Amendment no. 1

NO. <u>BPPI/DRUG/RC-116/2019</u>

Dated: 18/10/2019

Subject: - Tender No. BPPI/DRUG/RC-116/2019 dated 04/10/2019 for supply of Drugs to Bureau of Pharma Public Sector Undertakings of India (BPPI).

Reference: - Pre-Bid meeting held on 11.10.2019 at 11:00 AM in the premises of BPPI

The following amendment in Tender Document is hereby authorized: -

PART- A

Tender	Query/Suggestion	Clarification/ Amendment		
Clause/Reference				
Clause 3. (A) & Clause	Bidder has requested to reduce the EMD amount to 50	Tender provision prevails.		
6 (A)	thousand as against 10 lakhs stating that they are going			
	,	The clause no. Clause 3 (G) is amended as under: -		
Clause 3 (G)		Valid WHO-GMP (WHO-Good Manufacturing Practice) as		
	, , , , , , , , , , , , , , , , , , , ,	per revised Schedule- 'M'/COPP Certificate of the		
		manufacturing unit issued by the Licensing Authority/ Drugs		
		Control Department. The WHO-GMP certificate must be valid as on the last date of submission of tender. Self-		
	·	attested copies are to be submitted in hard copy.		
		attested copies are to be submitted in hard copy.		
	older than one year from the last date of submission of			
	tender implies mutatis mutandis that the GMP certificate			
	should remain valid till the last date of submission of tender.			
	Copies of WHO-GMP (WHO-Good Manufacturing Practice)	Copies of WHO-GMP (WHO-Good Manufacturing Practice)		
Sl. No. 6 of Annexure I Check List (Whether	_ ·	as per revised Schedule- 'M'/COPP Certificate of the		
	· ·	manufacturing unit issued by the Licensing Authority/ Drugs		
Uploaded the	Control Department/FDA. The WHO-GMP certificate must	Control Department/FDA. The WHO-GMP certificate must be valid as on the last date of submission of tender as per		
documents) COVER – A	not be older than one year from the last date of submission	Clause 3. G.		
	of tender as per Clause 3. G.	Clause 3. G.		
	Clause/Reference Clause 3. (A) & Clause 6 (A) Clause 3 (G) Sl. No. 6 of Annexure I Check List (Whether Uploaded the	Clause 7. (A) & Clause 6 (A) Bidder has requested to reduce the EMD amount to 50 thousand as against 10 lakhs stating that they are going to participate for only one drug. WHO-GMP (WHO-Good Manufacturing Practice) as per revised Schedule- 'M'/COPP Certificate of the manufacturing unit issued by the Licensing Authority/ Drugs Control Department. The WHO-GMP certificate must not be older than one year from the last date of submission of tender. Self-attested copies are to be submitted. Explanation- Generally the WHO-GMP Certificate issued for one-year validity. Hence the provision that it should not be older than one year from the last date of submission of tender implies mutatis mutandis that the GMP certificate should remain valid till the last date of submission of tender. Copies of WHO-GMP (WHO-Good Manufacturing Practice) as per revised Schedule- 'M'/COPP Certificate of the manufacturing unit issued by the Licensing Authority/ Drugs Control Department/FDA. The WHO-GMP certificate must not be older than one year from the last date of submission		

4	Sl. No. 14 of Annexure I Checklist and clause 3 (I)	Bidder asked to modify Sl. No. 14 in Annexure I as the turnover is mentioned 50 crores as against 25 Crores in Clause No. 3 (I) Sl. No. 14 ANNEXURE – I Audited Annual Balance sheet and Profit and loss statement showing details of their Annual average turn over not less than 50 (Fifty) crores for three consecutive financial years as per Clause 3. I.	Modified Sl. No. 14 of ANNEXURE – I can be read as under Audited Annual Balance sheet and Profit and loss statement showing details of their Annual average turn over not less than 25 (twenty-five) crores for three consecutive financial years as per Clause 3. I.
5	Clause 4(G)	Bidder asked clarification above, whether they should submit the declaration regarding the Active API Polymorphic use in formulation with technical bid	Bidder shall submit Declaration on their letter head that they are using Internationally accepted Active polymorphs for quoted drugs, whenever asked by BPPI.
6	Note of clause 3, serial no. (iii) and Annexure I (Checklist)	One of the bidders mentioned that they are not clear from tender as which of the document they need to submit in cover A in hard copies.	It is clearly communicated in the pre-bid meeting that all the documents shall reach BPPI Head-office in hard copy as a part of technical bid (Cover A) as per Annexure I checklist. Also note EMD instrument, ANNEXURE II, ANNEXURE IV, ANNEXURE V and ANNEXURE VI required in its original, whereas rest of the document shall be duly attested by authorized signatory/authorized person.
7	Clause no. 19 (D), Sr. No, 4 of delivery schedule table	Bidders has requested to amend the supply period against first order from 45 days to 60 days and for subsequent purchase orders from 30 days to 45 days respectively for all drugs except Injectable/Infusion/Vials (Products do not required sterility testing).	Clause no. 19 (D), Sr. No, 4 of delivery schedule table shall be read as: The Delivery Schedule against subsequent P.O. for all drugs except Injectable/Infusion/Vials (Products do not required sterility testing) is here by amended from 30 days to 45 days.
8	Clause 3(I)	One of the participants in the pre-bid meeting has requested to relax the condition of annual turnover of Rs. 25 crores to 2 crores.	Tender provision prevails.
9	Clause 17 (A)	In the Pre-bid meeting, representative of a MSME firm has requested to relax the provision of deduction of Performance Security Deposit @ 5% from each running bills for MSMEs.	Tender provision prevails.
10	Clause no. 15 B and 16 A	M/S Inventia Healthcare Pvt. Ltd. asked clarification about the new provision added in the subject tender	Tender provision prevails.

