Amendment no. 2

NO. BPPI/DRUG/RC-066/2018

Dated 17/10/2018

Subject: - Tender No. BPPI/DRUG/RC-066/2018 dated 29/09/2018 for supply of Drugs to Bureau of Pharma Public Sector Undertakings of India(BPPI).
Reference: - Pre-Bid meeting held on 12.10.2018 at 11:00 AM in the premises of BPPI

The following amendment in Tender Document is hereby authorized: -

PART- A

Sl. No.	Tender Clause/Reference	Query/Suggestion	Amendment
1	3 (ii), 7.1 & Sl No. 2 of Annexure V (Check list)	To reduce the EMD from Rs. 10 lakhs to Rs. 1 lakh as per earlier tender.	Tender provision prevails.
2	3 (viii), 4.1 (l) (m) & Sl No. 12 of Annexure V (Check list)	The bidder has informed that the study of Active Polymorphic Form of an API has never been part of any main testing neither with International Pharmacopeia nor Indian Pharmacopeia. They have also stated that as per tender document the active polymorphic form should be internationally accepted. Further, they have mentioned that requirement of a documented evidence is a very arbitrary requirement as such data may not be available even with NCL Pune, the API Manufacturers, CDSCO, your Approved NABL Laboratory etc. Therefore, they asked clarification/explanation saying as part of MSME Pharmaceutical manufacturer they strongly feel that inclusion of API Polymorphic study will be in favour of multinationals to bid for this tender as the same is not essential for Local FDA, CDSCO and International by major country.	Only declaration is sufficient from API manufacturer/ Manufacturer.

3	11. k), 16.2 & 16.4(ii) (b)	Revision in the payment terms of 90 days to 45 days mentioning the payment terms.	Tender provision prevails.
4	17	They requested for the removal of Handling and Testing charges i.e., 1.5 % of the supply value.	Tender provision prevails.
5	8.6, Annexure IX	Asked clarification about the contract period that whether the contract period will be from 2018-2020 or 2021-2023.	Tender provision prevails as the rate contract period shall be for two years from the date of issue of Letter of Acceptance of Tender for rate contract.
6	4.1 (f), 8.5, 8.10, 13.5 & 18.3	Bidder has requested to print **BPPI MRP** as Price (for BPPI) or MRP for (BPPI).	Tender provision prevails.
7	3.1 (vi) & 9.1 (i)	Bidder has requested to amend the quantity distribution between L1 and L2 + subsequent i.e., in ratio of 30:70. They have asked to amend the distribution of quantity between L1 and L2 + subsequent in ratio of 70:30 saying that distribution between L1 and L2 + subsequent in ratio of 30:70 will not be justified to L1 bidder for quoting most competitive price. They have given reference of Rajasthan Medical Services Corporation Limited(RMSCL)	Tender provision prevails.
8	12.8	Bidder has requested to amend the shelf life from 90% to 60% saying that in case of Recombinant Drug and Plasma Protein 90% shelf life is not possible. As the quality control Dept. takes 14-21 days for testing the Quality of the product. They have requested for the acceptance of the product with at least 75% shelf life.	Tender provision prevails.
9	**14.13 & Annexure I**	**Existing provision of Annexure I as discussed with the representatives of GS1 India.**	**Annexure I (Modified) with amended provision for Barcoding is attached.**

