गोपनीय : Confidential

मिसिल स.- 8(10)/2013 डी.पी./एन पी पी ए- डीवी-II

F. No. 8(10)/2013/DP/NPPA-Div. II

कार्यवाही स. : 142/10/2013/F

Proceeding No : 142/10/2013/F

Minutes of the 142nd and 10th meeting of Authority under DPCO, 2013 held on 17th December, 2013 at 12.00 Noon.

The 142nd meeting of the Authority which is 10th under the DPCO, 2013 was held on 17th December, 2013 at 12.00 Noon under the chairmanship of Shri C. P. Singh Chairman, NPPA. The following members of the NPPA were present:-

(i) Shri Sanjay Kumar, Member Secretary, 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. Gautam, Adviser (Cost)
(ii) Shri A.K. Saha, Director (Overcharging)
(iii) Shri Lalsanglur, Director (Admin. & Overcharging)
(iv) Shri Jagdish Kumar, Director (M&E)
(v) Shri A.K. Khurana, Director (Pricing & OC)
(vi) Shri S. K. Bhatt, Dy. Director (Technical)
(vii) Shri Singh Veer Pratap, Dy. Director (Cost)
(viii) Smt Manmohan Kaur, Dy. Director (Cost)
(ix) Shri Manish Goswami, Dy. Director (Cost)

(x) Shri S.S. Agrawal, Asstt. Director (Cost)
(xi) Shri T. R. Satish Chandran, Asstt. Director (Cost)
(xii) Shri Suneel Chopra, Consultant (Legal)

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 141st and 9th 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 had detailed deliberations regarding the price fixation of scheduled formulations under DPCO, 2013 relating to 13 cases proposed in the Agenda and noted that the price fixation under the present proposal was made based on the data from IMS Health and also the data furnished by the manufacturers. The Authority also recalled the observations during the 1st meeting and noted that NPPA is constrained to fix the ceiling price based on the "best available data" at present. It is also noted that even the data available on the internet also may be inadequate. Moreover, the MAT value of different manufactures is also not available from the data available through internet search. Therefore, the Authority took a view that initially the prices may be worked out based on the IMS Health/and other available data and later on the notified ceiling prices may be revisited in extra-ordinary circumstances and in public interest at large, if called for.

3.1 In case at S. No. 2 of Annexure-A, the Authority noted that M/s Maruti Air Products is selling Oxygen B type cylinder at PTR of Rs. 26.53/cu.m. with negligible MAT value of Rs. 14,700 i.e. 0.00% of MAT value. The Authority noted that this being a outlier i.e. zero % MAT value at two decimal points as having the highest price of Rs. 26.53/cu.m. whereas the other prices are in the range of Rs. 7.76 to Rs. 20 per cu.m.

and thus, may not be considered for price calculation purposes. The Authority also directed that the principle of ignoring outliers in the prices may be considered for ceiling price fixation as a policy decision in future cases also. Accordingly, the revised price after removing the aforesaid pack comes to Rs. 15.81/ cu.m. as against the earlier proposed price Rs. 17.31/cu.m. The Authority approved the revised ceiling price of Rs. 15.81/cu.m. Accordingly, the Authority considered and approved the prices of 4 formulation packs for fixing/notifying the ceiling price under Para 4 of DPCO, 2013 based on the data furnished by IMS Health and companies. A Statement showing the prices approved and percentage of decrease from the highest price in the zone of consideration in respect of each medicine is enclosed as Annexure - A.

3.2 The Authority considered and approved the prices of 3 formulation packs for fixing/notifying the ceiling price under Para 6 of DPCO, 2013 based on the Monopoly conditions/situation i.e. where data in respect of only one company is available. A Statement showing the prices approved in respect of each such medicine is enclosed as Annexure - B.

3.3 The six cases of price revision under DPCO, 2013 were proposed based on the representations received from the manufactures for the revision in the ceiling prices fixed by NPPA. The details of these cases are as under:

(i) & (ii) The existing price of Imatinib 100 mg and 400 mg tablet was fixed based on IMS-Health data as Rs. 87.59/tablet on 21.6.2013 and Rs. 268.33/tablet on 14.6.2013 respectively. The company i.e. M/s Novartis has submitted a representation on 22.8.2013 against the abovesaid price fixation. The main contention of the company was that they are one of the major manufacturers and their data was not correctly collected by the IMS-Health. The representation by the company was referred to the IMS-Health for the expert comments during the month of Sep., 2013. The IMS-Health vide their fax in Oct., 2013 has informed that "IMS Health data collection methodology captures information from the authorized stockiest sell out. For specialty products such as Oncology, critical care etc. the sales are through multiple channels which include

direct to patients, to institutions etc. The adoption of different distribution network alongwith the strict patient confidentiality clause brings limitations in capturing data for these products/brands".

NPPA also made attempts to collect the data from the other known manufacturer(s) on 22.11.2013. However, no reply has been received from them so far. Therefore, the data as provided by M/s Novartis was considered for revised price calculations. The Authority discussed these issues in details. The representative of DCG(I) also informed to the Authority that mostly oncology drugs are sold to the institutions, NGO's, Govt. supply etc. than in the trade. Since the company's medicines are not sold in the trade and are supplied to the designated institutions, may be through their own distribution network. The Chairman, NPPA also emphasized that the prices are fixed under DPCO, 2013 are for the medicines to be sold in the trade and not for the institutions, NGO's, Govt. supply etc.

