गोपनीय : Confidential

मिसिल स.. 8(15)/2014 डी.पी./एन पी पी ए- डीवी-II

F. No. 8(15)/2014/DP/NPPA-Div. II

कार्यवाही स. : 147/15/2014/F

Proceeding No : 147/15/2014/F

Minutes of the 147th and 15th meeting of Authority under DPCO, 2013 held on 16th May, 2014 at 12.00 noon.

The 147th meeting of the Authority which is 15th under the DPCO, 2013 was held on 16th May, 2014 at 12.00 noon under the Chairmanship of Sh. C. P. Singh Chairman, NPPA. The following members of the NPPA were present:-

(i) Shri A.K. Gautam, Member Secretary Incharge, NPPA.
(ii) Shri K.L. Prasad, Member (Ex-Officio), Adviser, Economic Division, Deptt. of Economic Affairs.
(iii) Shri L.M. Kaushal, Director (Cost), Member (Ex-Officio), Deptt. of Expenditure, Ministry of Finance.
(iv) Shri R. Chandrashekar, Deputy Drug Controller, representing the DCG(I), Department of Health.

The following officers also attended the meeting and assisted the Authority in its deliberations:-

(i) Shri Lal Sanglur, Director (Admn.)
(ii) Shri Jagdish Kumar, Director (Monitoring)
(iii) Shri A.K. Khurana, Director (Pricing & OC)
(iv) Shri S. K. Bhatt, Dy. Director (Technical)
(v) Shri Singh Veer Pratap, Dy. Director (Cost)
(vi) Smt. Manmohan Kaur, Dy. Director (Cost)
(vii) Shri Manish Goswami, Dy. Director (Cost)
(viii) Shri T. R. Satish Chandran, Asstt. Director (Cost)

Chairman, NPPA welcomed all the members present in the meeting.

1. Agenda Item no. 1:

1.0 Members of the Authority who participated in the 146th and 14th Meeting under DPCO, 2013 confirmed the minutes of the meeting.

2. Agenda Item no. 2: Action Taken Report:

2.0 Noted.

3. Agenda Item no. 3:

3.0 The Authority discussed the price revision in respect of the two cases based on the review order review order no. 31015/21/2013/PI.I dated 21.10.2013 issued by the DOP. The details of these cases are as under:-

Phenobarbitone 30 mg and 60mg tablet

3.1 The Authority discussed the proposal and approved the revised ceiling price of the price of Phenobarbitone 60 mg tablet at Rs. 2.53/tablet (including WPI factor of 6.32% as the base data is May, 2012) against the earlier ceiling price of Rs. 1.69/tablet (Rs. 1.80/tablet including WPI factor of 6.32%) notified vide S.O. no. 1569(E) dated 14.06.2013.

3.2 As the price of Phenobarbitone tablet 60 mg has a bearing on the price of Phenobarbitone tablet 30 mg. Therefore, the case of Phenobarbitone tablet 30 mg will be put up in the next Authority meeting as per the decision taken by the Authority, being a monopoly case.

4. Agenda Item no. 4:

4.0 The Authority discussed the definition of "new drug" as per para 2(u) of DPCO 2013 which states that *a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the National List of Essential Medicines*

(NLEM) by combining the drug with another drug either listed or not listed in the National List of Essential Medicines or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the National List of Essential Medicines.

4.1 The Authority noted that various manufacturers and marketing companies are submitting the Form I application for approval of price of "new drugs" under the DPCO 2013. The Authority noted that such application for "new drug" has to be from an "existing manufacturer" of a NLEM drug but Form-I do not contain any such details in this regard. Therefore, the Authority directed that in all the Form-I applications approved by NPPA till date and in future also, the companies may be asked to submit the declaration as to the effect that they are an "existing manufacturer" of a scheduled drug and also should furnish the price of such existing drugs for information. It was also decided that OM to this effect may be put on the website for information and may also be sent to Apex Pharma Associations for compliance.

