

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

Subject: Minutes of the 4th meeting of Multidisciplinary Committee of Experts under DPCO 2013 held on 27.09.2018 at 11:00 AM in NPPA

The 4th meeting of the “Multidisciplinary Committee of Experts” was held on 27.09.2018 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. K. Bangarurajan, Jt. Drugs Controller, CDSCO
2. Dr. Rajni Kaul, Scientist G, ICMR, New Delhi
3. Dr. Ujwal D. Kolhe, Assistant Professor NIPER, Raebareli, UP
4. Dr. Gaurav Pratap Singh, Sr. Scientific Officer, Indian Pharmacopoeia Commission
5. Sh. Amarपाल Singh Sawhney, Director (Pricing), NPPA
6. Sh. Baljit Singh, Assistant Director (Pricing), NPPA
7. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA

The members of the Committee first took up agenda under para 15 of DPCO, 2013. The item-wise deliberation and recommendation, if any, are given as under:

A. Agenda relating to Para 15 of DPCO 2013.

Agenda item No. 1 Brinzolamide 1% and Timolol 0.5% eye drops in 5ml vial of Ajanta Pharma Ltd.

The committee after deliberation recommended the retail price of Rs.283.25 for 5 ml pack as detailed below:

Sl No	Particulars	Worked out retail price (Rs.)	
1	a. Brinzolamide 1% w/v (Price worked out on the basis of PTR of M/s Ajanta Pharma)	49.08	per ML
2	b. Timolol 0.5% w/v (ceiling price before the date of application)	10.82	CP per ML
3	TOTAL for 1 ml	59.90	per ML
4	Less 30% of the lowest of (a) and (b) based on formula recommended in the Pronab Sen Committee report	3.25	Per ML
5	Worked out retail price per ml	56.65	Per ML
6	Worked out retail price for 5 ml	283.25	for 5ml Pack
7	Company's claim	493.37	for 5ml Pack

Agenda No. 2 Vaccine Easy four-TT PFS containing Diphtheria Toxoid 20LF 30 IU, Tetanus Toxoid 7.5LF 60IU, Inactivated w-B pertussis bulk 12IOU 4IU, Hib PRP conjugated with carrier protein Tetanus Toxoid 10 µg etc fully Liquid of M/s Panacea Biotech Ltd.

The Applicant gave technical presentation before the committee in the last Multidisciplinary Committee meeting held on 13.6.2018 and subsequently submitted justification of the cost. The Committee, after deliberation upon the claims made by the applicant, recommended the retail price of Rs.583.00 per pack based on the last price of Rs.530.00 (as of 2012) for three plus one pack earlier sold by the company after providing 10% increase under para 20.

Agenda item no. 3, 4, 31 and 32 - Volini Maxx Gel 20GM, 30GM and 15 GM contains: Diclofenac Diethylamine BP 2.32%w/w (eq. to Diclofenac Sodium 2% w/w), Methyl Salicylate IP 10% w/w Menthol IP 5% w/w Manufactured and marketed by M/s Sun Pharmaceuticals Industries Pvt. Ltd.

The committee deliberated upon the comparison of prices of gel and spray formulations and recommended the retail price of gel formulation be made applicable to spray formulation already notified for M/s Sun Pharmaceuticals Industries Pvt. Ltd. as detailed below:

Pack size	Claimed Price for Gel per pack	Recommended Price for Gel per pack
10GM	Rs. 75.00	Rs. 62.50
15GM	Rs. 105.00	Rs. 93.75
20GM	Rs. 160.00	Rs.125.00
30GM	Rs. 210.00	Rs.187.50

Agenda item no. 5 - TRIOLSAR 20 Tablet: Each film coated tablet contains Olmesartan Medoxomil 20mg, Chlorthalidone IP 6.25mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets Manufactured by M/s GKM New Pharma Ltd and Marketed by M/s Unichem Laboratories Limited.