Therefore, the Authority directed that the company may again be asked to give the complete details/break-up of the PTR and MAT sales value distinguishing the sale through retailers and directly to the patients/ Institutional supplies etc. duly signed by the Authorized signatory of the company and certified by the practicing Chartered/Cost Accountant. Further, the company may also confirm whether they have implemented the notified ceiling price or not. If so, the price-list in Form-V may also be furnished.

(iii) Heparin Injection 5000IU/ml: It was informed to the Authority that M/s Gland Pharma has filed a review in this case and during the personal hearing, it was observed that due to the oversight the price of 1000 IU/ml was considered instead of 5000 IU/ml. NPPA in the personal hearing indicated that it will be looked into. Accordingly, the price was re-worked out. The Authority discussed the case in detail and directed that the revised agenda note giving full facts of the case may be put up in the next Authority meeting. Accordingly, the case was deferred.

(iv) Anti-D Immunoglobulin (Human) Injection 300 mcg: The case was put up based on the representation received from M/s. Synergy Diagnostics. The matter was referred to

the IMS Health on 24.9.2013 for clarification in this regard. IMS Health replied that the company i.e. M/s Synergy Diagnostics does not reflect in IMS database. They have not done any differentiation as Polyclonal and Monoclonal Anti-D Immunoglobulin Injection etc. as it is not specified in NLEM 2011. It was also informed to the Authority that the DOP has rejected the review application of M/s Synergy Diagnostics being the time barred.

M/s Synergy Diagnostics has forwarded a clarification dated 05.12.13 issued by Joint Drugs Controller (India), CDSCO West Zone, Mumbai to them stated that *"there is a difference between the products Anti-D Immunoglobulin (Human) 300mcg, 2 ml and the product Anti-D Immunoglobulin (Monoclonal). It appears that the Govt. of India under DPCO has fixed the prices specifically for Anti-D Immunoglobulin (Human) 300mcg vide S.O.1670(E) dated 14.06.2013 which appears to be only for human and not the Monoclonal. However, this office is not involved in fixation of pricing as per DPCO which company can take-up the matter with appropriate DPCO authorities".*

M/s. Bharat Serums and Vaccines Ltd. vide fax dated 09.12.2013 stated that the Anti-D Immunoglobulin which they manufacture is from a Biotech process (i.e. Monoclonal Antibody) and not from any Human plasma and hence does not qualify as Anti-D Immunoglobulin (Human). Anti-D Immunoglobulin produced from human source suggest a product produced from HUMAN plasma and hence from a natural source. They have also stated that their product is produced by expressing Anti-D Immunoglobulin by the monoclonal antibody route and not human plasma. The company requested that in view of wrong inclusion, their product may kindly be excluded form 19.2.1.1 "Anti-D Immunoglobulin (human) injection", since it is not of human plasma. Considering the above, the price was re-worked out.

After detailed discussions, the Authority decided that the case may be referred to the DCG(I) for their advice in this matter and the case may accordingly be put up to the Authority. Hence, the case was deferred.

(v) Rabies Immunoglobin Injection 150 IU/ml: NPPA had earlier fixed the price of Rabies Immunoglobin Injection 150 IU/ml at Rs. 1255.84 on 05.11.2013 on the basis of data collected from companies/external sources as IMS did not have and has again confirmed that they don't have information on this product. The case was put up based on the representation received from M/s Synergy Diagnostics Pvt. Ltd. and M/s Reliance Life Sciences Pvt. Ltd. Both the above companies contended that the price fixed earlier for the subject formulation is incorrect due to the comparison of two different products and two different processes of production. Rabies Immunoglobin is manufactured from Human Plasma, by M/s Bharat Serums & Vaccines and M/s Synergy Diagnostics. Further, it is stated that M/s Indian Immunologicals is manufacturing it from Equine which is having a concentration of 300 IU/ml, thus requested to exclude their data since it is not a part of NLEM. However, M/s Reliance Life Sciences has not furnished any data, as they are yet to get the manufacturing license. M/s Synergy Diagnostics has forwarded a clarification dated 05.12.13 issued by Joint Drugs Controller (India), CDSCO West Zone, Mumbai to them stating that both the products having 150 IU/ml and 300 IU/ml are different and have different sources also. Bharat Serum has also given representation stating that the brands of Indian Immunologicals Ltd. (Abhay RIG) is available only in 300 IU/ml and not a part of NLEM and the brand Berirab (P) oF Synergy Diagnostics with concentration of 150 IU/ml has not been considered which has led to wrong calculation of ceiling price. So, the price was re-worked out.

After discussions, the Authority directed that this case may also be referred to the DCG(I) for their expert comments for processing the case and the case may accordingly be put up to the Authority. Hence, the case was deferred.

