HLL Lifecare Limited
(A Government of India Enterprise)

एचएलएल लाइफ़केयर लिमिटेड
स्वस्थ पीढ़ियों के लिए नवान्वेषण

AMENDMENT NO.1 Dated 17.05.2023

Ref IFB No: HLL/SD/RBD/2023-24/TENDER/01 Dt: 12.05.2023

E-Tender ID: 2023_HLL_154000_1

The following amendment has been incorporated in the above mentioned tender for **Tender for Supply of Pharmaceutical products for onward supplies to Fiji.**

1. **ITB-Section 1; Technical Specification, Annexure-7 List of Quoted Products, Annexure-11 Check List Point No.5 and Annexure 13 Technical Specification Compliance Sheet,**

FOR

All Pharmaceutical products must be manufactured from a valid WHO GMP certified facility. If the offered products are manufactured from more than one unit, all the units shall be WHO-GMP certified.

MAY BE READ AS

All Pharmaceutical products must be manufactured from a valid WHO prequalified or USFDA approved facility. If the offered products are manufactured from more than one unit, all the units shall be WHO prequalified or USFDA certified.

2. **ITB-Section 2:Eligible bidders;**

FOR

Bidders are requested to submit the Tender processing fee and EMD online on or before the due date as mentioned in the NIT. The bidders who failed to submit the tender fee and EMD before the submission deadline will be considered as technically non responsive.

A Bidder should have following eligibility criteria as of the date of bid submission and should continue to meet these till the award of the contract.

1.1. Valid manufacturing license/Factory License (Self–attested Copy) along with the list of products manufactured in this facility wherever applicable. The quoted products should be highlighted for ready reference.

1.2. All Pharmaceutical products must be manufactured from a valid WHO GMP certified facility. If the offered products are manufactured from more than one unit, all the units shall be WHO-GMP certified.

1.3. Original Manufacturers having a minimum average annual turnover of Rs.5 Crores (Rupees Five Crores only) during the last three years i.e., 2019-20, 2020-2021 and 2021-2022 (original/ provisional) will only be eligible for participation.

Authorized agents are also eligible to bid provided their minimum average turnover in the last three years i.e., 2019-20, 2020-2021 and 2021-2022 (original/ provisional) is Rs. 1 crore (Rupees One crore only) and their Principal manufacturers meets the eligibility criteria for principal manufacturer as specified above.

In case of bid by authorized agents, manufacturers authorization form must be attached with the bid submitted. If an Original Manufacture is participating in the tender but wishes to make the supplies through its authorised agent, the manufacturer has to ensure that the Authorised agent meets all the eligible criteria mentioned, including minimum average turnover in the last three years i.e., 2019-20, 2020-2021 and 2021-2022 (original/ provisional) (original / provisional) is Rs. 1 crore (Rupees One crore only and documentary proof for the same has to be attached along with original

authorization letter.

1.4. The offered supply should comply with the provisions of the relevant standards for the product as applicable as amended up to date.

1.5. The Bidder must submit an in-house Certificate of Analysis for every batch of items being supplied along with other documents as called for in this tender along with consignment & IF asked for, the Firm has to submit Test Reports from NABL Accredited Labs.

1.6. Firm should submit a non-conviction certificate issued by the State Drug Controller, to the effect that the manufacturer has not been convicted under the Drugs and Cosmetics Act, 1940 and rules thereunder during the preceding three years and that no case / proceedings is pending against the manufacturer in any Court of Law in India under the Drugs & Cosmetics Act and for Non-Pharma items self-declared non conviction from bidder/manufacture to be submitted.

1.7. Primary manufacturers/authorized agents are allowed to participate in the Tender. Manufacturer's authorization form in original may be submitted by participating authorized agents.

1.8. Suppliers must ensure strict compliance to all statutory regulations, quality standards and Packing material specifications (as applicable) detailed in Annexure 5.

1.9. A firm/bidder shall submit only one bid in the same bidding process. A Bidder (either as a firm or as an individual or as a partner of a firm) who submits or participates in more than one bid will cause all the proposals in which the Bidder has participated to be disqualified.

1.10. Bidders who are eligible as per the Provisions of Public Procurement –Preference to Make in India Order No.P-45021/12/2017PP (BE-II), 2017 (published by Department for Promotion of Industry and Internal Trade) inclusive of the latest amendments are eligible to participate in the tender. A self declaration as per Annexure 14 with respect to this order must be submitted.