The committee, after deliberation, recommended the retail price of Rs.9.585/tablet claimed by the company as detailed below:

Computation of Retail Price per Tablet	Source/Method	Unit Price (Rs.)
a. Olmesartan Medoxomil 20mg+Amlodipine 5 mg	S.O. No. 353(E) dated 23.01.2018	7.24
b. Chlorthalidone IP 6.25mg	As per para 5	3.42
Worked out Retail Price per tablet (a+b)		10.66
c. Less 20% of the lowest of (a) and (b) based on formula recommended in the Pronab Sen Committee report		0.68
Net Retail Price (a+b-c)		9.98
Company Claimed Price		9.585

Agenda item no 6 - TRIOLSAR 40 Tablet Each film coated tablet contains: Olmesartan Medoxomil 40mg, Chlorthalidone IP 6.25mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets Manufactured by M/s GKM New Pharma and Marketed by M/s Unichem Laboratories Limited

The committee, after deliberation, recommended the worked out retail price of Rs.15.61/tablet as detailed below:

Computation of Retail Price per Tablet	Source/Method	Unit Price (Rs.)
a. Olmesartan Medoxomil 40mg+Amlodipine 5 mg	S.O. No. 353(E) dated 23.01.2018	12.87
b. Chlorthalidone IP 6.25mg	As per para 5	3.42
Worked out Retail Price per tablet		16.29
c. Less 20% of the lowest of (a) and (b) based on formula recommended in the Pronab Sen Committee report		0.68
Net Retail Price (a+b-c)		15.61
Company Claimed Price		16.36

Agenda item no. 7 - TRILOSAR 6.25 Tablets Each film coated tablet contains: Losartan Potassium IP 50mg, Chlorthalidone IP 6.25mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets Manufactured by M/s GKM New Pharma. and Marketed by M/s Unichem Laboratories Limited

The committee, after deliberation, recommended the worked out retail price of Rs.6.36/tablet as detailed below:

Computation of Retail Price per Tablet	Source/Method	Unit Price (Rs.)
a. Losartan Postassium 50 mg + Chlorthalidone IP 6.25mg	S.O. No. 583(E) dated 24.02.2016	4.50
b. Amlodipine 5 mg	Ceiling Price	2.33
Worked out Retail Price per tablet		6.83
c. Less 20% of the lowest of (a) and (b) based on formula recommended in the Pronab Sen Committee report		0.47
Net Retail Price (a+b-c)		6.36
Company Claimed Price		9.459

Agenda Item no 8 - TRILOSAR 12.50 Tablets Each film coated tablet contains: Losartan Potassium IP 50mg, Chlorthalidone IP 12.5mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets Manufactured by M/s GKM New Pharma and Marketed by M/s Unichem Laboratories Limited

The committee, after deliberation, recommended the worked out retail price of Rs.6.41/tablet as detailed below:

Computation of Retail Price per Tablet	Source/Method	Unit Price (Rs.)
a. Losartan Postassium 50 mg + Chlorthalidone IP 12.50mg	S.O. No. 3146(E) dated 10.12.2014	4.55
b. Amlodipine 5 mg	Ceiling Price	2.33
Worked out Retail Price per tablet		6.88
c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		0.47
Net Retail Price (a+b-c)		6.41
Company Claimed Price		10.646

Agenda Item no 9 - Manufactured and Marketed by M/s Apex Laboratories Pvt. Ltd Cream contains: Sodium Fusidate IP eq. to Fusidic Acid 2%w/w, Halobetasol Propionate USP 0.05%w/w

Agenda Item withdrawn

Agenda Item no 10, 16, 17, 19, 22, 26, 27 and 28 - Tablet Contains: Tenofovir Alafenamide Fumarate 25mg (TAF)

The agenda Item was deferred.

