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

Date: - 14.07.2023

Minutes of Pre-bid Meeting
For Procurement of ARV Drugs for NACO
CPP Tender ID: 2023_CMSS_759614_1, dated 27.06.2023
Pre-bid Meeting held on 03.07.2023 at 11:00 AM

1. Following officials were present during the Pre-bid meeting: -
   (i) Dr. A K Puri, DDG (NACO)
   (ii) DR. S P Bhavsar, Dy. Director (NACO)
   (iii) Mr. D Mohapatra, GM (Finance), CMSS
   (iv) Ms. Anjana, GM (Procurement), CMSS
   (v) Mr. Lava Mishra, AGM (Procurement), CMSS
   (vi) Ms. Akanksha Jain, AGM (QA), CMSS

2. Following representatives from prospective bidders were present during the Pre-bid meeting: -

Sr. No.	Name of Representative	Name of firm
1	Mr. Manoj Singh	M/s Aurobindo Pharma Ltd.
2	Mr. Pawan Chopra	M/s Bharat Parenterals
3	Mr. Gaurav Sharma	M/s Emcure Pharma
4	Mr. Alok Kumar	M/s J Duncan Healthcare Pvt. Ltd.
5	Mr. Mudit Gupta	M/s Hetero Labs Ltd
6	Mr. Arun Sharma	M/s Mylan Laboratories Ltd

3. Queries from following prospective firms were received via email: -

Sr. No.	Name of the bidders	
1	M/s Aurobindo Pharma Ltd	M/s J Duncan Healthcare Pvt. Ltd.
2	M/s Centurion Laboratories Pvt Ltd	M/s Hetero Healthcare
3	M/s Mylan Laboratories	M/s Emcure Pharmaceuticals Ltd
4	M/s Macleods Pharmaceuticals Ltd	

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

TABLE-A

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

Sr. No.	As per tender	Tender clause no.	Bidder's Representation	Bidder's Name	Response
1.	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 item means quoted/any ARV Drug Supply/Sale/Service order under loan license arrangement shall not be considered.	4 (i) & 6.2 (e)	We are requesting to change the supplied 10% of the quoted quantity of same product and allow us certificate from company CA.	M/s Aurobindo Pharma Ltd	**Amended as: -** Tenderer should have supplied 20% 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/Practicing Chartered Accountant 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 20% of the quoted/ similar items. **Similar Items here relate to the following: -** Similar item means quoted/any ARV Drug **Supply/Sale/Service order under loan license arrangement shall not be considered.**
			Tenderer should have supplied 20% of the quoted quantity of same or similar items during the **last three 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 item means quoted/any ARV Drug. Supply/Sale/Service order under loan license arrangement shall not be considered. **Historically, CMSS also amend the requirement of performance criteria 10% in previous CMSS Tender no 13 FY 2023-24. Copy enclosed for reference.** **OR** Tenderer should have **submit any three Purchase order copies of any Govt. entities/ Autonomous body for any quantity of ARV Drugs during the last two financial years**. Bidder should submit Purchase order copies and	M/s J Duncan Healthcare Pvt Ltd	

			certificate duly issued by statutory auditor of the company on his letter head by certifying the quantities manufactured and marketed to government institutions. **OR** Tenderer should have supplied 40% of the quoted quantity of same or **similar items (Any Tablet) 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 item means any Tablet (we have Manufacturing Lic, CoPP, MMC-Manufacturing and Marketing standing certificate, Capacity Certificate which is issued by Licensing Authority).** **We had supplied various tablets in CMSS, BPPI, Punjab Health Corp., RMSCL, UPMSCL, MPPHSC, Maharashtra Govt, OMSCL, BMSCL etc.** Supply/Sale/Service order under loan license arrangement shall not be considered. **OR** Relaxation of Prior experience criteria for MSME and Startup entities as per Deptt. of Expenditure order no F.20/2/2014- PPD (pt.) dt. 20/09/2016. **Copy enclosed.**		