(vi) Methyl Ergometrine Injection 0.2mg/ml: The case was put up based on the representation received from M/s. Maneesh Pharmaceuticals Ltd. The Authority discussed the reply from IMS-Health and approved the revised ceiling price of Rs. 13.41/ml as against the earlier notified ceiling price of Rs. 12.89/ml notified on 28.6.2013.

Further, the Authority directed that if there are any data variations pointed out by the companies in their representations, they may be forwarded to IMS-Health for seeking clarification and if there are technical issues raised by the companies, they may be forwarded to the DCG(I) invariably for seeking their expert advice in the matter.

4. Agenda Item no. 4:

4.0 The Authority discussed these cases in detail and noted that DOP has passed the review order no. 31015/21/2013/PI.I dated 21.10.2013 in these cases. The review order states that:

"The review application of the Petitioners is rejected on the ground that NPPA strictly followed the provisions contained in DPCO, 2013, PTR of the company when compared with the others show that they were charging 200% to 300% more than other companies and they cannot be allowed to overcharge as per provisions of DPCO, 2013. ***However, the additional information brought to the notice of NPPA may be cross examined by them with the help of IMS Health and if deemed necessary, NPPA may revalidate such data by appropriate survey of evaluation as authorised under para 9 of DPCO, 2013"***

4.1 The Authority directed that the agenda note indicating the full facts of the case along with the chronology of the case may be clearly brought up in the revised agenda note and the same may be put up in the next Authority meeting. Further, the Authority directed that in future also the cases, where the impact of the cases submitted in the current meeting is going to make effect, may be put up in the next Authority meeting after having approval of such cases submitted before the Authority. Therefore, the Authority has deferred the proposal.

5. Agenda Item no. 5:

5.0 The case was put up based on the representation received from M/s Emcure wherein it was submitted that their product S-Metoprolol and S-Amlodipine are different

drug and therefore their products are not covered under the ceiling prices fixed by the NPPA.

5.1. The NPPA has taken up this issue to IMS-Health vide letter dated 23.9.2013. The IMS-Health has replied vide their letter dated 27.9.213 that S-Amlodipine (Asomex) and S-Metoprolol (Metpure XL) are Chiral forms of Amlodipine and Metoprolol respectively. While submitng the data in May 2012 and a further update on several molecules in June, 2013 which included Metoprolol, IMS-Health had flagged separately all brands pertaining to Chiral forms/Isomers including S-Amlodipine and S-Metoprolol.

5.2 The NPPA also took up the matter with the DCG(I) vide letter dated 30.10.2013 and reminder dated 13.11.2013 seeking his advice. The DCG(I) vide their letter dated 29.11.2013 stated that S-Amlodipine is a pharmacologically active enantiomer of Amlodipine and is considered as different drug than Amlodipine. Similarly S-Metoprolol is a pharmacologically active enantiomer of Metoprolol. Further, DCG(I) stated that S-Amlodipine and Amlodipine have been approved by this office as different drugs, similarly, S-Metoprolol and Metoprolol have also been approved by this office as different drugs.

5.3 Accordingly, the ceiling prices have been re-worked out after removing the above mentioned packs of M/s Emcure, as under:-

S.No.	Name of the Tablet	Ceiling Price (per Tablet)
1	Amlodipine 2.5 mg	1.79
2	Amlodipine 5 mg	2.83
3	Metoprolol 25 mg	3.38
4	Metoprolol 50 mg	5.01

5.4 The Authority approved the above revised ceiling prices and decided that the revised notification of the prices may not be applicable to the formulations containing S-Metoprolol and S-Amlodipine in line with the views and advice of the DCG(I). Further, the Authority also directed that the revised ceiling price notifications shall clearly

indicate in the notes that "the above prices may not be applicable to the formulations containing S-Metoprolol and S-Amlodipine".

6. Agenda Item no. 6:

6.0 The case was proposed based on the representations received from M/s. Bharat Immunoglogicals and M/s. Panacea Biotech, which were forwarded to IMS-Health. M/s. Panacea Biotech has also filed a review application with the DOP in this regard.

6.1. DOP vide O.M. dated 17.10.2013 directed that till such time NPPA re-visits the data and the calculation, the notification may be kept in abeyance as requested by the Ministry of Health & Family Welfare. Accordingly, the above mentioned notification was kept in abeyance vide S.O. 3211(E) dated 21.10.2013.

6.2. Based on the revised data received from IMS-Health, the price of Rs. 99.90/ml has been re-worked out against the earlier notified price of Rs. 52.52/ml. The re-worked price of Rs. 99.90/ml was included as an agenda item in the 8th Authority Meeting held on 01.11.2013. The Authority directed to put up a detailed note and re-look at the data. This case was therefore, deferred at that time.

6.3. Accordingly, the case has been re-examined in NPPA. Regarding two strains of oral polio vaccine available in the market namely bio-valent OPV(bOPV) and tr-valent (tOPV), it has been stated to Ministry of Health & Family Welfare vide letter dated 19.11.2013 that *under DPCO, 2013, price fixation is done based on the market based data and without any regard to actual cost of production. As per NLEM, 2011 there is a single category i.e. Oral Poliomyelitis Vaccine (LA) Solution under Section 19.3.1 and hence NLEM has not made any differentiation on the basis of strains of OPV.*

6.4 Therefore, the Authority was informed that for the purpose of pricing, both types of strains for price fixation as one category have been included. The Authority approved the revised ceiling price of Rs. 99.90/ml as against the earlier notified price of Rs 52.52/ml.

