मिसिलस.- 8(51)/2017/डी.पी/एनपीपीए-**डीवी-**॥

F. No. 8(51)/2017/DP/NPPA-Div. II

<u>कार्यवाहीस. : 183/51/2017/F</u> Proceeding No : 183/51/2017/F

Minutes of the 183rd and 51st meeting (continued) of Authority under DPCO, 2013 held on 20,12,2017 at 11.00 A.M.

- I. The $183^{\rm rd}$ overall meeting of the Authority, which is the $51^{\rm st}$ under the DPCO, 2013 continued on $20^{\rm th}$ December, 2017 at 11.00 AM under the Chairmanship of Shri Bhupendra Singh, Chairman, NPPA. The following members of the NPPA were present:-
 - (i) Shri Rakesh Ranjan, Member Secretary
 - (ii) Shri Umesh Dongre, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
 - (iii) Shri Arun Kumar, Adviser, Deptt. of Economic Affairs, Ministry of Finance.
 - (iv) Shri A. K. Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCG(I)).
- 1.1 The following officers of NPPA also attended the meeting and assisted the Authority in its deliberations:-
 - (i) Shri Kalyan Nag, Adviser (Cost)
 - (ii) Shri A.P.S. Sawhney, Director (Pricing)
 - (iii) Shri Baljit Singh, Asstt. Director (Pricing)
- 1.2 Chairman, NPPA welcomed all the members present in the meeting.
- II. Agenda items
- 1. Agenda item no. 9 Discussion on the analysis of trade margin regarding reports on the treatment in Fortis Memorial Research Institute, Gurgaon
- 1.1 After intensive deliberation, the Authority directed NPPA office to analyze the issue of exorbitant trade margins and inflated MRPs in all scheduled and non scheduled drugs and put up options of appropriate action in the next authority meeting.
- 2. Agenda item No. 11 (Supplementary Agenda) Fixation of the Retail price for the 'Without Price Approval' (WPA).
- 2.1 The Authority examined in details, fixation of the Retail price for the 'Without Price Approval' (WPA) cases referred by the M&E Division. With a view to rationalize the prices of new drugs, it has been decided in the Authority Meeting dated 15.12.2017, that wherever NPPA has already notified the price, the same price would be extended to subsequent applicants/ WPA cases also. Accordingly, the Authority approved the retail price of 15 new drugs on the basis of retail price already notified. The Authority also decided that in all such cases where the Pharmaceutical companies have sought approval of retail price for new drug/drugs where the price has already been notified for the same formulation/formulations, NPPA with the approval of the Chairman can extend the same price to subsequent applicants and may bring it to the Authority for information in next authority meeting. The details of retail price approved are as below:



S	o. Scheduled Formulation Brand Name	/ State of the sta	Unit	Manufacturer & Marketing Company	Retail Price excluding Local taxes (Pre-GST) (Rs.)	Retail Price excluding Goods and services tax (Post-GST
1		(3)	(4)	(5)	(6)	(Rs.) (7)
	Glimepiride + Metformin Tablets	Tablet Contains: Glimepiride 1mg & Metformin 500mg.	1 Table	t M/s Lupin Limited	4.00	3.84
2	Glimepiride + Metformin Tablets	Tablet Contains: Glimepiride 2mg & Metformin 500mg.	1 Tablet	M/s Lupin Limited	4.50	4.32
3	Metoprolol + Chlorthalidone Tablets	Tablet Contains: Metoprolol 25mg & Chlorthalidone 12.5mg.	1 Tablet	M/s Lupin Limited	5.81	5.57
4	Metoprolol + Chlorthalidone Tablets	Tablet Contains: Metoprolol 25mg & Chlorthalidone 12.5mg.	1 Tablet	M/s Lupin Limited	5.81	5.57
5	Metoprolol + Chlorthalidone Tablets	Tablet Contains: Metoprolol 50mg & Chlorthalidone 12.5mg.	1 Tablet	M/s Lupin Limited	7.22	6.92
6	Metoprolol + Chlorthalidone Tablets	Tablet Contains: Metoprolol 50mg & Chlorthalidone 12.5mg.	1 Tablet	M/s Lupin Limited	7.22	6.92
7	Moxifloxacin + Cefixime Tablets	Tablets contains: Moxifloxacin 400mg & Cefixime 400mg	1 Tablet	M/s Lupin Limited	34,46	33.05
8	Gliclazide + Pioglitazone + Metformin Tablets	Tablet containing: Gliclazide 60mg, Pioglitazone 7.5mg & Metformin 500mg.	1 Tablet	M/s Eris Life Sciences Ltd.	6.25	5.99
9		Tablet Contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg, Metformin HCl 1000mg.	1 Tablet	M/s Eris Life Sciences Ltd.	11.33	10.87
	Teneligliptin + Metformin Tablets	Tablet Contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin HCl 500mg.	1 Tablet	M/s Eris Life Sciences Ltd.	10.03	9.62