10	4.1(l) (i), 14.10, 15.1.1, Annexure II & Sl. No. 11 of Annexure V (Checklist)	Requested to submit the STP for awarded drug only after issue of letter of acceptance	Relevant clause of tender may read as under instead of existing clause: **STP (Standard Testing Procedure) for Non- Pharmacopoeia awarded drugs are required to submit within 15 days from date of issue of Letter of Acceptance and the copies of the specifications for all quoted drugs should be uploaded with technical bid.**
11	4.1 l (ii), 15.4	The supplier shall furnish evidence of the basis for shelf life and other stability data. The Supplier have explained that they have stability for shorter data than that of shelf life mentioned in the tender document and which should be acceptable.	Add the following clause: - **For new drugs, complete accelerated stability data of 6-month period shall be accepted.**
12	2 (d), 4.1 (h), Annexure I & Sl. No. 7 of Annexure V	Requested for their Non-conviction certificate older than 6-month upto one year may be accepted	Tender provision prevails.
13	14.3 & Sl. No. 13 of Annexure XI	Requested to Amend the outer carton/secondary packaging carton from 350 GSM to 250 GSM	Tender provision prevails.
14	4.1 (f), 13.5	Supplier have requested for stickering in shipper pack for Barcoding for drugs manufactured in foreign.	Tender provision prevails.
15	Clause 12	For cold chain items Shipper pack the supplier have requested to increase the shipper pack size.	Tender provision prevails.
16	4.1 (g), 5.1 (a), 5. (ii) (b), 9.1 (i), Annexure Ii & Sl. No. 10 of Annexure V	Supplier have requested to allow all Asian Accreditation i.e. (fix Audit Accreditation)	Tender provision prevails.
17	1. i	Supplier have requested for the extension of due date of the tender. (Synokem, Cipla, Lupin, Pure & Care & Biocon)	**The submission of tender and opening date of the tender is hereby amended as in part C of this document.**

18	4.1 I (ii), 15.4 & Annexure XIII Column VI	Supplier have requested that they have stability data for same composition of drug in different PVC colour than that of colour of PVC mentioned in the tender for that drug	Add the following clause: - **If tenderer do not have the stability data of packing as mentioned in the tender document (Annexure- XIII), they may submit existing stability data of their pack size and dosage form for the quoted drug against the tender.**
19	Clause no. 2. b. II. (ii	Supplier have requested to Amend the Clause no. 2. b. II. (ii) of eligibility criteria for Oncological products saying that to maintain safety profile data as well as for getting the approval from DCGI one batch needs to be analysed for 3 progressive years. They have also mentioned that in above condition if any supplier who will declare that they have manufactured and marketed 2 batches of that drug in last 3 years, will they be eligible for participating in the tender.	Tender terms prevail.

PART B: -

Sl. No.	Tender Clause/ Reference No.	Drug Code & Drug Specification	Query	Amendment
1	Annexure -VII Clause 8.1 & 8.2	DC 4 (Acetaminophen 325mg + Tramadol Hydrochloride 37.5mg Film Coated Tablet) DC 510 (PARACETAMOL 325 mg+ TRAMADOL 37.5 mg Tablets)	Supplier has requested to remove one as both the drugs are similar in composition.	Tender terms prevail.
2	Annexure -VII Clause 8.1 &8.2	DC 208 (Ondansetron 2 mg/ml I.P Injection)	Supplier suggested to waive printing of logo and barcode in 2ml Ampoule	Tender terms prevail.

3	Annexure -VII Clause 8.1 &8.2	DC 213 (Pantoprazole Injection IP 40mg) Unit Size-Vial	It was requested by the supplier that as this drug has come in BP slandered Monograph, it should be asked in BP in the tender. Also, the unit size should be in Vial with WFI	The Drug specification & unit size of DC 213 is amended as under: **Pantoprazole Injection BP 40mg in Unit size vial with WFI**
4	Annexure -VII Clause 8.1 &8.2	DC 274 (Dopamine HCl 200 mg/5ml Injection)	Supplier suggested for change in Unit Size	Tender terms prevail.
5	Annexure -VII Clause 8.1 &8.2	DC 362 (BIPHASIC ISOPHANE INSULIN INJECTION IP 4O IU/ML (50:50)	The supplier has asked clarification as there is contradiction in unit size in tender drug list as well as Amendment no. 1.	The Unit size of DC 362 in Annexure XIII (Amendment No. 1) is amended as " **10 ml Vial".**
6	Annexure -VII Clause 8.1 &8.2	DC 411 (BEVACIZUMAB INJECTION 25mg)	Supplier has asked clarification on 25mg as this strength is not available in the market and it should be 100mg per 4ml	The Drug specification of DC 411 is amended as under: - **BEVACIZUMAB INJECTION 25mg/ml.**
7	Annexure -VII Clause 8.1 &8.2	DC 540(LEVBUTEROL 1.25 MG + BUDESONIDE 1 MG REPSULE)	The supplier has requested to modify the composition as **LEVOSALBUTAMOL 1.25 MG + BUDESONIDE 1 MG REPSULE** stating that given tender specification was in older practice.	The Drug specification of DC 540 is amended as under: - **LEVOSALBUTAMOL** 1.25 MG + BUDESONIDE 1 MG REPSULE.
8	Annexure -VII Clause 8.1 &8.2	DC 568 (SALMETEROL 50mcg + FLUTICASONE PROPIONATE 250mcg Rota cap)	supplier requested to change specification from Rota cap to PUFF INHALER	The Drug specification of DC 568 is amended as under: - **SALMETEROL 50mcg + FLUTICASONE PROPIONATE 250mcg Puff inhaler.**

