

CENTRAL MEDICAL SERVICES SOCIETY

Date: 31.01.2023

AMENDMENT NO. 4

Tender for Procurement of ARV Drugs for NACO

Tender Ref No.: CMSS/PROC/2022-23/ NACO/028

The following amendment in the subject bid document is made:

Sr. No.	Reference	Existing	Modified
1.	Bid Document Download End date & time	01.02.2023	05.02.2023
2.	Bid Submission End date & time	02.02.2023 till 3.00 P.M.	06.02.2023 till 3.00 P.M.
3.	Original Documents submission	02.02.2023 till 3.00 P.M.	07.02.2023 till 3.00 P.M.
4.	Bid Opening date & time	02.02.2023 till 4:00 PM	07.02.2023 till 4:00 PM

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



GM (Procurement)
Central Medical Services Society

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: - 31.01.2023

Minutes of Pre-bid Meeting for Procurement of NACO Drugs

TENDER No: CMSS/PROC/2022-23/NACO/028

Pre-bid conference held on 09.01.2023

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

SI. No.	Name of Representative	Name of Firm
1.	Mr. Arun Sharma	M/s Mylan Laboratories Limited
2.	Mr. Balakishore	M/s Micron Pharmaceuticals
3.	Ms. Rohini	M/s Macleods Pharmaceuticals Limited

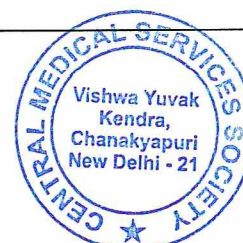
- Points raised by representatives of prospective bidders were discussed. After due consideration of the queries, the remarks are enclosed.



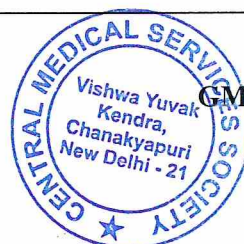
Sr. No.	Bidder	Query/ Classification Asked	Clarification/Amendment
	M/s Mylan Laboratories Limited	<p>1. Regarding Delivery Period (Tranche-I): As per the delivery period mentioned in the tender it is 60 days from the date of LOA for 1 tranche. Please note that the stocks are required in custom packing and specific marking we require lead time of at least 30 days to gear up and arrange required API, packing material and other arrangements to start production, moreover PDI is required to be done and once the test reports are received then only stocks to be dispatched. This whole process may take at least 15 days' time. Looking at these facts it is requested that for 1st tranche the delivery period may be amended as 90 days from the date of award of LOA for subsequent tranches it may be 60 days.</p> <p>2. Regarding Late supply penalty: Late supply penalty is 2.5% per week, which is far too high. Kindly consider the same as 0.5% per week.</p> <p>3. Regarding Packaging & Printing: In page 28, All the Tenderers are required to supply the product(s) with printed text "FWP SUPPLIES-NOT FOR SALE in red colour on the strips, blisters, vials, ampoules & bottles and in page no 38, Each pack will have the following printed in indelible ink across each label 'Central Government Supply Not for Sale. Kindly clarify which marking is required on the product</p>	<p><u>For Sch. I & II</u> Lot-I: - To be delivered within 75 days from the date of issues of LOA. Remaining lots will be same.</p> <p>No change</p> <p>As per artwork mentioned in the technical specification.</p>
	M/s Micron Pharmaceuticals	<p>1. Regarding Purchase Order: With reference to above mentioned subject, this is to bring to your kind notice that due to wide spread pandemic (COVID-19) during 2020-2021, there was lack of demand for ARV Drugs and our factory is not functional in its full capacity due to which we were not able to do the desire business during that period. So, we request you to kindly consider our Purchase Order for year 2022 to 2023 for Tender No: CMSS/PROC/2022-23/NACO/028, Procurement of ARV Drugs for NACO for the year 2022-23.</p>	No change.
	M/s Bharat Parenterals Ltd	<p>We would like to inform you that we are one of the past successful suppliers of ARV drugs to CMSS under National AIDS Control Programme and are very much interested to participate against the subject tender enquiry.</p> <p>Our submission against the above said tender enquiry for item Dolutegravir tablet is that as per data available and our information as on date there</p>	<p>For Sch. I : As per tender terms For Sch.II: Dolutegravir 10mg, Clause no 6.1.c:- The Tenderer should furnish the Manufacturing License (For domestic in form of 25 or 28 issued from State Licensing Authority) along with the approval of DCGI in form of 46 or CT-23 as new drug approved by DCGI valid on tender opening for</p>



