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: - 18.10.2023

Corrigendum-8

Minutes of Pre-bid Meeting
For Procurement of Tablet Rifapentine 300mg+ Isoniazid 300mg for NTEP
CPP Tender ID: 2023_CMSS_764141_1, dated 28.07.2023
Pre-bid Meeting held on 02.08.2023 at 11:00 AM

1. Following officials were present during the Pre-bid meeting: -
   (i) Dr. Alok Mathur, Addl. DDG (NTEP)
   (ii) Mr. D Mohapatra, GM (Finance), CMSS
   (iii) Ms. Anjana, GM (Procurement), CMSS
   (iv) Mr. Lava Mishra, AGM (Procurement), CMSS
   (v) Ms. Akanksha Jain, AGM (QA), CMSS
   (vi) Mr. P S Vignesh Manan, Consultant (NTEP)

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

Sr. No.	Name of Representative	Name of firm
1	Mr. Alok Kumar	M/s J Duncan Healthcare Pvt Ltd.
2	Mr. Ram Iyer	M/s Lupin Ltd.
3	Mr. Vemlata Raman CV	M/s Lupin Ltd.
4	Mr. Rajeev, Mr. Ajay Agarwal	M/s Macleods Pharma
5	Ms. Kinjal Bhanushali, Mr. Arihant Sethia- Zoom	M/s Oxalis Ltd.

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

Sr. No.	Name of the bidders
1	M/s J Duncan Healthcare Pvt Ltd.
2	M/s Lupin Ltd.
3	M/s Oxalis Ltd.

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

Annexure-1

Pre-bid queries raised by the prospective bidders & Clarification/ Response by CMSS

Sr. No.	As per tender	Tender clause no. & Pg No.	Bidder's Representation	Bidder's Name	Clarification/ Response
1.	Tender Inviting Authority invites tender through online bid submission at CPPP website: https://eprocure.gov.in/eprocure/app for supply of Drugs to Central Medical Services Society for the year 2022-23.	**Pg No. 8**	Pg. no 8- Tender Inviting Authority invites tender through online bid submission at CPPP website: https://eprocure.gov.in/eprocure/app for supply of Drugs to Central Medical Services Society for the year 2023-24.	M/s J Duncan Healthcare Pvt Ltd.	**Clarified as:** As per tender terms & conditions.
2.	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. 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).	**4 (d) & Pg No. 10** **And 6.2 (f) & Pg No. 15**	Eligibility Criteria 4.d- Requirement of MMC should be deleted. Reasons- (i) Product introduced in India 28/06/2021. **(ii) As per drug and cosmetic act definition of new drug pg. 148- "a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval."** **In view of drug and cosmetic ACT drug should be considered in new drug. Because first approval in 28/06/2021. Copy of the same is enclosed for reference.** (iii) For compliance of point (ii) as new drug, Product permission is mandatory requirement from DCGI in shape of CT 23. As per available records & historically data, prospective bidders have obtained manufacturing license from DCGI in form of CT 23 in Month on May 2022 & July 2022. In view of the above explanation, requirement of MMC should be deleted.	M/s J Duncan Healthcare Pvt Ltd.	**Amended as: -** The tender clause no. 4 (d) & 6.2 (f) has been deleted.
3.	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) & Pg No. 16**	**Tender Clause 6.i-** Requirement of Certificate of Pharmaceutical Product (COPP) as recommended by WHO in any pharmacopeia IP/BP/USP/ In-House Standard. **In line with tender clause 4.c** A valid WHO-GMP should be submitted.	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.
			Please confirm valid CoPP of any country of the said product is acceptable.	M/s Oxalis Labs	

