F. No. 12(7)/2017/DP/NPPA/Div.II / Vol-IV

National Pharmaceutical Pricing Authority

Subject: Minutes of the 32nd meeting of Multidisciplinary Committee of Experts held on 23.05.2021 at 12:00 noon in NPPA

32nd meeting of the "Multidisciplinary Committee of Experts" was held on 23.05.2021 under the Convenorship of Sh. N.I. Chowdhury, Adviser (Cost), in NPPA. The following members attended the meeting through video conferencing:-

1. Prof. Y. K. Gupta, Principal Scientific Advisor (Projects), THSTI-DBT, Gol &

Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi

2. Dr. Rakesh K. Singh, Assoc. Professor, NIPER, Raebareli

3. Shri A. K. Pradhan, Dy. Drugs Controller, CDSCO

4. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission

5. Dr. J.J. Cherian, Scientist D,IMCR, New Delhi

The following officers of NPPA attended and presented the cases to the Committee

1. Sh. S. S. Ojha, Jt. Director (Pricing), NPPA

2. Sh. Prasenjit Das, Deputy Director (Pricing), NPPA

1. Agenda No. 1 - Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing lvabradine Hydrochloride eq. to lvabradine 7.5 mg + Metoprolol Tartrate 25 mg for M/s Archimedis Healthcare Pvt. Ltd. (manufacturer) and M/s Lupin Ltd. (marketer)

1.1 The Committee deliberated upon the matter in detail and recommended the retail price of each film coated tablet containing lvabradine Hydrochloride eq. to lvabradine 7.5 mg + Metoprolol Tartrate 25 mg for M/s Archimedis Healthcare Pvt. Ltd. (manufacturer) and M/s Lupin Ltd. (marketer) at Rs. 20.68 per tablet excluding GST as detailed below:

Particulars	Source	Price in Rs (excluding GST)
Calculated price of Ivabradine 5 mg +	As per para 4	15.75
Metoprolol 25 mg tablet	based on	
Less: Calculated price of Ivabradine 5	September 2020	15.13
mg tablet	data	
Add: Calculated price of Ivabradine 7.5		20.06
mg tablet		
Worked out retail price		20.68

2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Darunavir Ethanolate eq. to Darunavir IP 800 mg +

Ritonavir IP 100 mg for M/s Hetero Labs Ltd. (manufacturer) and M/s Cipla Ltd. (marketer)

2.1 The Committee deliberated upon the matter in detail and recommended the retail price of each film coated tablet containing Darunavir Ethanolate eq. to Darunavir IP 800 mg + Ritonavir IP 100 mg for M/s Hetero Labs Ltd. (manufacturer) and M/s Cipla Ltd. (marketer) at Rs. 190.44 per tablet excluding GST as detailed below:

SI. No.	Company	PTR per tablet	
1	Hetero Healthcare Ltd	Rs. 5109.29 per 30 tablet	Rs.170.30
2	Emcure Pharmaceuticals Ltd	Rs. 4741.20 per 30 tablet	Rs. 158.04
Ther	efore, average PTR		Rs. 164.17
Add:	16% retailer margin	Rs. 26.27	
Worl	ked out retail price per tablet		Rs. 190.44

3. Agenda No. 3 – Application by M/s Otsuka Pharmaceuticals India Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect to Metronidazole Injection IP (0.5% w/v) 100ml in Non-glass pack having Special features

3.1 The Committee deliberated upon the matter in detail and decided that the M/s Otsuka Pharmaceuticals Pvt. Ltd be directed to make demonstration before the Committee in its next meeting along with the justification. The Committee also directed to make further analysis on the matter and place in the next meeting.

4. Agenda No. 4 - Application by M/s Otsuka Pharmaceuticals India Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect Mannitol Injection 20% in Non-glass pack having Special features

4.1 The Committee deliberated upon the matter in detail and decided that the M/s Otsuka Pharmaceuticals Pvt. Ltd be directed to make demonstration before the Committee in its next meeting along with the justification. The Committee also directed to make further analysis on the matter and place in the next meeting.

