गोपनीय : Confidential

मिसिल स.- 8(11)/2014 डी.पी./एन पी पी ए- डीवी-II

F. No. 8(11)/2014/DP/NPPA-Div. II

कार्यवाही स. : 143/11/2014/F

Proceeding No : 143/11/2014/F

Minutes of the 143rd and 11th meeting of Authority under DPCO, 2013 held on 13th February, 2014 at 12.00 Noon.

The 143rd meeting of the Authority which is 11th under the DPCO, 2013 was held on 13th February, 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.
(iii) 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 A.K. Saha, Director (Overcharging)
(ii) Shri Lalsanglur, Director (Admin. & Overcharging)
(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) Shri G. Pradhan, Dy. Director (Cost)
(vii) Shri Manish Goswami, Dy. Director (Cost)
(viii) Smt. Babita Singh, Asstt. Director (Cost)
(ix) 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 142nd and 10th Meeting under DPCO, 2013 confirmed the minutes of the meeting.

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

2.0 Noted.

2.1 In case of Anti-D Immunoglobulin (Human) Injection 300 mcg and Rabies Immunoglobin Injection 150 IU/ml, it was informed to the Authority that reply received from DCG(I) is incomplete and was without enclosures. The Authority directed that reminder may be issued to the DCG(I) regarding the same.

2.2 The Authority also discussed the status of pending Form-I applications for price fixation of "new drug" under DPCO, 2013. During the discussion, the DCG(I) representative mentioned that all the manufacturers/companies are required to take the prior permission of DCG(I) for launching any "new drug". The concerned State Licencing Authority can grant licence only after the completion of four years from the date of approval of a new drug. It was also decided that in all such cases where companies have not furnished the copies of DCG(I) permission along with the Form-I as well as in cases where the retail/non-ceiling prices have already been approved and notified till previous 10th meeting, a reminder may be issued to them to submit the requisite permission within 7 days positively failing which the Form-I application may be returned back to the concerned companies/their cases may be closed and the said S.O. (in case of retail/non-ceiling prices already notified) may be withdrawn, as the case may be.

3. Agenda Item no. 3:

3.0 The Authority had detailed deliberations regarding the price fixation of scheduled formulations under DPCO, 2013. The Authority, noting that in respect of 103 cases referred to the SDCs, Since the response is very poor the SDCs may be reminded again to provide the information available with them. The replies received in this regard may be forwarded to IMS Health for the re-validation of the data and matters processed further.

3.1 The Authority also directed that a reminder may be issued again in respect of 8 cases which were referred in DOP seeking clarification from the Ministry of Health.

3.2 The Authority also discussed the issues concerning price fixation of the drugs which are covered in DPCO 1995 and 2013. It was decided that the exercise of price fixation may be completed based on the IMS data and the time schedule in this regard may be adhered to strictly i.e. as per DPCO 2013, these are to be notified on 01.4.2014.

3.3 The Authority discussed the price revision in respect of five cases based on the representations received from the companies. The details of these cases are as under:-

(i) 5-Amino Salicylic Acid (5-ASA) 400 mg tablets: This case was discussed in detail and it has been observed that the product of M/s Win Medicare has a very high price in comparison to the other packs considered in this regard. The Authority was appraised that the higher price of M/s Win Medicare was also noted while processing the case and IMS-Health was requested twice to revisit the price data of the company. It was also noted that Since the formulation of M/s Win Medicare is imported as per the sample submitted by M/s Wallace, it is decided that the details of import along with the source, CIF price, landed cost, launch price, product profile and year-wise PTR and MRP, price list in Form-V for implementation of ceiling price, etc. for the period from June, 2011 to May, 2012 may be asked from the company. Matter may be examined and put up. Therefore, the case was deferred.

(ii) Paracetamol Syrup 125 mg/5ml: The Authority considered the agenda and approved the price of Rs. 0.32/ml by deleting the data of M/s Glaxo of 120 mg/5ml as against the existing price of Rs. 0.33/ml notified vide S.O. 1554(E) dated 14.6.2013.

(iii) Digoxin Injection 0.25mg/ml: The Authority discussed the proposal and approved the ceiling price of Rs. 3.74/ml as against the earlier price of Rs. 2.85/ml notified vide S.O. 3367(E) on 05.11.2013

(iv) Clotrimazole Pessaries 100mg The Authority discussed the proposal and approved the ceiling price of Rs. 8.69/pessary as against the notified price of Rs. 8.47/pessary notified vide S.O. 3330(E) dated 05.11.2013 and directed that the case of Clotrimazole Pessaries 200mg being a monopoly case may be put up in the next Authority meeting.

(v) Heparin Injection 5000IU/ML: The Authority discussed the proposal and noted that M/s Gland Pharma is selling the product at two different prices in two different names i.e. one is generic and other is branded, as informed by the representative of the DCG(I). The Authority also observed that the company has furnished the copies of sample invoices indicating the PTR of both the packs. The Authority directed that the necessary clarification may be sought from the company regarding the difference in the prices of these two packs. Accordingly, the case was deferred.

4. Agenda Item no. 4:

4.0 The Authority discussed the agenda note and the letter dated 11.07.2013 furnished by M/s Abbott to review the ceiling prices. The Authority noted that according to M/s Abbott, "*Phenobarbitone 30 & 60mg, the packs of M/s MedoPharma have also been included in the calculation despite the same not being in circulation in the market. Additionally, SKU Barbitoin Tabs (30mg & 60mg) of M/s MedoPharma is a combination drug of "Phenobarbitone + Phenytoin" and hence should be excluded while calculating*

SAP for Phenobarbitone. Prices of these medicines therefore need to be reworked and recalculated by the NPPA". The Authority noted that the two parts of the above statement of the company are contradictory, therefore, the clarification for the same may be called for from the company. The case was, accordingly, deferred.

