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: - 02.08.2023

Minutes of Pre-bid Meeting
For Procurement of Sofosbuvir 400mg + Declatasvir 60mg (FDC) for NVHCP
CPP Tender ID: 2023_CMSS_762632_1, dated 19.07.2023
Pre-bid Meeting held on 25.07.2023 at 11:00 AM

1. Following officials were present during the Pre-bid meeting: -
   (i) Dr. Partha Rakshit, Joint Director (NVHCP)
   (ii) Dr. Preeti Madan, Joint Director (NVHCP)
   (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
   (vii) Mr. Sarvesh Mani Tripathi, NVHCP

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

Sr. No.	Name of Representative	Name of firm
1.	Mr. Mudit Gupta	M/s Hetero Labs Limited
2.	Mr. Arun Kumar Sharma, Mr. Ankush	M/s Mylan Pharmaceuticals Ltd.
3.	Mr. Rajneesh Bhalla	M/s Zydus Lifesciences Ltd.

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

Sr. No.	Name of the bidders		
1	M/s Mylan Laboratories Ltd.	M/s Zydus Lifesciences Ltd.	M/s Hetero Labs Limited

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. & Pg No.	Bidder's Representation	Bidder's Name	Response
1.	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	**Market Standing Certificate:** Due to the virtually non-existent demand for the tendered drug, we have not manufactured the FDC of Sofosbuvir 400mg + Daclatasvir 60mg in the past 2-3 years. As a result, providing the Market Standing Certificate (MSC) for this specific FDC is not feasible. However, we can readily submit separate MMCs for the individual salts i.e. Tab. Sofosbuvir 400mg and Tab. Daclatasvir 60mg. We believe that other companies might also encounter similar challenges due to the limited demand for this FDC. Therefore, we earnestly request you to kindly consider relaxing the MSC criteria for the tendered drug. Concurrently, it is requested that the Annexure IV & VI may be amended.	M/s Hetero Labs Limited	**Clarified as:** The tendered item in In-House Standard was first approved by DCG (I) on 12.06.2018 and was introduced in IP in December 2022. Hence, no changes.
			Manufacturing & Marketing Experience Certificate: Due to virtually no demand of the tendered drug, we have not manufactured the said FDC in the past 2-3 years and thus, providing the Manufacturing & Marketing Experience Certificate (MMC) shall not be possible. We can however submit MMC for individual salts i.e. separately for Tab. Sofosbuvir 400mg and Tab. Daclatasvir 60mg. We ascertain that other companies may face a similar issue. You are therefore requested to relax the criteria for MMC for the tendered drug.	M/s Zydus Lifesciences Ltd.	
			We can submit 2 years MMC in IP as per tender condition.	M/s Mylan Laboratories Ltd.	
2.	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.	6.2 (i) & Pg No. 15	**Certificate of Pharmaceutical Product (CoPP):** The drug is not being imported by any country and thus procuring CoPP from the Drug Controller may be an issue. Considering the unique circumstances surrounding the drug's current status and its unavailability in major markets for Hepatitis C treatment, we anticipate that other potential suppliers might also encounter similar challenges in obtaining the CoPP. Hence, we respectfully request the waiver of the CoPP condition for this particular tender. Instead, we propose that CoPPs for the individual drug components (Sofosbuvir 400mg and Daclatasvir 60mg) be sought, if demand necessary. This approach will enable us to demonstrate our commitment to adhering to the highest quality standards for	M/s Hetero Labs Limited	**Clarified as:** The tendered item in In-House Standard was first approved by DCG (I) on 12.06.2018 and was introduced in IP in December 2022. Hence, no changes.

