

AMENDMENT NO. 3

No. BPPI/DRUG/RC-098/2019

Dated: 04.04.2019

Subject: Tender No. BPPI/DRUG/RC-098/2019 dated 12th March 2019 for supply of drugs to Bureau of Pharma Public Sector Undertaking of India (BPPI).

The following amendment in Tender Document is hereby authorised:

1. The following Amendment in Annexure VIII, IX, X and BOQ for unit size, pack size and shipper pack for certain drug codes is hereby amended as:

FOR:

| S.N. | Drug Code | Generic Name of Drug | Unit Size | Pack Size | Packing per Carton (Shipper Pack) | Indicative Requirement in Unit Size |
|------|-----------|--|-------------|------------|-----------------------------------|-------------------------------------|
| 29 | 72 | Azithromycin 500 mg Film Coated Tablet IP | 3's | 5's X 10 | [(5's x 10) x 10] x 10 | 5000000 |
| 371 | 807 | Biphasic Isophane Insulin Injection I.P 100 Iu/ml (30:70) (30% Soluble Insulin & 70% Isophane Ins | 3ml Vial | 3 ml X 10 | (3 ml X 10) X 10 | 4000000 |
| 409 | 920 | Insulin Regular (R-DNA Origin) Injection 100 IU I.P. | 3ml | 3 ml X 10 | (3 ml X 10) X 10 | 300000 |
| 487 | 1213 | Erlotinib 150mg Tablet | 10's Bottle | 1's X 10 | (1's X 10) X 10 | 10000 |
| 488 | 1217 | Temozolomide 100 mg Cap. | 5's | (5's X 10) | [(5's X 10) X 10] X 10 | 50000 |

READ:

| S.N | Drug Code | Generic Name of Drug | Unit Size | Pack Size | Packing per Carton (Shipper Pack) | Indicative Requirement in Unit Size |
|-----|-----------|---|---------------|-----------|-----------------------------------|-------------------------------------|
| 29 | 72 | Azithromycin 500 mg Film Coated Tablet IP | 3's | 3's X 10 | (3's x 10) x 100 | 5000000 |
| 371 | 807 | Biphasic Isophane Insulin Injection I.P 100 Iu/ml (30:70) (30% Soluble Insulin & 70% Isophane Insulin | 3ml cartridge | 3ml X 5 | (3 ml X 5) X 10 | 4000000 |

| | | | | | | |
|-----|------|--|---------------|------------|------------------|--------|
| 409 | 920 | Insulin Regular (R-DNA Origin) Injection 100 IU I.P. | 3ml cartridge | 3ml X 5 | (3 ml X 5) X 10 | 300000 |
| 487 | 1213 | Erlotinib 150mg Tablet | 10's | 10's X 3 | (10's X 3) X 20 | 10000 |
| 488 | 1217 | Temozolomide 100 mg Cap. | 5's in bottle | (1's X 10) | (1's X 10) X 100 | 50000 |

2. The following Amendment in Annexure IX for drug code 363 is hereby amended as:

FOR:

| (1) | (2) | (3) | (4) | (5) | (6) |
|------|-----------|--|----------------|------------------------------------|--|
| S.N. | Drug Code | Generic Name of Drug | Unit Size | Minimum Shelf Life Quoted (Months) | Manufacturing Capacity per Year in Units |
| 131 | 363 | INSULIN GLARGINE 100 IU / ml INJECTION | Cartridge 3 ml | 30 | |

READ:

| (1) | (2) | (3) | (4) | (5) | (6) |
|------|-----------|--|----------------|------------------------------------|--|
| S.N. | Drug Code | Generic Name of Drug | Unit Size | Minimum Shelf Life Quoted (Months) | Manufacturing Capacity per Year in Units |
| 131 | 363 | INSULIN GLARGINE 100 IU / ml INJECTION | Cartridge 3 ml | 24 | |