4.1 In case of Promethazine injection 25mg/ml, the Authority discussed the proposal and approved the ceiling price of Rs 2.84/ml as against the earlier price of Rs. 2.66/ml. notified vide 1918(E) dated 28.6.2013.

5. Agenda Item no. 5 (i) to (v):

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

S.No	Company name/Product name	Approved Price (Rs.)
1	**M/s Akums Drugs & Pharmaceuticals Limited (Manufacturer) & M/s Zuventus Healthcare Ltd. (Marketing Company)- Tusformin 2 Tablet** Each uncoated bilayered tablet contains: Glimepiride – 2 mg Pioglitazone HCl eq. to Piogliazone – 15mg Metformin HCL – 500mg (in sustained release Form)	6.94/tablet
2	**M/s Akums Drugs & Pharmaceuticals Limited (Manufacturer) & M/s Zuventus Healthcare Ltd (Marketing Company)- Tusformin 1 Tablet** Each uncoated bilayered tablet contains: Glimepiride – 1 mg Pioglitazone HCl eq. to Piogliazone – 15mg Metformin HCL – 500mg (in sustained release Form)	5.36/tablet
3	**M/s Hetero Labs Ltd. (Manufacturer) & M/s Abbott India Ltd. (Marketing Company)- Obimet V 0.2mg Tablet** Each uncoated bilayered tablet contains: Voglibose – 0.2mg Metformin HCL – 500 mg (as sustained release)	52.38/10's tab.

4	**M/s Hetero Labs Ltd. (Manufacturer) & M/s Abbott India Ltd. (Marketing Company)- Obimet V 0.3mg Tablet** Each uncoated bilayered tablet contains: Voglibose – 0.3mg Metformin HCL – 500 mg (as sustained release)	52.38/10's tab.
5	**M/s Newtramax Healthcare. (Manufacturer) & M/s Zuventus Healthcare Ltd (Marketing Company) – Trustocid D Capsule** Each hard gelatin capsule contains: Omeprazole – 20 mg (as enteric coated pellets) Domeperidone – 10 mg(As Pellets)	4.21/capsule

6. Agenda Item no. 6:

6.0 The Authority discussed the review order of the DOP and the agenda in detail. The Authority was appraised that though M/s Reckitt Benckiser is also marketing 60 ml, 110 ml and 210 ml pack in addition to pack sizes of 50 ml, 100 ml and 200 ml, this does not confer any additional benefit to the company as the norms notified by NPPA are proportionately adjusted to pack size/volume. However, the DCG(I) representative pointed out that Dettol Antiseptics are not an emulsion, as the name itself is Dettol antiseptic liquid. Therefore, extending the norms applicable to Emulsion may not be in order. Further, the Authority directed that as per review order, the norms as claimed may only be granted.

6.1 In view of the above, the Authority decided that the DOP may be requested to re-consider the review order in view of the observation of the representative of DCG(I). The cases were, accordingly, deferred.

7. Agenda Item no. 7:

7.0 The Authority discussed these cases in detail. It was deliberated that these cases were already closed by the NPPA and the company was informed accordingly. In view of this, the Authority decided that DOP may also be informed with regard to their letter dated 19.11.2013 that there is no pending case of M/s Ranbaxy in the NPPA as their

applications for price revision had earlier been closed consequent on announcement of NPPP, 2012 and they have not requested for re-opening of the same.

8. Agenda Item no. 8:

8.0 This agenda item regarding application for price fixation by M/s Nirma in respect of price fixation for I.V. Fluids in Non-PVC bags was discussed in detail and the proposal was not agreed to as the fixation of price in this regard may encourage the other companies to shift from conventional bottle packing to the non-PVC packing which is costlier for the patients.

8.1 The Authority also noted that these formulations are also NLEM drugs in DPCO, 2013 and their prices are required to be notified on 01.4.2014. Therefore, the Authority decided that the price fixation at this stage is not desirable and the company may be informed accordingly.

9. Agenda Item no 9(i) & (ii): Noted and Approved

10. Agenda Item no. 10:

10.0 The Authority was informed that the agenda item for price revision of the bulk drug Levosalbutamol was deferred in the previous 10th Authority meeting held on 17.12.2013, with the directions to examine the reasons for wide variations in the cost structure of the different companies. The Authority discussed the re-worked out price of Rs. 27484/kg for the bulk drug Levosalbutamol in detail, in compliance with the DOP's review order dated 15.5.2013. The Authority also noted that new DPCO, 2013 has been pronounced on 15.5.2013 on the basis of NPPP, 2012, under which mandate is for price fixation of formulations only in respect of NLEM drugs as specified in Schedule-I of DPCO, 2013. The Authority also noted that neither any formulation price application is pending based on Levosalbutamol nor Levosalbutamol drug is mentioned in Schedule-I of DPCO, 2013. Accordingly, the Authority decided that it would not be

prudent to fix the price of the bulk drug Levosalbutamol at this stage. DOP may also be informed accordingly.

11. Agenda Item no. 11:

11.0 The Authority noted the status and directed that a month-wise progress may also be put up from next Authority meeting. The Chairman, NPPA emphasised that the Overcharging Division is to put up the annual action plan for the remaining pending cases. The month-wise details of the cases initiated and finalised with the overcharged amount involved and recovered, if any, may also be indicated in the agenda in the future Authority meetings.

12.0 This issues with the approval of Chairman, NPPA.

(A.K. Gautam) 14/2/14

Member Secretary Incharge