5. Agenda No. 5 - Application by M/s Otsuka Pharmaceuticals India Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect Dextrose Injection (25% w/v) 100 ml in Non-glass pack having Special features

5.1 The Committee deliberated upon the matter in detail and decided that the M/s Otsuka Pharmaceuticals Pvt. Ltd be directed to make demonstration before the Committee in its next meeting along with the justification. The Committee also directed to make further analysis on the matter and place in the next meeting.

The meeting ended with a vote of thanks to all.

Sd/-(S. S. Ojha) Director (Pricing)

Copy to: All members of the Committee.

Computatation of Retail Price based on September, 2020 Data under Para 4 of DPCO, 2013

Each film coated tablet containing Ivabradine Hydrochloride eq. to Ivabradine 5 mg

Number of Companie	es cosisting of Ma	arket Share of 19	6 & Above			9
Sum of MAT value co	nber of Companies cosisting of Market Share of MAT value considered for price calculati nof PTR per unit considered for price calcula nber of Packs considered rage PTR : 16% Retailer Margin ail Price (without local taxes)	e calculation (in	Lakhs)			15,209.10
Sum of PTR per unit o	considered for pr	rice calculation				117.32
Number of Packs con	sidered					9
Average PTR						13.04
Add : 16% Retailer M	argin					2.09
Retail Price (without	local taxes)					15.13
% Reduction with cor	npared to Highe	st Price				18.75%

Minimumum Price (Rs.)		7.82
Maximum Price (Rs.)		16.05
Average of all considered (Rs	i.)	13.04
Retail Price (Rs.)		15.13

