

# PHARMACEUTICALS AND MEDICAL DEVICES BUREAU OF INDIA (PMBI)

(Set up under the Department of Pharmaceuticals, Govt. of India)

8<sup>th</sup>& 9<sup>th</sup> Floor, Videocon Tower, Block E1, Jhandewalan Extension, New Delhi-110055

## Amendment no. 2

No.: -PMBI/SURGICAL/RC-206/2022

DATED: 28/11/2022

**Subject: - Tender No. PMBI/SURGICAL/RC-206/2022 dated 01/11/2022 for supply of Diapers, Oxo-Biodegradable Sanitary Napkins & Other Consumable Items to Pharmaceuticals & Medical Devices Bureau of India (PMBI) for two years under rate contract.**

**Reference: - i. All queries of Pre-Bid meeting held on 16/11/2022 at 15:00 Hours in the premises of PMBI.**

**ii. Bidders query received through mails.**

1. Pharmaceuticals and Medical Devices Bureau of India (PMBI) has invited e-Bids from the interested parties for “e- Tender for Supply of Diapers, Oxo-Biodegradable Sanitary Napkins & Other Consumable Items for the year 2022- 2024”, vide Notice Inviting e-Tender No.- PMBI/SURGICAL/RC-206/2022. Detailed tender document containing eligibility criteria, selection mechanism, other terms and conditions are available on the website of Central Public Procurement Portal; [www.eprocure.gov.in](http://www.eprocure.gov.in) and PMBI Website; [www.janaushadhi.gov.in](http://www.janaushadhi.gov.in).
2. After considering the suggestions/ queries received from the prospective bidders, the clarifications/ amendments regarding the specification, packing and dates in tender document have been made as per Part-A, Part-B & Part- C. All other technical specifications, terms, and conditions along with the tender schedule as mentioned in tender document shall remain unchanged.
3. The following amendment in Tender Document is hereby authorized:

### Part-A

Sl. No.	Tender Clause/Reference	Query/Suggestion	Clarification/ Amendment
1	<b>Clause no. 3. A, Note (i)</b> Eligibility criteria (Technical bid -cover “A”) at page 8 of the tender document.	The Existing clause no. 3. A, Note (i) is as follows:- Tenderer may be exempted from the payment of EMD, if valid registration certificate from NSIC/MSME/ Udyam Registration Certificate is uploaded and submitted self-attested copy with Technical Bid for the product for which bidder has submitted quotation.	Clause no. 3. A, Note (i) is <b>amended</b> as: Tenderer falling under Micro Small Enterprises (MSEs) may be exempted from the payment of EMD, if valid registration certificate issued by NSIC/MSME/ Udyam Registration Certificate is uploaded and submitted self-attested copy with Technical Bid (Cover A).
2	<b>Clause no. 3. E, (a)I.</b> Eligibility criteria (Technical bid -cover “A”) at page 9 of the tender document.	Sanitary napkin is excluded from the recent list of items regulated under Medical Device as per recent guidelines dated 03.06.2022 issued by CDSCO.	Clause no. 3. E, (a) I. is <b>deleted</b> . For non-drug items, bidder must submit valid product manufacturing permission / registration along with a declaration on non-judicial stamp paper (Annexure XIV) that ‘the item is not covered under Medical Devices as of now. They must submit all valid document approved/issued by Licensing Authority if at any time the product comes under medical devices under Medical Devices Act during contract period.

			<b>Accordingly, Annexure XIV at page No. 65 is amended and the bidders are requested to refer Part C of this amendment.</b>
<b>3</b>	Annexure XII, S. No. 11 at page no. 57 of the tender document.	The Item code for Baby Diaper; Pant Style; Newborn (2kg - 5Kg) is DC-9030.	The Item code for Baby Diaper; Pant Style; Newborn (2kg - 5Kg) may be read as <b><u>DC-9038</u></b> instead of <b>DC-9030</b> in tender document as well as BOQ.
<b>4</b>	Annexure XIII, S. No. 11 at page no. 64 of the tender document.	The list of items mentioned at Annexure XIII does not match with the same as mentioned at Annexure XII.	<b>Annexure XIII is amended as per Annexure XII. The bidders are requested to refer Part-C of this amendment.</b>
<b>5</b>	Annexure IV, Clause 3 (K) at Page no. 40	Turn over to be submitted for financial years 2017-2018, 2018-2019, 2019-2020 and 2020-2021,	<b>Bidders are hereby clarified that below:</b> The turnover shall be submitted for financial years 2018-2019, 2019-2020, 2020-2021 and 2021-2022 along with relevant ITR and duly audited balance sheet for the same.