3. The following Amendment in Annexure X (Clause 8.2) for certain drugs is hereby amended as:

FOR:

| S. N. | Drug Code | Generic Name of Drug | Unit Size | Shape of Tablets / Size of Capsule | Packin g type | PVC Colour/ bottle shape | Thickness (mm)/ Length \pm 0.5 mm | Hardne ss (Kg/Sq. cm.) Range |
|-------|-----------|--|-----------|------------------------------------|---------------|--------------------------|-------------------------------------|------------------------------|
| 2 | 6 | DICLOFENAC 50 mg+ PARACETAMOL 325 mg+ CHLORZOXAZON E 500 mg Tablets | 10's | Oval | Blister | Milky White | 7.0mm | 4 to 7 |
| 5 | 14 | Ibuprofen 400 mg + Paracetamol 325 mg Tablets IP | 10's | Oval | Blister | Transparent | 7.0 mm | 4 to 7 |
| 32 | 81 | Cephalexin Capsules IP 250mg | 10's | Standard size | Blister | Transparent | 19.4 | NA |
| 33 | 84 | Ciprofloxacin 500mg + Tinidazole 600 mg) film coated Tablet | 10's | Oval | Blister | Transparent | 5.0mm | 5 to 7 |
| 38 | 92 | Doxycycline Capsules IP 100mg | 10's | Standard size | Blister | Transparent | 15.9 | NA |
| 40 | 101 | Ofloxacin Film Coated Tablets IP 200mg | 10's | Round biconvex | Blister | Yellow/Orange | 4.0mm | 4 to 7 |
| 69 | 180 | Bisacodyl Tablets IP 5mg | 10's | Round biconvex | Blister | Milky White | 3.7 mm | 3 to 6 |
| 70 | 183 | Dicyclomine Tablets IP 10mg | 10's | Round biconvex | Blister | Transparent | 3.7 mm | 3 to 6 |
| 78 | 198 | Dried Aluminium Hydroxide IP 250mg, Magnesium Hydroxide IP 250mg, Activated Methyl | 170 ml | Plastic bottle | Round | Milky White | 5.0mm | 5 to 7 |

| | | | | | | | | |
|---------|------|--|-------------------------|-------------------|----------------|-------------|--------|--------|
| | | Polysiloxane 50/5ml syrup | | | | | | |
| 81 | 208 | Ondansetron 2 mg/ml I.P Injection | 2ml Amp | Ampule | Monoca rton | Transparent | NA | NA |
| 10 2 | 268 | Clonidine 0.1 mg I.P Tablet | 10's | Round biconvex | Blister | Lilac | 3.7 mm | 3 to 6 |
| 16 3 | 419 | HEPARIN SODIUM 50 IU + Benzyl Nicotinate 2mg Gel | 20 gm Tube | Lami tubes | Blister | Transparent | 4.0 mm | 3 to 6 |
| 16 9 | 429 | ATORVASTATIN 10 mg+ FENOFIBRATES 160 mg Tablets IP | 15's | Oval /Round | Blister | Transparent | 3.7 mm | 4 to 7 |
| 17 6 | 441 | LOSARTAN POTASSIUM 50mg AND AMLODIPINE 5mg TABLETS IP | 10's | Round biconvex | Blister | Green | 4.0 mm | 3 to 6 |
| 18 0 | 446 | AMLODIPINE 5 MG + HYDROCHLORO THIAZIDE 12.5 MG TABLETS | 10's | Round biconvex | Blister | Transparent | 3.7 mm | 3 to 6 |
| 40 8 | 917 | Imipramine Hcl Tablets 25mg | 10's | Round biconvex | Strip | Silver | 3.7 mm | 3 to 6 |
| 48 7 | 1213 | Erlotinib 150mg Tablet | 10's Bottl e | Round biconvex | Blister | Purple | 4.0 mm | 4 to 7 |
| 48 8 | 1217 | Temozolomide 100 mg Cap. | 5's | Standard size | Blister | Transparent | 19.4 | NA |
| 51 4 | 1265 | Arginine Sachet 3gm | 8.5g m Sach et | Lami tubes | Standar d | Milky white | NA | NA |
| 52 5 | 1308 | Ethinylestradiol 0.03mg + Levonorgestrel 0.15mg Tablet | 21's | Round biconvex | Blister | Transparent | 3.7 mm | 3 to 6 |
| 56 2 | 1435 | Capecitabine Film Coated Tablets I.P 500mg | 10's | Oval | ALU- ALU | Silver | 5.0 mm | 5 to 7 |