7. Agenda Item no. 7:

7.0 The Authority discussed the cases of retail price fixation of new drug based on Form-I application received from the following 11 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 Alembic Glisen VM1 tablet Each uncoated bilayer tablet contains: Voglibose – 0.2 mg Glimeperide – 1 mg Metformin HCL (in sustained release form) – 500 mg	8.48/tablet
2	M/s Alembic Glisen VM2 tablet Each uncoated bilayer tablet contains: Voglibose – 0.2 mg Glimeperide – 2 mg Metformin HCL (in sustained release form) – 500 mg	10.79/tablet
3	M/s Blue Cross Lab. Ltd Olmeblu – H 20 tablets Each film coated tablet contains: Olmesartan Medoxomil BP – 20 mg Hydrochlorthiazide – 12.5 mg	7.10/tablet
4	M/s Blue Cross Lab. Ltd	11.52/tablet

	Olmeblu – H 40 tablets Each film coated tablet contains: Olmesartan Medoxomil BP – 40 mg Hydrochlorthiazide – 12.5 mg	
5	M/s Blue Cross Lab. Ltd Olmeblu – AM tablets Each film coated tablet contains: Olmesartan Medoxomil BP – 20 mg Amlodipine Besylate – 5 mg	7.55/tablet
6	M/s Plenteous Pharmaceuticals Telmisartan 40mg + Hydrochlorhiazide 12.5 mg tablet Each uncoated Bilayered Tablet contains: Telmisartan – 40mg Hydrochlorothiazide – 12.5mg	7.47/tablet
7	M/s Ajanta Pharma Ltd Telmisartan 40mg and Metoprolol Tartrate 50mg ER tablet Each film coated bilayered tablet contains: Telmisartan – 40 mg Metoprolol succinate – 47.5mg eq. to Metoprolol Tartrate – 50 mg(as extended release form)	9.62/tablet
8	M/s Ajanta Pharma Ltd Telmisartan 40mg and Metoprolol Tartrate 25mg ER tablet Each film coated bilayered tablet contains: Telmisartan – 40 mg Metoprolol succinate – 23.75mg eq. to Metoprolol Tartrate –	8.10/tablet

	25 mg(as extended release form)	
9	M/s Plenteous Pharmaceuticals and M/s Amazing Research Labs. Ltd. Cefixime 200mg + Azithromycin 250mg tablet Each film coated tablet contains: Cefixime as Trihydrate eq. to Anhydrous cefixime – 200mg Azithromycin as Dihydrate eq. to Anhydrous Azithromycin – 250mg	15.88/tablet
10	M/s Unimed Technologies Ltd. Trivolib Forte 2 tablets Each tablet contains: Voglibose – 0.3mg Metformin HCl – 500 mg (as extended Release) Glimepiride – 2 mg	10.46/tablet
11	M/s Unimed Technologies Ltd. Trivolib Forte 1 tablets Each tablet contains: Voglibose – 0.3mg Metformin HCl – 500 mg (as extended Release) Glimepiride – 1 mg	8.47/tablet

Further, the Authority directed the retail prices of the new drugs may be uploaded on website under separate heading and working sheets of retail prices may also be uploaded on website for better transparency.

8. Agenda Item no. 8:

8.0 In compliance to the six review orders received from DOP in connection with the price revision under DPCO 1995, the price has been re-worked. The details of which are as follows:

1. Review order no. 31015/11/2013-PI.I dated 27.11.2013 for M/s Lupin Ltd. against S.O. 1497(E) dated 10.06.2013 under DPCO 1995 in respect of Rifampicin based formulations.

2. Review order no. 31015/19/2013-PI.I dated 27.11.2013 for M/s IPCA Ltd. against S.O. 1498(E) dated 07.06.2013 under DPCO 1995 in respect of Chloroquine Phosphate based formulations.

3. Review order no. 31015/12/2013-PI.I dated 27.11.2013 for M/s IPCA Ltd. against S.O. 1495(E) dated 10.06.2013 under DPCO 1995 in respect of Erythromycin based formulations.

4. Review order no. 31015/18/2013-PI.I dated 27.11.2013 and no. 31015/17/2013-PI.I dated 27.11.2013 for M/s J.B.Chemicals & M/s Lekar Pharma respectively against S.O. 1496(E) dated 10.06.2013 under DPCO 1995 in respect of Metronidazole based formulations.

5. Review order no. 31015/22/2013-PI.I dated 03.12.2013 for M/s Abbott India against S.O. 1492(E) dated 10.06.2013 under DPCO 1995 in respect of Ibuprofen based formulations.

8.1 In all the above mentioned review orders, the *'NPPA was directed by DOP to allow MAPE as per the previous practice followed by them i.e. 100% MAPE for domestic manufacturers. The decision of the reviewing authority to be implemented within 15 days from the date of issue of these orders'.*

8.2 It was informed to the Authority that in the agenda note the calculation of ceiling prices have been worked out correctly considering the 100% MAPE, However, in the

Column indicating MAPE % is not correctly mentioned as 100% in the column no. 11 of MAPE [against R (i.e. Revised) row] as well as some errors in column no. 3 (i.e. Pack size) due to typographical error.