9	Annexure -VII Clause 8.1 &8.2	DC 712 (Paracetamol DS Syrup 250 mg Per 5ml / Paracetamol ORAL suspension IP 250 mg Per 5 ml)	Supplier suggested clarity on Syrup or Suspension	The Drug specification of DC 712 is amended as under: - **Paracetamol ORAL suspension IP 250 mg Per 5 ml**
10	Annexure -VII Clause 8.1 &8.2	DC 807 (Biphasic Isophane Insulin Injection I.P 100 IU/ml (30:70) (30% Soluble Insulin & 70% Isophane Ins	The supplier has asked clarification as there is contradiction in unit size in tender drug list as well as Amendment no. 1. They have suggested that it should be 3 ml Cartridge.	The unit size of DC 807 is amended as "**3 ml Cartridge**" instead of **3 ml** in Annexure VII, VIII & BOQ and amended as "3 **ml Cartridge" instead** of "**Glass vial**" in Annexure XIII .
11	Annexure -VII Clause 8.1 &8.2	DC 893 (Filgrastim 300mcg/1ml Prefilled Syringe)	The supplier has asked clarification as there is contradiction in unit size in tender drug list as well as Amendment no. 1.	The Unit size of DC 893 in Annexure XIII (Amendment No. 1) is amended as **1's.**
12	Annexure -VII Clause 8.1 &8.2	DC 974(Natural Micronized Progesterone Capsules 100mg)	Supplier suggested to change the Capsules as Capsules/Tablets	Tender terms prevail.
13	Annexure -VII Clause 8.1 &8.2	DC 1037 (Recombinant Human Erythropoietin Injection 4000 IU	Unit size is mentioned as **Vial** Where it should be **PFS as PFS** is better and controlled technology of administration of Drug.	Tender terms prevail.
14	Annexure -VII Clause 8.1 &8.2	DC 1038 (Recombinant Human Erythropoietin Injection 2000 IU)	Unit size is mentioned as **Vial** Where it should be **PFS as PFS** is better and controlled technology of administration of Drug.	Tender terms prevail.
15	Annexure -VII Clause 8.1 &8.2	DC 1129 (Teneligliptin 20mg + Metformin 500mg Tablet Sustained Release)	The supplier has requested to relax the stability data stating that this is new drug they will not have stability data as per tender provision.	Tender terms prevail.