READ:

| S. N. | Drug Code | Generic Name of Drug | Unit Size | Shape of Tablets / Size of Capsule | Packing type | PVC Colour/ bottle shape | Thickness (mm)/ Length \pm 0.5 mm | Hardness (Kg/Sq.cm) Range |
|-------|-----------|--|-----------|------------------------------------|--------------|--------------------------|-------------------------------------|---------------------------|
| 2 | 6 | DICLOFENAC 50 mg+ PARACETAMOL 325 mg+ CHLORZOXAZONE 500 mg Tablets | 10's | Oval | Blister | Transparent | 6.5 mm | 4 to 7 |
| 5 | 14 | Ibuprofen 400 mg + Paracetamol 325 mg Tablets IP | 10's | Oval | Blister | Transparent | 7.0 mm | 5 to 10 |
| 32 | 81 | Cephalexin Capsules IP 250mg | 10's | Standard size | Blister | Transparent | Standard size | NA |
| 33 | 84 | Ciprofloxacin 500mg + Tinidazole 600 mg) film coated Tablet | 10's | Oval | Blister | Transparent | 7.5mm | 5 to 7 |
| 38 | 92 | Doxycycline Capsules IP 100mg | 10's | Standard size | Blister | Transparent | Standard size | NA |
| 40 | 101 | Ofloxacin Film Coated Tablets IP 200mg | 10's | Round biconvex | Blister | Transparent | 4.0mm | 4 to 7 |
| 69 | 180 | Bisacodyl Tablets IP 5mg | 10's | Round biconvex | Blister | Amber | 3.7 mm | 3 to 6 |
| 70 | 183 | Dicyclomine Tablets IP 10mg | 10's | Round biconvex | Blister | Dark green | 3.7 mm | 3 to 6 |
| 78 | 198 | Dried Aluminium Hydroxide IP 250mg, Magnesium Hydroxide IP 250mg, Activated Methyl Polysiloxane 50/5ml suspension. | 170 ml | Plastic bottle | Round | Milky White | NA | NA |
| 81 | 208 | Ondansetron 2 mg/ml I.P Injection | 2ml Amp | Ampule | Monocar ton | Amber | NA | NA |

| | | | | | | | | |
|---------|------|---|-------------------------|-----------------------|-------------|-------------|------------------|--------|
| 10 2 | 268 | Clonidine 0.1 mg I.P Tablet | 10's | Round biconve x | Blister | Transparent | 3.7 mm | 3 to 6 |
| 16 3 | 419 | HEPARIN SODIUM 50 IU + Benzyl Nicotinate 2mg Gel | 20 gm Tube | Lami tubes | Standard | White | NA | NA |
| 16 9 | 429 | ATORVASTATI N 10 mg+ FENOFIBRATE S 160 mg Tablets IP | 15's | Oval /Round | ALU- ALU | Silver | 4.5 mm | 4 to 7 |
| 17 6 | 441 | LOSARTAN POTASSIUM 50mg AND AMLODIPINE 5mg TABLETS IP | 10's | Round biconve x | ALU- ALU | Silver | 4.0 mm | 3 to 6 |
| 18 0 | 446 | AMLODIPINE 5 MG + HYDROCHLOR OTHIAZIDE 12.5 MG TABLETS | 10's | Round biconve x | ALU- ALU | Silver | 3.7 mm | 3 to 6 |
| 40 8 | 917 | Imipramine Hcl Tablets 25mg | 10's | Round biconve x | Strip | Silver | 3.7 mm | 2 to 6 |
| 48 7 | 1213 | Erlotinib 150mg Tablet | 10's | Round biconve x | Blister | Transparent | 4.0 mm | 4 to 7 |
| 48 8 | 1217 | Temozolomide 100 mg Cap. | 5's in bottl e | Standard size | Bottle | Milky White | Standard size | NA |
| 51 4 | 1265 | Arginine Sachet 3gm | 8.5g m Sach et | NA | Standard | NA | NA | NA |
| 52 5 | 1308 | Ethinylestradiol 0.03mg + Levonorgestrel 0.15mg Tablet | 21's | Round biconve x | Blister | Transparent | 2.5 mm | 3 to 6 |
| 56 2 | 1435 | Capecitabine Film Coated Tablets I.P 500mg | 10's | Oval | Blister | Transparent | 5.0 mm | 5 to 7 |

