गोपनीय: Confidential

मिसिल स.- 8(24)/2015/डी.पी./एनपीपीए- डीवी-II

F. No. 8(24)/2015/DP/NPPA-Div. II

कार्यवाहीस. : 156/24/2015/F
Proceeding No : 156/24/2015/F

Minutes of the 156th and 24th meeting of Authority under DPCO, 2013 held on 24.8.2015 at 12.30 PM.

The 156th overall meeting of the Authority, which is the 24th under the DPCO, 2013 was held on 24th August, 2015 at 12.30 PM under the Chairmanship of Shri Injeti Srinivas, Chairman, NPPA. The following members of the NPPA were present:-

(i) Dr. Sharmila Mary Joseph K, Member Secretary, NPPA.
(ii) Dr. K.L. Prasad, Member (Ex-Officio), Adviser, Economic Division, Deptt. of Economic Affairs.
(iii) Shri Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
(iv) Shri R. Chandrashekar, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCGI).

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.K. Khurana, Director (Pricing & Admn.)
(iii) Shri A.P.S. Sawhney, Director (Overcharging)
(iv) Shri Suneel Chopra, Dy. Director (Legal)
(v) Shri Rakesh Kakkar, Dy. Director (OC-I)
(vi) Shri Anand Prakash, Dy. Director (M&E)
(vii) Shri T.R. Sathish Chandran, Asstt. Director (OC-II)
(viii) Shri Baljit Singh, Asstt. Director (Legal)

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

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1. Agenda Item no. 1: Confirmation of Minutes of the 23nd Meeting held on 13.7.2015.

Members of the Authority who participated in the 155th and the 23rd Meeting under DPCO, 2013 confirmed the minutes of the meeting.

2. Agenda Item no. 2: Action Taken Report

Noted.

3. Agenda Item no. 3: Review order of DOP on the review application filed by M/s Seagull Pharmaceuticals Pvt. Ltd. in respect of Superspas-AQ Injection.

3.1 The DOP's abovesaid review order dated 14.7.2015 directed NPPA not to consider subject formulation as a scheduled formulation. The Authority observed that the Deptt. had recorded the following points in its review order:-

- Dept of Legal Affairs (DoLA) opined on 28.02.2013 that *once the price has been fixed by NPPA, then the drug loses its character of non-scheduled formulation.*
- The opinion of DoLA pertained to an exercise under para 10(b) of DPCO,1995; which is close to para 19 of DPCO, 2013.
- *Para 17(2) of DPCO, 2013* mentions that medicines omitted from the first schedule shall fall under the category of non-scheduled medicines.

3.2 The Authority after deliberations, observed that para 17(2) should not be read in isolation, instead it should be read along with para 2 (u) and para 5 of DPCO, 2013. The Authority also held that this is not an item which is close to para 19 of DPCO, 2013 as unlike para 19 provision price fixation with respect to a "new drug" is mandatory. Further, while the formulation for which retail price has been fixed may not be a part of Schedule-I of DPCO, 2013, the formulation de-facto becomes 'deemed scheduled', after price fixation.

3.3 Notwithstanding these observations, in the light of DOP's review order, the Authority discussed the proposal for amendment of notification issued vide S.O. 1806 dated 10.7.2015 by removing the word 'scheduled' and 'Note (f)' from the notification and approved the revised notification.

4 Agenda Item no. 4: Review order of DOP for Retail Price notification of Ilaprazole + Domperidone Capsules (Checkcid-D SR) issued vide S.O. 3151(E) dated 10.12.2014 in case of M/s Aristo Pharmaceuticals Ltd.

4.1 After receipt of DOP's review order, NPPA placed an O.M. dated 26.5.2015 requesting the concerned manufacturing companies to provide data in respect of the subject formulation. PTR duly supported with invoice was received from M/s Lupin. However, M/s Akumentis reported that their two brands of the product were launched in the market only in July, 2014 and April, 2015.The Authority reworked the ceiling price of the formulation on the basis of data of M/s Lupin and M/s Ajanta Pharma. The Authority

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discussed the proposal of price revision in detail and approved the revised ceiling price of Rs. 8.84/capsule.

5 Agenda Item no. 5: Review order of DOP in case of M/s Kedrion S.p.A. and Representation of M/s Bharat Serums and Vaccines Limited against S.O. 3371(E) and 3372 (E) dated 05.11.2013 for pricing of Antitetanus Human Immunoglobulin Injection 250 IU/pack and 500 IU/pack.

