPP certificate are applicable for exports and not for domestic supplies. B) If the above is not considered, waiver to be given for these 4 schedules as getting these certificates would require application for the same, plant visit of the concerned authorities etc.</p>	<p>WHO-GMP & CoPP are mandatory requirements of CMSS' tender. However, one time waiver may be granted for this particular tender and the clause may be amended as follows: "WHO-GMP is required to be submitted for the particular manufacturing plant whereas, CoPP is required to be submitted for the particular schedule. Those who have applied for WHO-GMP & CoPP, shall be eligible, subject to the prospective bidder enclosing/attaching a copy of their application made to the concerned issuing authority with proper documentary evidence".</p>
		<p>EMD Waiver requested</p> <p>In the MOH tenders through GEM, EMD was waived off for manufacturers with turnover of more than 500 Cr.</p>	<p>Precedent to previous Ministry of Health & Family Welfare (MoH&FW) tender and in accordance with the GeM GTC, Earnest Money Deposit (EMD) is hereby exempted for all the prospective bidders having annual financial turnover equal to or greater than 500cr in any of the previous three financial years .However, all the prospective bidder(s) are required to submit a 'Bid security Declaration' in lieu of EMD as per the format given at Form:7 of bid document.</p> <p>Bid Security Declaration, in original must reach the Tender Inviting Authority (TIA), physically before the tender opening date.</p>
		<p>Amendment in shelf life conditions at the time of supply (As per CMSS tender conditions-5/6 the shelf life needed at the time of supply). a) To consider minimum 18 months remaining shelf life at the time of supply in line to UNICEF tender conditions.</p>	<p>The clause is amended as follows: "At the time of supply to the consignee, the shelf life of vaccine should not have crossed more than 6 months from the date of manufacturing.</p>



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		b) To continue with the earlier MOH tender condition regards shelf life to not have crossed 6 months at the time of supply.	
		<p>LD Charges – To continue with the existing practice as per MOH/GEM tender conditions The request is made considering the larger complexities involved in vaccine manufacturing and clearances as well as the payment cycles.</p> <p>Existing LD charges are @0.5% per week to a maximum of 10%. The proposed change of charges applicable @2.5% per week from 5th week onwards is not encouraging and may not be applied.</p>	<p>The clause is amended as follows:</p> <p><i>“Subject to GCC clause 9.11, 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). Besides liquidated damages during such a delay, the denial clause as per GCC-clause 9.11-2(b) shall also apply.”. Refer Amendment No.1</i></p>
		<p>Clarity on min. past performance requirement <i>Though CMSS officials confirmed that as of now they are not considering past performance as the tender condition: Requesting for confirmation of the same.</i></p>	<p>Purchase orders w.r.t Past performance, not required.</p>
		<p>Delivery Schedules- Bi-monthly and taking into consideration the existing schedules. <i>Considering the long manufacturing and testing timelines, to continue with existing practice of bi-monthly schedule and the delivery schedules to consider the ongoing supplies against existing orders as well as tolerance orders.</i></p>	<p>The amended delivery schedule may please be seen as detailed in the <u>Amendment-1</u>.</p>
		<p>Request for extension of tender submission date by 2 weeks Anticipated time required for preparation of tender documents</p>	<p>As per amendment issued.</p>