16	Annexure -VII Clause 8.1 &8.2	DC 1130 (Teneligliptin 20mg + Metformin 1000mg Tablet Sustained Release)	The supplier has requested to relax the stability data stating that this is new drug they will not have stability data as per tender provision.	Tender terms prevail.
17	Annexure -VII Clause 8.1 &8.2	DC 1134 (Natural Micronized Progesterone Capsules 200mg)	Supplier suggested to change the Capsules as Capsules/Tablets	Tender terms prevail.
18	Annexure -VII Clause 8.1 &8.2	DC 1219 (Amino Acid Solution for IV 200ml bottle)	Supplier suggested to reduce the Shipper Size and Packing in Glass Bottle instead of Plastic Bottle	1. Packing per Carton (Shipper Pack) in Annexure-VII for this drug is amended as "(1's x 10) X 4" instead of "(1's x 10) X 6" 2. In Annexure-XIII in column no.4, word "Plastic Bottle" to be read as " Glass Bottle" and in column no.6, word "Amber" to be read as "Transparent"
19	Annexure -VII Clause 8.1 &8.2	DC 1409 (Teicoplanin Injection 400mg)	The unit size of this drug is mentioned as **1 ml vial.**	For Dc 1409-, unit size is amended as **"Vial"** instead **of "1ml Vial".**
20	Annexure -VII Clause 8.1 &8.2	DC 1414 (Terlipressin Injection 100mcg)	Supplier have asked that drug Terlipressin Injection 100mcg should be as **Terlipressin Injection 100mcg/ml**	Word "100mcg" to be read as "100mcg/ml"

PART- C: -

The following Amendment in the last date of online submission of the tender and Opening of the technical bid is hereby authorised as follow:-

(i). 2nd page of tender document: -

FOR: -

Last date and time for submission of Online Bid i.e. Bid Submission End Date and time	**23/10/2018 up to 11.00 A.M.**

Last Date and time for submission of EMD and Original Annexure-II (Declaration) in physical Form in office of Bureau of Pharma PSUs of India, 8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055	**24/10/2018 upto 11.00 A.M.**
Time and date of opening of Technical Bid	**11:30 AM on 24/10/2018 (Wednesday)**

READ: -

Last date and time for submission of Online Bid i.e. Bid Submission End Date and time	**30/10/2018 up to 11.00 A.M.**
Last Date and time for submission of EMD and Original Annexure-II (Declaration) in physical Form in office of Bureau of Pharma PSUs of India, 8th Floor, Videocon Tower, Block-E1, Jhandewalan Extension, New Delhi-110055	**31/10/2018 upto 11.00 A.M.**
Time and date of opening of Technical Bid	**11:30 AM on 31/10/2018 (Wednesday)**

(ii). Clause 1. Last date and time for submission of online tender: -

FOR:-

i. Online Bids [in two separate Cover {Technical bid (Cover "A") and price bid (Cover "B")}] will be submitted till **11:30 AM on 23/10/2018 (Tuesday) on CPP portal i.e.** https://eprocure.gov.in.

READ: -

i. Online Bids [in two separate Cover {Technical bid (Cover "A") and price bid (Cover "B")}] will be submitted till **11:30 AM on 30/10/2018 (Tuesday) on CPP portal i.e.** https://eprocure.gov.in.

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

Enclosure – Annexure I (modified)

All other contents of tender document remain unaltered.

ANNEXURE I (Modified)

(BARCODE REQUIREMENTS}

Reference clause 2(i)

GS1 barcode requirements on Drugs procured by Bureau of Pharma Public Sector undertakings of India (BPPI)

These requirements cover medicines/drugs procured by Bureau of Pharma Public Sector Undertakings of India (BPPI), New Delhi meant for supply and distribution through BPPI regulated distribution channel.

Barcode based on GS1 identification standards are provided below at various levels of product packaging which includes primary, secondary and shipper/carton levels and need to be complied with while supplying medicines/drugs to BPPI.

GS1 India is unique identification & barcoding standards body setup by Ministry of Commerce & Industry, Govt. of India along with APEDA, BIS, Spices board, IIP and apex industry chambers like CII, FICCI, ASSOCHAM to assist India industry and govt. bodies on adoption of global standards.

Suppliers are also required to provide GS1 subscription validity certificate at the time of supply of medicines/drugs issued by GS1 India. For validity certificate suppliers can contact GS1 India at 011-42890-846.

Barcodes based on GS1 global standards are required to be printed on product packaging at primary, secondary and tertiary packaging levels **in addition** to other, existing statutory labelling & marking requirements.

Tertiary Level Pack:

Is defined as a level of packaging that shall contain one or more secondary/primary levels of packaging and is also considered as the final logistics unit like shippers/pallets.