			Stipulated tender conditions also amended in CMSS previous tender also. (ARV Tender No- 013 for 2023-24 for NACO, NACO HIV Kit Tender for 2022-23, NACO CD 4 Tender, DEC Tablet Tender for NVBDCP, First Line Anti TB Drugs etc. **Stipulated tender conditions restrictive to participate the bidder and eliminate the wider participation.** **Stipulated tender conditions not required by Any other Govt. Procurement entities.**		
			Kindly reduce to 10% for supplied qty only for SCH- I as per last cancelled tender.	M/s Centurion Laboratories Pvt Ltd.	
			Performance Clause: To encourage more competition and bearing in mind the COVID situation during the past 3 years, it is requested that the performance clause may be please be revised to 20% of total quoted quantity during the last 3 financial years.	M/s Hetero Healthcare	
2.	LIST OF PRODUCT & THEIR TECHNICAL SPECIFICATIONS	Annexure -I Pg No. 39	Our Abacavir 600 + Lamivudine 300 is for adults and therefore as per norm, it should not in scored, likewise our product is not scored. **Request you to please accept AL (A) without scored form.**	M/s Aurobindo Pharma Ltd	**Clarified as:** As per Technical Specifications of ARV drugs.
			As per the specification Tab. Tenofovir 300 mg + Lamivudine 300 mg + Dolutegravir 50 mg is required in a pack of bottles containing 30 tabs. Please note that globally this product is supplied in a bottle of 90 tabs. It is requested that kindly consider packing 90 tabs in the bottle for this product.	M/s Mylan Laboratories	**Clarified as:** As per Technical Specifications of ARV drugs.
3.	PROFORMA FOR PERFORMANCE STATEMENT	Annexure -IV Pg No. 60	i. Is Sales data required only for 2 Year or 3 year? ii. Is export data with USD Currency will be accepted	M/s Aurobindo Pharma Ltd	**Clarified as:** i. 2 years. ii. Yes.

			or need to be converted in INR?		
			Under Annexure IV, it has been mentioned need to be a signed by a Statutory Auditor of the company. However, we request to allow these Forms to be signed by a Practising Chartered Accountant.	M/s Emcure Pharmaceuticals Ltd	Kindly refer Table-B of this Corrigendum.
			Performance-Production Certificate as per Annexure IV: In line with the previous tender, it is requested that the said certificate issued by practicing CA may be accepted. Please note that getting such details attested by the statutory auditor is a time-consuming and tedious process, and we ascertain that the same may not be completed with the given timeline.	M/s Hetero Healthcare	Kindly refer Table-B of this Corrigendum.
			Request for last 3 years -20-21, 21-22 & 22-23 Or Allow any tablets instead of ARV as per earlier tenders before 2019.	M/s Centurion Laboratories Pvt Ltd.	No changes.
4.	In case fungus/termites develops within 15 days of delivery at specified locations, suppliers at their own cost would lift the entire batch from various locations and supply fresh replaced batches. For LD purposes the date of receipt of replaced batches would count.	15.6, Pg No. 29	We request you to only entire quantity of damage bottle should be replaced by supplier their own cost, not the total Batch quantity from different location. Please amend the same. This may happen during Pandemic & lockdown Time.	M/s Aurobindo Pharma Ltd	No changes.
5.	If the supply reaches the designated consignee places or CMSS Warehouse after scheduled delivery date mentioned in LOA/P.O, liquidated damages will be	18.2	We request you to please take LD as on minimum basis.	M/s Aurobindo Pharma Ltd	No changes.
			Please reduce liquidated damages from 2.5% per week to 0.5% per week.	M/s Mylan Laboratories	

	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.		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).**	M/s J Duncan Healthcare Pvt Ltd	
6.	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.	6.2 (u) & Pg No. 17	Request you to please allow the local content certificate from Cost Accountant of the company (in case of company)	M/s Aurobindo Pharma Ltd	**Clarified as:** The order of Department of Pharmaceuticals under Ministry of Chemicals and Fertilizers order no. F.No 31026/65/2020-MD dated 30.12.2020 shall be appliacable. For Schedule VIII, X & XIII, the estimated Procurement value is below Rs. 10 Crore.
			Local Content Declaration Certificate: Please clarify whether the local content certificate has to be issued by the statutory auditor or cost auditor of the company.	M/s Hetero Healthcare	
			As per tender terms and conditions Technical Bid Packet -1 Clause U " Tenderer should submit a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing-chartered accountant (in respect of suppliers other than companies) giving the percentage of local content at the same time of submission of the bid as per annexure - XVII. Whereas in the format of annexure XVII, it is mentioned as a statutory	M/s Mylan Laboratories	