			the components of the FDC that we will manufacture at our WHO-GMP compliant facility.		
			We can submit COPP in IP as per tender condition	M/s Mylan Laboratories Ltd.	
3.			Labelling will be as per page no. 41 i.e. 'Government of India- Not For Sale' and the condition mentioned at the page no 28 – the printed text is required as "NVHCP SUPPLIES – NOT FOR SALE" is not applicable	M/s Mylan Laboratories Ltd.	**Clarified as:** Labelling will be as per the technical specification.
4.			The certificate for supply of 40% of the quoted quantity of same or similar items will be accepted from Practicing CA.	M/s Mylan Laboratories Ltd.	**Clarified as:** Accepted. All certificate issued by Chartered Accountant (CA) and submitted by the bidder in their bid should contain UDIN number.
5.			We will provide Long term stability data in IH or IP as per tender condition.	M/s Mylan Laboratories Ltd.	**Clarified as:** As per tender terms & conditions.
6.			**Technical Specifications:** We acknowledge that the FDC of Sofosbuvir 400mg + Daclatasvir 60mg has been recently included in the Indian Pharmacopeia in Addendum 2021 of IP 2018, taking effect from January 1, 2022 onwards. However, we regret to inform you that the drug has not been manufactured by us or other major companies in the past 2-3 years. Consequently, we are unable to provide documents such as Certificate of Pharmaceutical Product & Stability Study Data in India Pharmacopeia. While we can furnish all other necessary documents in IH / previously approved pharmacopeia, we kindly request that you consider accepting these alternative formats for the mentioned documents, keeping in mind that unique circumstances surrounding this drug.	M/s Hetero Labs Limited	**Clarified as:** As per tender terms & conditions.
			Technical Specification of the Tendered Drug: Please note that FDC of Sofosbuvir 400mg + Daclatasvir 60mg has recently been included in Indian Pharmacopeia in Addendum 2021 of IP 2018 that came into effect January 1, 2022 onwards. It is brought to your notice that the drug has not been manufactured by us or other major companies in the past 2-3 years, and therefore, documents such as Certificate of Pharmaceutical Product & Stability Study Data can be provided in IH / any other previously approved pharmacopeia only.	M/s Zydus Lifesciences Ltd.	

			Further, the revised product permission may be issued now. In view of the same, it is requested that all documents except Drug Manufacturing License may be accepted in IH / previously approved pharmacopeia.		
7.			**Quantities to be provided in Annexure IV & VI:** As detailed in the above point, since no quantities have been manufactured in the past 2-3 years, the quantity of the tendered drug shall be mentioned as NIL. We can however provide data for similar drugs such as Tab. Sofosbuvir 400mg, Tab. Daclatasvir 60mg, Tab. Entecavir 0.5mg and Tab. Tenofovir. You are requested to amend the condition accordingly.	M/s Zydus Lifesciences Ltd.	**Clarified as:** As per tender terms & conditions.

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

-sd/-
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 - I & Pg No. 39</td><td>
<table>
<tr><th>Sch. No.</th><th>Item Name</th><th>Total Tentative Quantity</th><th>Unit</th><th>Detailed Technical Specifications of the Goods/Drugs</th><th>Order Distribution Criteria</th><th>Inspection Methodology (PDI/Non-PDI)</th><th>Consignee Location</th></tr>
<tr><td>I</td><td>Sofosbuvir 400mg + Declatasvir 60mg (FDC)</td><td>45,51, 120</td><td>Tablet</td><td>Annexure-IA</td><td>70:30 as per clause no. 13</td><td>Pre-Dispatch Inspection</td><td>CMSS Warehouses</td></tr>
</table>
</td><td>
<table>
<tr><th>Sch. No.</th><th>Item Name</th><th>Total Tentative Quantity</th><th>Unit</th><th>Detailed Technical Specifications of the Goods/Drugs</th><th>Order Distribution Criteria</th><th>Inspection Methodology (PDI/Non-PDI)</th><th>Consignee Location</th></tr>
<tr><td>I</td><td>Sofosbuvir 400mg + Daclatasvir 60mg (FDC)</td><td>45,51, 120</td><td>Tablet</td><td>Annexure-IA</td><td>100% quantity to L1 bidder</td><td>Pre-Dispatch Inspection</td><td>CMSS Warehouses</td></tr>
</table>
</td></tr>
<tr><td>2.</td><td></td><td></td><td>Kindly read Sofosbuvir 400mg + Daclatasvir 60mg (FDC) in place of Sofosbuvir 400mg + Declatasvir 60mg (FDC) where it is mentioned in the tender document.</td></tr>
<tr><td>3.</td><td>10.1 (i) & Pg No. 22</td><td>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.</td><td>Central Medical Services Society (CMSS) will have the right to increase up to 25% or decrease up to 50% 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.</td></tr>
</table>

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

-sd/-

GM (Procurement)