4.	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) & Pg No. 15**	**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.	M/s J Duncan Healthcare Pvt Ltd.	Accepted.
5.	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) & Pg No. 15**	**Tender Clause 6.d-** Requirement should be deleted in compliance of tender clause no. 4 (d).	M/s J Duncan Healthcare Pvt Ltd.	**Amended as: -** The tender clause no. 4 (d) & 6.2 (f) has been deleted.
6.	Non-Conviction Certificate issued by the FDA/ Drugs Controller of the State certifying that the firm/company (as well as the manufacturer firm in case of non-manufacturer bidders) has not been convicted and the products quoted have not been cancelled during last two years i.e. 2020-21 and 2021-22 OR 2021-22 and 2022- 23.	**6.2 (g) & Pg No. 16**	**Tender Clause 6.g-** Non-Conviction Certificate issued by the FDA/ Drugs Controller of the State certifying that the firm/company (as well as the manufacturer firm in case of non-manufacturer bidders) has not been convicted and the products quoted have not been cancelled during last two years i.e. **2021- 22 and 2022-23.**	M/s J Duncan Healthcare Pvt Ltd.	No changes.
7.	(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 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	**6.2 (n) & Pg No. 16**	Tender Clause 6.n- Requirement of Point (i) & (ii) Long Term Stability data should be deleted. **Only point (iii) & (iv) should be applicable.** **Reasons-** (i) Product introduced in India 28/06/2021. **(ii) As per drug and cosmetic act definition of new drug pg. 148-** ***"a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval."*** **In view of drug and cosmetic ACT drug should be considered in new drug. Because first approval in 28/06/2021. Copy of the same is enclosed for reference.** **(iii) For compliance of point (ii) as new drug, Product permission is mandatory requirement from DCGI in shape of From CT-23. Before issuance of Product permission in Shape of Form CT 23 with 24 months standard shelf life, DCGI examined the**	M/s J Duncan Healthcare Pvt Ltd.	No changes.

	batch of the quoted product should be submitted.		**accelerated data of the said product for a period of six months & BE study report. On behalf of Six Months Accelerated Stability data and BE report, DCGI issue product permission.** As per available records & historically data, prospective bidders have obtained manufacturing license from DCGI in form of CT 23 in Month on May 2022 & July 2022. In view of the above explanation, requirement of Long Term Stability Data should be deleted. As per similar of point no.4.d. & 6.f		
			Regarding clause (i): As the product Rifapentine300/Isoniazid 300mg tablets have become 'OLD" on 27th June 2023, considering the 1st DCGI approval granted on 28th June 2021, we request CMSS to remove from the clause ***(i): However, For the drugs recently introduced drugs in the county (introduced in the last two years), the requirement for Long Term (Real Time) Stability Dato 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.*** And just ask for: Long Term (Real Time) Stability Data of the quoted product in specified packing for at least for 3 batches, to support **24 months shelf life.** We request CMSS to ask supplier to submit SSD to support **24 months** shelf life. Clause (iii)-shall be removed. Regarding clause (iv): Please ask suppliers to submit COA containing CPNP results.	M/s Oxalis Labs	
8.	2) The WHO Prequalification Unit - Medicines Assessment Team (PQT/MED) has issued an FAQ around the Nitrosamine concerns for rifapentine and rifampicin in December 2020. This explicitly mentions the CPNP temporary limit of 20 ppm as accepted by USFDA and recognized by POT/MED as acceptable from the point of view of a benefit/risk assessment 3) Bidder has to submit an	**14.6 & Pg No. 28**	We would like to highlight the following points in this critical and sensitive above-mentioned product: 1. Based on the news published by WHO and USFDA on 26th August 2020, companies were made aware of the presence of CPNP (1-cyclopentyl-4-nitrosopiperazine) impurity in Rifapentine containing products and on 29th October 2020, USFDA/WHO published the	M/s Oxalis Labs	No changes.

