AMENDMENT NO.1 Dated 25.06.2021

AMENDMENT TITLE:

Inclusion of points in the Eligibility of Bidders (Clause 2), Documents to be submitted along with the Technical Bid (Clause 8.2.1) and Indicative Quantity per UOM in the Product List (Annexure 04) of the tender document.

Ref No: HLL/SD/RBD/2021-22/TENDER/01 dt: 18.06.2021

TENDER TITLE:

Tender for Supply of Anti-HIV Drugs for onwards supplies to Rwanda (Re-tender)

The following points have been incorporated in the bid document for the above tender.

Point No. 1: Inclusion of an additional point as Clause 2.9 in the Clause 2 of Eligibility of Bidders under Instructions to the Bidders of the tender document

FOR

2. ELIGIBILITY OF BIDDERS

2.1. Bidders are requested to submit the Bid Securing Declaration as per Annexure 13

2.2. A Bidder should have following eligibility criteria to submit bids against this tender.

2.2.1. Original Manufacturers having a minimum average annual turnover of Rs. 15 Crores (Rupees Fifteen Crores only) during the last three years i.e. 2017-2018, 2018-19 and 2019-2020 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., 2017-2018, 2018-19 and 2019-2020 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 authorized agent, the manufacturer has to ensure that the Authorized agent meets all the eligible criteria mentioned, including minimum average turnover in the last three years i.e., 2017-2018, 2018-19 and 2019-2020 is Rs. 1 crore (Rupees One crore only and documentary proof for the same has to be attached along with original authorisation letter.

2.2.2. For Drugs/Medicines, the manufacturer should have valid WHO-Prequalified/US FDA approved certificates.

2.2.3. For Items Covered under Drugs and Cosmetics Rules, 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.

2.2.4. For Items Covered under Drugs and Cosmetics Rules, the firm should have a valid drug manufacturing license from the State Drug Controller and must submit a copy of the same.

2.2.5. The Bidder shall submit Certificate of Analysis both in-house and NABL accredited external laboratory for every batch of drug being supplied along with other documents as called for in this tender along with consignment.

2.2.6. The Bidder shall submit CoPP of the product along with the technical bid and also along with the consignment.

2.2.7. The Bidder must submit Certificate of origin for every batch of drug being supplied along with other documents as called for in this tender along with consignment.

2.3. The bidder must submit the technical dossier-product wise, which contains the latest three batch wise Certificate of Analysis both from in-house laboratory and NABL accredited laboratory, Certificate of origin, certificate of good manufacturing practices for the concerned manufacturing facility and CoPP of the product along with their technical bid in the tender. The soft copy of the same shall be submitted along with the technical bid and hard copy shall be submitted for the supplied batches at the time of supply along with the consignment.

2.4. 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.

2.5. All Injectables are to be manufactured as per USP/ BP standards.

2.6. The products offered in the tender must be only manufactured in INDIA and relevant manufacturing licenses along with product list to be submitted.

2.7. MRP should not be printed on any package.

2.8. Labels and leaflets of all pharmaceutical products shall be in **English and French**. There is also a branding requirement in **English and French** for the secondary and territory packaging. The artwork details of all the above shall be mentioned in the purchase order.

MAY BE READ AS

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2.9. Bidders have to submit artworks of labels for primary, secondary and tertiary packaging (as applicable), and artwork of the Instructions for Use (IFU) along with the technical bid. This shall form part of the technical evaluation parameter. Supplier need to make the supplies as per the approved artworks only.

Point No. 2: Inclusion of additional points as Clause 8.2.1.XXII & Clause 8.2.1.XXIII in the Clause 8.2 of Documents to be submitted along with the Technical Bid under Instructions to the Bidders of the tender document

FOR

8.2. Documents to be submitted along with the Technical Bid

8.2.1. The online bid submitted by the bidder shall comprise documentary proof of the following:

I. Self Declaration as per Annexure 1

II. Bid form as per Annexure-2

III. Valid manufacturing license (Self–attested Copy) along with the list of products manufactured in this facility. All the quoted products should be highlighted for ready reference. This document also need to be submitted during the time of supply.