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2.	Bidder-2	<p>CMSS Tender section II-Clause 9.2.1 3(b) on page 27 and section IV- clause C on Page 52:</p> <p>Tenderer must submit WHO GMP certificate valid on the date of tender opening (technical bid)</p> <p>This condition is incorporated for the first time in UIP procurements on 6th may and tender last date is 14th June 2024. Certificates are not required for Indian market and for UIP. However, to obtain these certificates from regulatory dept., we need extra time since, this requires inspection from regulatory agencies. Kindly accept the "applied for" status of WHO-GMP certificate, pending formal inspections from Regulatory agencies and obtaining final certificate</p> <p>Alternatively, Schedule-M GMP may also be accepted.</p> <p>CMSS tender Section II -Clause 9.2.1 (3) (c) on page 27 &Section IV - Clause D on page 52:"Tenderer must submit Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia (IP'BP/VSP) or In-house Standards valid on the date of tender opening (technical bid)".</p> <p>This condition is incorporated for the first time in UIP procurements on 6th May and tender last date is 14th June'24. Certificates are not required for Indian market and for UIP.</p> <p>This certificate is required for Purpose and after inspection and certification of WHP-GMP Kindly accept the applied for" status of WHO-GMP / CoPP certificate, pending formal inspections from Regulatory agencies and obtaining final certificate. Alternatively, Schedule- M GMP may also be accepted.</p> <p>CMSS tender Section VIII- Clause GCC 8.7.' on page 207: contractors shall ensure that at least 5/6th of shelf-life remains balance on delivery date recent past m U IP, product is acceptable if it is delivered within 6 months from date of</p>	<p>WHO-GMP & CoPP are mandatory requirements of CMSS' tender. However, one time waiver may be granted for this particular tender and the clause may be amended as follows:</p> <p><i>"WHO-GMP & CoPP are required to be submitted for the particular schedule. Those who have applied for WHO-GMP &CoPP, shall be eligible, subject to the prospective bidder enclosing/attaching a copy of their application made to the concerned issuing authority with proper documentary evidence"</i>.</p> <p>WHO-GMP & CoPP are mandatory requirements of CMSS' tender. However, one time waiver may be granted for this particular tender and the clause may be amended as follows:</p> <p><i>"WHO-GMP & CoPP are required to be submitted for the particular schedule. Those who have applied for WHO-GMP &CoPP, shall be eligible, subject to the prospective bidder enclosing/attaching a copy of their application made to the concerned issuing authority with proper documentary evidence"</i>.</p> <p>The clause is amended as follows: "For those vaccines having shelf-life of 24 months or more, at the time of supply to the consignee, the shelf life of vaccine should not have crossed more than 6 months from the date of manufacturing.</p>



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		<p>manufacture. But this clause will reduce further to 4 months it is advisable that shelf life of vaccine has to be factored with - Lead time for manufacturing; Lead time for Internal testing, Lead time for CDL clearance and Lead time for schedule supply calendar of (now CMSS)- For any vaccine to go through the above steps, it takes minimum 4-6 months' time, subject to CDL batch clearance on time. With any staggered supply schedule, this becomes more vulnerable to cut-off dates- Our suggestion is that the vaccine should have either of the following conditions. 18 months shelf life at the time of submission of the product for sampling to CDL. 2/3rd shelf life should be there at the time of supplies. It is advisable that shelf life of vaccine has to be factored with - Lead time for manufacturing; Lead time for Internal testing, Lead time for CDL clearance and Lead time for schedule supply calendar of (now CMSS)- For any vaccine to go through the above steps, it takes minimum 4-6 months' time, subject to CDL batch clearance on time. With any staggered supply schedule, this becomes more vulnerable to cut-off dates- Our suggestion is that the vaccine should have either of the following conditions.</p> <ul style="list-style-type: none"> • 18 months shelf life at the time of submission of the product for sampling to CDL. <p>2/3rd shelf life should be there at the time of supplies.</p>	
		<p>Page-3 EMD Requirement: EMD Required for 100% tendered quantity</p> <p>As per General Terms and Conditions (GTC) on GeM 3.0, version 1.14 - Point -4 (n) Exemption of EMD for all manufacturers with more than Rs. 500 Cr turnover</p> <p>There is no EMD provision for companies higher than Rs-500 Cr. Hence, this condition should be waived off from CMSS tender for UIP vaccines</p>	<p>Precedent to previous Ministry of Health & Family Welfare (MoH&FW) tender and in accordance with the GeM GTC, Earnst Money Deposit (EMD) is hereby exempted for all the prospective bidders having annual financial turnover equal to or greater than 500cr in any of the financial year considering previous 3 F.Ys However, all the prospective bidder(s) are required to submit a 'Bid security Declaration' in lieu of EMD as per the format given at Form:7 of bid document.</p>
		<p>Section V Schedule of Requirements: Delivery Schedule on monthly basis. As per practice while supplying to UIP, bi-monthly schedule is given considering the</p>	<p>Kindly refer Amendment No.1 for detailed delivery schedule.</p>