11	Glimepiride + Metformin Tablets	Tablet containing: Glimepiride 1 mg & Metformin 1000 mg.	1 Tablet	M/s Eris Life Sciences Ltd.	5.93	5.69
12	Glimepiride + Metformin Tablets	Tablet containing: Glimepiride 2mg & Metformin 1000mg.	1 Tablet	M/s Eris Life Sciences Ltd.	7.50	7.19
13	Glimepiride + Metformin Tablets	Tablet containing: Glimepiride 3mg & Metformin 1000mg.	1 Tablet	M/s Eris Life Sciences Ltd.	8.73	8.37
14	Metformin + Glimepiride + Pioglitazone Tablets	Tablet containing: Metformin 500mg, Glimepiride 1mg & Pioglitazone 15mg.	1 Tablet	M/s Unison Pharmaceuticals Pvt Ltd.	2.23	2.14
15	Metformin + Glimepiride + Pioglitazone Tablets	Tablet containing: Metformin 500mg, Glimepiride 2mg & Pioglitazone 15mg.	1 Tablet	M/s Unison Pharmaceuticals Pvt Ltd.	2.45	2.35

The Authority also decided that the Status of new drug applicationshould be updated on NPPA's website fortnightly and in cases where new drug has been launched without price approval, prompt action should be taken to issue show cause notices and do the recoveries as per law.

3. Agenda item No. 12 (Supplementary Agenda) - Appreciation of contribution Shri Suneel Chopra, Principal Legal Consultant

3.1 The Authority noted the usual presence of Shri Suneel Chopra, PLC in the meeting and took note of the fact that there are 224 active court cases in the Hon'ble Supreme Court of India and various High Courts and put on record the outstanding services rendered by Shri Suneel Chopra, former Principal Legal Consultant. The Authority also acknowledged the significant contribution made by Shri Chopra in pursuing all court cases efficiently and successfully to obtain a large number of favourable landmark judgments pronounced by Hon'ble Supreme Court and High Courts especially in CA 329/2005 UOI vs. Cipla Ltd & connected cases, CA 5117/2013 UOI vs. Swiss Garnier & mars, CA 1939/2004 Glaxosmithklin vs. UOI, SLP(C) 30089/2016 & WP(C) 2700/2014 filed by IPA vs UOI etc. which helped NPPA in recovery of about Rs.400 crore government dues in the last two years. Further, the authority put on record that Shri Chopra was the only professional in NPPA having legal as well as technical knowledge and well versed with all these cases and therefore, services of Shri Chopra as Principal Legal Consultant should be continued further to properly and effectively safeguard the interest of NPPA/Government in larger public interest. Authority was briefed that the selection committee set up by DoP has chosen Shri Chopra as the only suitable candidate and the file is pending for approval in Govt. for approval of the Competent Authority. Authority asked NPPA to write to DoP again to expedite the approval.

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

(Rakesh Ranjan) Member Secretary