	undertaking in technical bid that Certificate of Analysis (Cod) report shall be submitted by the manufacturers in compliance with tender clause 14.6 (1) and the prevailing global standards as mentioned at 14.6 (2) above at the time of supply. Annexure XXII Undertaking is attached.		acceptable control of 20 ppm for this, degradant, CPNP impurity. 2. Rifapentine is a sensitive molecule and is recommended to protect Rifapentine from high humidity and temperature *(as per USAID, product information Rifapentine, USP)*. So to stabilize a product at 30°C/75%, a robust formulation is required. And robustness can only be seen by studying long term stability data over 24-36 months. 3. As the said nitrosamine impurity i.e. CPNP is not just a general degradant impurity, but it is nitrosamine impurity and it is evident that this impurity shows high degradation at accelerated conditions of temperature and humidity. Hence for such sensitive molecule, and for such impurities, 6 months accelerated stability data is not significant for depicting the control of this impurity in real time. 4. In the published *TAG information note (Treatment Action Group) on N-nitrosamine and TB medicines, in February 2021,* it is very clearly instructed to manufacturer that any finished pharmaceutical product that tests above 20 ppm should be held back and not distributed to patient. Hence, it is not advisable to rely on 6 months accelerated data which cannot be extrapolated to the real time shelf-life condition. Based on the above technical rationale, it is not advisable to waive off the real time stability data. In fact, clause #2 of page 28 contradicts clause "n" of page 16. It cannot be proven that a product with less CPNP value at 6 months will comply the 20-ppm limit at shelf life. Therefore, we request your office to make stability data of 24 months mandatory in order to qualify technically for participation in this tender. We strongly request your office to reconsider the eligibility criteria for stability study data for such a critical product and for such a degradant carcinogenic impurity.		

9.	**Annexure-VIII** NOTARISED UNDERTAKING BY MSE COMPANIES (In 20-Rupees stamp paper).		Pg. no 8- Tender Inviting Authority invites tender through online bid submission at CPPP website: https://eprocure.gov.in/eprocure/app for supply of Drugs to Central Medical Services Society for the year **2023-24.**	M/s J Duncan Healthcare Pvt Ltd.	No changes.
10.	**For SCH. I** TRANCHE I- 35% of the total quantity to be delivered within 90 days from the date of issue of LOA. TRANCHE II- 35% of the total quantity to be delivered within 180-210 days from the date of issue of LOA. TRANCHE III- 30% of the total quantity to be delivered within 270-300 days from the date of issue of LOA.	Annexure -I & Pg No. 39	**Annexure I- Delivery Schedule** For SCH. I **TRANCHE I- 35% of the total quantity to be delivered within 120 days from the date of issue of LOA. (Reasons- PDI (PDI take 30 days time from inspection to dispatch clearance or conditional dispatch clearances should be given to supplier after inspection.)** **TRANCHE II- 35% of the total quantity to be delivered within 121- 240 days from the date of issue of LOA.** **TRANCHE III- 30% of the total quantity to be delivered within 241-360 days from the date of issue of LOA.** **OR** **TRANCHE I- 25% of the total quantity to be delivered within 90 days from the date of issue of LOA for Non PDI.** **TRANCHE II- 25% of the total quantity to be delivered within 91-180 days from the date of issue of LOA.** **TRANCHE III- 25 % of the total quantity to be delivered within 181- 270 days from the date of issue of LOA.** **TRANCHE IV- 25 % of the total quantity to be delivered within 271- 360 days from the date of issue of LOA.** Reasons:- Huge Qty. and new drug in India time & supply of API.	M/s J Duncan Healthcare Pvt Ltd.	**Amended as:** **For SCH. I** TRANCHE I- 25% of the total quantity to be delivered within 90 days from the date of issue of LOA. TRANCHE II- 35% of the total quantity to be delivered within 180-210 days from the date of issue of LOA. TRANCHE III- 40% of the total quantity to be delivered within 270-300 days from the date of issue of LOA.
			The quantities given for the supply in Tranche 1, 2 and 3 are huge (minimum 4 months production). From receipt of the LOA or PO, for the supply of drugs to CMSS, the supply period for Tranche I- 35% quantity as per the tender clause is 90 days which is not possible because of the below mentioned reasons: -	M/s Oxalis Labs	

			It will take 120 days to complete the production. After production, it takes a further 10 to 15 days to receive COA. After the products have been inspected by CMSS appointed inspector, it takes additional 20-30 days to receive the inspection reports. After receiving the reports, it takes at least 30 days for the goods to be delivered to the designated locations, making the delivery possible in roughly 100 to 130 days. In light of the fact that it will actually be unable to get first tranche dispatched in 90 days, we hereby request you consider or give us a minimum of days 180-200 days rather than 90 days in order to deliver timely.		
11.	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.	18.2 & Pg No. 33	**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).**	M/s J Duncan Healthcare Pvt Ltd.	No changes.
			Refer to this clause, we hereby request to remove this clause or reduce the percentage of penalty per week.	M/s. OXALIS LABS	
12.			**Requirement of EMD –** As per tender – Beneficiary Name: Central Medical Services Society As per CPPP- GM, CMSS **Pl. confirm or correct**	M/s J Duncan Healthcare Pvt Ltd.	**Clarified as:** As per Tender terms & conditions.