			auditor/ Chartered accountant. You are requested to kindly make corrections in the format and add the Cost accountant in the same.		
7.	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.	6.2 (n)	For Sch. I & V: Long Term Stability Data may be provided in IH/any other previously approved pharmacopeia for at least for 3 batches, to support shelf life. **We will offer Stability data as in-house for TLD & DTG.**	M/s Aurobindo Pharma Ltd	**Amended as: -** i. Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life. However, For the drugs recently introduced drugs in the county (introduced in the last two years), the requirement for Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support shelf life shall be waived off. Point no (iii) shall be applicable. ii. Only for the drugs introduced in Indian Pharmacopoeia in the recent past (last 2yrs), Long Term (Real Time) Stability Data for previously approved Pharmacopoeia or In-house Standards shall be accepted, as the case may be. iii. Accelerated Stability data for a period of 6 months in
			Request to accept Long Term (Real Time) Stability Data for previously approved Pharmacopoeia or In-house Standards for the drugs introduced in Indian Pharmacopoeia in the recent past (last 2yrs).	M/s Mylan Laboratories	
			Tender Clause 6.n- **For Sch. I** Long Term (Real Time) Stability Data of the quoted product (30 tablets) **or pack of 90 tablets** 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. **Sch. I - TLD drug recently introduced in IP. Therefore, Long term stability data of the previous approved Pharmacopeia/IHS (In House Standard) should be accepted.** **Sch. II- Atazanavir 300mg+ Ritonavir 100mg drug recently introduced in IP. Therefore, Long term stability data of the previous approved Pharmacopeia/ IHS (In House Standard) should be accepted.** **For Sch. VI & VII** Long Term (Real Time) Stability Data of the quoted	M/s J Duncan Healthcare Pvt Ltd	

			product (Scored tablets) **or plain tablets** 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.		specified packing for at least 3 batches and available long term (Real Time) stability data as available for the quoted product shall be submitted. iv. Certificate of Analysis of one batch of the quoted product should be submitted.
			Stability Study of Drugs recently introduced in Indian Pharmacopoeia: A select few of the tendered drugs were included in IP in January 2022, prior to which they were manufactured as per In-House specification. These drugs are supplied primarily to NACO Centres in India and no other country imports drugs manufactured as per Indian Pharmacopeia. Thus, the demand for drugs manufactured as per IP is extremely limited. Thus, producing 3 stability batches in Indian Pharmacopeia may not be possible as the studies have not been initiated or the requisite number of batches have not been charged till date. In this regard, it is requested that the condition of stability study may be be relaxed. The condition may be revised as follows: "Stability Study reports for 3 batches to be provided in previously approved pharmacopeia/specification along with ongoing IP stability studies, if available.	M/s Hetero Healthcare	
8.	All goods must be of fresh manufacturing and must bear the dates of manufacturing and expiry. The bidder further warrants that all goods supplied will have, at least 5/6th of the minimum shelf life must remain at the time of delivery to the consignee. The supplier will provide manufacturer's stability test data substantiating the claimed shelf life in the offered package.	14.4 & Pg No. 27	Shelf life mentioned is 24 months. **Please confirm if 36 months shelf life is ok or not.**	M/s Aurobindo Pharma Ltd	**Clarified as:** 36 months shelf life is acceptable by Programme division.

9.	Subject to para (13.6) to para (13.9) above, CMSS will process the invoices submitted by the supplier and the payments against supply will be made within 60 days from the date of submission of all relevant documents to the CMSS provided the items supplied has been declared of STANDARD QUALITY, by the Empanelled Laboratory of CMSS.	13.10 & Pg No. 26	Please ensure that payments should be cleared within 60 days from the date of submission of Invoices. Currently payments are invariably delayed by Tender Authority.	M/s Aurobindo Pharma Ltd	**Clarified as:** As per Tender terms & conditions.
10.	**Delivery Schedule for SCH. I, II, III, IV, V, VI, VII, VIII, IX, X, XII and XIII** **TRANCHE I-** To be delivered within 90 days from the date of issue of LOA. **TRANCHE II-** To be delivered within 91-180 days from the date of issue of LOA. **TRANCHE III-** To be delivered within 181-330 days from the date of issue of LOA. **TRANCHE IV-** To be delivered within 331-480 days from the date of issue of LOA. **For SCH. XI** only **TRANCHE I-** To be delivered within 90 days from the date of issue of LOA. **TRANCHE II-** To be delivered within 91-180 days from the date of issue of LOA. **TRANCHE III-** To be delivered within 181-330 days from the date of issue of LOA.	**Annexure -I** Delivery Schedule Pg No. 40	Amend or confirm delivery period for proper Perf. Security validity (days) calculation.	M/s Centurion Laboratories Pvt Ltd.	**Clarified as:** As per Tender terms & conditions.
			Page No: 40, Annexure I (b)- Delivery schedule to be extended to 120 days for Tranche 1 & Tranche 2 instead of 90 days.	M/s Emcure Pharmaceuticals Ltd	**Clarified as:** As per Tender terms & conditions.
			For SCH. I to XIII **TRANCHE I- 25%** of the total quantity to be delivered within 120 days from the date of issue of LOA. Excluding PDI period. 120 days should be considered upto the PDI ordered date and given conditional dispatch clearance for supply of goods. **(Condition apply for PDI tranche)** **TRANCHE II- 25%** of the total quantity to be delivered within 121- 240 days from the date of issue of LOA. **TRANCHE III- 25%** of the total quantity to be delivered within 241- 360 days from the date of issue of LOA. **TRANCHE IV- 25%** of the total quantity to be delivered within 361- 480 days from the date of issue of LOA. **For Sch. I (TLD)- Huge Qty. Required Sch. I- Tranche I- 25% Qty.- 150 days.**	M/s J Duncan Healthcare Pvt Ltd	**Clarified as:** As per Tender terms & conditions.