							TOTAL MAT	1,57,24,39,738	1009	6		M3	
S.No.	पैक विवरण	छाप	कंपनी	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise	Brandwis		Price	Price per Unit
	Pack Description	BRAND	Company						MAT %			per Unit	(Rs.) Considered
										(ignoring O% MAT)		(Rs.)	
	1 ALBADIN 5 MG TABLET 10	ALBADIN	SALUD CARE (I) PVT LTD	5 MG	10	TABLET	96.43	44357.8	0.00%	0.00%	N N	9.64	
	2 BEAT HF 5 MG TABLET 10	BEAT HF	EMCURE PHARMACEUTICALS LTD	5 MG	10	TABLET	68.43	8424964.74	0.54%	0.54%	N	6.84	
	3 BRADISWIFT 5 MG TABLET 10	BRADISWIFT	INDSWIFT LABORATORIES LTD.	5 MG	10	TABLET	95	5605	0.00%	0.00%	N	9.50	
	4 CORABRAD 5 MG TABLET 10	CORABRAD	MANKIND PHARMACEUTICALS LTD.	5 MG	10	TABLET	135		0.07%	0.07%	N	13.50	
	5 CORALAN 5 MG TABLET 14	CORALAN	SERDIA PHARMACEUTICALS (INDIA) PVT. LTD.	5 MG	14	TABLET	196.43	42282146.79	2.69%	2.69%	Y	14.03	14.03
	6 INAPURE 5 MG TABLET 10	INAPURE	SUN PHARMA LABORATORIES LTD.	5 MG	10	TABLET	131.43	129119738.1	8.21%	8.21%	Y	13.14	13.14
	7 IRBAN 5 MG TABLET 10	IRBAN	GLENMARK PHARMACEUTICALS LTD.	5 MG	10	TABLET	78.22	20679960.04	1.32%	1.32%	Y	7.82	7.82
	B IVABEAT 5 MG TABLET 10	IVABEAT	CIPLA LTD.	5 MG	10	TABLET	137.85	36315118.06	2.31%	2.31%	Y	13.79	13.79
	9 IVABID 5 MG TABLET 14	IVABID	ABBOTT HEALTHCARE PVT. LTD	5 MG	14	TABLET	224.71	269988087.4	17.17%	17.17%	Y	16.05	16.05
1	VIVABLES 5 MG TABLET 15	IVABLES	LLOYD HEALTHCARE PVT.LTD	5 MG	15	TABLET	148.51	11306158.23	0.72%	0.72%	N	9.90	
1	1 IVABRAD 5 MG TABLET 15	IVABRAD	LUPIN LTD	5 MG	15	TABLET	219.93	880718704.7	56.01%	56.01%	Y	14.66	14.66
1	2 IVABRATCO 5 MG TABLET 10	IVABRATCO	NATCO PHARMA LTD	5 MG	10	TABLET	103.57	2846621.45	0.18%	0.18%	N	10.36	
1	3 IVAMAC 5 MG TABLET 10	IVAMAC	MACLEODS PHARMACEUTICALS PVT.LTD	5 MG	10	TABLET	125.71	41328653.42	2.63%	2.63%	Y	12.57	12.57
1.	VANODE 5 MG TABLET 10	IVANODE	TORRENT PHARMACEUTICALS LTD.	5 MG	10	TABLET	150.54	81130786.62	5.16%	5.16%	Y	15.05	15.05
1	5 IVAPACE 5 MG TABLET 10	IVAPACE	CORONA	5 MG	10	TABLET	102.14	19347052.38	1.23%	1.23%	Y	10.21	10.21
1	6 IVAREST 5 MG TABLET 10	IVAREST	ERGOS LIFE SCIENCES	5 MG	10	TABLET	120.79	11052285	0.70%	0.70%	N	12.08	
1	7 IVASAFE 5 MG TABLET 10	IVASAFE	ACMEDIX PHARMA LLP	5 MG	10	TABLET	60.71	445793.53	0.03%	0.03%	N	6.07	
1	^B IVAZINE 5 MG TABLET 10	IVAZINE	TORRENT PHARMACEUTICALS LTD.	5 MG	10	TABLET	145.86	14116039.08	0.90%	0.90%	N	14.59	
1	9 IVERZAC 5 MG TABLET 10	IVERZAC	AJANTA PHARMA LTD	5 MG	10	TABLET	113.57	2186336.07	0.14%	0.14%	Ν	11.36	
<u> </u>													
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<u> </u>													
		Rs. Per Tablet											
<u> </u>	Worked out Detail Dries												
<u> </u>	Worked out Retail Price	15.13	Excluding GST										
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Computatation of Retail Price based on September, 2020 Data under Para 4 of DPCO, 2013

Each film coated tablet containing Ivabradine Hydrochloride eq. to Ivabradine 5 mg + Metoprolol Tartrate 25 mg for M/s Archimedis Healthcare Pvt. Ltd. (manufacturer) and M/s Lupin Ltd. (marketer)

	Number of Companie	es cosisting of Ma	arket Share of 19	6 & Above					1
s	Sum of MAT value co	nsidered for pric	e calculation (in	Lakhs)			0.10		
5	Sum of PTR per unit c	onsidered for pr	ice calculation					13.58	
	Number of Packs con	sidered						1	
	Average PTR							13.58	
	Add : 16% Retailer M	argin						2.17	
	Retail Price (without I	local taxes)						15.75	
	% Reduction with cor	npared to Highe	st Price					0.00%	

Minimumum Price (Rs.)		13.58
Maximum Price (Rs.)		13.58
Average of all considered (Rs	.)	13.58
Retail Price (Rs.)		15.75

							TOTAL MAT	10,3	17 100	%		M3	
S.No.	पैक यिवरण Pack Description		कंपनी Company	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise MAT %	Brandwis e MAT (ignoring O% MAT)	Y/N) Y=Yes	Price per Unit (Rs.)	Price per Unit (Rs.) Considered
	1 IVA MET XL 5/25 MG TABLET 10	IVA MET	AJANTA PHARMA LTD	5/25 MG	10	TABLET	135.75	10	100.00%	100.00%	Y	13.58	13.58
										_			
		Rs. Per Tablet											
	Worked out Retail Price		Excluding GST										
	Claimed Retail Price	18.65											
	Proposed retail Price	15.75	Excluding GST										

