

F.No. 12(7)/2017/DP/NPPA/Div.II/ Vol-III
National Pharmaceutical Pricing Authority

Subject: Minutes of the 16th meeting of Multidisciplinary Committee of Experts held on 13.02.2020 at 11:00 AM in NPPA

16th meeting of the "Multidisciplinary Committee of Experts" was held on 13th February, 2020 under the Convenorship of the Sh. Kalyan Nag, Adviser (Cost), in the Conference Room of NPPA. The following members/officers attended the meeting:-

1. Dr.C.D.Tripathi, Head Department of Pharmacology, VMMC & Safdarjung Hospital.
2. Dr. Rajni Kaul, Scientist-G, ICMR, New Delhi
3. Shri Jayant Kumar, DDC(I), CDSCO
4. Dr. U. D. Kolhe, Asstt. Professor, NIPER, Rai Bareli
5. Dr. Gaurav Pratap Singh, Sr. Scientific Officer, Indian Pharmacopoeia Commission
6. Sh. Shiv Shankar Ojha, Joint Director (Pricing), NPPA
7. Sh. Prakash Hemani, Assistant Director (Pricing), NPPA

The following specialists being the special invitees also attended the meeting for deliberation on Agenda No. 1 i.e. Ringer Lactate Injection

1. Dr. Lalit Pursnani, Associate Professor (Nephrology), Dr. RML Hospital, New Delhi
2. Dr. Subhal Dixit, President, Indian Society of Critical Care Medicine (ISCCM)

Agenda No. 1 - Review application against ceiling price fixation of Ringer lactate Injection fixed vide S.O. 2401(E) dated 28.07.2017 filed by

- (i) M/s Albert David Ltd
- (ii) M/s Aculife healthcare Pvt. Ltd
- (iii) M/s B. Braun Medical (india) Pvt. Ltd
- (iv) M/s Fresenius Kabi India Pvt. Ltd
- (v) M/s Ostuka Pharmaceuticals India Pvt. Ltd

The Committee deliberated upon the matter in details. The committee noted that the only three out of five companies submitted data of formulations with sample invoice, however, the applicant companies could not provide the summary of invoices as sought vide NPPA letter dated 20th May, 2019 in support of the PTR of the products claimed to have special features. Therefore, the data submitted by the companies, being incomplete, cannot be considered for fixation of ceiling price.

Further, the Pharmaceutical Form-Fill-Seal Association of India vide letter dated 13th June, 2019 highlighted a few PTRs appeared in the working sheet of ringer lactate injection notified vide SO 2401(E) dated 28th July, 2017 as products with special features. The committee observed that such highlighted PTRs in the working sheet are not supported by any documentary evidence of special features.

The committee also noted that there is minor innovation in the packaging of the ringer lactate in packaging having special features like (i) self collapsibility and self-sealability (ii) not

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having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels.

Therefore, the committee recommends that an increase of 15% over and above the ceiling price notified for ringer lactate injection may be allowed to the products of the applicant companies having special features. The recommended price is as below:

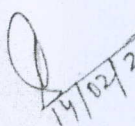
S. No.	Formulations	Unit	Present applicable CP as per SO. 1485(E) dtd 29.03.2019	Recommended Ceiling Price
1	Ringer lactate injection	100 ml pack	Rs. 20.44	Rs. 23.51
2	Ringer lactate injection	250 ml pack	Rs. 34.85	Rs. 40.08
3	Ringer lactate injection	500 ml pack	Rs. 44.41	Rs. 51.07
4	Ringer lactate injection	1000 ml pack	Rs. 78.06	Rs. 89.77

Agenda No. 2 Retail price fixation under Para 5 of DPCO, 2013 for M/s J. B. Chemicals & Pharmaceuticals Ltd (marketer) and M/s Windlas Biotech Pvt. Ltd (manufacturer/ importer).

The Committee deliberated upon the matter in details and recommended that the retail price at Rs. 4.86 per tablet excluding GST for each film coated tablet containing Ranitidine 150 mg + Dicyclomine Hydrochloride 10 mg + Simethicone IP 20 mg which was earlier approved for M/s Windlass Biotech Pvt. Ltd (manufacturer)/ M/s Mankind Pharma Ltd (marketer) may be extended to M/s Windlass Biotech Pvt. Ltd (manufacturer)/ M/s J. B. Chemicals & Pharmaceuticals Ltd (marketer).