<table>
<tr>
<td>13.</td>
<td>Technical Specification-

Point 1- Description-

The FDCs in blister strip pack shall confirm to general requirements of tablets and the requirements under individual monograph given in IP or any other international Pharmacopeia of equivalent accuracy.

Each FDC Tablet Shall contain-

Isoniazid 300mg, Pharmacopeia (IP/BP/USP/Other International Pharmacopeia).

Rifapentine 300mg, Pharmacopeia (IP/BP/USP/Other International Pharmacopeia).

The quality of Isoniazid and Rifapentine shall conform to the requirements of the individual monograph given in IP or any other International Pharmacopeia of equivalent accuracy.</td>
<td>Annexure -IA & Pg No. 40</td>
<td>Point 1- Description-

The FDCs in blister/ strip pack shall confirm to general requirements of tablets and the requirements under individual monograph given in IP or any other international Pharmacopeia or In House Standard of equivalent accuracy.

Each FDC Tablet Shall contain-

Isoniazid 300mg, Pharmacopeia (IP).

Rifapentine 300mg, In House Standard. (Reasons- Rifapentine not available in any Pharmacopeia)

The quality of Isoniazid and Rifapentine shall conform to the requirements of the individual monograph given in IP or any other International Pharmacopeia or In House Standard of equivalent accuracy.</td>
<td>M/s J Duncan Healthcare Pvt Ltd.</td>
<td>Clarified as:

As per Tender terms & conditions.</td>
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<td>14.</td>
<td>Technical Specification-

Point 3- Blister strip pack design and labelling (Blister Strip)</td>
<td>Annexure -IA & Pg No. 41</td>
<td>Technical Specification-

Point 3- Blister/ strip pack design and labelling (Blister/ Strip)

Reasons- Blister and Strip both are different.</td>
<td>M/s J Duncan Healthcare Pvt Ltd.</td>
<td>Clarified as:

Agreed.
(Either Blister / Strip)</td>
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<td>15.</td>
<td>Technical Specification-

Point 9- Primary Packaging (Blister Strip)</td>
<td>Annexure -IA & Pg No. 42</td>
<td>Technical Specification-

Point 9- Primary Packaging (Blister / Strip)

Reasons- Blister and Strip both are different.</td>
<td>M/s J Duncan Healthcare Pvt Ltd.</td>
<td>Clarified as:

Agreed.
(Either Blister / Strip)</td>
</tr>
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<td>16.</td>
<td>Technical Specification-

Point B- Storage & Shelf Life

Shelf Life- Packaging Blister Strip Pack

<table>
<tr><td>Study</td><td>Storage Conditions</td></tr>
<tr><td>Long Term Stability</td><td>25 °C ± 2°C/ 60% RH ±5 % RH

OR

30 °C ± 2°C/ 65% RH ±5 % RH</td></tr>
</table>
</td>
<td>Annexure -IA & Pg No. 43</td>
<td>Technical Specification-

Point B- Storage & Shelf Life

Shelf Life- Packaging Blister/ Strip Pack

Reasons- Blister and Strip both are different.

