

CENTRAL MEDICAL SERVICES SOCIETY

Ministry of Health and Family Welfare (Government of India)
2nd floor, VishwaYuvak Kendra, Pt. Uma Shankar DikshitMarg, Teen Murti Road, Opposite
Police Station ChankayaPuri, New Delhi-110021
Telephones: 011-21410905, 21410906,

Dated: - 18.10.2023

Minutes of Pre-bid Meeting for Procurement of DSTB (Regimens) for NTEP

TENDER No: CMSS/PROC/2023-24/NTEP/042

Pre-bid conference held on 22.09.2023

- Following officials were present during the Pre-bid meeting: -
 - Dr. Alok Mathur, NTEP
 - Ms. Anjana, GM (Procurement) CMSS
 - Mr. D. Mahapatra, GM (Finance)CMSS
 - Ms. Sakshi Juneja, AGM (Procurement)CMSS
 - Ms. Akanksha Jain, AGM (QA)CMSS
- Following representatives from prospective bidders were present during the Pre-bid meeting:-

Sl. No.	Name of Representative	Name of Firm
1.	Mr. Atul Yadav & Mr. Pawan Thakran	M/s. Lupin Limited
2.	Mr Harish Joshi & Ms. Kinjal Bhanushali	M/s Macleods Pharmaceuticals Ltd.
3.	Mr. B.S Rajput	M/s. Concept Pharmaceuticals Limited.

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

Sr. No	Bidder	Pg No. & Clause	Query/ Classification Asked	Clarification/Amendment
1.	M/s Lupin Ltd:	<p>Annexure 1 :</p> <p>(b) Delivery Schedule for all the above mentioned three schedules will be as follows: Tranche - 1 : 25% quantity to be delivered within 60 from the date of issuance of LOA at CMSS Stores.</p> <p>Tranche - 2 : 25% quantity to be delivered between 60 to 90 days from the date of issuance of LOA at CMSS Stores.</p> <p>Tranche - 3 : 25% quantity to be delivered after 120 days to 150 days from the date of issuance of LOA at CMSS stores.</p> <p>Tranche - 4 : 25% quantity to be delivered after 180 days to 210 days from the date of issuance of LOA at CMSS stores</p>	<p>We request you to kindly consider the following delivery schedule :</p> <p>Tranche - 1 : 25% quantity to be delivered within 120 days from the date of issuance of LOA at CMSS stores.</p> <p>Tranche - 2 : 25% quantity to be delivered between 120-180 days from the date of issuance of LOA at CMSS stores.</p> <p>Tranche - 3 : 25% quantity to be delivered after 180 days to 240 days from the date of issuance of LOA at CMSS stores.</p> <p>Tranche - 4 : 25% quantity to be delivered after 240 days to 300 days from the date of issuance of LOA at CMSS stores.</p>	<p>Revised delivery Schedule for all the three DSTB regimens is as follows:</p> <p>Tranche-1 : 20% quantity to be delivered within 60 days from the date of issuance of LOA at CMSS Stores.</p> <p>Tranche-2: 20% quantity to be delivered between 61 to 90 days from the date of issuance of LOA at CMSS Stores.</p> <p>Tranche-3: 20% quantity to be delivered between 91 days to 120 days from the date of issuance of LOA at CMSS stores.</p> <p>Tranche-4: 20% quantity to be delivered between 121 days to 150 days from the date of issuance of LOA at CMSS stores.</p> <p>Tranche-5: 20% quantity to be delivered between 151 days to 180 days from the date of issuance of LOA at CMSS stores.</p> <p>(Tranche-1 is PDI with conditional dispatch clearance & rest all are non PDI)</p>
		Annexure XVII : Local Content	Manufacturer should declare the API vendor source of the APIs along with vendor consent letter from the API manufacturer for supply of API to meet the tender requirements	The details are not required as the procurement is for finished product which will be tested as per IP. Not done