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		<p>margin of errors in vaccine clearance time. Bi-Monthly schedule should be given instead of monthly schedule.</p> <p>120 days lead time should be given to start supplies and if there are existing orders from UIP, then supplies will only start after completion of earlier tolerance quantity from earlier UIP Rate Contracts</p> <p>Page 2 & 4 of the document vis-à-vis Form 6 – Check List Sr. No. 7 and 7a of CMSS tender.</p> <p>As per GeM build document - The Past performance is mentioned as 40 % WHEREAS, As per CMSS tender - Form 6 - Check List, Sr. No. 7 and 7a are deleted. The requirement in tender is unknown/ unclear. It has been clarified in the 31st May 2024 meeting in CMSS that this 40% Past performance clause is scrapped. Hence, Delete this clause.</p> <p>Minimum Capacity of 50% for each Schedule.</p> <p>Minimum capacity as per earlier UIP Tenders was 20% which has been increased to 50% by CMSS. This will only encourage all the large and big vaccine manufacturers. Hence, this condition should be revised to 20% only</p> <p>Extension of time for tender: In proposal to the clarifications given in the pre-bid meeting on 31 May 2024, documentations we need time for documentation since these documents are issued by CDSCO and other regulatory /statutory authorities- we request you you to postpone the tender due date by another minimum 2 weeks and circulate new corrigendum.</p>	<p>Purchase orders w.r.t Past performance, not required.</p> <p>No Change in the minimum quantity to be quoted.</p> <p>Kindly refer <u>Amendment No.1</u></p>
3.	Bidder-3	<p>Shelf Life of Vaccines: As emphasized during our meeting, we kindly request your consideration for establishing a standard shelf life of 18 months at the time of vaccine delivery. This standardization would immensely aid in our inventory planning and streamline the crucial delivery process to various consignees across India. Notably, this aligns with the tender terms of esteemed multilateral organizations such as UNICEF, WHO, and GAVI. For your reference and necessary action, we have enclosed copies of two such global tender documents.</p>	<p>The clause is amended as follows: “For those vaccines having shelf-life of 24 months or more, at the time of supply to the consignee, the shelf life of vaccine should not have crossed more than 6 months from the date of manufacturing”.</p>



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		<p>It is also worthwhile to mention that meeting the 516th shelf-life clause in respect of vaccines is not feasible as the total period for fill, finish and test release usually ranges between 90 and 150 days. Therefore, for vaccines (such as PCV (36), TD (36) & Pentavalent (30)) that have an approved shelf life Of 24 to 36 months, we will not be able to meet the shelf-life clause under any circumstance as currently stipulated in the tender document.</p> <p>In view thereof, and for the sake of standardized, it is once again requested that the shelf life of <i>vaccines may please be revised to 18 months at the time of delivery to the consignee.</i></p>	
		<p>Earnest Money Deposit Clause on GeM Portal: It has come to our attention that while GeM Terms & Conditions exempt us from the payment of Earnest Money Deposit (EMD), previous CMSS tender documents have mandated the submission of EMD without extending the exemption as per GeM terms & conditions.</p> <p>We respectfully request your office to align with the GeM terms and conditions, which explicitly state that any additional clauses incorporated by the Buyer regarding EMD submission contrary to GeM policy shall be deemed null and void.</p> <p>Therefore, we earnestly seek exemption from EMD submission in accordance With GeM Terms & Conditions.</p> <p>The relevant excerpt from additional terms & conditions of GeM bids that are part of every bid document is also reproduced below:</p> <p><i>"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. Any clause(s) incorporated by the Buyer regarding following shall be treated as 6 / 7 null and void and would not be considered as part of bid.</i></p>	<p>Precedent to previous Ministry of Health & Family Welfare (MoH&FW) tender and in accordance with the GeM GTC, Earnst Money Deposit (EMD) is hereby exempted for all the prospective bidders having annual financial turnover equal to or greater than 500cr in any of the financial year considering previous 3 F. Ys However, all the prospective bidder(s) are required to submit a 'Bid security Declaration' in lieu of EMD as per the format given at Form:7 of bid document.</p>
		Seeking EMD submission from bidder(s),	Precedent to previous Ministry of Health & Family Welfare