### **Part - B: -**

**The following Amendment in Specification is hereby authorized: -**

### **Annexure -XII (A)**

#### **I. Detailed specification of Adult Diaper (Item code 8107, 8108 & 8109)**

Sl.NO	Particulars/Tests	Limits		
1	Description	Non allergic, Soft feel, Fit for purpose, Totally chlorine free, free from foreign matter, Side wings with 3/4 adhesive tapes for secure lock and with wetness indicator.		
2	Size	Medium Waist size: 24 inch - 36 inch	Large Waist size: 34 inch - 50 inch	Extra Large Waist size: 48 inch - 58 inch
3	Diaper Length (Total)	800mm ± 10 mm	975mm ± 10 mm	1030mm ± 10 mm
4	Diaper width (Total)	650mm ± 5mm	760mm ± 5mm	830mm ± 5mm
5	Diaper weight	Not less than 70g	Not less than 80g	Not less than 100g
6	Diaper crotch length	450 mm ± 10 mm	470 mm ± 10 mm	540 mm ± 10 mm
7	Absorbent Core Length	650 mm ± 10 mm	750 mm ± 10 mm	760 mm ± 10 mm
8	Absorbent Core width Back	240 mm ± 10 mm	280 mm ± 10 mm	280 mm ± 10 mm
9	Absorbent Core width Front	240 mm ± 10 mm	280 mm ± 10 mm	280 mm ± 10 mm
10	Core Crotch width	170 mm ± 5 mm	170 mm ± 5 mm	170 mm ± 5 mm
11	Leg elastic with standing Leak guard leg cuff width	43 mm±5 mm	43 mm±5 mm	43 mm±5 mm
12	Absorbency	Not less than	Not less than	Not less than

		700 ml	800 ml	1000 ml
13	No. of Leg elastic with standing leak guard	3	3	3
14	Top sheet	Soft feel, hydrophilic, non-irritable to skin and Nonwoven material with high wicking ability. 20 gsm $\pm$ 5%		
15	2nd Layer (Acquisition layer/ Distribution layer)	Composed of a cellulose patch and a polyester nonwoven to facilitate the spread of fluid evenly across the entire area, transfer to the next absorbent layer and prevent fluid reflux (rewet < 1%).		
16	3rd Layer (Absorbent Core)	Made up of SAP and encapsulated in nonwoven cellulose. The absorbent filler shall be arranged to form a uniform thickness throughout without any wrinkles or distortion. It shall be placed in the covering in such a way that it neither cause lump formation nor release absorbed fluid with the effect of sudden/applied pressure.		
17	4th Layer (Back sheet)	Water-proof material composed of polypropylene film laminated with non-woven polypropylene preventing fluid from leaking i.e., NLT 24 gsm $\pm$ 5%		
18	PH Value Absorbent Material	5.5 to 8.0		
19	Primary Packing	The baby diaper shall be supplied hermetic sealed LDPE package of not less than 75 micron (as per revised CPCP guidelines applicable at the time of supply) that protect the product from moisture, soiling and contamination during storage and transportation.		
20	Labelling	As per specification & approved artwork		
21	Shelf life	3 years		
22	Standards	Other parameters should comply with IS 17508:2020 (updated)		
23	Hygiene Testing Requirement	Total viable count (total number of bacteria and fungi) shall not be more than 1000 CFU/gm and <i>Staphylococcus aureus</i> shall be absent.		

## II. Detailed specification of Adult Diaper; Pant Style (Item code 9034, 9035, 9036 & 9037)

Sl.NO	Particulars/Tests	Limits			
1	Description	Non allergic, soft feel, Fit for purpose, Totally chlorine free, free from foreign matter with wetness indicator, Elastic waist and tear able side panels			
2	Size	Small Waist size: 24 inch - 36 inch	Medium Waist size: 28 inch - 46 inch	Large Waist size: 38 inch - 55 inch	Extra Large Waist size: 48 inch - 65 inch
3	Diaper Length (Total)	770mm $\pm$ 10 mm	790mm $\pm$ 10 mm	830mm $\pm$ 10 mm	940mm $\pm$ 10 mm
4	Diaper width (Total)	580mm $\pm$ 5mm	590mm $\pm$ 5mm	710mm $\pm$ 5mm	830mm $\pm$ 5mm
5	Diaper weight	Not less than 70g	Not less than 75g	Not less than 80g	Not less than 100g
6	Diaper crotch	350 mm $\pm$ 10 mm	350 mm $\pm$ 10 mm	360 mm $\pm$ 10 mm	430 mm $\pm$ 10 mm
7	Absorbent Core Length	460 mm $\pm$ 10 mm	470 mm $\pm$ 10 mm	530 mm $\pm$ 10 mm	540 mm $\pm$ 10 mm
8	Absorbent Core width Back	180 mm $\pm$ 10 mm	200 mm $\pm$ 10 mm	200 mm $\pm$ 10 mm	200 mm $\pm$ 10 mm
9	Absorbent Core width Front	180 mm $\pm$ 10 mm	200 mm $\pm$ 10 mm	200 mm $\pm$ 10 mm	200 mm $\pm$ 10 mm