where it is mentioned to offer Purchase preference as	
against price preference in earlier tenders in case of the	
bidders submit COPP/USFDA or approval from any	
other foreign accreditation for quoted product as	
mentioned	

<u>PART B: - (i)</u>

Sl. No.	Tender Clause/ Reference No.	Drug Code & Drug Specification	Query/Suggestion	Amendment	
1	Sr. No. 167 of Annexure -XII	Drug code 560, FLUTICASONE PROPIONATE NASAL SPRAY 50 mcg Each spray delivers: Fluticasone Propionate IP 50 mcg Unit size 120 MD	Amendment the unit size from 120	The following amendment in unit size for Drug Code 560 (FLUTICASONE PROPIONATE NASAL SPRAY 50 mcg) is hereby authorized as under: - UNIT SIZE - 100 MD.	
2	Annexure-XII, (Clause 18 E and F)			Annexure -XII, Clause 18 (E) and (F) shall be read as Annexure XII 18 (M)	

(ii) The following drug is hereby stands deleted from BOQ (Cover B), Annexure XII, Annexure XIII and Annexure XIV.

S.N.	Drug Code	Generic Name of Drug	Composition/Strength	Unit Size	Pack Size
1	130	Chlorhexidine Gluconate and Cetrimide Solution (1.5% w/v and 3% w/v)	Chlorhexidine Gluconate 1.5% w/v, Cetrimide 3% w/v Solution	100ml Bottle	1 x 100 ml
2	220	Calcium with Vitamin D3 Tablets IP (500mg+250IU)	Each film-coated tablet contains: 1250mg Calcium Carbonate equivalent to Elemental Calcium IP 500mg Vitamin D3 IP 250IU	10's	10's X 10
3	524	LIGNOCAINE INJECTION IP 2%	Each ml contains: Lignocaine Hydrochloride IP 21.33 mg Sodium chloride IP 6.0 mg	30 ML VIAL	1's x 10

			Methyl Paraben IP 1.0 mg (as preservative)		
4	621	Carbonyl Iron, Zinc and Folic Acid Capsules	Each capsule contains: Elemental Iron 50 mg (in the form of Carbonyl Iron) Zinc Sulphate Monohydrate 61.8 mg (equivalent to 22.5 elemental Zinc) Folic Acid 0.5 mg	15's	10 x 15's
5	635	Clobetasol Propionate, Neomycin Sulphate, Miconazole Nitrate and Chlorhexidine Gluconate Cream	Contains: Clobetasol Propionate 0.05% w/w Neomycin Sulphate 0.50% w/w Miconazole Nitrate 2.00% w/w Chlorhexidine Gluconate Solution 0.20% w/w Chlorocresol (as preservative) 0.10% w/w In a cream base q. s.	10 gms tube	1's x 20
6	659	Chlorhexidine Gluconate and Cetrimide Solution (0.3% w/v and 0.6% w/v)	Chlorhexidine Gluconate 0.3% w/v + Cetrimide 0.6%w/v	200 ml	1x 200 ml
7	662	Gamma Benzene Hexachloride and Cetrimide Lotion	contains: Gamma Benzene Hexachloride 1% w/v Cetrimide 0.1% w/v	200ML	24 x 1 x 200ml
8	682	Rabeprazole 20mg + Domperidone 10mg Capsule	Each hard gelatin capsule contains: Rabeprazole sodium Ip (as enteric coated pellets) 20mg Domperidone Ip (as immediate release pellets) 10mg	10's	10's X 10
9	1243	Betamethasone Valerate & Salicylic Acid (0.05% w/w + 3.0% w/w) Ointment	Contains: Betamethasone Valerate IP equivalent to betamethasone 0.05% w/w Salicylic Acid IP 3.0%w/w in a greasy base	20gm Tube	1's x 20

PART- C: -

The following Amendment in the key dates of Tender schedule shall be referred as below:

- (a) Last date of online submission of the tender in the CPP portal: 11/11/2019 (MONDAY) Till 17.00 Hours
- (b) Last date of submission of original documents (Cover A): 15/11/2019 (FRIDAY) at 13.00 Hours
- (c) Opening of the technical bid: 15/11/2019 (FRIDAY) at 16.00 Hours

The bidders are requested to quote their rate in BOQ considering above amendment/modification/Deletion of drugs in tender document and specification, unit size, pack size in Annexure VII Annexure VIII and BOQ and Amendment in Annexure XII, Annexure XIII and Annexure XIV.

All other contents of tender document remain unaltered.

Yours faithfully, Sd/-(Anurag Dwivedi) GM (Procurement) For & on behalf of BPPI Ph: 011-49431811