5.1 After receipt of DOP's review order in the case of M/s Kedrion S.p.A, NPPA placed an O.M. dated 14.3.2014 requesting the concerned manufacturing companies to provide the data in respect of the subject formulation. PTRs duly supported with invoices were received from M/s Synergy Diagnostics Pvt. Ltd. and M/s Bharat Serum Vaccine Ltd. The Authority also noted that a representation in this regard was received from M/s Bharat Serum on 30.4.2015. The Authority discussed the proposal of price revision in detail and decided to seek information regarding price charged before the notification, date of launch and price implemented post notification from all the concerned companies. Therefore, the Authority deferred this case.

6. Agenda Item no. 6: Representation by M/s Cipla Ltd. in respect of Ondansetron 4mg & 8mg Orally Disintegrating Strips.

6.1 The Authority discussed the representation of M/s Cipla that the price fixation of Ondansetron 4mg and 8mg orally disintegrated strips was carried out by NPPA by considering the data of orally disintegrated strips/tablets as well as plain tablets. M/s Cipla represented that orally disintegrated tablets and orally disintegrated strips are two different dosage forms, for which separate manufacturing licenses are required/granted by the licensing Authority under Drugs & Cosmetics Act. They also enclosed the samples/ strips and documents downloaded from website in order to substantiate their claim. The Authority discussed the proposal of price revision in detail and decided to refer the case to NIPER, Mohali and DCG(I) to seek clarification whether the Orally disintegrated strip would qualify as a drug listed in Schedule-I of NLEM, 2011 or whether it is a new drug under para 5 of DPCO, 2013. The Authority also decided to call for details of the products on technical, scientific and pharmacological aspects and therapeutic value/ efficacy of different dosage forms of this drug i.e. Ondansetron Orally Disintegrating Strips. The Authority deferred the case accordingly.

7. Agenda Item no. 7: Fixation of retail price in respect of new drugs.

7.1 The Authority discussed the cases of retail price fixation of 19 new drugs.

7.2 Out of 19 cases, 3 cases were deferred by the Authority whose details are as follows:

(a) The case at sr.no. (xvii) relating to Ondansetron HCl 2mg Disintegrating Strip was deferred. It was decided to refer the case to NIPER, Mohali and DCG(I) to seek clarifications as pointed out in para 6.1 above.

(b) The case at sr.no. (xviii) relating to Rosuvastatin calcium eq. to Rosuvastatin 20mg (As pellets) + Aspirin 75mg (as enteric coated Pellets) and Clopidogrel Bisulphate eq. to

Clopidogrel 75mg (As pellets) was deferred as the drug delivery system appeared to be different. It was decided to refer the case to NIPER, Mohali and DCG(I) to seek technical clarifications on scientific and pharmacological aspects, therapeutic value and efficacy.

(c) The case at sr.no. (xix) relating to Hyoscine Butylbromide 10mg + Paracetamol 325mg was deferred The Authority observed that the SDC, Karnataka had stated vide his letter dated 28.5.2015 that application for endorsement of marketing company name and brand name (i.e. M/s Boehringer Ingelheim india Pvt. Ltd/"Buscogast Plus") for the product (Hyoscine butylbromide and Paracetamol) [under reference no. DCD/MFG/CR-342/14-15 dated 18.9.2014] could not be considered. The Authority noted that SDC, Karnataka had vide manufacturing permit no. DCD/MFG/CR-869/10-11 dated 04.3.2011 issued to M/s Geltec (manufacturer), permitted manufacture of Diclofenac Sodium Tablet I.P. (Voveran 50 GE) [modified as Diclofenac Gastro-resistant tablet vide endorsement of 09.5.2014] for N/s Novartis India Ltd. (Marketing company). The Authority decided to seek clarification from SDC, Karnataka as to why he has adopted a different stand in the instant case.

7.3 The Authority discussed the remaining 16 retail price fixation cases of new drugs and approved the proposals as per para 5 of the DPCO 2013, as under:

S. No.	Company name/Product name	Approved Price (Rs.)
7(i)	M/s Astam Healthcare Pvt. Ltd., (Manufacturer) and M/s Alkem Lab. Ltd., (Marketing company) –Albendazole 400mg and Ivermectin 6mg - (Albekem Plus tablet).	Rs. 17.08 per tablet
7 (ii)	M/s Apex Lab. Pvt. Ltd. (Manufacturer as well as Marketing company) – Clotrimazole IP 1% w/w – (Clotrimazole cream).	Rs. 2.82 per gm
7 (iii)	M/s G.S. Pharmbutor Pvt. Ltd. (Manufacturer) and M/s Win Medicare Pvt. Ltd. (Marketing company) – Mesalamine 1200mg – (Mesalamine delayed Release tablet 1200mg).	Rs. 19.12 per tablet
7 (iv)	M/s Korten Pharmaceuticals Pvt. Ltd. (Manufacturer) and M/s Neon Lab. Ltd. (Marketing company) – Paracetamol Infusion (Paracetamol Infusion 10mg/ml).	Rs. 2.10 per ml
7 (v)	M/s Innova Captab (Manufacturer) and M/s Indoco Remedies Ltd. (Marketing company) - Paracetamol 325mg and Tramadol 37.5mg – (Dolinsta-P tablet).	Rs. 5.81 per tablet
7 (vi)	M/s Relief Biotech Pvt. Ltd., (Manufacturer) and M/s Radicura Pharmaceuticals Pvt. Ltd. (Marketing company) – Omeprazole 20mg (as enteric coated Pellets) + Domperidone 10mg – (Ulcure D capsule).	Rs. 4.15 per capsule
7 (vii)	M/s Pure and Cure Healthcare Pvt. Ltd., (Manufacturer) and M/s RPG Life Sciences Ltd., (Marketing company) – Telmisartan 40mg + Amlodipine Besilate eq. to Amlodipine 5mg – (RPTEL-AM tablet).	Rs. 7.19 per tablet
7 (viii)	M/s Cadila Pharmaceuticals Ltd. (Manufacturer as well as Marketing company) –Chlorthalidone 12.5mg and Metoprolol 25mg tablet – (Chlorthalidone 12.50mg + Metoprolol succinate 23.75 eq. to Metoprolol tartrate 25mg tablet as extended release form).	Rs. 5.81 per tablet

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7 (ix)	M/s Neon Lab. Ltd., (Manufacturer as well as Marketing company) – Vancomycin HCl eq. to vancomycin 250mg – (Vanking Infusion).	Rs. 256.30 per pack
7 (x)	M/s Sparsha Pharma International Pvt. Ltd., (Manufacturer) and M/s Zuventus Healthcare Ltd. (Marketing company) – Diclofenac Diethylamine 100mg/50cm^2 patch (Diclofenac Transdermal Patch).	Rs. 42.00 per patch
7 (xi)	M/s Aristo Pharmaceuticals Pvt. Ltd. (Manufacturer as well as Marketing company) – Oxetacaine 10mg + Aluminium Hydroxide 0.291gm and Magnesium Hydroxide 98mg (Pantop OX Gel 200ml Anesthetic Antacid Gel).	Rs. 76.19 for pack of 200ml
7 (xii)	M/s Embiotics Lab. Pvt. Ltd. (Manufacturer as well as Marketing company) – Oxetacaine 10mg + Aluminium Hydroxide 0.291gm and Magnesium Hydroxide 98mg (Delcid O suspension).	Rs. 76.19 for pack of 200ml
7 (xiii)	M/s Aristo Pharmaceuticals Pvt. Ltd. (Manufacturer as well as Marketing company) – Activated Dimethicone 50mg+ Magnesium Hydroxide 250mg+Dried Aluminium Hydroxide Gel 250mg+Sorbitol Solution (70%) (non-crystallising) 1.25g. (Pantop MSP liquid 200ml Antacid Antigas Liquid).	Rs. 0.29 per ml
7 (xiv)	M/s Nirma Ltd., (Manufacturer as well as Marketing company) – Fluconazole 200mg + Sodium Chloride 0.9 % w/v (Fluconazole Injection USP 2mg/ml).	Rs. 1.06 per ml
7 (xv)	M/s Theon Pharmaceuticals Ltd., (Manufacturer) and M/s Aristo Pharmaceuticals Pvt. Ltd., (Marketing company) – Pregabalin 75mg + Mecobalamin 750mcg + Vit. B6 1.5mg + Folic Acid 0.75mg and Benfotiamine 7.5mg (Meganeuron PG/Gabamax Gold Capsule).	Rs. 10.92 per capsule
7 (xvi)	M/s Intas Pharmaceuticals Ltd. (Manufacturer as well as Marketing company) – Glimepiride 0.5mg + Metformin HCL 1000mg (in sustained release form) – (Zoryl M 0.5 Forte tablet).	Rs. 4.83 per tablet

8. Agenda Item no. 8: Price fixation cases of new drugs which were launched in the market without applying for price approval under Para 5 of DPCO, 2013 from NPPA- (i) Hyoscine Butylbromide 10mg + Paracetamol 325mg Tablet manufactured by M/s Acme Pharmaceuticals and marketed by M/s German Remedies (A division of M/s Cadila Healthcare i.e. Zydus Cadila) and (ii) Methyldopa 500mg tablet manufactured by M/s Medibios Lab. Pvt. Ltd. and marketed by M/s Wockhardt Ltd.