4. The following Amendment in Annexure II (Integrity Pact) (Pg. no. 38) in reference to clause 2(j) is hereby amended as:

FOR:

Preamble

The Principal intends to award under laid down organizational procedures, contract/s for supply of surgical consumables against BPPI Tender No. BPPI/Drug/RC--098/2019. The Principal values full compliance with all relevant laws of the land, rules, regulations, economic use of resources & of fairness /transparency in its relations with its bidder(s) and /or Contractor(s).

READ:

Preamble

The Principal intends to award under laid down organizational procedures, contract/s for supply of drugs against BPPI Tender No. BPPI/Drug/RC-098/2019. The Principal values full compliance with all relevant laws of the land, rules, regulations, economic use of resources & of fairness /transparency in its relations with its bidder(s) and /or Contractor(s).

5. The following Amendment in Annexure VI (Checklist) (Pg. No. 46) in reference to clause 4.1(r) is hereby amended as:

FOR:

| | | | |
|----|--|--|--|
| 21 | Annexure XIV (Additional Document in CPP portal) | | |
|----|--|--|--|

READ:

| | | | |
|----|-----------------------------------|--|--|
| 21 | Annexure XV (Additional Document) | | |
|----|-----------------------------------|--|--|

NOTE: 1. Thickness shall be informative quality parameter to maintain the uniformity of drug product in procuring from various suppliers. It may not consider conclusive quality test parameter. Thickness of tablet may vary ± 0.5 mm as already specified in Annexure X.

2. The bidders are requested to quote their rate in BOQ considering above amendments /modifications in the tender document and specification, unit size, pack size, shipper pack of drug in respective Annexures.

Enclosure – Annexure II (modified) and Annexure VI (modified)

All other content of the tender document remains unaltered.

Sd/-

(Anurag Dwivedi)

General Manager (Procurement)

For & on behalf of BPPI

Ph: 011-49431811

ANNEXURE-II (MODIFIED)

INTEGRITY PACT

{Clause No. 2(j)}

Between

Bureau of Pharma Public Sector Undertakings of India (BPPI) hereinafter referred to as “**The Principal**”,

and

..... hereinafter referred to as “**The Bidder/Contractor**”

Preamble

The Principal intends to award under laid down organizational procedures, contract/s for supply of drugs against BPPI Tender No. BPPI/Drug/RC-098/2019. The Principal values full compliance with all relevant laws of the land, rules, regulations, economic use of resources & of fairness /transparency in its relations with its bidder(s) and /or Contractor(s).

Section 1- Commitments of the Principal

(1) The Principal commits itself to take all measures necessary to prevent corruption & to observe the following principles: -

- a. No employee of the Principal, personally or through family members, will in connection with the tender for, or the execution of contract, demand, take a promise for or accept, for self or third person, any material or immaterial benefit which the person is not legally entitled to.
- b. The Principal will, during the tender process, treat all Bidder(s) with equity and reason. The Principal will in particular, before and during the tender process, provide to all Bidder(s) the same information and will not provide to any Bidder (s) confidential/additional information through which the Bidder(s) could obtain an advantage in relation to the tender process or the contract execution.
- c. The Principal will exclude from the process all known prejudiced persons.

(2) If the Principal obtains information on the conduct of any of his employees which is a criminal offence under the IPC (Indian Penal Code) /PC (Prevention of Corruption) Act, or if there be a substantive suspicion in this regard, the Principal will inform its Vigilance Officer and in addition can initiate disciplinary action.

