AMENDMENT NO.1 Dated 27.03.2019

Ref No: HLL/SD/RBD/2018-19/TENDER/11 Dt: 14.03.2019

Title: Supply of Pharmaceutical Products for onward supplies to foreign countries

The following amendment has been incorporated to the bid document for the above tender;

1. **Minimum Eligibility Criteria - Page No. 6**

   FOR

   Point No. 3

   The manufacturing facility must be approved by US FDA and the products quoted must be approved by US FDA.

   MAY BE READ US

   The manufacturer should have either WHO Pre-Qualification for Products/USFDA Approval for Manufacturing Facility/EU GMP for Manufacturing Facility/ Country Registration for Products at MALAWI

2. **Mandatory documents to be submitted along with Technical bid – Page No.8**

   A. For Manufacturers

   FOR

   Point No. 5

   Copy of US FDA certificate along with the list of products approved by US FDA. (Self-attested copy)

   MAY BE READ US

   Should submit copy of either WHO Pre-Qualification for Products/USFDA Approval for Manufacturing Facility/EU GMP for Manufacturing Facility/ Country Registration for Products at MALAWI

3. **Mandatory documents to be submitted along with Technical bid – Page No.8**
   B. <u>For Authorized Agents</u>

   FOR

   Point No. 5

   Copy of US FDA certificate along with the list of products approved by US FDA.

   MAY BE READ US

   Should submit copy of either WHO Pre-Qualification for Products/USFDA Approval for Manufacturing Facility/EU GMP for Manufacturing Facility/ Country Registration for Products at MALAWI

4. **Annexure 10 – Check List**

   FOR

   Sl. No. 5

   Copy of valid WHO GMP Certificate along with product. From the product list, the quoted products should be clearly highlighted

   MAY BE READ US

   Should submit copy of either WHO Pre-Qualification for Products/USFDA Approval for Manufacturing Facility/EU GMP for Manufacturing Facility/ Country Registration for Products at MALAWI

5. **Annexure 9 – List of Quoted product**

   FOR

   Column - 9

   US FDA approved (Yes/No)

   MAY BE READ US

   Either WHO Pre-Qualification for Products/USFDA Approval for Manufacturing Facility/EU GMP for Manufacturing Facility/ Country Registration for Products at MALAWI

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.

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