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		<p>including via Additional Terms & Conditions, in contravention to exemption provided to such sellers under GeM GTC. <i>It is also worthwhile to mention that even the Ministry of Health & Family Welfare, Government of India extended EMD exemption benefits as per GeM Terms & Conditions. Copy of one such tender is enclosed with this letter for your ready reference.</i></p>	<p>(MoH&FW) tender and in accordance with the GeM GTC, Earnst Money Deposit (EMD) is hereby exempted for all the prospective bidders having annual financial turnover equal to or greater than 500cr in any of the financial year considering previous 3 F.Ys However, all the prospective bidder(s) are required to submit a 'Bid security Declaration' in lieu of EMD as per the format given at Form:7 of bid document.</p>
		<p>Page 6 of Tender Document, Point 2.4.3: Regarding Information Provided Information contained</p> <p>in the Tender Document or subsequently provided to the Bidder(s) is on the terms and conditions set out in the Tender Document or subject to which that was provided. Similar terms apply to information provided verbally or in documentary or any other form, directly or indirectly, by the procuring Entity or any of its employees or associated agencies:</p> <p>It is requested that this clause may be amended and the word 'verbally' may be removed as it can lead to unnecessary disputes. The clause may therefore be revised as follows:</p> <p><i>"Regarding Information Provided Information contained in the Tender Document or subsequently provided to the Bidder(s) is on the terms and conditions set out in the Tender Document or subject to which that was provided Similar terms apply to Information provided in documentary or any other form, directly or indirectly, by the Procuring Entity or any Of its employees or associated agencies.</i></p>	<p>No Change, the tender document is prepared based on the guidelines as detailed by DOE. Therefore, no change in the said clause.</p>
		<p>Page 44 of Tender Document, 13.2.3 Letter of Award (LOA). The Bidder, whose bid has been accepted, shall be notified of the award by the Procuring Entity before the expiration Of the Bid Validity period by written or electronic means. This notification (hereinafter and in the Conditions of Contract called the "Letter of Award - LOA") shall state the sum (hereinafter and in the contract called the "Contract Price") that the Procuring Entity shall pay the contractor in consideration of the supply of the Goods.</p>	<p>No Change</p>



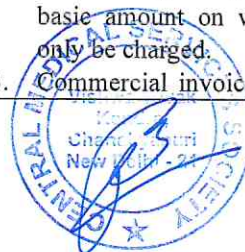
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		<p>The Letter of Award (LOA) shall constitute the legal formation of the contract, subject only to the furnishing of performance security as per the provisions of the sub-clause below.": It is requested that the LOA clause may be removed and PO along with consignee list may issued at the first instance to enable us to undertake production. Furnishing complete consignee list along with formal purchase order is necessary for us to undertake production optimally.</p> <p>Page 180 of Tender Document, 9.12 Liquidated damages I): Subject to GCC clause 9.11, 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 0.5 % (half percent) Of the delivered price (including elements of GST & freight) of the delayed Goods and/ or incidental Works/ Services 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 a 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). Besides liquidated damages during such a delay, the denial clause as per GCC-clause 9.11-2(b) shall also apply.</p> <p>It is requested that the said penalty clause is very high and should be amended as per liquidated damages policy adopted by Ministry of Health & Family Welfare that is also in line with GFR 2017 Clause.</p> <p>It is therefore requested that the LD clause may please be amended to 0.5% per week of the total invoice value with maximum LD not exceeding 10%.</p>	<p>The clause is amended as follows:</p> <p><i>"Subject to GCC clause 9.11, 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). Besides liquidated damages during such a delay, the denial clause as per GCC-clause 9.11-2(b) shall also apply."</i> Refer Amendment No.1</p>



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		<p>Delivery Period: It is requested that the delivery period for the 1st Tranche may be as below: Doses of Vaccine to be supplied within 150 days of issue of LOA or within 120 days of issue of Purchase Order. Delivery of subsequent tranches to be done in subsequent period of 30 days from the last date of <i>supply of previous tranche. "</i></p>	<p>Delivery schedule has been amended and detailed in <u>Amendment-1.</u></p>
		<p>Performance Criteria: <i>Please confirm that the performance clause has been deleted as the same is part of the GeM Bid Document and is mentioned as "deleted" in the ATC Tender Document of CMSS.</i></p>	<p>As per directives of Government of India, the tender is published on GeM platform with GeM terms and conditions. However, in case of ambiguity or contradiction in terms and conditions of GeM bid, the clauses of the tender document uploaded in Additional Terms and Conditions (ATC) shall prevail.</p>
		<p>Experience with Bunch Bids: It is submitted that GeM Portal provides limited space for uploading technical bid and in our experience, we usually face difficulties in uploading voluminous bids for multiple items. Further, with bunch bids, we usually receive a single order for multiple items. In the case of CMSS and as per tender terms, this bunch order may limit our ability to claim payment as we will have to complete 50% delivery for each item. It is therefore requested that it may please be confirmed <i>that orders for each item will be placed separately on GeM and CMSS E-Aushadhi Portal. (Tender Document Point 10.3.7 - Page 187)</i></p>	<p>The purchase orders will be released from e-aushadhi portal of CMSS. The P.O will be released item-wise/ schedule-wise. The quantity of minimum 50% supplies shall be for a particular lot of the Purchase order (PO) for the specific item.</p>
		<p>Additional Queries It is mentioned in the tender documents that all copies of below mentioned Techno-Commercial documents are to be uploaded on GeM portal and originals are to be submitted physically to CMSS office.</p> <ol style="list-style-type: none"> Bidder information Eligibility declarations Qualification criteria Technical specifications Checklist Term and conditions Compliance and Deviation etc. <p>Is our understanding correct?</p>	<p>Please go through the tender document and submit your response accordingly.</p>
		<p>Additional Queries Please clarify whether Price Bid is to be uploaded on GeM portal in given format of BOQ. Please also clarify while quoting in BOQ, whether Ex-works (basic) price plus GST</p>	<p>The price bid is to be uploaded, as per the BOQ available on GeM portal.</p>