Section 2 – Commitments of the Bidder/Supplier

- (1) The Bidder(s)/Contractor(s) commit themselves to take all measures necessary to prevent corruption. The Bidder(s)/Contractor(s) commit themselves to observe the following principles during his participation in the tender process and during the contract execution.
 - a. The Bidder(s)/Contractor(s) will not directly or through any other person or firm, offer, promise or give to any of the Principal's employees involved in the tender process or the execution of the contract or to any third person any material or other benefit which he/she is not legally entitled to, in order to obtain in exchange any advantage of any kind whatsoever during the tender process or during the execution of the contract.
 - b. The Bidder(s)/Contractor(s) will not enter with other Bidder(s) into any undisclosed agreement or understanding, whether formal or informal. This applies in particular to prices, specifications, certifications, subsidiary contracts, submission or non-submission of bids or any other actions, to restrict competitiveness or to introduce cartelization in the bidding process.
 - c. The Bidder(s)/Contractor(s) will not commit any offence under the relevant IPC/PC Act; further Bidder(s)/Contractor(s) will not use improperly, for purposes of competition or personal gain, or pass on to others, any information or document provided by the Principal as part of the business relationship, regarding plans, technical proposals and business details, including information contained or transmitted electronically.
 - d. The Bidder(s)/Contractor(s) of foreign origin shall disclose the name & the address of agents /representatives in India, if any. Similarly, the Bidder(s)/Contractor(s) of Indian nationality shall furnish the name and address of foreign principals, if any. Further, details as mentioned in the "Guidelines of Indian Agents of Foreign Suppliers" shall be disclosed by the Bidder(s)/Contractor(s). Further, as mentioned in the Guidelines all the payments made to Indian agent/representative have to be Indian Rupees only.
 - e. The Bidder(s)/Contractor(s) will, when presenting his bid, disclose any and all payments he has made, is committed to or intends to make to agents, brokers or any other intermediaries in connection with the award of the contract.
- (2) The Bidder(s)/Contractor(s) will not instigate third persons to commit offences outlined above or be an accessory to such offences.

Section 3-Disqualification from tender process and exclusion from future contracts

If the Bidder(s)/Contractor(s), before award or during execution has committed a transgression through a violation of Section 2 above, or in any other form such as to put his reliability or credibility in question, the Principal is entitled to disqualify the Bidder(s)/Contractor(s) from the tender process or take action as per the procedure mentioned in the Tender document.

Section 4- Compensation for Damages

- (1) If the Principal has disqualified in terms of the provisions in Section 3, the Bidder(s)/Contractor(s) from the tender process prior to the award of contract, the Principal is entitled to demand and recover the damages equivalent to Earnest Money Deposit/ Bid

Security.

- (2) If the Principal has terminated the contract during execution in terms of the provisions under Section 3, the Principal shall be entitled to demand and recover from the Supplier the damages equivalent to Performance Security/Performance Bank Guarantee.

Section 5- Previous transgression

- (1) The Bidder declares that no previous transgression occurred in the last 3 years with any other Company in any country conforming to the Anti-Corruption approach or with any other Public-Sector Enterprise in India that could justify his exclusion from the tender process.
- (2) If the Bidder makes incorrect statement on this subject, he can be disqualified from the tender process or action can be taken as per the tender provision.

Section 6- Equal treatment of all Bidders/Contractors/Subcontractors

- (1) In case of subcontracting, the principal contractor shall take responsibility of the adoption of the Integrity Pact by the subcontractor.
- (2) The Principal will enter into agreements with identical conditions as this one with all bidders and contractors.
- (3) The Purchaser will disqualify from the tender process all bidders who do not sign this Pact or violate its provisions.

Section 7- Criminal charges against violating Bidders(s) / Contractor(s)/Subcontractor(s)

If the Principal obtains knowledge of conduct of a Bidder, Contractor or Subcontractor or of an employee or a representative or an associate of a Bidder, Contractor or Subcontractor which constitutes corruption, or if the Principal has substantive suspicion in this regard, the Principal will inform the same to its Vigilance Officer.

Section 8- Pact Duration

This pact begins when both parties have legally signed it. It expires for the Contractor 12 months after the last payments under the contract, and for all other bidders, 6 months after the contract has been awarded. Any violation of the same would entail disqualification of the bidder and exclusion from future business dealings.

If any claim is made/lodged during this time the same shall be binding and continue to be valid despite the lapse of this pact specified above, unless it is discharged/determined by CEO, BPPI.