Computatation of Retail Price based on September, 2020 Data under Para 4 of DPCO, 2013

Each tablet containing Ivabradine Hydrochloride eq. to Ivabradine 7.5 mg

Number of Companie	es cosisting of Ma	arket Share of 19	6 & Above			5
Sum of MAT value co	nsidered for pric	e calculation (in	Lakhs)			1,218.50
Sum of PTR per unit o	onsidered for pr	ice calculation				103.74
Number of Packs con	sidered					6
Average PTR						17.29
Add : 16% Retailer M	argin					2.77
Retail Price (without	local taxes)					20.06
% Reduction with cor	npared to Highe	st Price				10.92%

Minimumum Price (Rs.)		14.14
Maximum Price (Rs.)		19.41
Average of all considered (Rs	i.)	17.29
Retail Price (Rs.)		20.06

							TOTAL MAT	12,36,17,417	100%	5		M3	
S.No.	पैक विवरण	छाप	कंपनी	Strength	Pack Size	Unit	PTR(Rs.)	MAT(Rs.)	SKU wise	Brandwis	Qualify (Price	Price per Unit
	Pack Description	BRAND	Company	-					MAT %	e MAT	Y/N)	per Unit	(Rs.) Considered
										(ignoring	Y=Yes	(Rs.)	
										O% MAT)			
	BEAT HF 7.5 MG TABLET 10	BEAT HF	EMCURE PHARMACEUTICALS LTD	7.5 MG	10	TABLET	107.14	1124648.58		0.91%	N	10.71	
1	2 CORABRAD 7.5 MG TABLET 10	CORABRAD	MANKIND PHARMACEUTICALS LTD.	7.5 MG	10	TABLET	167.14	166972.86	0.14%	0.14%	N	16.71	
	3 CORALAN 7.5 MG TABLET 14	CORALAN	SERDIA PHARMACEUTICALS (INDIA) PVT. LTD.	7.5 MG	14	TABLET	237.86	5418926.52	4.38%	4.38%	Y	16.99	16.99
4	4 IRBAN 7.5 MG TABLET 10	IRBAN	GLENMARK PHARMACEUTICALS LTD.	7.5 MG	10	TABLET	130	2340		0.00%	N	13.00	
	⁵ IVABID 7.5 MG TABLET 10	IVABID	ABBOTT HEALTHCARE PVT. LTD	7.5 MG	10	TABLET	176.55	11586446.85	9.37%	21.10%	Y	17.66	17.66
6	6 IVABID 7.5 MG TABLET 14	IVABID	ABBOTT HEALTHCARE PVT. LTD	7.5 MG	14	TABLET	271.8	14506237.8	11.73%	21.10%	Y	19.41	19.41
1	7 IVABLES 7.5 MG TABLET 10	IVABLES	LLOYD HEALTHCARE PVT.LTD	7.5 MG	10	TABLET	117.08	473471.52		0.38%	N	11.71	
8	B IVABRAD 7.5 MG TABLET 15	IVABRAD	LUPIN LTD	7.5 MG	15	TABLET	283.96	85971960.25	69.55%	69.55%	Y	18.93	18.93
9	9 IVAPACE 7.5 MG TABLET 10	IVAPACE	CORONA	7.5 MG	10	TABLET	141.43	3042914.2	2.46%	2.46%	Y	14.14	14.14
10	IVAZINE 7.5 MG TABLET 10	IVAZINE	TORRENT PHARMACEUTICALS LTD.	7.5 MG	10	TABLET	166.06	1323498.2	1.07%	1.07%	Y	16.61	16.61
		Rs. Per Tablet											
	Worked out Retail Price	20.06	Excluding GST										