8.3 The Authority approved the prices with 100% MAPE as proposed in the agenda in line with the above review orders of the DOP. The existing and the approved revised worked out prices are as follows:

Sl No.	Name of the Formulation/Composition	Pack Size	Existing Notified Price (Rs)	Approved Revised Price(Rs)/ Increase (%)
1	2	3	4	6
	REVIEW CASES			
	M/s Lupin Ltd. s.o. no.1497(E) dated 07.06.2013			
1	**Rifampicin Capsule 150 mg**	**10's**	16.95	**17.54**
	Each Capsule contains	**ST/BL**		**3.47%**
	Rifampicin IP 150 mg			
	(R Cin 150Capsule)			
2	**Rifampicin Capsule 300 mg**	**10's**	30.51	**31.68**
	Each Capsule contains	**ST/BL**		**3.84%**
	Rifampicin IP 300 mg			
	(R Cin 300Capsule)			
3	**Rifampicin Capsule 450 mg**	**10's**	44.17	**45.92**
	Each Capsule contains	**ST/BL**		**3.96%**
	Rifampicin IP 450 mg			
	(R Cin 450Capsule)			
4	**Rifampicin Capsule 600 mg**	**10's**	58.28	**60.62**
	Each Capsule contains	**ST/BL**		**4.01%**
	Rifampicin IP 600 mg			

	(R Cin 600Capsule)			
5	**Rcinex 450**	**10's**	47.58	49.34
	Each Capsule contains	**ST/BL**		**3.69%**
	Rifampicin IP 450 mg			
	Isoniazid - 300 mg			
6	**Akurit kid**	**6's**	4.83	**4.90**
	Each Uncoated Dispersible Tablet contains	**Al/St**		**1.52%**
	Rifampicin IP 60 mg			
	Isoniazid IP 30 mg			
7	**Akurit kid**	**6's**	4.69	**4.76**
		AL/BL		**1.52%**
8	**Rimactazid Disped**	**10 's**	11.66	**11.66**
	Each dispersible tablet contain	**St/bl**		**0.00%**
	Rifampicin IP 100 mg			
	Isoniazid IP 50 mg			
9	**Rimactazid Disped**	**10 's**	11.70	**12.50**
		Alu-alu St/bl		**6.84%**
10	**Rcinex Kid**	**10's**	13.01	**13.40**
	Each uncoated Dispersible Tablet Contains	**Al/St**		**2.99%**
	Rifampicin 100mg			
	Isoniazide 100mg			
11	**Rcinex Kid**	**10's AL/BL**	12.65	**13.04**
				3.09%
12	**R Cinex Z Kid**	**10's**	20.03	**20.42**
	Each uncoated Dispersible Tablet Contains	**Al/St**		**1.94%**
	Rifampicin 100mg			
	Isoniazide 50mg			

	Pyrazinamide 300 mg			
13	**Rinizide Forte DT**	**10's**	29.04	**29.62**
	Each uncoated Dispersible Tablet Contains	**Al/St**		**1.99%**
	Rifampicin 150mg			
	Isoniazide 100mg			
	Pyrazinamide 500 mg			
14	**Rinizide Forte DT**	**10's AL/BL**	28.46	**29.04**
				2.04%
15	**Akurit Z kid**	**6's**	7.22	**7.36**
	Each Uncoated Dispersible Tablet contains	**Al/St**		**1.99%**
	Rifampicin IP 60 mg			
	Isoniazid IP 30 mg			
	Pyrazinamide - 150 mg			
16	**Akurit Z kid**	**6's**	6.98	**7.12**
		AL/BL		**1.99%**
17	**Akurit Tablet**	**6's**	10.37	**10.72**
	Each Film Coated Tablet contains	**ST/BL**		**3.36%**
	Rifampicin IP 150 mg			
	Isoniazid IP 75 mg			
18	**Akurit Tablet**	**6's**	10.61	**10.96**
	Each Film Coated Tablet contains	**AL/PVDC**		**3.31%**
	Rifampicin IP 150 mg	**PVC FILM**		
	Isoniazid IP 75 mg	**Blister**		
19	**R Cinex Z**	**10's**	41.14	**42.02**
	Each film coated tab Contains	**ST/BL**		**2.15%**
	Rifampicin USP 225 mg			
	Isoniazid USP 150 mg			
	Pyrazinamide - 750 mg			