IV. For Drugs/Medicines, the manufacturer should submit copy of valid WHO-prequalified/US FDA approved certificate for the quoted product.

V. The Bidder shall submit valid CoPP certificate of the products quoted.

VI. The bidder shall submit soft copy of the technical dossier-product wise, which contains the latest three batch wise Certificate of Analysis both from in-house laboratory and NABL accredited laboratory, Certificate of origin, certificate of good manufacturing practices for the concerned manufacturing facility and CoPP of the product

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

VIII. Copy of GST Certificate (self-attested copy)

IX. Copy of recent Non Conviction certificate issued by state drug controller.

X. Copy of Permanent Account Number (Self–attested Copy)

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

XII. Under taking letter for replacement of complaint/defective goods as per Annexure-3

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

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

XV. Documentary proof for establishing the average annual turnover of Original Manufacturers having a minimum average annual turnover of Rs.15 Crores (Rupees Fifteen Crores only) during the last three years i.e. 2017-2018, 2018-19 and 2019-2020. In case of Authorized agents they must submit the documentary proof for minimum average turnover in the last three years i.e., 2017-2018, 2018-19 and 2019-2020 is Rs. 1 crore (Rupees One crore only). and documentary proof 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.

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., 2017-2018, 2018-19 and 2019-2020 is Rs. 1 crore (Rupees One crore only)and documentary proof for the same has to be attached

XVI. 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."

XVII. Duly filled, signed and sealed Annexure 9 - Indemnity Certificate

XVIII. Annexure 10- Requisition for Online Payment (DELETED)

XIX. Annexure 11 - Performance Bank Guarantee Format

XX. Annexure 12 - Check List

XXI. Duly filled, signed and sealed Annexure 13 – Bid Securing Declaration

MAY BE READ AS

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V. The Bidder shall submit valid CoPP certificate of the products quoted.

VI. The bidder shall submit soft copy of the technical dossier-product wise, which contains the latest three batch wise Certificate of Analysis both from in-house laboratory and NABL accredited laboratory, Certificate of origin, certificate of good manufacturing practices for the concerned manufacturing facility and CoPP of the product

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

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X. Copy of Permanent Account Number (Self–attested Copy)

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

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XXII. **Artworks of labels for primary, secondary and tertiary packaging (as applicable), and artwork of the Instructions for Use (IFU). This shall form part of the technical evaluation parameter. Supplier need to make the supplies as per the approved artworks only.**

XXIII. **All other documents as mentioned in Clause 2 of Eligibility of Bidders under Instructions to the Bidders of the tender document**

Point No. 3: **Inclusion of an additional statement as a NOTE along with Annexure - 04 of the tender document**

FOR

Annexure-04

PRODUCT LIST

TENDER No – HLL/SD/RBD/2021-22/Tender/01 Dated 18.06.2021

SL NO	COMPOSITION / PRODUCT DETAILS	UNIT	Indicative Quantity Per UOM (Tab/Cap/inj/Bottle/Per Piece)
1	Atazanavir and Ritonavir 300/100mg	Pack of 30 Tablets	7300 packs (apx.)
2	Dolutegravir 50mg	Pack of 30 Tablets	7300 packs (apx.)

MAY BE READ AS

Annexure-04

PRODUCT LIST

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SL NO	COMPOSITION / PRODUCT DETAILS	UNIT	Indicative Quantity Per UOM (Tab/Cap/inj/Bottle/Per Piece)
1	Atazanavir and Ritonavir 300/100mg	Pack of 30 Tablets	7300 packs (apx.) *
2	Dolutegravir 50mg	Pack of 30 Tablets	7300 packs (apx.) *

NOTE: * **The quantities mentioned above are only the indicative quantities, and may increase or decrease based on the prices being quoted and budget earmarked for this procurement.**

All relevant clauses of the tender document are to be read in accordance with the above change and documents to be submitted are to be in compliance of the above. All other specifications, terms and conditions of the original tender document shall remain unchanged.

Deputy General Manager (RBD)
Sourcing Division
HLL Lifecare Ltd.
HLL Bhavan, Poojappura,
Thiruvananthapuram