8.1 The Authority discussed the cases in detail and decided that the proposal of price fixation of products launched without price approval need not be considered until recovery of the entire amount of sales proceeds as overcharged amount from the companies as per provision of Para 15(5) of DPCO, 2013.

9. Agenda Item no. 9: Representation of companies against S.O. 3128(E) dated 10.12.2014 for pricing of Hormone Releasing IUD.

9.1 The Authority discussed the retail price fixation of Hormone Releasing IUD on the basis of the representation of M/s Bayer Zydus Pharma and M/s Hindustan Latex Ltd. (HLL), a GOI undertaking. The Authority noted the submissions of the companies that the price fixation of hormone releasing IUD at 18.3.1.3 was done on the basis of price of 'copper releasing IUD' of M/s Organon (I) Ltd. The Authority noted that M/s Organon

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had subsequently clarified that it had not manufactured or marketed hormone releasing IUD in May, 2012 or thereafter or currently. The Authority discussed the issue in detail and decided to refer this case to NIPER, Mohali and DCG(I) to seek inputs on technical, scientific and pharmacological aspects of Hormone Releasing IUD and Copper containing IUD; and also inputs on therapeutic value and efficacy.

10. Agenda Item no. 10: Representation regarding Bleaching Powder.

10.1 The Authority discussed the retail price fixation of Bleaching powder on the basis of the representations of Office of the Drugs Controller, Drug Control Department, Kerala and Kerala Medical Services Corporation Ltd. (KMSCL). The Authority discussed the issue in detail and observed that the price fixation of NPPA was based on the price of commercial grade bleaching powder and not that of IP grade bleaching powder which is listed in Schedule-I of DPCO, 2013. The Authority after detailed deliberation decided to refer the case to NIPER, Mohali and DCG(I) to seek clarification on technical aspects of bleaching powder- commercial grade and IP grade.

11. Agenda Item no. 11: Amendment of Price fixation order no S.O. 619(E) dated 26.02.2015 regarding Paclitaxel injection 30mg/5ml.

11.1 Noted and approved.

12. Agenda Item no. 12: Discontinuation of scheduled formulations under Para 21(2) of DPCO, 2013 (M&E Division)

12.1 Noted and approved.

13. Agenda Item no. 13: Draft internal guidelines for dealing with cases where new drugs have been launched Without Price Approval (WPA) (Overcharging Division).

13.1 Noted and approved.

14. Agenda item no. 14:- Review of functioning of Legal division

14.1 The Authority noted the contents of the agenda note.

14.2 The Authority put on record its deep appreciation of the outstanding services rendered by Sh. Suneel Chopra, Dy. Director (Tech./Legal) on deputation from IDPL, who is superannuating on 31st August, 2015 at the age of 58 years. The Authority acknowledged the significant contribution made by Sh. Chopra in pursuing various court cases efficiently, in the different courts, and in obtaining several favourable orders for NPPA/Govt. from the Hon'ble Supreme Court and the High Courts in matter of price fixation of formulations and other related matters during his long tenure with the NPPA.

The Authority took note of the fact that there are active 210 court cases in Hon'ble Supreme Court and High Courts. Further, many important cases with huge financial implications and hence larger public interest are coming up for hearing in the forthcoming months in the Hon'ble Supreme Court. Sh. Chopra, is technically and legally qualified and very well versed with the DPCO and related issues. He has been briefing the Ld. Law Officers and attending the court proceedings in these cases. There is no other officer in the NPPA having legal qualification and experience in handling such cases.

In view of the foregoing, the Authority observed that it is essential to continue the services of Sh. Suneel Chopra as Consultant in the NPPA.

14.3 The Authority took note of the Supreme Court order dated 15.7.2015 in W.P. (C) 423/2003 filed by M/s All India Drug Action Network (AIDAN) and Ors. Vs. UOI. The Supreme Court order touched upon four important aspects of pricing of drugs currently in vogue:

- the price control order ignores the rate of institutional supply of medicines to State Governments;
- exclusion of certain drugs and combination of drugs; and exclusion of different dosages and strengths of scheduled drugs from price control;
- the price control order does not address irrational combinations of drugs;
- exclusion of patented drugs from price control.

The Authority decided to form a Committee under the Chairpersonship of Member Secretary, to study the above four issues and to submit a Report thereon.

15. This issues with the approval of Chairman, NPPA.

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(Dr. Sharmila Mary Joseph K)
Member Secretary