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		Clause 14.6 L: 2 I) The CoA should specify the tests undertaken for quality assurance, including acceptable levels of impurities in general, if any, at the time of supply'. 2. The WHO Prequalification Unit- Medicines Assessment Team (PQT/MED) has issued an FAQ around the Nitrosamine concerns for rifampicin and rifapentine in December 2020. This explicitly mentions the MNP (1-methyl-4-nitrosopiperazine) temporary limit of 5 pm as accepted by USFDA and recognized by PQT/MED as acceptable from the point of view of benefit/risk assessment.	Kindly clarify if each and every batch that would be supplied must be tested for MNP impurities and should be part of specification & COA.	in the past cases also. No Change. As per Tender Clause 14.6 COA of each batch delivered to be submitted along with shipping documents.
2.	M/s Macleods Pharmaceuticals Ltd.	Refer to Annexure I & IA – List of Product & Their Technical Specifications – Delivery Terms (b) :- For SCH. I Tranche - 1 : 25% quantity to be delivered within 60 from the date of issuance of LOA at CMSS Stores. Tranche - 2 : 25% quantity to be delivered between 60 to 90 days from the date of issuance of LOA at CMSS Stores. Tranche - 3 : 25% quantity to be delivered after 120 days to 150 days from the date of issuance of LOA at CMSS stores. Tranche - 4 : 25% quantity to be delivered after 180 days to 210 days from the date of issuance of LOA at CMSS stores 3) Refer to Inspection Methodology (PDI/NON PDI) - Non-PDI (Inspection at Delivery Stages)	The supply quantities for Tranche I, II, III and IV are significantly large. Since it takes 10 to 15 days to get the COA after production, it takes an extra 20–30 days to get the inspection reports after the goods have been inspected by CMSS. After then, it will take at least 30 days to send the goods to every state, making delivery possible 75 days after the goods have been produced. Thus achieving Tranche 1- 25% in 90 days is challenging. 1) We request that the tranche 1 quantity be reduced to 20% to be delivered in 90 days. The remaining 80% would thereafter be delivered in tranches II, III, or IV with the acceptance of partial deliveries with regard to each tranche's quantities.	Revised delivery Schedule for all the DSTB regimens is as follows: Tranche-1 : 20% quantity to be delivered within 60 days from the date of issuance of LOA at CMSS Stores. Tranche-2: 20% quantity to be delivered between 61 to 90 days from the date of issuance of LOA at CMSS Stores. Tranche-3: 20% quantity to be delivered between 91 days to 120 days from the date of issuance of LOA at CMSS stores. Tranche-4: 20% quantity to be

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				<p>delivered between 121 days to 150 days from the date of issuance of LOA at CMSS stores.</p> <p>Tranche-5: 20% quantity to be delivered between 151 days to 180 days from the date of issuance of LOA at CMSS stores.</p> <p>(Tranche-1 is PDI with conditional dispatch clearance & rest all are non PDI)</p>
		<p>Refer to Point 18 (18.2) – Delays in Suppliers Performance (Page 33) :- If the supply reaches the designated consignee places or CMSS Warehouse after scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied @ 2.5% per week to be applied proportionately on per day basis up to a maximum of 10% of P.O. Cost, irrespective of the fact that whether the CMSS has suffered any damage/loss or not, on account of delay in effecting supply. If the last scheduled delivery day happens to be a holiday the supply will be accepted on the next working day without any penalty.</p>	<p>1. Refer to this clause, we hereby request you to kindly remove this clause or to reduce the percentage of penalty per week.</p>	No Change
		<p>Refer to point 10 (10.1 & 2) – Other Conditions :- (i) Central Medical Services Society (CMSS) will have the right to increase or decrease up to 25% of the quantity of goods and/or services specified in the schedule of requirements without any change in the</p>	<p>Refer to this clause we request you to remove this clause as our costing is based on tender quantities, so request to be keep the same quantity effective till the validity of the bid.</p>	No change.

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		<p>unit price or other terms and conditions at the time of award of contract.</p> <p>(ii) In exceptional situation where the requirement is of an emergent nature and/ or it is necessary to ensure continued supplies from the existing vendors, the purchaser reserves the right to place repeat order up to 50% of the quantity of the goods and/or services contained in the running tender/contract up to a period of twelve months from the earliest date of Long Term agreement (LTA) at the same rate or a rate negotiated (downwardly) with the existing vendors considering the reasonability of rates based on prevailing market conditions and the impact of reduction in duties and taxes etc.</p>		
		<p>Refer to Annexure I-A (A – Storage & Shelf Life) :- At least 5/6th of the total stipulated Shelf Life must remain at the time of arrival at the consignee's warehouse. The Supplier will provide manufacturer's test data substantiating the claimed shelf life in the proposed package (Blister pack) Not only pharmaceuticals , but also the packaging components should also conform to specifications suitable for use in a climate prevailing in India. The product supplied should have been subjected to long term stability conditions as per the below requirements:</p> <p>Study - Long Term Stability Storage Condition - 25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH</p>	<p>Refer to this clause we have long Term Stability data as per USP. We would like to bring to your kind attention that the quality and performance parameters in IP/BP/USP are all same and the specifications available in the stability data assigned by us are all well covered and very well in limit also. Hence request you to please consider.</p>	<p>Long term stability data of the quoted product has to be submitted as per clause 6.2(n) of the bid document.</p>