1.11. Any bidder from a country which shares a land border with India will be eligible to bid in this tender only if the bidder is registered with Competent Authority, as per order no F.No.6/18/2019-PPD dated 23-July-2020 (Rule 144 (xi) of the GFR, 2017 and any amendments issued thereafter) inclusive of the latest amendments issued by Ministry of Finance, GOI at Annexure 13 of this bidding document. The bidder must comply with all provisions mentioned in this order. A self-declaration as per Annexure 13 with respect to this order must be submitted.

1.12. Purchase preference to Micro and Small Enterprises (MSEs): Purchase preference will be given to MSEs as defined in Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Micro, Small and Medium Enterprises and its subsequent Orders/Notifications issued by concerned Ministry.

1.13. (a) Bidder/ manufacturer who has been de-recognized/debarred/banned/blacklisted by any other State Government / Central Govt. Organization /State Medical Corporations/ Director Health Services and or convicted by any court of law due to (i) quality failure of the drug(s) supplied (NSQ/ Spurious/ Adulterated/ Misbranded etc.) (ii) Submission of fake or forged documents (iii) Submission of incorrect information / Suppression of vital information & facts can't participate in the tender during the period of de-recognition / debarment/ Banned/blacklisted. Bidder / manufacturing unit which has been de-recognized/ debarred/banned/blacklisted by State Medical Corporation for any reasons can't participate in the tender during the period of de-recognition/debarment/banned.

(b) Any bidder who has been convicted by a competent court of law for supplying (NSQ/ Spurious/ Adulterated/ Misbranded etc.) drugs within a period of last 3 years from the date of floating of tender shall not be eligible to participate in the tender.

(c) Any bidder who is a distributor/ authorized agent then they should ensure that their Principal manufacturer is not been de-recognized/debarred/banned/blacklisted by any other State Government / Central Govt. Organization /State Medical Corporations/ Director Health Services and or convicted by any court of law due to (i) quality failure of the drug(s) supplied (NSQ/ Spurious/ Adulterated/ Misbranded etc.) (ii) Submission of fake or forged documents (iii) Submission of incorrect information / Suppression of vital information & facts can't participate in the tender during the period of de-recognition / debarment/ Banned/blacklisted. Bidder / manufacturing unit which has been de-recognized/ debarred/banned/blacklisted by State Medical Corporation for any reasons can't participate in the tender during the period of de-recognition/debarment/banned.

1.15. The products offered in the tender must be only manufactured in INDIA

1.16. For the Items quoted in the tender enquiry, firm will have to submit the samples on demand. If firm fails to submit the samples, the tender will be rejected.

1.17. MRP should not be printed on any package.

MAY BE READ AS

Bidders are requested to submit the Tender processing fee and EMD online on or before the due date as mentioned in the NIT. The bidders who failed to submit the tender fee and EMD before the submission deadline will be considered as technically non responsive.

A Bidder should have following eligibility criteria as of the date of bid submission and should continue to meet these till the award of the contract.

1.1. Valid manufacturing license/Factory License (Self–attested Copy) along with the list of products manufactured in this facility wherever applicable. The quoted products should be highlighted for ready reference.

1.2. **All Pharmaceutical products must be manufactured from a valid WHO prequalified or USFDA approved facility. If the offered products are manufactured from more than one unit, all the units shall be WHO prequalified or USFDA certified.**

1.3. Original Manufacturers having a minimum average annual turnover of Rs.5 Crores (Rupees Five Crores only) during the last three years i.e., 2019-20, 2020-2021 and 2021-2022 (original/ provisional) will only be eligible for participation.

Authorized agents are also eligible to bid provided their minimum average turnover in the last three years i.e., 2019-20, 2020-2021 and 2021-2022 (original/ provisional) is Rs. 1 crore (Rupees One crore only) and their Principal manufacturers meets the eligibility criteria for principal manufacturer as specified above.

In case of bid by authorized agents, manufacturers authorization form must be attached with the bid submitted. If an Original Manufacture is participating in the tender but wishes to make the supplies through its authorised agent, the manufacturer has to ensure that the Authorised agent meets all the eligible criteria mentioned, including minimum average turnover in the last three years i.e., 2019-20, 2020-2021 and 2021-2022 (original/ provisional) (original / provisional) is Rs. 1 crore (Rupees One crore only and documentary proof for the same has to be attached along with original authorization letter.

1.4. The offered supply should comply with the provisions of the relevant standards for the

product as applicable as amended up to date.

1.5. The Bidder must submit an in-house Certificate of Analysis for every batch of items being supplied along with other documents as called for in this tender along with consignment & IF asked for, the Firm has to submit Test Reports from NABL Accredited Labs.