Marketed by	Manufactured by	Date of filing the Application	Price claimed for 30 Tablets	Recommended Price per Tablet (excluding GST)
M/s Mylan Laboratories Pvt. Ltd. (10)	M/s Mylan Laboratories Pvt. Ltd.	11.5.2018	1900	Deferred
M/s Cadila Healthcare Ltd	M/s Hetero Pvt Ltd	4.5.2018	2100	Deferred

(16)				
M/s Cipla Ltd (17)	M/s Hetero Pvt Ltd	11.5.2018	1900	Deferred
M/s Emcure Pvt Ltd.(19)	M/s Hetero Pvt Ltd	21.5.2018	2280	Deferred
M/s Sun Pharma Laboratories (22)	M/ Natco Ltd.	14.6.2018	1900	Deferred
M/s Abbott India Ltd. (26)	M/s Natco Ltd.	26.6.2018	1900	Deferred
M/s Natco Ltd (27)	M/s Natco Ltd	2.7.2018	1900	Deferred
M/s Cadila Healthcare Ltd. (28)	M/s Natco Ltd.	13.7.2018	2100	Deferred

Agenda Item no 11 - Each film coated tablet contains: Darunavir Ethanolate eq. to Darunavir 600mg and Ritonavir IP 100mg tablet Manufactured & Marketed By M/s Emcure Pharmaceuticals Limited.

The committee, after deliberation, recommended the worked out retail price of Rs.172.52/tablet as detailed below:

Computation of Retail Price per Tablet	Source/Method	Unit Price (Rs.)
a. Darunavir 600mg	Ceiling Price	151.46*
b. Ritonavir IP 100mg	Ceiling price	26.33*
Worked out Retail Price		177.79
c. Less 20% of the lowest of (a) and (b) based on formula recommended in the Pronab Sen Committee report		5.27
Net Retail Price (a+b-c)		172.52
Company Claimed Price		210.00

Agenda Item no 12. JENVAC Injection - Each dose of 0.5ml contains: Purified, Inactivated Japanese Encephalitis Virus Protein (JEV Strain 821564-XY) NLT 5.0mcg, Aluminium (Al+++) as Aluminium Hydroxide gel 0.25mg, Thiomersal (as Preservative) IP 0.025mg & Phosphate Buffered Saline qs to 0.5ml Injection Manufactured and marketed by M/s Bharat Biotech International Limited.

The Applicant gave technical presentation before the committee in the last Multidisciplinary Committee meeting held on 13.6.2018 and subsequently submitted the cost justification. The committee noted the marginal economic cost benefit of Jenvac with a single dose course regimen compared to a two course dose regimen as submitted by the applicant and better compliance due to single dose course regime and recommended the retail price of Rs. 1,250/- per PFS vial (excluding GST).

Agenda Item no 13 - Durart R 450 each film coated tablet contains: Darunavir 400mg and Ritonavir IP 50mg, Manufactured & Marketed By M/s Mylan Pharmaceuticals Limited (application dated 9.4.2018, base data: Sep-2017)

The committee, after deliberation, recommended the worked out retail price of Rs.123.71/tablet as detailed below:

Computation of Retail Price per Tablet	Source/Method	Unit Price (Rs)
a. Darunavir 400mg	Ceiling Price # (600mg Price : 151.46*)	111.07

b. Ritonavir IP 50mg	Ceiling Price ## (100mg Price : 26.33)	15.80
Worked out Retail Price		126.87
c. Less 20% of the lowest of (a) and (b) based on formula recommended in the Pronab Sen Committee report		3.16
Net Retail Price (a+b-c)		123.71
Company Claimed Price		150.00

$151.46 \times [1 + 0.8 (400-600)/600] = 111.07$

$26.33 \times [1 + 0.8 (50-100)/100] = 15.80$

Agenda Items no 14 - Diclotal MR Gel Manufactured by M/s The Madras Pharmaceuticals and marketed by M/s Blue Cross Laboratories Pvt. Ltd. Gel Contains: Diclofenac Diethylamine BP 1.16%w/w (eq. to Diclofenac Sodium 1%), Methyl Salicylate IP 5% w/w, Mephenesin IP 85 5%w/w, Menthol IP 2% w/w, Turpentine Oil BP 3%w/w

The committee, after deliberation, recommended the worked out retail price of Rs.2.46/gm considering all products containing Diclofenac Diethylamine BP 1.16%w/w (eq. to Diclofenac Sodium 1%) based on para 5, against the claimed price of Rs. 2.57/gm.