20	**R Cinex Z**	**10's**	41.78	**42.66**
	Each film coated tab Contains	**AL/PVDC**		**2.10%**
	Rifampicin USP 225 mg	**PVC FILM**		
	Isoniazid USP 150 mg	**Blister**		
	Pyrazinamide - 750 mg			
21	**Akurit - 3**	**10's Al/St**	28.33	**28.92**
	Each Film coated Tablet Contains			**2.09%**
	Rifampicin 150mg			
	Isoniazide 75mg			
	Ethambutol HCL 275 mg			
22	**Akurit - 3**	**10's**	28.97	**29.56**
	Each Film coated Tablet Contains	**AL_PVDC**		**2.04%**
	Rifampicin 150mg	**PVC FILM**		
	Isoniazide 75mg	**Blister**		
	Ethambutol HCL 275 mg			
23	**Rcinex E**	**6's**	46.67	**47.72**
	Each film coated tab Contains	**St/Bl**		**2.24%**
	Rifampicin USP 450 mg			
	Isoniazid USP 300 mg			
	Ethambutol HCL USP 800 mg			
24	**Akurit - 4**	**10's**	38.54	**39.12**
	Each Film coated Tablet Contains	**AL_PVDC**		**1.49%**
	Rifampicin 150mg	**PVC FILM**		
	Isoniazid USP 75 mg	**Blister**		
	Pyrazinamide - 400 mg			
	Ethambutol HCL 275 mg			
25	**Rcinex EZ**	**6's**	34.95	**35.48**
	Each film coated tab Contains	**AL_PVDC**		**1.52%**
	Rifampicin USP 225 mg	**PVC FILM**		
	Isoniazid USP 150 mg	**Blister**		
	Pyrazinamide - 750 mg			
	Ethambutol HCL 400 mg			

26	AKT- FD	3's	12.55	12.72
	Each Film coated tablet Contains	St/Bl		1.32%
	Isoniazide USP 100 mg			
	Pyrazinamide USP 500mg			
27	AKT- 2	10's	49.63	51.38
	Each Film Coated Tablet Contains	Al/St		3.52%
	Rifampicin 450mg			
	Isoniazide 300mg			
28	AKT- 2	10's	50.13	51.88
	Each Film Coated Tablet Contains	Al/PVDC/		3.49%
	Rifampicin 450mg	PVC FILM		
	Isoniazide 300mg	Blister		
29	Rcinex 600	10's	61.81	64.14
	Each coated tablet contains:	ST/BL		3.78%
	Rifampicin IP 600 mg			
	Isoniazid - 300 mg			
30	Rcinex 600	10's	62.45	64.78
		Al/PVDC/		3.73%
		PVC FILM		
		Blister		
31	AKT- 3	2's Kit	8.18	8.36
	Each Kit Contains	(1 cap +		2.25%
	1 Capsue of Rifampicin 450 mg	3 tab.)		
	1Tablet of Ethambutol 800mg+			
	& Isoniazide 300 mg			
32	AKT- 4	4's Kit	11.96	12.14
	Each Kit Contains	(1 cap +		1.54%
	1Cap of Rifampicin 450mg	3 tab.)		
	1Tab Containing Ethambutol 800mg &			

	& Isoniazide 300 mg			
	2 tablet of Pyrazinamide 750 mg			
33	**4D Plus Tablet**	**10 X 4's**	141.47	**143.70**
	Each film coated tablet contain	**Al_PVDC/**		**1.57%**
	Rifampicin IP 600 mg	**PVC FILM**		
	Isoniazid IP 300 mg (1tablet)	**Blister**		
	Each uncoated tablet contain			
	Pyrazinamide IP 800 mg (2 tablet)			
	Ethambutol IP 1100 mg (1 tablet)			
34	**R Cin Suspension**	**200 ml**	63.36	**64.90**
	Each 5 ml contains:	**Glass**		**2.43%**
	Rifampicin 100 mg	**Bottle**		
		with M		
		cup		
	M/s. Ipca Laboratories Limited S.O. 1498			
	dated 07.06.2013			
1	Lariago Tablets	**10's**	6.66	**7.14**
	Each film coated tablet	**ST/BL**		**7.18%**
	Chloroquine Phosphate - 250mg			
2	Lariago DS Tablets	**5's**	6.45	**6.94**
	Each Film Coated Tab contains	**ST/BL**		**7.64%**
	Chloroquine Phosphate IP 500 mg			
3	Lariago Suspension	**60 ml**	16.32	**16.64**
	Each 5 ml contains:	**with M.Cup**		**1.94%**
	Chloroquine Phosphate eq. to	**& Carton**		
	Chloroquine - 50 mg			
4	Lariago Injection	**30 ml**	18.20	**18.58**
	Each ml contains	**vial**		**2.11%**
	Chloroquine Phosphate IP 64.5mg	**with f-off**		

	Equivalent to chloroquine base 40mg	Seal &		
	water for inj. IP q.s.	carton		
5	Lariago Injection	10*2 ml	36.66	38.80
	Each ml contains	Amber		5.84%
	Chloroquine Phosphate IP 64.5mg	Ampule		
	Equivalent to chloroquine base 40mg			
	water for inj. IP q.s.			
6	Lariago Injection	5*5 ml	28.35	30.48
	Each ml contains	Amber		7.52%
	Chloroquine Phosphate IP 64.5mg	Ampule		
	Equivalent to chloroquine base 40mg			
	water for inj. IP q.s.			
	M/s J.B Chemicals & Pharmaceuticals Ltd. S.O. no 1496 (E) dated 10.06.2013			
1	**Metronidazole Tablets**	10's	3.87	4.14
	Each Film coated tablet contains:	St/Bl		6.95%
	Metronidazole IP 200 mg			
2	**Metronidazole Tablets**	10's	6.77	7.32
	Each Film coated tablet contains:	St/Bl		8.11%
	Metronidazole IP 400 mg			
3	**Metrogyl Compund tablet**	15's	25.43	32.70
	Each Coated Tablet Contains :	St/Bl		28.61%
	Metronidazole IP 400 mg			
	Diloxanide Furoate IP 500 mg			
4	**Nor -Metrogyl Tablets**	10's	16.40	17.66
	Each coated tablet contain	St/Bl		7.70%
	Metronidazole I.p 500 mg			