The Tertiary label will carry two barcodes in GS1-128 format

First Barcode

a) Unique product identification code (GTIN - Global Trade Identification Number)
b) Manufacturing Date
c) Expiry date
d) Batch no.
e) Quantity

Second Barcode

f) Serial Shipping Container Code (SSCC) –

Note-

1) *While encoding Manufacturing and expiry date in the barcode, if a specific Manufacturing or expiry date is not printed on the finished pack/drug then Supplier should select first day of the month as the Manufacturing date and Last day of the month as expiry date.*

   Example- If Shelf life is 24 months, April 2019 manufacturing date should be encoded as 190401 and March 2021 expiry date as 210331.

2) *SSCC number of the Tertiary pack should never be reused on another Tertiary pack irrespective the Item, Batch or expiry is different.*

3) *For converting, GTIN-13 into GTIN-14, kindly use "0" as a prefix for all levels of packaging.*

Attribute	Description	Length	Nature	Data Type
(02)	*Application Identifier to indicate GTIN-14 Brackets not encoded in the barcode*	*2*	*Fixed*	*Numeric*
0 8901072 00253 3	*Unique Product Number-GTIN-14*	*14*	*Fixed*	*Numeric*
(11)	*Application Identifier to indicate*	*2*	*Fixed*	*Numeric*

	Manufacturing date Brackets not encoded in the barcode			
180101	*Expiry Date in YYMMDD format*	*6*	*Fixed*	*Date*
(17)	*Application Identifier to indicate Expiry date Brackets not encoded in the barcode*	*2*	*Fixed*	*Numeric*
220131	*Expiry Date in YYMMDD format*	*6*	*Fixed*	*Date*
(10)	*Application identifier to indicate Lot/batch number* *Brackets not encoded in the barcode*	*2*	*Fixed*	*Numeric*
BATCH123	*Batch No / Lot No*	*20*	*Variable*	*Alphanumeric*
(37)	*Application identifier to indicate Quantity in Outer Carton*	*2*	*Fixed*	*Numeric*
500	No of Primary packs like number of strips/Bottles in the tertiary.	*Upto 8*	*Variable*	*Numeric*
(00)	*Application identifier to indicate the SSCC Brackets not encoded in the barcode*	*2*	*Fixed*	*Numeric*
1 8901072 000000000 6	*Unique number of the tertiary pack. It should never be reused.*	*18*	*Fixed*	*Numeric*

Recommended Barcode – GS-128	To, BPPI Mnfd By, AAA Pharma Company 125, SEZ Ahmedabad-382213 Gujrat Drug Name: Dobucin 500 mg Exp Date: 31 Jan 2022 Batch No: BATCH123  (02) 0 8901072 00255 3 (11) 180101 (17) 220131 (10) BATCH123 (37) 500  (00) 1 8901072 000000000 6

Secondary Level Pack:

Is defined as a level of packaging that may contain one or more primary packages usually termed as Mono-carton/carton

Secondary level barcode can be generated using 2D- GS1 Datamatrix or 1D- GS1-128 format.

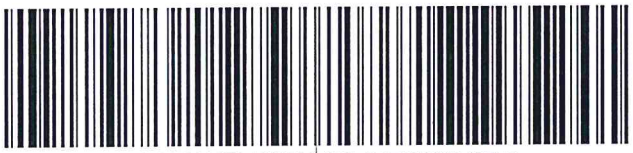
Note-

1) Shrink wrap packaging will not be considered as Secondary level packaging.
2) *For converting, GTIN-13 into GTIN-14, kindly use "0" as a prefix for all levels of packaging.*

Data Attributes Captured in GS1 Datamatrix format

1) *Unique product identification code (GTIN)*
2) *Batch No.*
3) *Qty- No of strips/bottle*

Attribute	Description	Length	Nature	Data Type
(02)	*Application Identifier to indicate GTIN-14. Brackets not encoded in the barcode*	*2*	*Fixed*	*Numeric*