1.6. Firm should submit a non-conviction certificate issued by the State Drug Controller, to the effect that the manufacturer has not been convicted under the Drugs and Cosmetics Act, 1940 and rules thereunder during the preceding three years and that no case / proceedings is pending against the manufacturer in any Court of Law in India under the Drugs & Cosmetics Act and for Non-Pharma items self-declared non conviction from bidder/manufacture to be submitted.

1.7. Primary manufacturers/authorized agents are allowed to participate in the Tender. Manufacturer's authorization form in original may be submitted by participating authorized agents.

1.8. Suppliers must ensure strict compliance to all statutory regulations, quality standards and Packing material specifications (as applicable) detailed in Annexure 5.

1.9. A firm/bidder shall submit only one bid in the same bidding process. A Bidder (either as a firm or as an individual or as a partner of a firm) who submits or participates in more than one bid will cause all the proposals in which the Bidder has participated to be disqualified.

1.10. Bidders who are eligible as per the Provisions of Public Procurement –Preference to Make in India Order No.P-45021/12/2017PP (BE-II), 2017 (published by Department for Promotion of Industry and Internal Trade) inclusive of the latest amendments are eligible to participate in the tender. A self declaration as per Annexure 14 with respect to this order must be submitted.

1.11. Any bidder from a country which shares a land border with India will be eligible to bid in this tender only if the bidder is registered with Competent Authority, as per order no F.No.6/18/2019-PPD dated 23-July-2020 (Rule 144 (xi) of the GFR, 2017 and any amendments issued thereafter) inclusive of the latest amendments issued by Ministry of Finance, GOI at Annexure 13 of this bidding document. The bidder must comply with all provisions mentioned in this order. A self-declaration as per Annexure 13 with respect to this order must be submitted.

1.12. Purchase preference to Micro and Small Enterprises (MSEs): Purchase preference will be given to MSEs as defined in Public Procurement Policy for Micro and Small Enterprises (MSEs) Order, 2012 dated 23.03.2012 issued by Ministry of Micro, Small and Medium Enterprises and its subsequent Orders/Notifications issued by concerned Ministry.

1.13. (a) Bidder/ manufacturer who has been de-recognized/debarred/banned/blacklisted by any other State Government / Central Govt. Organization /State Medical Corporations/ Director Health Services and or convicted by any court of law due to (i) quality failure of the drug(s) supplied (NSQ/ Spurious/ Adulterated/ Misbranded etc.) (ii) Submission of fake or forged documents (iii) Submission of incorrect information / Suppression of vital information & facts can't participate in the tender during the period of de-recognition / debarment/ Banned/blacklisted. Bidder / manufacturing unit which has been de-recognized/ debarred/banned/blacklisted by State Medical Corporation for any reasons can't participate in the tender during the period of de-recognition/debarment/banned.

(b) Any bidder who has been convicted by a competent court of law for supplying (NSQ/ Spurious/ Adulterated/ Misbranded etc.) drugs within a period of last 3 years from the date of floating of tender shall not be eligible to participate in the tender.

(c) Any bidder who is a distributor/ authorized agent then they should ensure that their Principal manufacturer is not been de-recognized/debarred/banned/blacklisted by any other State Government / Central Govt. Organization /State Medical Corporations/ Director Health Services and or convicted by any court of law due to (i) quality failure of the drug(s) supplied (NSQ/ Spurious/ Adulterated/ Misbranded etc.) (ii) Submission of fake or forged documents (iii) Submission of incorrect information / Suppression of vital information & facts can't participate in the tender during the period of de-recognition / debarment/ Banned/blacklisted. Bidder / manufacturing unit which has been de-recognized/ debarred/banned/blacklisted by State Medical Corporation for any reasons can't participate in the tender during the period of de-recognition/debarment/banned.

1.15. The products offered in the tender must be only manufactured in INDIA

1.16. For the Items quoted in the tender enquiry, firm will have to submit the samples on demand. If firm fails to submit the samples, the tender will be rejected.