			Reasons: - Huge Qty. & supply of API.		
			Refer to clause we hereby request you to kindly provide us the quantities need to supply in each tranche for our understanding & planning.	M/s Macleods Pharmaceuticals Ltd	**Clarified as:** Kindly refer Annexure I-B of tender document.
11.			Refer to this clause we hereby request you to kindly reconfirm that original CRC submission along with the post shipment documents is mandatory as the 1st lot (Tranche 1) is PDI & for Tranche II, III, IV lot CRC is not to submit as it is Non PDI. Please confirm.	M/s Macleods Pharmaceuticals Ltd	**Clarified as:** As per Tender terms & conditions.
12.	Para wise compliance of technical specification of the quoted items.	6.2 (y) & Pg No. 17	Provide format for the same.	M/s Centurion Laboratories Pvt Ltd.	**Clarified as:** As per Tender terms & conditions.
13.	Technical Specification & Artwork	Annexure - IA Pg No. 44	**Page No: 44, Annexure 1 A, Item No 6- ATV/r Tabs, Request for deletion of 60 tabs pack to offer level playing field to all manufacturers.** The Schedule II product is available universally in 30 tablets pack which is the monthly dose. Dispensing to patients of other ARV medicines co-administered with ATV/r tabs are also done in monthly pack. It appears only one manufacturer has a 60 tabs pack and including 60 tabs pack in tender amounts to undue advantage to the specific and only manufacturer offering 60 tabs packing. Instead pack size to be mentioned as 30 tabs per pack which is available with all manufacturers and is similar to dosing of other medicines.	M/s Emcure Pharmaceuticals Ltd	**Clarified as:** As per Technical Specifications of ARV Drugs.
14.		16.5 Inspection Methodology Pg No. 30	Considering the huge quantity to be supplied in this Tender, we request sampling quantity be defined & commensurate with the	M/s Emcure Pharmaceuticals Ltd	Kindly refer Table-B of this Corrigendum.

			requirements of the testing.		
15.			Tab. Tenofovir 300 mg + Lamivudine 300 mg + Dolutegravir 50 mg and Tab. Dolutegravir 50 mg and Tab. Dolutegravir 10 mg are under patent and supplied under agreement from the patent holder. So, this product is to be procured from the patent medicine pool suppliers. please confirm.	M/s Mylan Laboratories	Kindly refer Table-B of this Corrigendum.
16.			Please clarify whether tendered ARV products can be supplied without outer cartons. If yes, we would like to supply configuration PKI with a pad/book consisting of 1:10 per bottle or 1 :1 per bottle	M/s Mylan Laboratories	**Clarified as:** Product can be provided without outer carton, patient information leaflet (PKI) to be placed on the top of the Bottle in the ratio of 1:10 per bottle.
17.	Tenderer shall be a manufacturer of the quoted product and having valid own manufacturing license in the indicate pharmacopeia (in technical specification at Annexure IA) and Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia IP/BP/USP. The manufacturing license & COPP 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.	4 (c) & 6.2 (c)	Tenderer shall be a manufacturer of the quoted product and having valid own manufacturing license in the indicate pharmacopeia (in technical specification at Annexure IA) and Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia IP/BP/USP/**IHS (In House Standard).** The manufacturing license & COPP 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. For drugs that are not available in IP, other official Pharmacopeia (s) are applicable. If a drug is not available in any of the official pharmacopeias, 'In House' standards are applicable as per the Drugs and Cosmetics Act 1940 and the Rules therein. Bidder is requested to submit an undertaking that the drug is not available in IP or any	M/s J Duncan Healthcare Pvt Ltd	**Amended as: -** Tenderer shall be a manufacturer of the quoted product and having valid own manufacturing license in the indicate pharmacopeia (in technical specification at Annexure IA) and Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any of the pharmacopeia IP/BP/USP/IHS (In-House Standard). The manufacturing license & COPP 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.