Sr. No	Bidder	Pg No. & Clause	Query/ Classification Asked	Clarification/Amendment
		Refer to Annexure – I – List of Product & their Technical Specifications:- I- 4FDC –A – Strips of 28 Tablets. - 1,32,70,560 II- 3FDC-A – Strips of 28 Tablets. - 2,32,58,880 III- 2FDC –P – Strips of 28 Tablets. - 12,98,400	Refer to this point, request you to confirm whether the given quantities are in Strips or Tablets, kindly confirm.	Indicative quantity is in strips.
		Refer to page 42 – (Technical Specification – Primary Packaging) – Blister Strips should have perforations and spacing between tablets enough to allow removal by patients with finger deformities and easier separation of individual tablets from the strips	Refer to this point; this is to inform you that we have supplied in the current supply without perforations of individual tablets earlier. So therefore request you to remove this said clause.	Technical Specification – Primary Packaging – Blister / Strips should have perforations and spacing between tablets enough to allow removal by patients with finger deformities and easier separation of individual tablets from the strips / blisters.
		Refer to Pg 65, Blister Pack design and Labelling (blister)	Refer to clause, request you to accept Alu Alu Strip Pack.	Blister / Strips in Alu Alu pack is accepted.
		Refer to pg 83 – Checklist (Annexure-VII -Y) - Para-wise compliance of technical specification of the quoted item (Clause 6.2 y)	Request to please provide us the Format of the same.	There is no format for this, the compliance of technical specifications may please be provided.
3.	M/s J Duncan	Tender Clause 6.d- 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 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.	Tender Clause 6.d- Duly notarized general power of Attorney (on non-judicial stamp paper of worth Rs. 50/- or More) in favour of authorized signatory in case of partnership firm (to be signed by all 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.	Duly notarized general power of Attorney (on non-judicial stamp paper of worth Rs. 50/-or More) in favour of authorized signatory in case of partnership firm (to be signed by all 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

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				proprietor with specimen signature.
		Annexure-VIII NOTARISED UNDERTAKING BY MSE COMPANIES (In 20- Rupees stamp paper)	Annexure-VIII NOTARISED UNDERTAKING BY MSE COMPANIES (In 20- Rupees or more rupees stamp paper)	NOTARISED UNDERTAKING BY MSE COMPANIES (In 20- Rupees or more rupees stamp paper)
		Tender Clause 18.2 Liquidated damages If the supply reaches the designated consignee places or CMSS Warehouse after scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied @ 2.5% per week to be applied proportionately on per day basis up to a maximum of 10% of P.O. Cost, irrespective of the fact that whether the CMSS has suffered any damage/ loss or not, on account of delay in effecting supply. If the last scheduled delivery day happens to be a holiday the supply will be accepted on the next working day without any penalty.	Tender Clause 18.2 Liquidated damages If the supply reaches the designated consignee places or CMSS Warehouse after scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied @ 0.5% per week to be applied proportionately on per day basis up to a maximum of 10% of un-supplied goods, irrespective of the fact that whether the CMSS has suffered any damage/ loss or not, on account of delay in effecting supply. If the last scheduled delivery day happens to be a holiday the supply will be accepted on the next working day without any penalty. Reasons:- As per provision of GFR and Manual of Procurement and Guidelines of MoF (DoE).	No Change.
		Annexure I- Delivery Schedule for all the above mentioned three schedules will be as follows: Tranche - 1 : 25% quantity to be delivered within 60 from the date of issuance of LOA at CMSS Stores. Tranche - 2 : 25% quantity to be delivered between 60 to 90 days from the date of issuance of LOA at CMSS Stores.	Annexure I- Delivery Schedule for all the above mentioned three schedules will be as follows: Tranche - 1 : 25% quantity to be delivered within 120 from the date of issuance of LOA at CMSS Stores. Tranche - 2 : 30% quantity to be delivered between 121 to 240 days from the date of issuance of LOA at CMSS Stores. Tranche - 3 : 25% quantity to be delivered after 241 days to 360 days from the date of issuance of LOA at CMSS stores.	Revised delivery Schedule for all the three DSTB regimens is as follows: Tranche-1 : 20% quantity to be delivered within 60 days from the date of issuance of LOA at CMSS Stores. Tranche-2: 20% quantity to be delivered between 61 to 90 days from the date of issuance of LOA at CMSS Stores.