4.2 In the meantime, the Authority decided to continue with the procedure for the price fixation based on Form-I application submitted by the concerned companies as per existing practice. The case of retail price fixation of "new drug" based on Form-I application received from the following company was examined accordingly, the details of approved price is as under:

S.No	Company name/Product name	Approved Price (Rs.)
1.	M/s Swiss Garnier Life Sciences (Manufacturer) and M/s Mankind Pharma Ltd. (Marketing company) – **Nitrofurantoin Capsules** Each Hard Gelatin Capsule Contains: Nitrofurantoin (Hydrous/Anhydrous-Macrocrystals) Eq. to Nitrofurantoin-100 mg	7.63/Capsule

5. Agenda Item no. 5:

5.0 The Authority discussed the agenda note regarding Monitoring of movement of prices of non-scheduled formulations under DPCO, 1995/DPCO, 2013 in detail and noted that there is a an explicit provision in the DPCO, 2013 to deal with the cases of price increase beyond the permissible limit of 10% per annum in respect of "non-scheduled formulations" and to recover the overcharged amount beyond the cap of 10%. Whereas there was no such provision in DPCO, 1995 and the monitoring of price movement of non-scheduled formulations was based on the internal guidelines followed by the NPPA. The increase in price beyond 10% on account of change in excise duty/VAT was well within 1%. It was also recalled that earlier there was a practice to not to notify the prices where suo-motu price revision was worked out within 1%. The Authority also noted that out of 1374 cases of non-scheduled formulations examined by the NPPA, 53 such cases relating to excise duty/VAT were identified. In addition, there were 69 cases pending for disposal on account of incomplete/no reply from the companies. In the circumstances, the Authority after due deliberation decided that the cases of price increase beyond 10% on account of upward revision in the excise duty/VAT pertaining to DPCO, 1995 may not be pursued further. With regard to the cases of incomplete reply/no reply from the companies, the Authority directed that Monitoring Division should give a final opportunity to the companies for submission of requisite information/data within 15 days and disposed of these cases within 2 months as per the guidelines and refer the cases of defaulter companies for price fixation.

5.1 The Authority also discussed the proposal submitted for analyzing the cases of monitoring of prices of non-scheduled formulations under para 20 of DPCO, 2013. The Authority decided that the companies should be given 21 days time for submission of information/data from the receipt of preliminary notice, failing which a show cause notice may be given to the companies for providing the information within the time limit of 15 days with personal hearing, if sought for by them. The Authority also directed that the cases of price monitoring under para 20 of DPCO, 2013 should be disposed off within the period of 6 months from the date of receipt of information.

5.2 As regards the IMS-Health monthly data required for monitoring of price movement of non-scheduled formulations, the Authority noted that MRP based data has not been received

so far. The Authority directed that the issue may be taken up with IMS-Health to expedite the same and a status note should be put up in the next Authority Meeting in this regard.

6. Supplementary Agenda Item no. 1:

6.0 The Authority discussed the price revision in respect of one case based on the representation received from the company. The details of this case are as under:-

(i) Salbutamol Sulphate Inhaler 100mcg/dose:

6.1 The Authority discussed the proposal and approved the ceiling price of Rs. 0.48/one MT dose as against the earlier ceiling price of Rs 0.43/ one MT dose notified vide S.O. 1021(E) dated 02.04.2014. The price was revised based on the representation of M/s Cipla.

7. Agenda Item no. 2:

7.0 The Authority discussed the cases of retail price fixation of "new drug" based on Form-I application received from the following companies. The details of approved prices are as under:

S.No	Company name/Product name	Approved Price (Rs.)
2(i)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Plenteous Pharmaceuticals Ltd. (Marketing company) – **Choline Salicylate & Lignocaine Hydrochloride Gel** Choline Salicylate Solution BP Equivalent to Choline Salicylate 8.7% w/w Lignocaine Hydrochloride IP 2% w/w Preservative: Benzalkonium Chloride Solution IP 0.01% w/w In pleasant flavored Gel Base	3.26/gm
2(ii)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Jubilant Life Sciences Limited (Marketing company) – **Metoprolol Succinate & Amlodipine besylate Tablets (Evimeto™ AM)** Each uncoated bilayer tablet contains:	5.92/tablet