<table>
<tr><td>Study</td><td>Storage Conditions</td></tr>
<tr><td>Long Term Stability</td><td>25 °C ± 2°C/ 60% RH ±5 % RH

OR

30 °C ± 2°C/ 75% RH ±5 % RH</td></tr>
</table>
In line with Indian climate (India under Zone IV b)</td>
<td>M/s J Duncan Healthcare Pvt Ltd.</td>
<td>Clarified as:

As per Tender terms & conditions.</td>
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</table>

17.	Bid submission end date is 12/08/2023 at 3.00PM		**Kindly extend the Bid submission end date is 20/08/2023 at 3.00PM**	M/s J Duncan Healthcare Pvt Ltd.	**Clarified as:** Accepted.
18.			Tender **CMSS/PROC/2023-24/NTEP/026** was cancelled after the bid was opened and the technical evaluation was processed. It is quite unprecedented and no reasons other than administrative reason has been mentioned as the reason for cancellation. The fresh tender issued **CMSS/PROC/2023-24/NTEP/033** is similar to the previous tender without any changes. **Query:** We request for the administrative reason which led to the cancellation of the tender **CMSS/PROC/2023-24/NTEP/026.**	M/s Lupin Ltd.	**Clarified as:** Kindly refer tender clause no. 11.3.
			This is just to understand why the said product tender is getting cancelled multiple times, this is the fourth time the tender is published with a deadline of 12th August. We again need to apply for fresh set of documents from bank, CA, auditors etc.	M/s Oxalis Labs	
19.	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	Source of API needs to be mentioned by the tenderer to ascertain local content requirement.	M/s Lupin Ltd.	**Clarified as:** As per Tender terms & conditions.
			We request CMSS to ask the suppliers to submit the source of Rifapentine Raw material & its grade in the tender submission.	M/s Oxalis Labs	
20.	Annual turnover statement for 3 years i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 should be furnished in the format given in Annexure-V duly certified by the Chartered Accountant. Copies of the audited Annual reports including the Balance Sheet and Profit and Loss Account along with all the annexure for the last three years i.e. 2019-20, 2020-21 and 2021-22 OR 2020-21, 2021-22 and 2022-23 duly certified by a practicing Chartered Accountant.	6.2 (k & l) & Pg No. 16	Refer to this clause we hereby request you to kindly accept the Annual Turnover Statement for 3 year i.e. 2019-20, 2020-21 and 2021-22. As 2022-23 audit report is under preparation. Kindly amend the year in Annexure-V as well, so that the information for 2019-20, 2020-21 and 2021-22 can be submitted.	M/s Oxalis Labs	**Clarified as:** As per Tender terms & conditions.
21.	Each page of submitted bid (along with tender document) be properly page numbered and shall be signed by the authorized signatory of the Tenderer with office seal.	6.2 (q) & Pg No. 17	Refer to this point, need clarification if whether we have to submit the tender booklet signed and stamped, as this point is not mentioned in the checklist of documents (Annexure VII). However, it was asked in previous tenders.	M/s Oxalis Labs	**Clarified as:** As per Tender terms & conditions.

22.	16.8 In the event of the samples of Drugs/goods supplied fails in quality tests or found to be not as per specifications at any of testing stages (as mentioned in clause no. 16.3), depending upon the type, nature and seriousness of failure, consequences resulting from such default, availability of alternate sources, the CMSS is at liberty to either: (i) Ask the supplier to replace the entire quantity of relevant batches, in addition to imposition of penalty @ 25% of batch supply cost or (ii) To make alternative purchase of the items of Drugs from other approved suppliers or in the open market or from any other Tenderer who might have quoted higher rates, at the risk and the cost of the supplier. (iii) In addition to (i) or (ii) above, action to debar/blacklist the supplier for suitable period, as decided by CMSS may also be initiated. In addition to forfeiture of Performance Security Deposit. (iv) In addition, the FDA/ Drugs Control Authority of concerned State will be informed for initiating necessary action on the Tenderer in their state. Security deposit will also be forfeited without any intimation. (v) The decision of the CMSS or any officer authorized by CMSS, as to the quality of the supplied drugs, medicines, vaccines etc., shall be final and binding.		Please be informed that we can replace the quantities of the relevant batch, if any batch fails in the testing at the lab designated by CMSS, provided testing is done as per Oxalis's methods of Analysis only.	M/s Oxalis Labs	**Clarified as:** As per Tender terms & conditions.