		<p>are only two manufacturers who are having manufacturing & marketing experience with real time stability data of Dolutegravir 10mg tablet, as we are holding product permission of Dolutegravir 10mg tablet as well as for Dolutegravir 50mg tablet also with past experience and real time stability data of Dolutegravir 50mg tablet only. Here we would like to request you to kindly allow us to participate and consider our offer for item Dolutegravir 10mg tablet on the basis of manufacturing & marketing experience with long term stability data of Dolutegravir 50mg tablet. Further, please also note that if you give relaxation for the item Dolutegravir 10mg tablet in respect of clause no. 4(c), 6.2 (f) and 6.2 (L) and accept the past experience, market standing certificate and long term stability data of the same API with any other strength i.e. Dolutegravir 50mg etc. etc., you will not only have more parties but will receive competitive prices also for the same and this will definitely help to reduce the budgeting of the project.</p> <p>In view of the National Programme and to encourage a healthier competition we request you to kindly consider our above request and issue a suitable amendment in this regard & oblige.</p>	<p>each item 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.</p>
	M/s Macleods Pharmaceuticals Limited	<p>Please find attached the DCGI approval obtained for Dolutegravir 10mg DT from MPL Baddi manufacturing site.</p> <p>We have obtained it in April 2021. As it is a new product with DCGI approval received less than two years ago thus request you to waive off the requirements of "Market standing certificate, Performa for performance statement (annex IV) and List of item quoted (annex VI)".</p>	
		<p>6.2.1: Long term real time Stability data for at least 3 batches. As schedule II is a new product request you to remove this clause for real time stability data and accept the available data.</p>	<p>For Sch. I : As per tender terms For Sch. II: Clause 6 (l) : Accelerated Stability data for a period of 6 months in specified packing for at least for 3 batches and available Long term (Real Time) stability data of the quoted product is acceptable.</p>
		<p>Clause 6 (f): Market standing certificate issued by the Licensing Authority as a Manufacturer for each item quoted for at least last 2 years i.e. 2020-21 and 2021-22. However, this would not apply to regulated products which have been licensed by DCG (1) less than two years ago.</p> <p>Clause 6.2 (m): List of item quoted and relevant pharmacopoeia annual production for 3 years - Annex VI</p>	<p>For Sch. I : As per tender terms For Sch.II: Clause 6 (f) Requirement of Manufacturing and Market Standing Certificate/ Market Standing Certificate has been deleted.</p>



	<p>Clause 6.2(1): Performance statement - Annex IV</p> <p>Request you to remove Market standing certificate, Proforma for performance statement (annex IV) and List of item quoted (annex VI) clause for Schedule II - Dolutegravir 10mg DT considering the product is newly licensed by DCGI</p> <p>OR</p> <p>Accept the data for similar products under these clauses.</p>	
	<p>Clause 18.2: 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. Penalty of 2.5% per week is too high. Can this be reduced to a viable number?</p>	No Change
	<p>Regarding Technical Specification of ARV:- Drugs-Annexure 1A</p> <p>a. Please confirm if we can supply each pack without carton?</p> <p>b. Please also confirm if 10% leaflet per shipper quantity is acceptable?</p> <p>This is the request to meet the United Nations Sustainability Development Goals.</p> <p>c. Please confirm if we can supply in multi month dispensing pack for Schedule II i.e. 90 Tablet per container</p>	<p>a. Packing as per technical specifications.</p> <p>b. 1 Leaflet per bottle is required. Pack size as mentioned is the technical specification submitted by Programme Division.</p>
	<p>Delivery Schedule, Tranche 1: within 60 days of placing the LOA</p> <p>Can the delivery timeline for tranche 1 extended to 90-120 days?</p> <p>Also, please confirm if these timelines are for goods to get ready at the factory for inspection or to deliver the goods at the CMSS warehouses of different states?</p>	<p>For Sch. I & II</p> <p>Lot-I: - To be delivered within 75 days from the date of issues of LOA.</p> <p>Remaining lots will be same.</p>
	<p>Critical Date Sheet:</p> <p>Bid Submission End Date and Time: 17.10.2023 (03:00 PM)</p> <p>We have been given only two weeks to compile the documents. Considering the need to apply bank related documents again, request you to consider extending the deadline by a week-10 days.</p>	Please see amendment.



CM(Procurement)