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		<p>Tranche - 3 : 25% quantity to be delivered after 120 days to 150 days from the date of issuance of LOA at CMSS stores.</p> <p>Tranche - 4 : 25% quantity to be delivered after 180 days to 210 days from the date of issuance of LOA at CMSS stores</p>	Tranche - 4 : 25% quantity to be delivered after 361 days to 480 days from the date of issuance of LOA at CMSS stores	<p>Tranche-3: 20% quantity to be delivered between 91 days to 120 days from the date of issuance of LOA at CMSS stores.</p> <p>Tranche-4: 20% quantity to be delivered between 121 days to 150 days from the date of issuance of LOA at CMSS stores.</p> <p>Tranche-5: 20% quantity to be delivered between 151 days to 180 days from the date of issuance of LOA at CMSS stores.</p> <p>(Tranche-1 is PDI with conditional dispatch clearance & rest all are non PDI)</p>
		<p>Technical Specification- Packaging integrity test</p> <p>10 strips (Combipacks)</p>	<p>Technical Specification- Blister/ strip pack design and labelling (Blister/ Strip)</p> <p>Reasons- Blister and Strip both are different.</p>	Technical Specification- Blister/ strip pack design and labelling (Blister/ Strip)
		<p>Technical Specification-</p> <p>Study - Long Term Stability Storage Condition - 25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH</p>	<p>Technical Specification-</p> <p>Storage Condition - 25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/75% RH ± 5% RH</p> <p>In line with Indian climate (India under Zone IVb)</p>	As per technical Specifications, No Change
4.	M/s Oxalis	<p>Refer to Annexure I & IA – List of Product & Their Technical Specifications – Delivery Terms (b) :- For SCH. I</p> <p>Tranche - 1 : 25% quantity to be delivered within 60 from the date of issuance of LOA at CMSS Stores.</p> <p>Tranche - 2 : 25% quantity to be delivered between 60</p>	<p>The supply quantities for Tranche I, II, III and IV are significantly large.</p> <p>Since it takes 10 to 15 days to get the COA after production, it takes an extra 20–30 days to get the inspection reports after the goods have been inspected by CMSS. After then, it will take at least 30 days to send the goods to every state,</p>	<p>Revised delivery Schedule for all the three DSTB regimens is as follows:</p> <p>Tranche-1 : 20% quantity to be delivered within 60 days from the date of issuance of LOA at CMSS Stores.</p>

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		<p>to 90 days from the date of issuance of LOA at CMSS Stores.</p> <p>Tranche - 3 : 25% quantity to be delivered after 120 days to 150 days from the date of issuance of LOA at CMSS stores.</p> <p>Tranche - 4 : 25% quantity to be delivered after 180 days to 210 days from the date of issuance of LOA at CMSS stores</p> <p>3) Refer to Inspection Methodology (PDI/NON PDI) - Non-PDI (Inspection at Delivery Stages)</p>	<p>making delivery possible 75 days after the goods have been produced. Thus achieving Tranche 1- 25% in 90 days is challenging.</p> <p>1) We request that the tranche 1 quantity be reduced to 20% to be delivered in 90 days. The remaining 80% would thereafter be delivered in tranches II, III, or IV with the acceptance of partial deliveries with regard to each tranche's quantities.</p>	<p>Tranche-2: 20% quantity to be delivered between 61 to 90 days from the date of issuance of LOA at CMSS Stores.</p> <p>Tranche-3: 20% quantity to be delivered between 91 days to 120 days from the date of issuance of LOA at CMSS stores.</p> <p>Tranche-4: 20% quantity to be delivered between 121 days to 150 days from the date of issuance of LOA at CMSS stores.</p> <p>Tranche-5: 20% quantity to be delivered between 151 days to 180 days from the date of issuance of LOA at CMSS stores.</p> <p>(Tranche-1 is PDI with conditional dispatch clearance & rest all are non PDI)</p>
		<p>Refer to Point 18 (18.2) – Delays in Suppliers Performance (Page 33)</p> <p>:- If the supply reaches the designated consignee places or CMSS Warehouse after scheduled delivery date mentioned in LOA/P.O, liquidated damages will be levied @ 2.5% per week to be applied proportionately on per day basis up to a maximum of 10% of P.O. Cost, irrespective of the fact that whether the CMSS has suffered any damage/loss or not, on account of delay in effecting supply. If the last</p>	<p>1. Refer to this clause, we hereby request you to kindly remove this clause or to reduce the percentage of penalty per week.</p>	<p>No Change.</p>