Agenda no. 3 Retail price fixation under Para 5 of DPCO, 2013 for M/s Cadila Healthcare Ltd (marketer) and M/s Cadila Healthcare Ltd (manufacturer/ importer).

The company made their presentation before the committee and submitted the comparison of price sought for their formulation with Anti-rabies immunoglobulin (HRIG), being a scheduled formulation. The Committee deliberated upon the matter in details and observed that the matter is very specific and pertains to Anti-rabies therapy. Therefore, Specialist / Incharge of Anti-rabies department of Safdurjung Hospital and Dr. Ram Manohar Lohiya Hospital may be invited in the next meeting to have further deliberation on the issue.


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Agenda no. 4 Retail price fixation under Para 5 of DPCO, 2013 for M/s Blue Cross Laboratories Private Limited (marketer) and M/s Akums Drugs & Pharmaceuticals Limited (Manufacturer).

The Committee deliberated the matter in details and recommended the retail price of Suspension each 5ml containing Paracetamol IP 250mg, Phenylephrine HCL IP 5mg, Chlorpheniramine Maleate IP 2mg, Sodium Citrate IP 60mg & Ammonium Chloride IP 120mg & Menthol IP 1mg for M/s Blue Cross Laboratories Private Limited (marketer) and M/s Akums Drugs & Pharmaceuticals Limited (Manufacturer) at Rs. 1.08 per ml excluding GST as detailed below:

Computation of Retail Price	Source/Method	Amount (Rs.) per ml
Composition – Paracetamol IP 250mg + Phenylephrine HCL IP 5mg + Chlorpheniramine Maleate IP 2mg + Sodium Citrate IP 60mg + Ammonium Chloride IP 120mg + Menthol IP 1mg		
a. Paracetamol oral liquid 250mg / 5ml	Notified Ceiling price	0.59
b. Phenylephrine HCL IP 5mg + Chlorpheniramine Maleate IP 2mg syrup	Retail Price calculated as per Para 4 (May 19 data)	0.86
c. Sodium Citrate IP 60mg + Ammonium Chloride IP 120mg + Menthol IP 1mg	Data not available	-
Worked out Retail Price		1.45
d. Less 30% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report *		0.18
Net Retail Price (a+b-c)		1.27
Company Claimed Price		1.08
Recommended price		Rs. 1.08 per ml

Agenda no. 5 Issues relating to launch of drugs under para 32 of DPCO 2013.

The Committee deliberated the matter in details and recommended the retail price as detailed below:


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A. Remogliflozin 100mg + Metformin 500 mg tablet for M/s Glenmark Pharmaceuticals Limited


Sl. No.	Particulars	Source/ Method	Unit price in Rs. (ex. GST)
1	Remogliflozin 100 mg tablet	calculation as per para 4 based on the month Sept 2019	10.36
2	Metformin 500 mg IR tablet	SO. 1485(e) dtd 29.03.2019	1.47
3	Total (1) +(2)		11.83
4	Less 20% of the lowest of (1) and (2) based on formula recommended in the Pronab Sen Committee report		0.294
5	Recommended retail price (3) -(4)		11.54

B. Remogliflozin 100mg + Metformin 1000 mg tablet for M/s Glenmark Pharmaceuticals Limited

Sl. No.	Particulars	Source/ Method	Unit price in Rs. (ex. GST)
1	Remogliflozin 100 mg tablet	calculation as per para 4 based on the month Sept 2019	10.36
2	Metformin 1000 mg IR tablet	SO. 1485(e) dtd 29.03.2019	3.52
3	Total (1) +(2)		13.88
4	Less 20% of the lowest of (1) and (2) based on formula recommended in the Pronab Sen Committee report		0.704
5	Recommended retail price (3) -(4)		13.18

C. Dapagliflozin 5mg + Metformin 1000 mg tablet for M/s Sun Pharma & M/s Abbott Healthcare Limited

Sl. No.	Particulars	Source/ Method	Unit price in Rs. (ex. GST)
1	Dapagliflozin 5mg tablet	calculation as per para 4 based on the month June 2018	37.28
2	Metformin 1000 mg IR tablet	SO. 1461(e) dtd 02.04.2018	3.38
3	Total (1) +(2)		40.66