	Metoprolol Succinate USP 47.5 mg Eq. to Metoprolol Tartrate 50 mg (In extended release form) Amlodipine Besilate IP Eq. to Amlodipine 5 mg Excipients q.s. Colour- Lake of Sunset Yellow FCF	
2(iii)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Jubilant Life Sciences Limited (Marketing company) – **Metformin Hydrochloride Prolonged –Release Tablets IP (Glybza 1000)** Each uncoated prolonged release tablet contains: Metformin Hydrochloride IP 1000 mg	30.77/10's tab
2(iv)	M/s Akums Drugs & Pharmaceuticals Ltd. (Manufacturer) and M/s Jubilant Life Sciences Limited, (Marketing company) – **Metoprolol Succinate Extended Release Tablets USP (Evimeto™ 100)** Each film coated extended release tablet contains: Metoprolol Succinate USP 95 mg Eq. to Metoprolol Tartrate 100 mg Excipients q.s. Colour- Titanium Dioxide IP	7.39/tablet
2(v)	M/s Hetero Labs Limited (Manufacturer) and M/s Jubilant Life Sciences Limited, (Marketing company) – **Metformin Hydrochloride (Prolonged Release) 500 mg & Voglibose 0.3 mg Tablets (AgivogTM M 0.3)** Each uncoated bilayered tablet contains: Metformin Hydrochloride (In prolonged release form) IP 500 mg Voglibose IP 0.3 mg Excipients q.s. Colour- Lake Indigo Caramine Yellow	52.38/10's tab
2(vi)	M/s Synokem Pharmaceuticals Limited (Manufacturer) and M/s Intas Pharmaceuticals Ltd., (Marketing company) – **Atorvastatin & Clopidogrel Capsules (CLAVILIP 10)** Each hard gelatin capsule contains: Atrovastatin Calcium IP Eq. to Atrovastatin 10 mg (As pellets) Clopidogrel Bisulphate IP Eq. to Clopidogrel 75mg (As pellets) Colour : Approved colours used	10.29/Capsule
2(vii)	M/s Hetero labs Limited (Manufacturer) and M/s Torrent Pharmaceuticals Ltd., (Marketing company) – **TRIVOGLITOR 1** Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500 mg (in sustained release form) Glimepiride IP 1 mg and	8.46/Tab

	Voglibose – 0.2 mg Excipients Colours : Sunset Yellow FCF	
2(viii)	M/s Hetero labs Limited (Unit II) (Manufacturer) and M/s Torrent Pharmaceuticals Ltd., (Marketing company) – **TRIVOGLITOR 2** Each uncoated bilayered tablet contains: Metformin Hydrochloride IP 500 mg (in sustained release form) Glimepiride IP 2 mg and Voglibose – 0.2 mg	10.47/Tab

8. **Agenda Item no. 3:**

8.0 The Authority discussed the internal guidelines proposed for fixation/revision of prices of formulations under para 19 of the DPCO, 2013 in respect of 'inter-brand price difference' and the 'launch price' of non-scheduled formulations. The Authority decided that the guidelines proposed for specified therapeutic groups may also be extended to other therapeutic groups and in this regard, Drugs Controller General (India) and State Drugs Controllers should also be requested to identify any other therapeutic group/ disease to be covered under the guidelines. The Authority also decided that para 2 (c) of the guideline may be revised as under:

'the cases of shortages of scheduled and non-scheduled formulations reported by the SDCs/Governments may be examined on case to case basis, for price fixation/ revision under para 19 of DPCO, 2013'

8.1 While approving the guidelines as above, the Authority also decided that these guidelines may be reviewed after 6 months.

9.0 This issues with the approval of Chairman, NPPA.

(A.K. Gautam)
Member Secretary Incharge