1.17. MRP should not be printed on any package.

3. ITB-Section 2: PREPARATION OF BIDS , Documents to be submitted along with the Technical Bid

FOR

The online bid submitted by the bidder shall comprise the following:

a) Self Declaration as per Annexure 1

b) Bid form as per Annexure-2

c) Valid manufacturing license/Factory License/Drug Licence issued by state drug controller (Self–attested Copy) along with the list of products manufactured in this facility wherever applicable. The quoted products should be highlighted for ready reference.

d) All Pharmaceutical products must be manufactured from a valid WHO GMP certified facility. If the offered products are manufactured from more than one unit, all the units shall be WHO-GMP certified.

e) Firm should submit a non-conviction certificate issued by the State Drug Controller (For Category No.1), to the effect that the manufacturer has not been convicted under the Drugs and Cosmetics Act, 1940 and rules thereunder during the preceding three years and that no case / proceedings is pending against the manufacturer in any Court of Law in India under the Drugs & Cosmetics Act.

f) Power of attorney for signatory of bid in Rs 200/- stamp paper duly notarized.

g) Copy of GST Certificate (self-attested copy)

h) Copy of Permanent Account Number (Self–attested Copy)

i) Certificate of incorporation and associated documents like Article of Association and Memorandum of Association/Partnership deed/HUF etc as applicable. (Self–attested Copy).

j) Under taking letter for replacement of complaint/defective goods as per Annexure-3

k) Product List – Annexure 4

l) Suppliers must ensure strict compliance to all statutory regulations, quality standards and packing material specifications (as applicable) detailed in Annexure – 5

m) Authorization letter from manufacturer (Original) must be submitted as per Annexure 6.

n) List of all quoted products offered to HLL as per Annexure 7.

o) Documentary proof attested by Charted Accountant for establishing the average annual turnover of Original Manufacturers having a minimum average annual turnover of Rs.5 Crores (Rupees Five Crores only) during the last three years i.e. 2019-20, 2020-2021 and 2021-2022 (original/ provisional). In case of Authorized agents they must submit the documentary proof for minimum average turnover in the last three years i.e., 2019-2020, 2020-21 and 2021-2022 (original/ provisional) is Rs. 1 crore (Rupees One crore only) and documentary proof attested by Charted Accountant for establishing their Principal manufacturers meets the eligibility criteria for original manufacturer as specified above. In case of bid by authorized agents, manufacturers authorization form must be attached with the bid submitted.

p) If an Original Manufacture is participating in the tender but wishes to make the supplies through its authorised agent, the manufacturer has to ensure that the Authorised minimum average turnover in the last three years i.e., 2019-20, 2020-2021 and 2021-2022 (original/ provisional) is Rs.1 crore (Rupees One crore only) and documentary proof attested by Charted Accountant for the same has to be attached.

q) Annexure 8 - Category details of organization, in case of MSME / MSE, If the bidder is a MSME, it shall declare in the bid document the Udyog Aadhar Memorandum Number issued to it under the MSMED Act, 2006. If a MSME bidder do not furnish the UAM Number along with bid documents, such MSME unit will not be eligible for the benefits available under Public Procurement Policy for MSEs Order 2012."

r) Duly filled, signed and sealed Annexure 9 - Indemnity Certificate

s) Annexure 11 - Check List

t) Annexure 12 – Compliance To Rule 144 (XI) of GFR 2017 (Self Declaration)

u) Annexure 13 – Technical Compliance Sheet

v) Annexure 14 - Make In India Preference (Self Declaration)

w) Annexure 15 - Pre Contract Integrity Pact

x) Annexure 16- Fall Clause Declaration

MAY BE READ AS

The online bid submitted by the bidder shall comprise the following:

a) Self Declaration as per Annexure 1

b) Bid form as per Annexure-2

c) Valid manufacturing license/Factory License/Drug Licence issued by state drug controller (Self–attested Copy) along with the list of products manufactured in this facility wherever applicable. The quoted products should be highlighted for ready reference.

d) **Bidder must submit valid WHO Pre-Qualification for products/USFDA approval for manufacturing facility**

e) Firm should submit a non-conviction certificate issued by the State Drug Controller (For Category No.1), to the effect that the manufacturer has not been convicted under the Drugs and Cosmetics Act, 1940 and rules thereunder during the preceding three years and that no case / proceedings is pending against the manufacturer in any Court of Law in India under the Drugs & Cosmetics Act.

f) Power of attorney for signatory of bid in Rs 200/- stamp paper duly notarized.

g) Copy of GST Certificate (self-attested copy)

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t) Annexure 12 – Compliance To Rule 144 (XI) of GFR 2017 (Self Declaration)

u) Annexure 13 – Technical Compliance Sheet

v) Annexure 14 - Make In India Preference (Self Declaration)

w) Annexure 15 - Pre Contract Integrity Pact

x) Annexure 16- Fall Clause Declaration

All relevant clauses of the tender document are to be read in accordance with the above change and in case if any bids were already submitted, if required you may resubmit the documents in compliance of the above amendment. All other specifications, terms and conditions of the original tender document shall remain unchanged.

Deputy General Manager (SD-RBD)