Agenda Item no 15 - Manufactured by M/s Theon Pharmaceutical Ltd. and marketed by M/s Jubilant Life Sciences Limited Jubinerv Capsule each hard gelatine capsule contains:

Alpha Lipoic Acid USP 100mg,

Methylcobalamin 1500mcg,

Vitamin B6 IP 3mg,

Folic Acid IP 1.5mg,

Benfotiamine 50mg,

Biotin USP 5mg,

Chromium Picolinate USP eq. to Chromium 200mcg

The committee directed to present the case in the next meeting alongwith the prices of similar products already available in the market.

Agenda Item no 18 and 24 - Each film coated tablet contains: Each tablet contains: Tenofovir Disoproxil Fumarate 300mg, Lamivudine 300mg and Dolutegavir 50mg tablet Manufactured & Marketed By M/s Emcure Pharmaceuticals Limited.

and

ACRIPTEGA TABLET Manufactured by M/s Mylan Laboratories Limited and marketed by M/s Mylan Pharmaceuticals Private Limited Each uncoated tablet contains: Lamivudine IP 300mg, Tenofovir Disoproxil Fumarate IP 300mg, Dolutegavir Sodium eq. to Dolutegavir 50mg.

The committee, after deliberation, recommended the worked out retail price of Rs.114.06/tablet as detailed below:

Computation of Retail Price per Tablet	Source/Method	Unit Price (Rs.)
a. Tenofovir (A) + Lamivudine (B) Tablet 300 mg(A) + 300 mg(B)	Ceiling Price	40.73
b. Dolutegavir 50mg	As per para 5	81.48
Worked out Retail Price		122.21

c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		8.15
Net Retail Price (a+b-c)		114.06
Company Claimed Price	-M/s Emcure -M/s Mylan Lab	Rs.183.33 Rs.116.07

Agenda Item no 20 - ULFREE Gel Manufactured by M/s Group Pharmaceuticals Limited and marketed by M/s Hetero Healthcare Ltd. Each film coated tablet contains: Choline Salicylate Solution B.P. eq. to Choline Salicylate 8.7% w/w, Benzalkonium Chloride Solution IP 0.001% w/w, Lignocaine Hydrochloride IP 2.0% w/w

Agenda Item withdrawn.

Agenda Item no 21 - Danavir R Manufactured by M/s Hetero Labs Limited and marketed by M/s Hetero Healthcare Limited Each film coated tablet contains: Darunavir Ethanolate eq. to Darunavir 800mg,Ritonavir 100mg Tablet

The committee, after deliberation, recommended the worked out retail price of Rs. 212.91/tablet as detailed below:

Computation of Retail Price per Tablet	Source/Method	Unit Price (Rs.)
a. Darunavir 800mg	Ceiling Price (600mg Price : 151.46)#	191.85
b. Ritonavir 100mg	Ceiling Price	26.33
Worked out Retail Price		218.18
c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		5.27
Net Retail Price (a+b-c)		212.91
Company Claimed Price		296.13

$$\# 151.46 \times [1 + 0.8 (800-600)/600] = 191.85$$

Agenda Item no 23 - Manufactured and marketed by M/s KonTest Chemicals Limited

Each hard gelatine capsule contains:

Alpha Lipoic Acid USP 200mg,

Methylcobalamin 1500mcg,

Vitamin B6 IP 3mg,

Folic Acid IP 1.5mg,

Benfotiamine 50mg,

Biotin USP 5mg,

The committee directed to present the case in the next meeting alongwith the price of similar products already available in the market.