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4	Less 20% of the lowest of (1) and (2) based on formula recommended in the Pronab Sen Committee report	0.676
5	Recommended retail price (3) -(4)	39.98

D. Dapagliflozin 10mg + Metformin 1000 mg tablet for M/s Sun Pharma & M/s Abbott Healthcare Limited

Sl. No.	Particulars	Source/ Method	Unit price in Rs. (ex. GST)
1	Dapagliflozin 10mg tablet	calculation as per para 4 based on the month June 2018	39.31
2	Metformin 1000 mg IR tablet	SO. 1461(e) dtd 02.04.2018	3.38
3	Total (1) +(2)		42.69
4	Less 20% of the lowest of (1) and (2) based on formula recommended in the Pronab Sen Committee report		0.676
5	Recommended retail price (3) -(4)		42.01

E. Dapagliflozin 10mg + Metformin 500 mg tablet for M/s Sun Pharma & M/s Abbott Healthcare Limited

Sl. No.	Particulars	Source/ Method	Unit price in Rs. (ex. GST)
1	Dapagliflozin 10mg tablet	calculation as per para 4 based on the month June 2018	39.31
2	Metformin 500 mg IR tablet	SO. 1461(e) dtd 02.04.2018	1.41
3	Total (1) +(2)		40.72
4	Less 20% of the lowest of (1) and (2) based on formula recommended in the Pronab Sen Committee report		0.282
5	Recommended retail price (3) -(4)		40.44


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F. Empagliflozin 12.5mg + Metformin 500mg Tablet for M/s Lupin Limited / Boehringer Ingelheim

Sl. No.	Particulars	Source/ Method	Unit price in Rs. (ex. GST)
1	Empagliflozin 25 mg tablet	calculation as per para 4 based on the month June 2018	49.59
2	Empagliflozin 12.5 mg tablet	based on formula recommended in the Pronab Sen Committee report on sl. no. 1	29.75
3	Metformin 500 mg IR tablet	SO. 1461(e) dtd 02.04.2018	1.41
4	Total (2) +(3)		31.16
5	Less 20% of the lowest of (2) and (3) based on formula recommended in the Pronab Sen Committee report		0.282
6	Recommended retail price (4) -(5)		30.88

G. Empagliflozin 12.5mg + Metformin 1000mg Tablet for M/s Lupin Limited / Boehringer Ingelheim

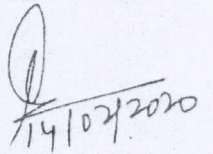
Sl. No.	Particulars	Source/ Method	Unit price in Rs. (ex. GST)
1	Empagliflozin 25 mg tablet	calculation as per para 4 based on the month June 2018	49.59
2	Empagliflozin 12.5 mg tablet	based on formula recommended in the Pronab Sen Committee report on sl. no. 1	29.75
3	Metformin 1000 mg IR tablet	SO. 1461(e) dtd 02.04.2018	3.38
4	Total (2) +(3)		33.13
5	Less 20% of the lowest of (2) and (3) based on formula recommended in the Pronab Sen Committee report		0.676
6	Recommended retail price (4) -(5)		32.45


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H. Empagliflozin 5mg + Metformin 500mg Tablet for M/s Lupin Limited / Boehringer Ingelheim

Sl. No.	Particulars	Source/ Method	Unit price in Rs. (ex. GST)
1	Empagliflozin 10 mg tablet	calculation as per para 4 based on the month June 2018	40.89
2	Empagliflozin 5 mg tablet	based on formula recommended in the Pronab Sen Committee report on sl. no. 1	24.53
3	Metformin 500 mg IR tablet	SO. 1461(e) dtd 02.04.2018	1.41
4	Total (2) +(3)		25.94
5	Less 20% of the lowest of (2) and (3) based on formula recommended in the Pronab Sen Committee report		0.282
6	Recommended retail price (4) -(5)		25.66

The meeting ended with a vote of thanks to the Convener.


 (Shiv Shankar Ojha)
 Joint Director (Pricing)

Copy to:
 All members of the Committee.