0 8901072 00253 3	*GTIN-14- Unique product code with first digit being the packaging indicator*	*14*	*Fixed*	*Numeric*
(10)	*Application identifier to indicate Lot/batch* *Brackets not encoded in the barcode*	*2*	*Fixed*	*Numeric*
BATCH123	*Batch No / Lot No*	*Upto 20*	*Variable*	*Alphanumeric*
(37)	*Application Identifier to indicate serial number* *Brackets not encoded in the barcode*	*2*	*Fixed*	*Numeric*
5	*Quantity/Units in Secondary pack*	*Upto 8*	*Variable*	*Alphanumeric*
Recommended Barcode depending upon the space available – GS1 Data matrix *Or* *GS1-128*	 (02) 0 8901072 00255 3 (10) BATCH123 (37) 5 *or*  (02) 0 8901072 00255 3 (10) BATCH123 (37) 5			

Primary Level Pack:

Is defined as the first level of packaging in direct contact with the product like Strip, Vial, Bottle etc

Scenario-I Primary pack with a Mono-carton/Carton/Secondary level pack

For primary packaging packed in a Mono-carton/Secondary pack carton

a. *Unique product identification code (GTIN)*

Note-

1) *For converting, GTIN-13 into GTIN-14, kindly use "0" as a prefix for all levels of packaging.*

Attribute	Description	Length	Nature	Data Type
(01)	*Application Identifier to indicate GTIN-14* *Brackets not encoded in the barcode*	*2*	*Fixed*	*Numeric*
0 8901072 00253 3	*GTIN-14 with first digit being the packaging indicator*	*14*	*Fixed*	*Numeric*
Recommended Barcode – GS1 Datamatrix,	 (01) 0 8901072 00255 3			

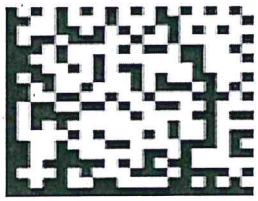
Scenario-II Primary pack without Mono-carton/Secondary level pack

For Primary packaging going directly into Tertiary pack without a Carton/Mono-carton/Secondary pack

1) *Unique product identification code (GTIN)*
2) *Batch No.*

Note-

1) *For converting, GTIN-13 into GTIN-14, kindly use "0" as a prefix for all levels of packaging.*



(01)08901072002533
(10)BATCH123

Attribute	Description	Length	Nature	Data Type
(01)	*Application Identifier to indicate GTIN-14. Brackets not encoded in the barcode*	*2*	*Fixed*	*Numeric*
0 8901072 00253 3	*GTIN-14- Unique product code with first digit being the packaging indicator*	*14*	*Fixed*	*Numeric*
(10)	*Application identifier to indicate Lot/batch Brackets not encoded in the barcode*	*2*	*Fixed*	*Numeric*
BATCH123	*Batch No / Lot No*	*Upto 20*	*Variable*	*Alphanumeric*

Mapping of Manufacturer GTIN with BPPI Drug code-

- GS1 has facilitated an online application to link Manufacturer GTIN code with BPPI Drug code. The manufacturer must update the same before sending the physical consignment to BPPI.
- Kindly contact Mr. Ankit Arora or Mr. Amrit Garg for the same at 011-42890846/42890818 or write email at ankit@gs1india.org or amrit@gs1india.org

Barcode Design and Printing-

- For BPPI suppliers, GS1 India has facilitated an online application to generate the barcode designs for each level of packaging.

- Using the same, the supplier will be able to generate Primary, secondary and Tertiary barcodes as per BPPI format.

- Kindly contact Mr. Ankit Arora or Mr. Amrit Garg for the same at 011-42890846/42890818 or write email at ankit@gs1india.org or amrit@gs1india.org

Please contact GS1 India office for any further assistance –

GS1 India
(Under Min. of Commerce, Govt. of India)
330, 2nd Floor, 'C' Wing, August Kranti Bhawan,
Bhikaji Cama Place, New Delhi - 110066
T +91-11-42890890, (D) +91-11-42890846
F +91-11-26168730
E ankit@gs1india.org
W http://www.gs1india.org