PHARMACEUTICALS AND MEDICAL DEVICES BUREAU OF INDIA (PMBI)

(Set up under the Department of Pharmaceuticals, Govt. of India)

8th& 9th Floor, Videocon Tower, Block E1, Jhandewalan Extension, New Delhi-110055

Amendment no. 1

No.: -PMBI/DRUG/RC-209/2023/-I **DATE: 21/04/2023**

Tender No. PMBI/DRUG/RC-209/2023 dated 31/03/2023 for supply of Drugs to Pharmaceuticals & Medical Devices Bureau of India (PMBI) for two years under rate contract.

Reference: - i. Queries of Pre-Bid meeting held on 11/04/2023 at 15:30 Hours in the premises of PMBI.
ii. Bidders query received through mails.

Pharmaceuticals and Medical Devices Bureau of India (PMBI) has invited e-Bids from the interested parties for "e- Tender for Supply of Drugs for the year 2023- 2025", vide Notice Inviting e-Tender No.- PMBI/DRUG/RC-209/2023. Detailed tender document containing eligibility criteria, selection mechanism, other terms and conditions are available on the website of Central Public Procurement Portal; www.eprocure.gov.in and PMBI Website; www.janaushadhi.gov.in.

After considering the suggestions/ queries received from the prospective bidders, the clarifications/ amendments regarding the specification and packing in tender document have been made as per Part-A & Part-B. All other technical specifications, terms, and conditions along with the tender schedule as mentioned in tender document shall remain unchanged.

The following amendment in Tender Document is hereby authorized:

Part-A

Sl. No.	Tender Clause/Reference	Query/Suggestion	Clarification/ Amendment
1	**Clause no. 3. A** Eligibility criteria (Technical bid -cover "A") at page 8 of the tender document.	The prospective bidders requested to consider their earlier deposited EMD amount or rotate the same for this current tender as EMD amount.	***No Change*** Tender condition prevails.
2	**Clause no. 3. Note (vi)** Eligibility criteria (Technical bid -cover "A") at page 10 of the tender document.	The Existing clause no. 3. I, is as follows:- "In case, if renewal application for Manufacturing License has been filled by the bidder or joint inspection has been carried out by the concerned Licensing Authority for the renewal of WHO-GMP certification and/or CoPP certification (as per official pharmacopoeia reference for such drug), scanned copy of same duly receipted by drug authorities must be uploaded along with the validity	Clause no. 3. Note (vi) is amended as: In case, if renewal application for Manufacturing License has been filed by the bidder or joint inspection has been carried out by the concerned Licensing Authority for the renewal of WHO-GMP certification and/or CoPP certification (any official pharmacopoeia), scanned copy of same duly receipted by drug authorities must be uploaded along with the validity certificate from State Licensing Authority (SLA). ***In case, if CoPP has been***

		certificate from State Licensing Authority (SLA). It shall be issued before the last date of submission of tender by the Licensing Authority."	***newly applied for the quoted product, the scanned copy of same duly receipted by drug authorities must be uploaded. However, Letter for award of Contract and purchase orders shall be issued only after submission of CoPP certificate for the awarded product or else the bid shall be considered invalid ab-initio.*** ***All above mentioned certificates should be issued before the last date of submission of tender by the Licensing Authority. For DC-2243 "Free Sale Certificate" issued by licensing Authority is acceptable.***
3	**Clause no. 3. Note (vii)** Eligibility criteria (Technical bid -cover "A") at page 10 of the tender document.	The Existing clause no. 3. Note (vi) is as follows: - "In case of Loan Licensee, the host company shall also have WHO-GMP (WHO-Good Manufacturing Practice) as per revised Schedule- 'M' of the manufacturing unit issued by the Drug Licensing Authority/ Drugs Control Department."	***No Change*** Tender condition prevails.
3	**Clause no. 18 P.** Methodology For Placing Orders at page 19 of the tender document.	The prospective bidders requested to make the rate contract for one year instead of two years to avoid fluctuation in raw material price.	***No Change*** Tender condition prevails.
4	**Clause no. 24** Handling and Testing Charges at page 26 of the tender document.	The prospective bidders requested to reduce the existing testing charges from 1.5% to 1 % of the supply value.	***No Change*** Tender condition prevails.

Part - B: -

I: The following Amendment in Specification is hereby authorized: -

Sl. No.	Tender Clause/ Reference	Sl. No. in the tender document	Drug Code	Generic Name of the Drug	Detailed Specification	Unit Size	Pack Size	Bidders Query	Amendment
1	Annexure - XII Clause 18 (M)	1	DC-2243	Oral Rehydration Salts IP (Liquid Form), Orange Flavour, 200 ml	Each 200 ml Tetra pack contains: Sodium 75 mOsmol/L Potassium 20 mOsmol/L Chloride 65 mOsmol/L Trisodium Citrate 10 mOsmol/L Dextrose 75 mOsmol/L Orange Flavour	01's	1's X 10	The bidder requested to amend the pack size of the drug	The pack size is amended as :- 1's X 30

2	Annexure - XII Clause 18 (M)	69	DC-2449	Oral Rehydration Salts IP (WHO Formula) Orange Flavour Sachet, 2	Each Sachet contains: Sodium Chloride IP 2.6 g Potassium Chloride IP 1.5 g Trisodium Citrate 2.9 g Dextrose (Anhydrous) 13.5 g Orange Flavour	01's	1's X 50	The bidder requested to amend the generic name of the drug	The generic name is amended as :- Oral Rehydration Salts IP (WHO Formula) Orange Flavour Sachet, 21g

All other contents of tender document remain unaltered. Bidders are requested to quote their rates considering all the terms and condition of the tender document. Bidders are also requested to refer MoM of the pre-bid meeting for clarification.

Sd/-
DGM (Procurement& Quality)
For & on behalf of PMBI
PH: 011-49431800 (811)