			other approved pharmacopeia. **Loan License should not be eligible to bid.**		
18.	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.	4 (h)	Tenderer should quote at least for **25% 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. **Reasons: - Huge qty. required.**	M/s J Duncan Healthcare Pvt Ltd	No changes.
19.	A valid Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any pharmacopeia IP/BP/USP and a valid WHO-GMP.	6.2 (i)	A valid Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any pharmacopeia IP/BP/USP/ **IHS (In House Standard** and a valid WHO-GMP.	M/s J Duncan Healthcare Pvt Ltd	**Amended as: -** A valid Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any pharmacopeia IP/BP/USP/IHS (In-House Standard) and a valid WHO-GMP.
20.	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. 2020-21 & 2021-22 OR 2021-22 & 2022-23 for compliance of tender clause no. 4 (d).	6.2 (f)	**Amended as:** 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 & 2021-22 OR 2021-22 & 2022-23. However, this would not apply to regulated products which have been licensed by DCG (I) less than two years ago. **For All Schedules:** Market standing certificate may be provided in **IH/IP/BP/USP/any other previously approved pharmacopeia (Including Domestic & Export)** for at least last 2 financial years i.e. 2020-21 & 2021-22 OR 2021-22 & 2022-23. **Reasons:** -Sch. I - TLD drug recently introduced in IP. Sch. II- Atazanavir 300mg+ Ritonavir 100mg drug recently introduced in IP.	M/s J Duncan Healthcare Pvt Ltd	Kindly refer Table-B of this Corrigendum.

			Same amended in previous ARV tenders.		
21.	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.	6.2 (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.	M/s J Duncan Healthcare Pvt Ltd	Accepted.
22.	RTGS/NEFT e-receipt or Bank Guarantee (if applicable) in respect of EMD as per Clause 9 of this Tender document or in case of MSE, a copy of their valid registration certificate in support of their being an MSE and a notarised undertaking given in Annexure-VIII.	6.2 (a)	NOTARISED UNDERTAKING BY MSE COMPANIES (In 20-Rupees **or more rupees stamp paper**)	M/s J Duncan Healthcare Pvt Ltd	Accepted.
			Bid security declaration also allowed in compliance of GFR 2017 Rule no 170(iii). In place of a Bid security, the Ministries/ Departments may require Bidders to sign a Bid securing declaration accepting that if they withdraw or modify their Bids during the period of validity, or if they are awarded the contract and they fail to sign the contract, or to submit a performance security before the deadline defined in the request for bids document, they will be suspended for the period of time specified in the request for bids document from being eligible to submit Bids for contracts with the entity that invited the Bids. **Reasons: - Wider participation for small entities.**	M/s J Duncan Healthcare Pvt Ltd	No changes.
23.		Technical Specifications	**For Sch. I-** Tenofovir 300mg+	M/s J Duncan Healthcare Pvt	No changes.

			Lamivudine 300mg+ Dolutegravir 50mg (TLD)- Pack Size 30/ 90 Tablets. Same as per previous tender. **Please note if TIA not amend the same. Please accept the Long-Term Stability Data with 90 tablet pack and we will supply the 30-tablet pack after receipt of PO.**	Ltd	
24.		Technical Specifications	**For Sch. VI-** Zidovudine 300mg+ Lamivudine 150mg (Scored Tablet/ Plain Tablet) Same as per previous tender. We are previously supplier of the same. **Please note if TIA not amend the same. Please accept the Long-Term Stability Data of the Plain Tablet and we will supply the scored tablet after receipt of PO.**	M/s J Duncan Healthcare Pvt Ltd	No changes.
25.		Technical Specifications	**For Sch. VII** Abacavir 600mg + Lamivudine 300mg (Scored Tablet/ Plain Tablet) Same as per previous tender. **We are previously supplier of the same.** **Please note if TIA not amend the same. Please accept the Long-Term Stability Data of the Plain Tablet and we will supply the scored tablet after receipt of PO.**	M/s J Duncan Healthcare Pvt Ltd	No changes.
26.		Technical Specifications	**For Sch. X-** Tablet/ Capsule Ritonavir 100mg Previously amended in all ARV Tenders. Copy enclosed for same. **We are past supplier of**	M/s J Duncan Healthcare Pvt Ltd	**Clarified as:** Ritonavir 100mg is acceptable in capsule form by programme division.

