# Amendment No. 1

**Subject:**- e-Tender No. BPPI/DRUG-050/2017 Dated 22/05/2017 for supply of 453 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:-

clause 2.b (ii) 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 5.1 (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.

Clause 5.1 (ii) (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.

- Clause 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 7 of BOQ considering price preference for bioequivalent product and higher shelf life. However, to have additional source of supply, the L1 bidder shall be awarded contract/agreement for 50% of tender quantity indicated in the tender document. Balance 50% of the tender quantity indicated in the tender document shall be awarded to L2 & L3 bidders or higher bidders quoted rates in ascending order having same or higher Shelf life that of L1 bidder in the ratio of 30:20 respectively if they agree to supply the drugs at L1 rates. In case only 2 bids, the L1 bidder shall be awarded contract/agreement for 50% of tender quantity indicated in the tender document quantity. Balance 50% of tender quantity shall be awarded L2 bidders having same or higher Shelf life at L1 rate.
- (ii) In case, either of L2 or L3 bidder does not agree to match L1 rate, balance 50% quantity shall be awarded to any of these two bidders who agrees to match L1 rate. In case, both L2 and L3 bidders do not agree to match L1 rate, 100% tender quantity shall be awarded to L1 bidder. The purchase order shall be issued to L1 bidders and in case they fail to supply in stipulated time, the purchase order shall be issued to L2 bidder. Similarly, if L2 bidder fails to supply drug in stipulated time, the purchase order shall be issued to L3 bidder. During the agreement period of 2 years, in case L1 bidder completes the supply of drugs for contracted quantity, next supply shall be taken from L2 & L3 bidders accordingly for contracted quantity. However, if any supplier fails to supply the drugs due to quality failure or any other reason during agreement period of two years, such quantity shall be distributed to remaining suppliers.
- Note 1.:- No quantity distribution shall be applicable if (i) Only one bid is available (ii) Same L1 rates quoted by more than one bidder keeping in view of sharing of quantity as per clause no. 11(c) (iii)L1 bidder is offering bioequivalent product and (iii) higher bidder/bidders have offered lower Shelf life.
- 2. (a) If tender quantity of any drug is upto 50000 unit size, full tender quantity of that drug shall be placed on L1 bidder.(b) If tender quantity of any drug is more than 50000 unit size and up to 1,00,000 unit size,, full tender quantity of that drug shall be distributed in ratio of 50:50 to L1 and L2 bidder.(c) If tender quantity of any drug is more than 1,00,000 unit size,, full tender quantity of that drug shall be distributed in ratio of 50:30:20 to L1, L2 and L3 bidder.

## READ:-

<u>clause 5.1 (ii) (b)</u> 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.

<u>clause 5.1 (ii) (C)</u> 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 preference over the clause clause 5.1 (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.

Clause 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 7 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. However, to have additional source of supply, the L1 bidder shall be awarded contract/agreement for 60% of tender quantity indicated in the tender document. Balance 40% of the tender quantity indicated in the tender document shall be awarded to **L2 bidders if they agree to supply the drugs at L1 rates.** 

(ii) In case, L2 bidders do not agree to match L1 rate, 100% tender quantity shall be awarded to L1 bidder. The purchase order shall be issued to L1 bidders and in case they fail to supply in stipulated time, the purchase order shall be issued to L2 bidder. During the agreement period of 2 years, in case L1 bidder completes the supply of drugs for contracted quantity, next supply shall be taken from L2 bidder accordingly for contracted quantity. However, if any supplier fails to supply the drugs due to quality failure or any other reason during agreement period of two years, such quantity shall be distributed to remaining suppliers.

Note 1.:- No quantity distribution shall be applicable if (i) Only one bid is available (ii) L1 rates quoted by more than one bidder then distribution will be as per clause no. 11(c)

2. (a) deleted.(b)deleted.(c) deleted.

#### FOR:-

Clause 12.6. 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 12.8. Tenderer should supply the product (a) within 2 months from the date of manufacture of products having shelf life upto 2 years, (b) within 3 months from the date of manufacture of products having shelf life more than 2 years & upto 3 years and (c) within 4 months from the date of manufacture of products having shelf life more than 3 years. Products beyond the above mentioned period from the date of manufacture shall not be accepted. For example, product having manufacturing of November 2017 must be supplied before Jan 31, 2018 in case shelf life less than 2 months.

### READ:-

Clause 12.6. 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.

12.8. Tenderer should supply the product (a) within 2 months from the date of manufacture of products having shelf life upto 2 years, (b) within 3 months from the date of manufacture of products having shelf life more than 2 years & upto 3 years and (c) within 4 months from the date of manufacture of products having shelf life more than 3 years. Products beyond the above mentioned period from the date of manufacture shall not be accepted. For example, product having manufacturing of November 2017 must be supplied before Dec.31<sup>st</sup>, 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