10	Core Crotch width	170 mm ± 5 mm	180 mm ± 5 mm	180 mm ± 5 mm	180 mm ± 5 mm
11	Leg elastic with standing Leak guard leg cuff width	43 mm±5 mm	43 mm±5 mm	43 mm±5 mm	43 mm±5 mm
12	Spandex Front	220 mm ± 10 mm	240 mm ± 10 mm	300 mm ± 10 mm	320 mm ± 10 mm
13	Spandex Back	220 mm ± 10 mm	240 mm ± 10 mm	300 mm ± 10 mm	320 mm ± 10 mm
14	Absorbency	Not less than 600 ml	Not less than 700 ml	Not less than 800 ml	Not less than 1000 ml
15	No. of Leg elastic with standing leak guard	3	3	3	3
16	No. of elastic strands at front panel	20	20	20	20
17	No. of elastic strands at back panel	20	20	20	20
18	Top sheet	Soft feel, hydrophilic, Non irritable to skin and Nonwoven material with high wicking ability. 20 gsm ± 5%			
19	2nd Layer (Acquisition layer/ Distribution layer)	Composed of a cellulose patch and a polyester nonwoven to facilitate the spread of fluid evenly across the entire area, transfer to the next absorbent layer and prevent fluid reflux (rewet < 1%).			
20	3rd Layer (Absorbent Core)	Made up of SAP and encapsulated in nonwoven cellulose. The absorbent filler shall be arranged to form a uniform thickness throughout without any wrinkles or distortion. It shall be placed in the covering in such a way that it neither cause lump formation nor release absorbed fluid with the effect of sudden/applied pressure.			
21	4th Layer (Back sheet)	Water-proof material composed of polypropylene film laminated with non-woven polypropylene preventing fluid from leaking i.e., 24 gsm ± 5%			
22	pH Value Absorbent Material	5.5 to 8.0			
23	Primary Packing	The baby diaper shall be supplied hermetic sealed LDPE package of not less than 75 microns (as per revised CPCP guidelines applicable at the time of supply), that protect the product from moisture, soiling and contamination during storage and transportation.			
24	Labelling	As per specification & approved artwork			
25	Shelf life	3 years			
26	Standards	Other parameters should comply with IS 17508 : 2020 (updated)			
27	Hygiene Testing Requirement	Total viable count (total number of bacteria and fungi) shall not be more than 1000 CFU/gm and <i>Staphylococcus aureus</i> shall be absent.			

### **III. Detailed specification of Baby Diaper; Pant Style (Item code 9038, 9031, 9032 & 9033)**

Sl.NO	Particulars/Tests	Limits			
1	Size	New Born (2kg - 5Kg)	Small (3kg - 8Kg)	Medium (6kg - 11Kg)	Large(9kg - 13Kg)
2	Description	Non allergic, Soft feel, Fit for purpose, Totally chlorine free, free from foreign matter, Elastic waist and tear able side panels			
3	Diaper Length (Total)	420mm ± 10 mm	460mm ± 10 mm	480mm ± 10 mm	520mm ± 10 mm
4	Diaper width (Total)	330mm ± 5mm	330mm ± 5mm	340mm ± 5mm	340mm ± 5mm