Agenda Item no 25, 29 and 30 - Each film coated tablet contains: Daclatasvir Dihydrochloride eq. to Daclatasvir 60mg, Sofosbuvir 400mg Manufactured and marketed by M/s Natco Pharma Limited HEPCINAT PLUS TABLET

and

Each film coated tablet contains: Daclatasvir Dihydrochloride eq. to Daclatasvir 60mg, Sofosbuvir 400mg Manufacturer by M/s Natco Pharma Limited and marketed by M/s Cadila Healthcare Limited

and

HEPCINAT PLUS TABLET Each film coated tablet contains: Daclatasvir Dihydrochloride eq. to Daclatasvir 60mg, Sofosbuvir 400mg Manufactured by M/s Mylan Laboratories Pvt. Ltd. and marketed by M/s Mylan Pharmaceuticals Pvt. Ltd.

The committee, after deliberation, recommended the worked out retail price of Rs.556.442/tablet as detailed below:

Computation of Retail Price per Tablet	Source/Method	Unit Price (Rs.)
a. Sofosbuvir 400mg,	Ceiling Price	605.66
b .Daclatasvir 60mg	As per para 5	193.99
Worked out Retail Price		799.65
c. Less 20% of the lowest of (a) and (b) based on formula recommended in the Pronab Sen Committee report		38.80
Net Retail Price (a+b-c)		760.85
Company Claimed Price	Natco Cadila Mylan	558.036 687.500 556.442

Agenda Item no 33 & 34 - Cyblex MV 40.2 each tablet contain Metformin HCL 500mg + Gliclazide 40mg + Voglibose 0.2mg and Cyblex MV 40.3 each tablet contain Metformin HCL 500mg + Gliclazide 40mg + Voglibose 0.3mg by M/s Eris Lifesciences Ltd.

It has been brought to the notice of the committee by representative of CDSCO that the above said two formulations are not in the list of the approved FDCs. It has also been brought to notice of the committee by NPPA that the said formulations are already in the market in name of Cyblex MV 40.2 and Cyblex MV 40.3 without price approval. In view of the above, the committee is of the view that price of these formulations cannot be fixed and recommends to forward these cases to CDSCO for further necessary action.

B. Agenda relating to Para 11(3&4) of DPCO 2013

Agenda Item no 1 - Review order no.31015/08/2017-Pricing dated 30.10.2017 Review order in respect of Timolol Drops 0.5% Eye Drops filed by M/s Sun Pharma Laboratories Ltd.

The Committee noted that the directions/comment of the Department of Pharmaceuticals are awaited. The matter is deferred for the want of specific directions/comment

Agenda Item no 2 - Review order no.31015/86/2017-Pricing dated 26.2.2018 Review order in respect of Ciprofloxacin Tablets filed by M/s Sun Pharmaceuticals Ltd.

The Committee noted that the directions/comment of the Department of Pharmaceuticals are awaited. The matter is deferred for the want of specific directions/comment

Agenda Item no 3 - Review order in respect of Ringer Lactate Injection filed by Aculife Healthcare Private Ltd (Review Order No. 31015/81/2017-Pricing dated 21.03.2018), Albert David Ltd (Review Order No. 31015/76/2017-Pricing dated 21.03.2018), B.Braun Medical (India) Pvt. Ltd (Review

Order No. 31015/84/2017-Pricing dated 21.03.2018), Fresenius Kabi India Private Ltd (Review Order No. 31015/82/2017-Pricing dated 21.03.2018) and Otsuka Pharmaceutical India Private Limited (Review Order No. 31015/79/2017-Pricing dated 21.03.2018)

Due to paucity of time, the agenda was deferred and directed to convene a separate meeting of the committee for making presentations by the respective companies.

Agenda Item no 4 - Review order in respect of Insulin Cartridges 3 ml 100 IU filed by M/s Koye Pharmaceuticals Pvt. Ltd.

The committee deliberated the matter and noted that there is no significant therapeutic advantage of insulin cartridges vis-a-vis insulin vials and recommended no separate pricing for cartridges or vial.

2. The meeting ended with a vote of thanks to the Convenor.

(APS Sawhney)
Director (Pricing)

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All members of the Committee