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

Sd/-
GM (Procurement)

Annexure-2

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

Sr. No.	Tender Clause No. & Page No.	As per Tender	After Amendment
1.	4 (f, g) and & Pg No. 11	Tender should not be submitted by the firm/company for the Product(s) for which the firm/ Company has been blacklisted/ banned/ debarred by CMSS/ State Governments/ Central Government/MOH&FW or any of the procurement agencies/Autonomous Bodies under the organisations stated above or if the Firm/Company is debarred as a whole by these organisations or any of its procurement agencies/Autonomous Bodies. Department of Expenditure, Ministry of Finance, GOI vide OM No: F.1/20/2018/PPD dtd. 02.11.2021 has issued guidelines on debarment of firms from bidding. The bidders blacklisted by any firm/company/ CMSS /State Govt. /Central Govt./its drug procuring agencies prior to issuance of DOE OM No: F.1/20/2018/PPD dtd. 02.11.2021 are eligible to bid if:- The blacklisting order has been revised post facto with clearly mentioning of category (i) of OM No: F.1/20/2018/PPD dtd. 02.11.2021 and that the debarment is limited to the issuing ministry/department/ organization only. Such vendors should clearly mention the status of blacklisting in the undertaking to be submitted in compliance with clause 6.1 (t) of tender documents and also attach revised blacklisting order. For blacklisting orders issued after 02.11.2021, the following shall be applicable: - • If the blacklisting order is issued by DoE, the bid of blacklisted bidder shall be out rightly rejected. • If the blacklisting order is issued by CPSUs, attached offices/autonomous bodies etc of MoHFW/ Other Ministries/ department and MoHFW/ Other Ministries/ department by written approval has delegated powers under Sr. no. (8) of OM dated 02.11.2021 to such organizations /bodies that the blacklisting is applicable only for the Procurement made by such organization /bodies, the bid of such blacklisted bidders shall be accepted for further evaluation. • In absence of such delegation extended by MoHFW/ Other Ministries/ department, the bid of the blacklisted bidder shall be rejected.	The bidder should not be blacklisted/ banned/ debarred (as whole) or for the tendered goods by CMSS, MoHFW and Department of Expenditure on the date of tender opening. Aforesaid debarred/banned/blacklisted bidder are not eligible to bid in the tender.
2.	6.2 (x) & Pg No. 17	Tenderer should submit an undertaking that ***"I/ We do hereby declare that our firm has not been blacklisted/ banned/debarred by CMSS/ State Governments/ Central Government/ MOH&FW or any of the procurement agencies/ Autonomous Bodies under the organizations stated above or the Firm/ Company (as whole)***	Tenderer should submit an undertaking that ***"I/ We do hereby declare that our firm has not been blacklisted/ banned/debarred by CMSS, MoHFW and Department of Expenditure or the Firm/ Company (as whole) has not been debarred as a whole by these organizations"***

		has not been debarred as a whole by these organizations or any of its procurement agencies/ Autonomous Bodies"	
3.	4 (i) and 6.2 (e) & Pg No. 11 and 15	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/ 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 40% of the quoted/ similar items. **Similar Items here relate to the following: -** Similar item means quoted/any TB Drug **Supply/Sale/Service order under loan license arrangement shall not be considered.**	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/ 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 40% of the quoted/ similar items. **Similar Items here relate to the following: -** Similar item means quoted/any TB Drug **Supply/Sale/Service order under loan license arrangement shall not be considered.** **Note:** Bidder should submit Purchase order copies along with the copy of GST invoice and E-way bill against the proof of execution of order for every submitted Purchase Order. If GST invoice is not applicable for any Purchase Order, the affidavit to that effect on stamp paper of Rs. 100/- should be submitted. For the supply of export, bidder should submit the copy of invoice, bill of lading/airway bill/any other document issued by custom authority against the proof of execution of order for every submitted Purchase Order.

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

Sd/-
GM (Procurement)

Annexure-3

REVISED CRITICAL DATE SHEET ARE AS UNDER:

Description	Scheduled date
Bid Document Download End Date & time	02.11.2023 till 03:00 PM
Bid Submission End Date and Time	02.11.2023 till 03:00 PM
Last date of submission of original documents	03.11.2023 till 03:00 PM
Bid Opening Date and Time	03.11.2023 at 04:00 PM

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

Sd/-
GM (Procurement)