5	Diaper weight	Not less than 20g	Not less than 22g	Not less than 26g	Not less than 30g
6	Diaper crotch	215 mm ± 10 mm	225 mm ± 10 mm	240 mm ± 10 mm	270 mm ± 10 mm
7	Absorbent Core Length	320 mm ± 10 mm	320 mm ± 10 mm	380 mm ± 10 mm	400 mm ± 10 mm
8	Acquisition Length	200 mm ± 5 mm	200 mm ± 5 mm	210 mm ± 5 mm	250 mm ± 5 mm
9	Absorbent Core width Back	110 mm ± 10 mm	110 mm ± 10 mm	110 mm ± 10 mm	120 mm ± 10 mm
10	Absorbent Core width Front	110 mm ± 10 mm	110 mm ± 10 mm	110 mm ± 10 mm	120 mm ± 10 mm
11	Core Crotch width	85 mm ± 05 mm	85 mm ± 05 mm	85 mm ± 05 mm	85 mm ± 05 mm
12	Flap cuff height	40 mm	40 mm	40 mm	42 mm
13	Spandex Front	100 mm ± 10 mm	120 mm ± 10 mm	130 mm ± 10 mm	150 mm ± 10 mm
14	Spandex Back	110 mm ± 10 mm	140 mm ± 10 mm	150 mm ± 10 mm	170 mm ± 10 mm
15	Absorbency	Not less than 300 ml	Not less than 420 ml	Not less than 480 ml	Not less than 570 ml
16	No. of Leg elastic with standing leak guard	2	2	2	2
17	No. of elastic strands at front panel	12	14	15	16
18	No. of elastic strands at back panel	14	16	17	18
19	Top sheet	Soft feel, hydrophilic, non-irritable to skin and Nonwoven material with high wicking ability. 20 gsm ± 5%			
20	2nd Layer (Acquisition layer/ Distribution layer)	Composed of a cellulose patch and a polyester nonwoven to facilitate the spread of fluid evenly across the entire area, transfer to the next absorbent layer and prevent fluid reflux (rewet < 1%).			
21	3rd Layer (Absorbent Core)	Made up of SAP and encapsulated in nonwoven cellulose. The absorbent filler shall be arranged to form a uniform thickness throughout without any wrinkles or distortion. It shall be placed in the covering in such a way that it neither cause lump formation nor release absorbed fluid with the effect of sudden/applied pressure.			
22	4th Layer (Back sheet)	Water-proof material composed of polypropylene film laminated with non-woven polypropylene preventing fluid from leaking. 24 gsm ± 5%			
23	pH Value Absorbent Material	5.5 to 8.0			
24	Primary Packing	The baby diaper shall be supplied hermetic sealed LDPE package of not less than 75 microns (as per revised CPCP guidelines applicable at the time of supply), that protect the product from moisture, soiling and contamination during storage and transportation.			
25	Labelling	As per specification & approved artwork			
26	Shelf life	3 years			
27	Standards	Other parameters should comply with IS 17509 : 2021 (updated)			

28	Hygiene Testing Requirement	Total viable count (total number of bacteria and fungi) shall not be more than 1000 CFU/gm and <i>Staphylococcus aureus</i> shall be absent.
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#### IV. Detailed specification of Maternity Pad (item code 8198)

Sl.NO	Particulars/Tests	Limits
1	Description	Non allergic, Soft feel, Fit for purpose, Totally chlorine free and free from foreign matter
2	Overall Length	550 ± 10 mm
3	Fluff Core/Pad Length	300 ± 10 mm
4	Overall Width	160 mm ± 5 mm
5	Fluff Core/Pad Width	110 mm ± 5 mm
6	Thickness of Pad	20mm ± 2 mm
7	Weight of pad	20 gm ± 02 gm
8	Top sheet	Soft feel, Non irritable to skin and Nonwoven material with high wicking ability. 20 gsm ± 5% Width- 110 mm ± 5 mm (fluff core)
9	2nd Layer (Acquisition layer/ Distribution layer)	Composed of a cellulose patch and a polyester nonwoven to facilitate the spread of fluid evenly across the entire area, transfer to the next absorbent layer and prevent fluid reflux (rewet < 1%). Width- 110 mm ± 5 mm
10	3rd Layer (Absorbent Core)	Made up of SAP and encapsulated in nonwoven cellulose and free from lumps, oil spots, dirt or foreign material. The absorbent filler shall be arranged to form a uniform thickness throughout without any wrinkles or distortion. It shall be placed in the covering in such a way that it neither cause lump formation nor release absorbed fluid with the effect of sudden/applied pressure. Width- 110 mm ± 5 mm
11	4th Layer (Back sheet)	Water-proof material composed of polypropylene film laminated with non woven polypropylene preventing fluid from leaking. 24 gsm ± 5% Width- 110 mm ± 5 mm
12	pH Value Absorbent Material	5.5 to 8.0
13	Absorbency	Not less than 100ml of coloured water or normal saline when flowed in the centre of the napkin (at the rate 15 ml per minute) and it shall not show up at the bottom or sides of the sanitary napkin, when tested.
14	Primary Packing	Sanitary napkins shall be packed in hermetic sealed LDPE package of not less than 75 micron (as per revised CPCP guidelines applicable at the time of supply) that protect the product from contaminants during shipment and storage.
15	Labelling	As per specification & approved artwork
16	Napkin and elastic belts	6 Pads and 2 belts with adjustable ends in one primary packing
17	Shelf life	3 years
18	Hygiene Testing Requirement	Total viable count (total number of bacteria and fungi) shall not be more than 1000 CFU/gm and <i>Staphylococcus aureus</i> shall be absent. (Tested as per ISO 11737 (Part 1).
19	Standards	Other parameters should comply with IS 5405 : 2019 (updated)

