Amendment No. 1

Subject:- e-Tender No. BPPI/DRUG-051/2017 Dated 22/05/2017 for supply of 53 Drugs for Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) to Bureau of Pharma Public Sector Undertakings of India (BPPI).

The following amendment in subject e-tender's document is hereby authorized:-

FOR:-

Clause 2 (b) (ii) Average Annual turnover of manufacturer in the last three years i.e.2013-14, 2014-15 and 2015-16 shall not be less than **Rs. 20 Crores.** In case of loan licensees and Marketer, average annual turnover of manufacturer in the last three years i.e. 2013-14, 2014-15 and 2015-16 shall not be less than **Rs. 20 Crores.**

READ:-

<u>clause 2 (b) (ii)</u> Average Annual turnover of manufacturer in any of the last three years i.e. 2014-15, 2015-16 and 2016-2017 should be atleast **Rs. 20 Crores (but not less than Rs 10 crores in any of the year**

or

manufacture should have gross fixed plant machinery assets not less than Rs 10 crores in any of last the two financial years i.e. 2015-16, 2016-17 as per balance sheet.

FOR :-

- **Clause 5. ii (b)** The Price preference up to 10% over L1 bidder (if not offering bio-equivalent product) shall be given to the bidder having Bio-equivalence studies from DCG(I) approved centres/laboratories /drug authorities of concerned country for imported drug and the bidder offering Bio-equivalence studies shall be awarded contract.
- (c) The bidders are required to offer maximum shelf life of their quoted product complying Drug & Cosmetic Act 1940 and rules 1945 amended up to date if any. Additional price preference up to 2% per extra quarter (three months) of shelf life subject to maximum 10% (5 quarters i.e. 15 months) over L1 bidder shall be given to the bidder who offers shelf life more than L1 bidder and the bidder offering higher shelf life shall be awarded contract.
- Note 1:- (a) No price preference for comparatively higher shelf life shall be given if L1 bidder is offering bioequivalent product. However, price preference for higher bidders offering bioequivalent product shall be given as mentioned above.
- (b) If L1 bidder is not offering bioequivalent product, the price preference shall be applicable as mentioned above and preference shall be given to bioequivalent product irrespective of lower shelf life.

- Note 2:- Ceiling of total 20% Price preference on account of Bioequivalence product and higher shelf life shall be applicable.
- Note 3:- Later on, if product does not comply Bioequivalence or shelf life as declared in tender, the extra price paid to the supplier shall be recovered in addition to other penal action.
- **9.1.** (i) Evaluation of the tender and determination of the L1 rate (Lowest rate) will be done on the basis of rate per unit landed price as mentioned in column 8 of **BOQ** considering price preference for bioequivalent product and higher shelf life. Negotiation if required will be done at our premises and the same will be done strictly as per Central Vigilance Commission guidelines.

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clause 5.1 (ii) (b) The Price preference of up to 5% over L1 bidder (if L1 bidder is not offering certificate of pharmaceutical product i.e. CPP or CoPP issued in the format recommended by the World Health Organization) shall be given to the bidder having CoPP for the particular drugs and shall be awarded contract. Scanned copy of Valid CoPP issued by the Licensing Authority must be uploaded.

5.1 (iii) c The Price preference up to 10% over L1 bidder (if L1 is not offering product approved by from US FDA, TG Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa) shall be given to the bidder having product approval from US FDA. TG Australia, Health Canada, EU approval, MCC South Africa approval, Brazil Anvisa.

Note 1:- (a) Price preference as in Clause 5.1 (ii) c will be get performance over the clause 5.ii b.

(b) deleted

Note 2:- deleted.

Note 3:- Later on, if product does not comply CoPP and product having approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa approved product as declared in tender, the extra price paid to the supplier shall be recovered in addition to other penal action.

9.1. (i) Evaluation of the tender and determination of the L1 rate (Lowest rate) will be done on the basis of rate per unit landed price as mentioned in column 8 of **BOQ** considering price preference for <u>CoPP</u> and for product having approval of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa approved product. Negotiation if required will be done at our premises and the same will be done strictly as per Central Vigilance Commission guidelines.

FOR:-

Clause 12.3. The supplied Drugs (covered in SCHEDULE "P" of Drugs and Cosmetics Act) should have the prescribed potency throughout the shelf life period as prescribed in the Drugs and Cosmetics Act 1940 and rules there under and in relevant Pharmacopoeias. However, in case of thermolabile drugs not covered in SCHEDULE "P" of Drugs and Cosmetics Act, the minimum shelf life should be 2 years from the date of manufacture.

Clause 12.5. Tenderer should supply the product within 2 months from the date of manufacture of products. Products beyond the above-mentioned period from the date of manufacture shall not be accepted. For example, product having manufacturing of July 2017 must be supplied before September 30, 2017.

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Clause 12.3 The bidders are required to supply their quoted product with shelf life of 36 months or the maximum shelf life mentioned in schedule P under D& C Act and rule, whichever is lower complying under Drug & Cosmetic Act 1940 and rules 1945 amended up to date if any. However, in case of thermolabile drugs not covered in SCHEDULE "P" of Drugs and Cosmetics Act, the minimum shelf life should be 2 years from the date of manufacture. The other drugs not covered in schedule P should have minimum shelf life of 3 years.

Clause 12.5. Tenderer should supply the product within 2 months from the date of manufacture of products. Products beyond the above-mentioned period from the date of manufacture shall not be accepted. For example, product having manufacturing of July 2017 must be supplied before August 30, 2017.

Note:- All the interested bidders may upload their bids along with other relevant document mentioned in the tender document.

All other contents of the tender document are unaltered.

Mahadev Agarwal Manager (Procurement), BPPI For & Behalf of BPPI