	Norfloxacin 400 mg			
5	**Gromogyl suspension**	**60 ml**	14.28	**14.88**
	Each 5 ml contains:	**Glass**		**4.17%**
	Metronidazole Benzoate eq. to	**Bottle**		
	Metronidazole - 100 mg	**With**		
	Norfloxacin 100 mg	**M.Cup**		
6	**Metrogyl suspension**	**30 ml**	9.30	**9.30**
	Each 5ml Contains	**Pet Bottle**		**0.00%**
	Metronidazole Benzote eq to	**With**		
	Metronidazole 200 mg/5 ml	**M.Cup**		
7	**Metrogyl suspension**	**60 ml**	14.54	**14.54**
	Each 5ml Contains	**Pet Bottle**		**0.00%**
	Metronidazole Benzote eq to	**With**		
	Metronidazole 200 mg/5 ml	**M.Cup**		
8	**Metrogyl IV 100 ml**	**100 ml**	11.49	**12.34**
	Each 100 ml Contains :	**Plastic**		**7.41%**
	Metronidazole IP 500 mg	**bottle**		
-	**M/s. Ipca Laboratories Limited S.O. no 1495 (E) dated 10.06.2013**			
1	**Eltocin Kid Tablet**	**10's AL/ST**	11.98	**14.36**
	Each dispeersible tablet contains:			**19.83%**
	Erythromycin estolate eq. to			
	Erythromycin - 125 mg			
2	**Eltocin Kid Tablet**	**10's**	11.86	**14.12**
	Each dispeersible tablet contains:	**Al/BL**		**19.05%**
	Erythromycin estolate eq. to			
	Erythromycin - 125 mg			
3	**Eltocin Tablet**	**10's**	22.00	**25.86**
	Each uncoated tablet contains:	**ST/BL**		**17.56%**

	Erythromycin estolate eq. to			
	Erythromycin - 250 mg			
4	**Eltocin DS Tablet**	**10's**	42.64	**50.36**
	Each uncoated tablet contains:	**ST/BL**		**18.11%**
	Erythromycin estolate eq. to			
	Erythromycin - 500 mg			
5	**Eltocin Suspension**	**60 ml**	23.72	**26.86**
	Each 5ml contains :	**Glass**		**13.25%**
	Erythromycin Estolate I.P	**Bottle**		
	Eq to Erythromycin 125mg	**With**		
		M.Cup		
	M/s Abbott India Ltd.			
1	**Brufen 200 mg**	**10's**	3.72	**3.77**
	Each film coated tab contains:-	**St/Bl**		**1.52%**
	Ibuprofen I.p 200 mg			
	Erythrosine & Titanium Dioxide			
2	**Brufen 400 mg**	**10's**	6.34	**6.45**
	Each film coated tab contains:-	**St/Bl**		**1.83%**
	Ibuprofen I.p 400 mg			
	Erythrosine & Titanium Dioxide			
3	**Brufen 600 mg**	**10's**	9.08	**9.25**
	Each film coated tab contains:-	**St/Bl**		**1.94%**
	Ibuprofen I.p 600 mg			
	Erythrosine & Titanium Dioxide			

9. Agenda Item no. 9:

9.0 It was informed to the Authority that the cases of Dettol Antiseptic Liquid formulations of M/s Reckitt Benckiser (India) Ltd. were included in the agenda in compliance with the review order no.31015/4/2011-PI.I dated 01.8.2013 of DOP. The price of these formulations were worked out as per the directions given in the abovesaid

review order and as per the practice followed by the NPPA as approved in earlier Authority meetings, accordingly, the CC and PC norms were applied based on the latest notified norms irrespective of the claim made. However this issue was discussed in detail. The Authority directed that a detailed note containing the past practice, duly approved by the Authority, for applying the latest CC & PC norms, though not claimed as such, be put up to the Authority. Therefore, these cases were deferred with the direction to put up again in the next Authority meeting.

10. Agenda Item no. 10:

10.0 It is informed to the Authority that these two cases of M/s Ranbaxy were earlier closed by the NPPA as the Authority had considered price revision of formulations in those cases only where the price of derivative bulk drug was increased by NPPA. In these two cases, there was no upward revision in the bulk drug price and also the details of 100% MAPE were not provided by the company.