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		and total price details are sufficient.	
		Additional Queries Whether all techno-commercial documents being submitted are to be physically signed, stamped, scanned, including tender documents (242 Pages) and are to be uploaded or are they to be digitally signed (with tick). Please clarify.	As per tender terms and conditions.
		Additional Queries It is mentioned that under clause 10.3.1 (4.f) Terms and Mode of Payment, Warranty Certificate is to be submitted along with the bill. Kindly clarify if this is required for vaccine supply.	No warranty certificate is required.
		Additional Queries We trust the new orders from CMSS would not be overlapping/hampering delivery schedule of existing orders. Please clarify.	The delivery schedule has been amended as detailed in <u>Amendmnt-1.</u>
		Additional Queries Kindly advise, if we have to submit PAC certificate as we are the manufacturer.	No, the nature of the tender does not warrant a Proprietary article certificate (PAC) to be submitted.
		Additional Queries In Form 3 : Technical Specifications and Quality Assurance – Compliance & Deviation, it is written on the last line “DA : Relevant documents like technical data, literature, drawings, and other documents.” Please advise what documents /information is expected to be provided in the tender submission.	As per tender terms and conditions.
		Additional Queries In the tender documents under Technical specifications of the vaccines the reference is mentioned of guidelines on the international packaging and shipping of vaccines. Since our supplies are domestic within India only, we trust these guidelines are not applicable for this supply.	In response to any query pertaining to the Technical specifications, the approved/existing technical specifications may be followed.
		Additional Queries In the tender documents it is mentioned that copy of E-invoice generated from GST Portal is required at the time of raising our bill along with other documents. Kindly note that as the supplies are from SEZ, the E-invoice copy generated from GST portal is having components viz. Custom duty etc. We trust the same is in order.	<ol style="list-style-type: none"> 1. SEZ units are exempted from submitting e-invoice. However, e-way bill needs to be submitted along with the commercial invoice. 2. As GST applicable is same for Domestic as well as manufacturer operating from SEZ, the rate quoted by the supplier from SEZ shall be inclusive of custom duty, if any. That amount will be treated as basic amount on which GST as applicable shall only be charged. 3. Commercial invoice should be raised with basic+



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			GST as applicable. Copy of BOE should also be enclosed with the invoice for reference. GST claim in the invoice enclosed shall be verified from GST portal by CMSS.
		<p>Additional Queries At the time of raising our bill, as required under Tender E-Aushadhi PO No. and Tranche is to be mentioned in the Bill. A separate bill as per requirement of Tender, duly incorporating E-Aushadhi PO No. and Tranche is to be submitted along with other documents including E-invoice generated from GST portal. We trust this understanding is correct.</p>	As per tender terms and conditions.
		<p>Additional Queries As discussed, in Pre-Bid meeting, can you kindly arrange to provide training, Login User ID and Password for using E-Aushadhi Portal.</p>	CMSS shall provide training as and when required.
		<p>Additional Queries In view of the clarifications being sought on the above mentioned points as well as those covered in our earlier email dated 31.05.2024 and since it is first time CMSS tender, may we request your goodself to kindly extend the Bid Submission date by two weeks from current submission date of 14.06.2024. This will enable us to prepare the Tender documents diligently and submit the same.</p>	Kindly refer <u>Amendment No.1</u>
All Certificated issued by Chartered Accountant shall mandatory include UDIN No.			