**Part - C: -**

**I: The following Amendment under ANNEXURE – XIII {Ref:- clause no. 19(K)} in drug code is hereby authorized following deletion of item baby diaper ; pant style ; Extra large (13kg and above) at sl. No. 15 and Adult Diaper (small), Waist Size: 28 inch -35 inch at Sl. No. 20.**

(1)	(2)	(3)	(4)	(5)	(6)
S.N.	Item Code	Generic Name of Item	Unit Size	Minimum Shelf Life Quoted (Months)	HSN Code of item
1	DC-8107	Adult Diaper (Medium) Waist size: 24 inch - 36 inch	5's in mono-pack		
2	DC-8108	Adult Diaper (Large), Waist size: 34 inch - 50 inch	5's in mono-pack		
3	DC-8109	Adult Diaper (XL- Extra Large), Waist size: 48 inch - 58 inch	5's in mono-pack		
4	DC-8134	Ice bag	1's		
5	DC-8146	Baby Feeding Bottle 250 ml	1 x Mono carton		
6	DC-8195	Cotton pads (Round)	Pack of 50 in a zip lock bag		
7	DC-8196	Heating pad (electrical)	1's in Mono carton		
8	DC-8197	Exercise Ball (Universal Size)	1's in Mono carton		
9	DC-8198	Maternity Sanitary Pads	Pack of 5 Napkins		
10	DC-8199	Oxo- Biodegradable Sanitary Napkins Regular Size with wings	Pack of 5 Napkins		
11	DC-9038	Baby Diaper; Pant Style; Newborn (2kg - 5Kg)	10's in mono-pack		
12	DC-9031	Baby Diaper; Pant Style; Small (3kg - 8Kg)	10's in mono-pack		
13	DC-9032	Baby Diaper; Pant Style; Medium (6kg - 11Kg)	10's in mono-pack		
14	DC-9033	Baby Diaper; Pant Style; Large (9kg - 13Kg)	10's in mono-pack		
15	DC-9034	Adult Diaper; Pant Style Small; Waist size: 28 inch - 35 inch	10's in mono-pack		
16	DC-9035	Adult Diaper; Pant Style Medium; Waist size: 28 inch - 45 inch	10's in mono-pack		
17	DC-9036	Adult Diaper; Pant Style Large; Waist size: 38 inch - 54 inch	10's in mono-pack		
18	DC-9037	Adult Diaper; Pant Style Extra Large; Waist size: 48 inch - 65 inch	10's in mono-pack		

**II. ANNEXURE XIV- DECLARATION FOR NON-DRUG ITEM(S) is here by amended as:**

**ANNEXURE XIV**  
**[Ref. clause no. 4 (C)]**  
**(To be submitted on firm's letterhead duly authorized)**  
**DECLARATION FOR NON-DRUG ITEM(S)**

I/we \_\_\_\_\_, am/are in the capacity of Proprietor/Managing Partner /Managing Director in M/s..... having its registered office at .....and its factory premises at.....do hereby declare that the quoted item(s) are neither covered under Drugs & Cosmetics Act 1940 and Rule their under nor Under Medical Device Rule 2017. **However, I /we promise to submit all document(s) approved by Licensing Authority if during contract period the product gets regulated as medical devices.**

That I/we are eligible to participate in the tender no. PMBI/SURGICAL/RC-206/2022 for the following item conforming the terms and conditions laid down in the tender document along with the amendment(s) if any following all the order (s) mentioned by various ministry/department referred in the subject tender:

Sl. No.	Item No.	Specification of the Item	Production Capacity (Per Annum)

That I am / We are aware of the Tender inviting Authority's right to forfeit the Performance Security Deposit and suspending/disqualifying/blacklist me/us for a period of 5 years if, any information furnished by us proved to be false at any time during the contract period.

Signed.....  
Name: .....  
Designation.....

(Company Seal)

(Above shall be furnished by Authorized Signatory)



- 4. All other contents of tender document remain unaltered. Bidders are requested to quote their rates considering all the terms and condition of the tender document including Amendment no. 1 dated 23/11/2022 and Amendment no. 2 dated 28/11/2022. Bidders are also requested to refer MoM of the pre-bid meeting for clarification.**

Sd/-  
DGM (Procurement & Quality)  
For & on behalf of PMBI  
PH: 011-49431811