गोपनीय: Confidential

मिसिलस.- 8(46)/2017/डी.पी/एनपीपीए-डीवी-॥ F. No. 8(46)/2017/DP/NPPA-Div. ॥

कार्यवाहीस. : 177/46/2017/F

Proceeding No : 177/46/2017/F

Minutes of the 178th and 46th meeting of Authority under DPCO, 2013 held on 08.6.2017 at 11.00A.M.

- The 178thoverall meeting of the Authority, which is the 46thunder the DPCO, 2013 was held on 8th June, 2017 at 11.00 AM under the Chairmanship of Shri Bhupendra Singh, Chairman, NPPA. The following members of the NPPA were present:-
 - (i) Dr. Sharmila Mary Joseph K, Member Secretary, NPPA.
 - (ii) Shri Umesh Dongre, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
 - Shri R. Chandrashekhar, 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) Smt. Roshni Sohni, Director (Enf./Admn.)
 - (iv) Shri A.K. Khurana, Director (Overcharging)
 - (v) Shri R. Nihal Pedric, Dy. Director (Monitoring)
 - (iv) Shri Baljit Singh, Asstt. Director (Pricing)
 - (vi) Shri Prasenjit Das, Asstt. Director (Pricing)
 - (vii) Shri Suneel Chopra, Pr. Legal Consultant
- 1.2 Chairman, NPPA welcomed all the members present in the meeting.

Agenda Items

- 1. Agenda Item no. 1: Confirmation of Minutes of the 45th Meeting held on 23.5.2017.
- 1.1 The Authority confirmed the minutes of the overall 177th and the 45thMeeting held on 23.5 2017 under DPCO, 2013.

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2. Agenda Item no. 2: Action Taken Report

2.1 Noted.

- 3. Agenda Item no. 3: GST impact on Pharmaceutical Pricing.
- 3.1 The Authority discussed in detail, the impact GST rates on pharmaceutical products. The Authority decided to re-notify the ceiling prices of scheduled formulations, excluding applicable GST rates, after notification of implementation of applicable GST rates by the Government, as detailed below:
 - a) In case of scheduled formulations, where presently excise duty is levied on MRP, the revised ceiling price exclusive of applicable GST rates would be calculated by applying a factor of 0.95905 to the existing notified ceiling price. The factor has been worked out as follows:

	Computation of the Factor to arrive at the revised ceiling prices	(Rs.)
а	Ceiling Price fixed before 30.6.2017 (Incl. Excise Duty)	100.00
ь	Add, Local Taxes/VAT on above (@ 5%)	5.00
С	MRP (inclusive of all-taxes)	105.00
d	Less. Excise Duty of 6% on 65% of MRP	4.095
e	Less: Local taxes/VAT as applicable	5.00
f	Revised Ceiling Price to be re-notified (excluding GST)	
	FACTOR (f/a)	0.95905

- b) In case of scheduled formulations, which are exempted from excise duty, no multiplication factor would be applicable. The existing notified ceiling price would be the ceiling price exclusive of GST rates as applicable.
- c) In case of non-scheduled formulations, paragraph 20 of the DPCO, 2013 needs to be followed irrespective of any change in the tax structure or tax rates. The companies will have no option but to absorb the net increase, if any, in the incidence of tax on implementation of GST within the permissible limit of 10% for increase of Maximum Retail Price compared to the MRP of preceding 12 months as prescribed under paragraph 20 of the DPCO, 2013.

However, in case of savings due to lower rate of tax, the benefit may be passed on to the consumers as per the anti-profiteering clause in GST rules

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- 3.2 The Authority further decided that an OM may be issued immediately clarifying NPPA's stand on GST issue and after notification of GST by the Government, the ceiling price of scheduled formulations would be worked out and notified taking into account para 3.1 as applicable.
- 4. Agenda Item no. 4: Allegations regarding unethical innovative trade practices adopted by certain companies to bypass the order of NPPA regarding restricted trade margins
- 4.1 The Authority noted the concerns and discussed that NPPA will examine the issue after collection of necessary facts and take necessary action.
- Agenda Item no. 5:WP(C) 4762/2017 filed by M/s Reckitt Benckiser Healthcare India Ltd and Ceiling Price fixation of Clotrimazole 1% cream.
- 5.1 The Authority discussed the matter in detail and observed that in fixation of ceiling price of scheduled formulations under DPCO, 2013, the free goods (freebies), if any, given by the manufacturers/marketers were not factored so far due to non-availability of complete data. Moreover, the same details are also not clearly mentioned in PharmaTrac database. The Authority decided that since the company has clearly provided data of free goods (freebies) in their invoices submitted, the same is to be considered in the calculation of ceiling price and accordingly, approved the revised ceiling price of Rs. 2.57/gm of Clotrimazole 1% cream based on the summary of invoices furnished. The Authority discussed the issue and approved the speaking order in this regard.
- Agenda Item no. 6: Retail Price Fixation of New Drugs under DPCO, 2013
- 6.1 The Authority noted that the retail prices of the 'new drugs' listed below were approved in principle at the 40th Authority Meeting held on 23rd January, 2017, subject to IPDMS compliance by the companies. The Authority noted that the companies concerned have filed all mandatory forms for their products through IPDMS and accordingly decided to issue notification in respect of retail price of these 'new drugs'.

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SI. No.	Name of the Scheduled Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company respectively	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Pacimol 10mg/ml Infusion	Each 100ml contains: Paracetamol 1000mg	1 ML	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s IPCA Lab. Ltd.	2.06
2	Pacimol MF Tablet	Each uncoated tablet contains Mefenamic Acid – 500mg Paracetamol 325mg	10 Tablets	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s IPCA Lab. Ltd.	26.46
3.	Ten DC- M 500 tablet	Each uncoated bilayer tablet contains. Teneligiptin Hydrobromide Hydrate og to Teneligiptin 20mg Metformin HCI 500mg (as sustained release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd./ M/s FDC Ltd.	10.03
4.	Ten DC- M 1000 tablet	Each uncoated bisayer tablet contains. Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin HCl 1000mg (as sustained release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd./ M/s FDC Ltd.	11.33

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

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Member Secretary