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		scheduled delivery day happens to be a holiday the supply will be accepted on the next working day without any penalty.		
		Refer to point 10 (10.1 & 2) – Other Conditions :- (i) Central Medical Services Society (CMSS) will have the right to increase or decrease up to 25% of the quantity of goods and/or services specified in the schedule of requirements without any change in the unit price or other terms and conditions at the time of award of contract. (ii) In exceptional situation where the requirement is of an emergent nature and/ or it is necessary to ensure continued supplies from the existing vendors, the purchaser reserves the right to place repeat order up to 50% of the quantity of the goods and/or services contained in the running tender/contract up to a period of twelve months from the earliest date of Long Term agreement (LTA) at the same rate or a rate negotiated (downwardly) with the existing vendors considering the reasonability of rates based on prevailing market conditions and the impact of reduction in duties and taxes etc.	Refer to this clause we request you to remove this clause as our costing is based on tender quantities, so request to be keep the same quantity effective till the validity of the bid.	No Change
		Refer to Annexure I-A (A – Storage & Shelf Life) :- At least 5/6 th of the total stipulated Shelf Life must remain at the time of arrival at the consignee's warehouse. The Supplier will provide manufacturer's test data substantiating the claimed shelf life in the proposed package (Blister pack) Not only pharmaceuticals , but also the packaging components should also conform to	Refer to this clause we have long Term Stability data as per USP. We would like to bring to your kind attention that the quality and performance parameters in IP/BP/USP are all same and the specifications available in the stability data assigned by us are all well covered and very well in limit also. Hence request you to please consider.	Long term stability data of the quoted product has to be submitted as per clause 6.2(n) of the bid document.

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		<p>specifications suitable for use in a climate prevailing in India. The product supplied should have been subjected to long term stability conditions as per the below requirements:</p> <p>Study - Long Term Stability</p> <p>Storage Condition - 25 °C ± 2 °C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH</p>		
		<p>Refer to Annexure – I – List of Product & their Technical Specifications :-</p> <p>I- 4FDC –A – Strips of 28 Tablets. - 1,32,70,560</p> <p>II- 3FDC-A – Strips of 28 Tablets. - 2,32,58,880</p> <p>III- 2FDC –P – Strips of 28 Tablets. - 12,98,400</p>	Refer to this point, request you to confirm whether the given quantities are in Strips or Tablets, kindly confirm.	Tentative quantity is in Strips.
		Refer to page 42 – (Technical Specification - Primary Packaging) – Blister Strips should have perforations and spacing between tablets enough to allow removal by patients with finger deformities and easier separation of individual tablets from the strips	Refer to this point; this is to inform you that we have supplied in the current supply without perforations of individual tablets earlier. So therefore request you to remove this said clause.	Technical Specification - Primary Packaging) – Blister /Strips should have perforations and spacing between tablets enough to allow removal by patients with finger deformities and easier separation of individual tablets from the strips
		Refer to Pg 65, Blister Pack design and Labelling (blister)	Refer to clause, request you to accept Alu Alu Strip Pack.	Blister / Strips in Alu Alu pack is accepted.
		Refer to pg 83 – Checklist (Annexure-VII -Y) - Para-wise compliance of technical specification of the quoted item (Clause 6.2 y)	Request to please provide us the Format of the same.	There is no format for this, the compliance of technical specifications may please be provided.
All certificates issued by Chartered Accountant shall mandatorily include UDIN No.				