			Cap. Ritonavir 100mg to CMSS		
27.			We request you to extend the deadline to submit the bid, as we need to get the FDA documents which takes time.	M/s Macleods Pharmaceuticals Ltd	No changes.
28.			Refer to Annexure I (Page no. 39), in the column of unit it is mention as Dolutegravir 10mg as Tablet. But refer to Page no. 46, it is mentioned as Dispersible and Scored Tablet. Refer to this clause we hereby request you to kindly re-confirm that we can supply Dolutegravir 10mg Dispersible Tablet.	M/s Macleods Pharmaceuticals Ltd	**Clarified as:** Tablet Dolutegravir 10mg is required in dispersible and scored form as per the Technical specification.

Note: - Above changes will be part of the tender document.

(Anjana)
GM (Procurement)

TABLE-B

Pursuant to the Pre-bid meeting discussion, following amendment in the subject tender enquiry is hereby authorized: -

<table>
<tr><th>Sr. No.</th><th>Tender Clause No. & Page No.</th><th>As per Tender</th><th>After Amendment</th></tr>
<tr><td>1.</td><td>Annexure-IV & Pg No. 60</td><td>Annexure-IV of FY 2020-21 and 2021-22 should be signed by Statutory Auditor</td><td>Annexure-IV of FY 2021-22 and 2022-23 should be signed by Statutory Auditor/ Practicing Chartered Accountant</td></tr>
<tr><td>2.</td><td>6.2 (aa) & Pg No. 17</td><td></td><td>Added para “aa” as follows:

In order to ensure no legal issue and no disruption in supply for NACO, bidders were requested for providing the undertaking on Rs. 100 Stamp Paper (For Sch. I, V and XIII) as per Annexure A or B (whichever applicable).</td></tr>
<tr><td>3.</td><td>Annexure- I & Pg No. 39</td><td>For Schedule XI

<table><tr><th>Item Name</th><th>Total Tentative Quantity</th></tr><tr><td>Zidovudine 60mg+ Lamivudine 30mg</td><td>75,05,280 Tablets</td></tr></table></td><td>For Schedule XI

<table><tr><th>Item Name</th><th>Total Tentative Quantity</th></tr><tr><td>Zidovudine 60mg+ Lamivudine 30mg</td><td>0 (Zero)</td></tr></table>
The bidders are requested not to quote for Schedule XI (Zidovudine 60mg+ Lamivudine 30mg). The BOQ as available on CPP portal cannot be edit at this stage. Therefore, the bidders are advised not to quote for for Schedule XI (Zidovudine 60mg+ Lamivudine 30mg) considering the revised quantity is 0 (Zero).</td></tr>
<tr><td>4.</td><td>4 (e-i) & Pg No. 10</td><td>Average Annual turnover for Tenderers in the last three years i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 shall not be less than the following: -

<table><tr><th>Schedule</th><th>Amount (in Rs.) for 100% quantity quoted</th><th>Amount (in Rs.) for 50% Quantity quoted</th></tr><tr><td>I</td><td>363,00,00,000</td><td>182,00,00,000</td></tr><tr><td>II</td><td>25,38,00,000</td><td>12,69,00,000</td></tr><tr><td>III</td><td>4,88,00,000</td><td>2,44,00,000</td></tr><tr><td>IV</td><td>12,00,000</td><td>6,00,000</td></tr><tr><td>V</td><td>4,04,00,000</td><td>2,02,00,000</td></tr><tr><td>VI</td><td>30,00,00,000</td><td>15,00,00,000</td></tr><tr><td>VII</td><td>19,00,00,000</td><td>10,00,00,000</td></tr></table></td><td>Average Annual turnover for Tenderers in the last three years i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 shall not be less than the following: -

<table><tr><th>Schedule</th><th>Amount (in Rs.) for 100% quantity quoted</th><th>Amount (in Rs.) for 50% Quantity quoted</th></tr><tr><td>I</td><td>181,01,51,797</td><td>90,50,75,898</td></tr><tr><td>II</td><td>12,68,74,654</td><td>6,34,37,327</td></tr><tr><td>III</td><td>2,43,58,235</td><td>1,21,79,118</td></tr><tr><td>IV</td><td>5,62,173</td><td>2,81,087</td></tr><tr><td>V</td><td>2,01,93,662</td><td>1,00,96,831</td></tr><tr><td>VI</td><td>14,82,37,665</td><td>7,41,18,832</td></tr><tr><td>VII</td><td>9,02,31,694</td><td>4,51,15,847</td></tr></table></td></tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td>
<table>
<tr><td>VIII</td><td>1,02,00,000</td><td>51,00,000</td></tr>
<tr><td>IX</td><td>13,00,00,000</td><td>7,00,00,000</td></tr>
<tr><td>X</td><td>2,09,00,000</td><td>1,05,00,000</td></tr>
<tr><td>XI</td><td>56,00,000</td><td>28,00,000</td></tr>
<tr><td>XII</td><td>8,34,00,000</td><td>4,17,00,000</td></tr>
<tr><td>XIII</td><td>1,14,00,000</td><td>57,00,000</td></tr>
</table>
</td>
<td>
<table>
<tr><td>VIII</td><td>50,97,996</td><td>25,48,998</td></tr>
<tr><td>IX</td><td>6,06,79,848</td><td>3,03,39,924</td></tr>
<tr><td>X</td><td>1,04,17,686</td><td>52,08,843</td></tr>
<tr><td>XI</td><td>Deleted</td><td>Deleted</td></tr>
<tr><td>XII</td><td>4,16,66,034</td><td>2,08,33,017</td></tr>
<tr><td>XIII</td><td>56,82,784</td><td>28,41,392</td></tr>
</table>
</td>
</tr>
<tr>
<td>5.</td>
<td>Annexure -I
& Pg No. 39</td>
<td></td>
<td>Added as follows:

<table>
<tr><th>Schedule No.</th><th>Tentative Sample Size for Pre-Dispatch Inspection</th></tr>
<tr><td>I</td><td>360 Tablets/Batch</td></tr>
<tr><td>II</td><td>180 Tablets/Batch</td></tr>
<tr><td>III</td><td>360 Tablets/Batch</td></tr>
<tr><td>IV</td><td>360 Tablets/Batch</td></tr>
<tr><td>V</td><td>270 Tablets/Batch</td></tr>
<tr><td>VI</td><td>180 Tablets/Batch</td></tr>
<tr><td>VII</td><td>360 Tablets/Batch</td></tr>
<tr><td>VIII</td><td>180 Tablets/Batch</td></tr>
<tr><td>IX</td><td>360 Tablets/Batch</td></tr>
<tr><td>X</td><td>360 Tablets/Batch</td></tr>
<tr><td>XII</td><td>360 Tablets/Batch</td></tr>
<tr><td>XIII</td><td>510 Tablets/Batch</td></tr>
</table>
</td>
</tr>
<tr>
<td>6.</td>
<td>4 (d) and 6.2 (f) & Pg No. 10 and 15</td>
<td>For all regulated products, the bidder should have at least two years i.e. 2020-21and 2021-22 OR 2021-22 and 2022-23 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.</td>
<td>For all regulated products, the bidder should have at least two years i.e. 2020-21and 2021-22 OR 2021-22 and 2022-23 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.

Only for the drugs introduced in Indian Pharmacopoeia in the recent past last 2yrs), Market standing certificate for previously approved Pharmacopoeia or In house Standards (Export/ Domestic) shall be accepted, as the case may be.

For the recently introduced drugs in the county (introduced in the last two years), the requirement for Market standing certificate shall be waived off.</td>
</tr>
<tr>
<td>7.</td>
<td></td>
<td></td>
<td>Defaulting vendors whose EMD/SD has been forfeited by CMSS in last two years shall be summarily rejected.</td>
</tr>
</table>

TABLE-C

REVISED CRITICAL DATE SHEET ARE AS UNDER:

Description	Scheduled date
Bid Document Download End Date & time	20.07.2023 till 03:00 PM
Bid Submission End Date and Time	20.07.2023 till 03:00 PM
Last date of submission of original documents	21.07.2023 till 03:00 PM
Bid Opening Date and Time	21.07.2023 at 04:00 PM

Note: - Apart from above, all other terms & conditions of tender document will remain unchanged.

GM (Procurement)

Annexure A (on Rs.100 Stamp Paper)

Sub.: Undertaking in respect of Schedule I – Tenofovir 300mg+ Lamivudine 300mg+ Dolutegravir 50mg (TLD), Schedule V- Dolutegravir 50mg and Schedule XIII Dolutegravir 10mg
Tender No.: CMSS/PROC/2023-24/NACO/021
Name of Tender: Online tender for Procurement of ARV Drugs for NACO

Dear Sir, I _____, S/o _____, Proprietor / Partner / Managing Director of _____ (Proprietary Concern / Firm / Company Ltd.) execute this Undertaking for myself and on behalf of _____ (Proprietary Concern / Firm / Company Ltd.):

We equivocally and irrevocably undertake that we, M/s _____ are approved for supply of the drug, Schedule I – Tenofovir 300mg+ Lamivudine 300mg+ Dolutegravir 50mg (TLD), Schedule V- Dolutegravir 50mg and Schedule XIII Dolutegravir 10mg (Drug Name) in the Indian Market. In regard to the same, we undertake as under:

1. That We undertake that Medicine Patent Pool in India is not applicable and we are not liable to any innovator for royalty etc. & are free to supply and market both the items in Indian Market without infringement of Patent Act.
2. That the patent application in respect of Tab. Dolutegravir 50 mg & 10 mg is under review for the Indian Market. We undertake that in case the patent is granted at a later date i.e. during technical evaluation / after placement of LOA / orders by CMSS, we M/s _____ and its directors / partners / proprietor / authorized signatories shall be solely responsible for any claims that may be raised by the molecule innovator.
3. That both Tender Inviting Authority & Tender Approving Authority shall not be parties to any criminal / civil case that may arise due to infringement of Patent by Molecular Innovator and we further indemnify CMSS and above authorities from any legal ramifications.
4. That in case supplies are interrupted at a later date for the reasons mentioned above, we understand that CMSS shall be at liberty to invoke actions as stipulated in tender including blacklisting and CMSS can arrange balance supplies from any other approved source / open market at our risk & cost.

We hope you will find the same in order.

Yours faithfully,
For _____,

Name
Designation

Annexure B (on Rs. 100 Stamp Paper)

Sub.: Undertaking in respect of Schedule I – Tenofovir 300mg+ Lamivudine 300mg+ Dolutegravir 50mg (TLD), Schedule V- Dolutegravir 50mg and Schedule XIII Dolutegravir 10mg
Tender No.: CMSS/PROC/2023-24/NACO/021
Name of Tender: Online tender for Procurement of ARV Drugs for NACO

Dear Sir,

I _____, S/o _____, Proprietor / Partner / Managing Director of _____ (Proprietary Concern / Firm / Company Ltd.) execute this Undertaking for myself and on behalf of _____ (Proprietary Concern / Firm / Company Ltd.):

1. We equivocally and irrevocably undertake that we, M/s _____ are approved for supply of the drug, **Schedule I – Tenofovir 300mg+ Lamivudine 300mg+ Dolutegravir 50mg (TLD), Schedule V- Dolutegravir 50mg and Schedule XIII Dolutegravir 10mg** (Drug Name) in the Indian Market. In regard to the same, we undertake as under:
2. M/s..... (Bidder Name) is approved for supply of the drug.....(Drug Name) in the Indian Market under the Medicine Patent Pool by the Patent Holder and there is no infringement.
3. That both Tender Inviting Authority & Tender Approving Authority shall not be parties to any criminal / civil case that may arise due to infringement of Patent by Molecular Innovator and we further indemnify CMSS and above authorities from any legal ramifications. We hope you will find the same in order.

Yours faithfully,
For _____,

Name
Designation

REVISED Annexure-III

DETAILS OF E.M.D. SUBMITTED

We herewith submit the EMD (**Annexure-XIV**) in favour of Central Medical Services Society for the following items.

Sch. No.	Item Name	UOM	Quantity in Bid	Quantity Quoted	% of the Bid Quantity	Amount of EMD Payable (in INR) for 100% quantity	Amount of EMD Payable (in INR) for 50% quantity	Amount of Bid Security
I	Tenofovir 300mg+ Lamivudine 300mg+ Dolutegravir 50mg (TLD)	Tablet	126,86,08,290			18,10,15,180	09,05,07,590	
II	Atazanavir 300mg+ Ritonavir 100mg	Tablet	3,93,33,660			1,26,87,465	63,43,733	
III	Lopinavir 100mg + Ritonavir 25mg	Tablet	2,62,66,213			24,35,824	12,17,912	
IV	Lopinavir 40mg + Ritonavir 10mg	Capsule/ Sachet	3,68,880			56,217	28,109	
V	Dolutegravir 50mg	Tablet	4,08,84,480			20,19,366	10,09,683	
VI	Zidovudine 300mg+ Lamivudine 150mg	Tablet	10,88,44,620			1,48,23,766	74,11,883	
VII	Abacavir 600mg + Lamivudine 300mg	Tablet	2,88,75,990			90,23,169	45,11,585	
VIII	Tenofovir 300mg+ Lamivudine 300mg	Tablet	38,18,609			5,09,800	2,54,900	
IX	Darunavir 600mg	Tablet	1,11,75,420			60,67,985	30,33,993	

X	Ritonavir 100mg	Tablet	1,13,15,700			10,41,769	5,20,884	
XI	Zidovudine 60mg+ Lamivudine 30mg	Tablet	75,05,280			Item deleted	Item deleted	
XII	Abacavir 60mg + Lamivudine 30mg	Tablet	8,89,99,560			41,66,603	20,83,302	
XIII	Dolutegravir 10mg	Tablet	1,50,11,580			5,68,278	2,84,139	

Note: - Above changes will be part of the tender document.

GM (Procurement)