Section 9- Other Provisions

- (1) This agreement is subject to Indian Law. Place of performance and jurisdiction shall be as stated in the Contract Agreement.
- (2) Changes and supplements as well as termination notices need to be made in writing. Side agreements have not been made.
- (3) If the Contractor is a partnership or a consortium, this agreement must be signed by the all partners or consortium members.
- (4) Should one or several provisions in this agreement turnout to be invalid, the remainder of this agreement remains valid. In this case, the parties will strive to come to an agreement to their original intensions.

(For & on behalf of the Principal)

(For the Bidder/Supplier)

(Office Seal)

(Office Seal)

Place:.....

Place:.....

Date:.....

Date:.....

Witness 1(BPPI):

Witness 2 (Bidder/Supplier)

(Name & Address) -----

(Name & Address) -----

ANNEXURE – VI (MODIFIED)

Ref. Clause 4.1 (r)

CHECK-LIST (Whether Uploaded the documents)

COVER – A

| S.N. | Check List | YES/No | Please Indicate Page No. |
|-------------|--|---------------|---------------------------------|
| 1 | Check list - ANNEXURE – VI | | |
| 2 | EMD Rs. 10,00,000/- in the form of Bank Guarantee or National Electronic Fund Transfer (NEFT) or Bankers Cheque or Demand Draft uploaded as per ANNEXURE-IV DD No..... Dated.....issued by(name of bank) and delivered to BPPI . Uploaded NSIC or MSME certificate for exemption if any. | | |
| 3 | Scanned copies of documentary evidence for the constitutions of the company / concern. | | |
| 4 | Copies of the instruments such as power of attorney, resolution of board etc., authorizing an officer of the Tenderer as the Authorized signatory of the Company/Firm should be uploaded. | | |
| 5 | Scanned copy of Valid WHO-GMP (World Health Organization-Good Manufacturing Practices) Certificate of manufacturing company. | | |
| 6 | Scanned copy of Valid License for the Product duly approved by the Licensing Authority for each and every product quoted | | |
| 7 | Scanned copy of valid GS-1 registration certificate for bar coding | | |
| 8 | Scanned copy of Non-Conviction Certificate issued by the licensing authority not older than 6 months. | | |
| 9 | Scanned copy of 2 Years Market Standing Certificate issued by the Licensing Authority | | |
| 10 | Valid COPP certificate as per WHO format of their Principal Manufacturing company. | | |
| 11 | Copies of approval of Manufacturing Unit of the any agency like US FDA, TG Australia, Health Canada, EU, MCC South Africa approval, Brazil Anvisa, if any. | | |
| 12 | Scanned copies of the specifications for all quoted drugs and STP (standard testing procedure) for Non- Pharmacopoeia quoted drugs. | | |
| 13 | Scanned copy of declaration of active API polymorphic form used in formulation of each quoted drugs and declare that it is internationally accepted active polymorph if any . | | |

| | | | |
|----|--|--|--|
| 14 | Scanned copy of Financial Statements along with schedule of account for FY 2015-16, 2016-17 and 2017-18 duly attested by the competent authority. | | |
| 15 | Authorization letter nominating an employee of the tenderer to transact the business with the Tender Inviting Authority. | | |
| 16 | Scanned copy of ANNEXURE-II (Integrity Pact) Original ANNEXURE –II should be submitted to BPPI, New Delhi on or before the stipulate date of tender opening. | | |
| 17 | Scanned copy of ANNEXURE –III (Declaration for eligibility in participating the tender) original Annexure III delivered to BPPI. | | |
| 18 | Scanned copy of ANNEXURE V {certificate from the C.A. (Chartered Accountant) or Company Secretary. original Annexure V delivered to BPPI. | | |
| 19 | Scanned copy of ANNEXURE-IX (Details for Shelf Life & Manufacturing Capacity) | | |
| 20 | Scanned copy of ANNEXURE—XIV (Mandate form) | | |
| 21 | Annexure XV (Additional Document in CPP portal) | | |

NOTE: - EMD instrument, ANNEXURE II, ANNEXURE III and ANNEXURE V are to be delivered in original to BPPI, New Delhi on or before stipulate date as mentioned in the tender document.

Name and signature of authorized signatory (with company seal)