10.1 The Department of Pharmaceuticals (DOP) vide their letter dated 19.11.2013 requested NPPA to intimate the action taken in the matter of fixing/revising the prices under DPCO, 1995 after notification of DPCO, 2013. The clarifications/instructions are reproduced below:

'As may be seen from the opening sentence of notified DPCO, 2013 that it supersedes DPCO, 1995 except as respect to things done or omitted to be done before such supersession. Any action which was due under the DPCO, 1995 but could not be taken due to reasons beyond the control of NPPA need to be completed and the benefit or otherwise should be given to the individuals or companies as per the provisions of DPCO, 1995. It may be mentioned that Govt. of India is pursuing recovery of Government dues under the old DPCOs such as DPCO, 1979, DPCO, 1987 and similarly the old Govt. dues under DPCO, 1995 will be recovered by NPPA even after supersession of DPCO, 1995'.

10.2. It was decided in NPPA to re-visit all such cases where the company has asked for action in this regard and to implement the order issued by DOP on 31.5.2013 in the

matter of fixing/revising the prices under DPCO, 1995 after notification of DPCO, 2013. Accordingly, the cases of M/s Ranbaxy have been re-visited.

10.3 The Authority discussed these cases and directed that the detailed revised agenda note in this regard may be put up in the next Authority meeting and therefore these cases were deferred.

11. Agenda Item no. 11:

11.0 It was informed to the Authority that this is one of the pending cases under DPCO 1995. The company has earlier submitted the application for the non-PVC bag packing for which they were not having valid manufacturing licence. Therefore, the application of the company were rejected and company was informed to follow the existing ceiling price notified vide S.O. 2710 (E) dated 28.11.2011. Accordingly, the company was also informed vide letter dated 19.11.2012.

11.1 In April 2013, the company has again submitted the applications which were lying pending consequent upon the announcement of NPPP, 2012 and the NPPA was re-designing to the challenge of price fixation and other actions under DPCO, 2013 which was likely to be announced shortly. The company during the month of Oct., 2013 has submitted the reminder to the NPPA for early processing of their cases.

11.2 It was also informed to the Authority that the price of I.V. Fluids with the non-PVC packing is allowed only in case of M/s Claris and M/s Baxter only after the receipt of review order from the DOP. In line with the review order, the prices were fixed for these specific companies only.

11.3 The Authority noted the above and directed that these cases may be put up with detailed agenda note for the consideration of the next Authority meeting and therefore these cases were deferred.

12. Agenda Item no. 12:

12.0 The Authority has discussed the price revision of Bulk Drug Levosalbutamol Cost Price Study in detail. In view of having wide variations in the cost of production of the three companies viz. M/s Cipla, M/s Melody and M/s Supriya, the Authority deferred the proposal and directed to give elaborate explanations on the reasons for inter-se variations in the cost structure of different companies.

13. Agenda Item no. 13:

13.0 The status of the pending Overcharging cases and constraints of manpower was explained before the Authority. While taking note of the position, the Authority suggested to give thrust on high value items to process on priority, wherever it is possible to identify.

14. Agenda Item no. 14:

14.0 The judgment dated 09.12.2013 passed by the Hon'ble Supreme Court in M/s Glaxo and linked matters was seen and appreciated by the Authority. As directed, the judgment will be uploaded on the website for information to all the concerned. In addition to this, Pharma Industry and its apex Associations would be requested to deposit respective overcharged amount, if any, on suo-motu basis along with calculations for the same. Further, concerned divisions of Overcharging and Monitoring have been advised to take appropriate action accordingly.

15.0 This issues with the approval of Chairman, NPPA.

(Sanjay Kumar)
Member Secretary

Summary of Prices worked out based on Data furnished by IMS-Health/Companies						Annexure A		
Sl. No.	Medicines	Category	Route of Administration	Strengths	Ceiling Price excl. local taxes (Rs./unit)	Highest PTR (Rs./unit)	Lowest PTR (Rs./Unit)	% Reduction as compared to Highest PTR
Section: 1 – Anesthesia								
1.1 General Anesthetics and Oxygen								
1	Nitrous Oxide	P, S, T	Inhalation		**206.18/Cu. M.**	276.00	149.92	35.60%
2	Oxygen	P, S, T	Inhalation		**15.81/Cu. M.**	20.00	7.76	31.85%
Section: 10 –Medicines affecting the blood								
10.2: Medicines affecting coagulation								
3	Heparin Sodium	S, T	Injection	1000 IU/ml	**17.50/ml**	18.87	10.67	20.03%
Section: 20 – Muscle Relaxants (Peripherally acting) and Cholinesterase Inhibitors								
4	Succinyl choline chloride	S,T	Injection	50 mg/ml	**6.04/ml**	9.60	3.20	45.73%

Summary of Prices worked out based on Monopoly Conditions						Annexure B		
Sl. No.	Medicines	Category	Route of Administration	Strengths	Ceiling Price excl. local taxes (Rs./unit)	Highest PTR (Rs./unit)	Lowest PTR (Rs./Unit)	% Reduction as compared to Highest PTR
Section: 15 –Disinfectants and antiseptics								
15.1: Antiseptics								
1	Ethyl Alcohol 70%	P, S, T	Solution		0.49/ml			40.32%
2	Gentian Violet	P, S, T	Paint	1%	0.06/ml			40.32%
3	Hydrogen Peroxide	P, S, T	Solution	6%	0.05/ml			40.32%

-27-

(iv) Shri S. K. Bhatt, Dy. Director (Technical)