

Minutes of the 223rd (overall) and 91st meeting of the Authority under DPCO, 2013 held on 29.07.2021 at 11:30 AM

The 223rd meeting of the Authority (overall), which is the 91st meeting under the DPCO, 2013, was held on 29th of July 2021 at 11:30 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following Authority members of the NPPA were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Ms. A. Srija, Economic Advisor, Department of Economic Affairs through Video Conferencing
- (iii) Shri Amardeep Singh Chowdhary, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

Shri A. K. Pradhan, Deputy Drug Controller, CDSCO, Ministry of Health & Family Welfare (through Video Conferencing) was also present during the meeting.

1.1 The following officers of NPPA attended the meeting and assisted the Authority in its deliberations:

- (i) Shri N. I. Chowdhury, Advisor
- (ii) Ms. Rashmi Tahiliani, Jt Director (Pricing)
- (iii) Shri Prasenjit Das, Deputy Director (Pricing)
- (iv) Shri Mahaveer Saini, Deputy Director (Pricing & Monitoring)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 89th Meeting & 90th Meeting held on 28.06.2021 & 12.07.2021.

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 - Action Taken Report on decisions taken by NPPA in its 89th Meeting & 90th Meeting held on 28.06.2021 & 12.07.2021.

2.1 The Authority noted that due action has been taken.

2.2 The Authority was appraised about the outcome of the price capping of 5 medical devices (Pulse Oximeter, Blood Pressure Monitoring Machine, Nebulizer, Digital Thermometer, and Glucometer) based on the Trade margin rationalization (TMR) that was undertaken based on the decision of the Authority in its 90th Meeting held on

12.07.2021 and the notification issued on 13.07.2021. As a result 91% of more than 1000 brands of these devices have dropped prices up to 89%. It was further informed that downward revision of MRP has been reported by imported and domestic brands across all the categories. The Authority noted with satisfaction that price capping of medical devices based on TMR will result in passing on the benefits in price reduction to the consumers. The Authority deliberated upon the matter in detail and opined that for better compliance and enforcement of the price regulation, compulsory registration and standardization of the product is required and CDSCO may initiate action on the reference already made in this regard. The Authority also opined that State Drug Controller and Price Monitoring Resource Units (PMRUs) may take necessary steps for ensuring compliance and publicity for awareness generation.

3. Agenda item no. 3 – Status of New Drug application

3.1 Noted.

4. Agenda item no. 4 – New Drug application Price fixation under Para 5 and Para 15 of DPCO, 2013

4.1 Agenda item no. 4(i) to 4(xx) and 4(xxv)

4.1.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4(xxvi) (total 27 Form I applications containing retail price fixation of 27 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 25 (twenty five) new drugs under Para 5 and 15 of the DPCO 2013, as detailed below:

A. Retail price fixed under Para 5 and 15 of DPCO, 2013

| S. No. | Name of the Formulation / Brand Name | Strength | Unit | Manufacturer & Marketing Company | Retail Price (Rs.) |
|--------|--|---|--------------|--|--------------------|
| (1) | (2) | (3) | (4) | (5) | (6) |
| 4(i) | Budesonide Respule | Each 2 ml Respule contains: Budesonide IP 0.5 mg | Per 2ml pack | Softdeal Pharmaceutical Private Limited | 17.79 |
| 4(ii) | Paracetamol + Caffeine Tablet | Each uncoated tablet contains: Paracetamol IP 650mg Caffeine IP 50mg | 1 Tablet | M/s Micro Labs Limited | 2.81 (Note 2) |
| 4(iii) | Metoprolol Succinate (ER) + Cilnidipine + Telmisartan Tablet | Each film coated tablet contains: Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg, (As Extended Release), | 1 Tablet | M/s Pure & Cure Healthcare Pvt. Ltd. M/s Alembic Pharmaceuticals Ltd. | 10.16 |

| S. No. | Name of the Formulation / Brand Name | Strength | Unit | Manufacturer & Marketing Company | Retail Price (Rs.) |
|---------|--|---|-----------------------|---|--------------------|
| (1) | (2) | (3) | (4) | (5) | (6) |
| | | Cilnidipine IP 10mg Telmisartan IP 40mg | | | |
| 4(iv) | Metoprolol Succinate (ER) + Cilnidipine + Telmisartan Tablet | Each film coated tablet contains: Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg, (As Extended Release), Cilnidipine IP 10mg Telmisartan IP 40mg | 1 Tablet | M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Alembic Pharmaceuticals Ltd. | 12.41 |
| 4(v) | Atorvastatin + Ezetimibe Tablet | Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 40mg, Ezetimibe IP 10mg | 1 Tablet | M/s Safetab Life Science / M/s Lupin Limited | 33.14 |
| 4(vi) | Cefixime + Potassium Clavulanate tablet | Each film coated tablet contains: Cefixime Trihydrate IP eq. to Anhydrous Cefixime 200mg, Potassium Clavulanate Diluted eq. to Clavulanic acid IP 125mg | 1 Tablet | M/s Zeneka Healthcare Ltd. / M/s Cadila Pharmaceuticals Limited | 21.97 |
| 4(vii) | Diclofenac Sodium + Paracetamol Tablet IP | Each uncoated tablet contains: Diclofenac Sodium IP 50mg, Paracetamol IP 325mg | 1 Tablet | M/s Softdeal Pharmaceutical Pvt. Ltd. | 4.14 (Note 2) |
| 4(viii) | Calcium Carbonate + Vitamin D3 Tablet | Each Film coated tablet contains: Calcium Carbonate IP 1250mg eq. to Elemental Calcium 500mg, Vitamin D3 IP 1000IU | 1 Tablet | M/s Unison Pharmaceuticals Pvt. Ltd. | 5.36 (Note 2) |
| 4(ix) | Zinc Sulphate Monohydrate + Sodium Citrate + Potassium Chloride + Dextrose Anhydrous Oral Solution | Each pack of 200ml contains: Zinc Sulphate Monohydrate IP 0.0110 g Sodium Citrate IP 0.5800 g Potassium Chloride IP 0.3000 g Sodium Chloride IP 0.5200 g Dextrose Anhydrous IP 2.7000 g | Per 200 ml pack | M/s Halewood Laboratories Pvt. Limited / M/s FDC Limited | 30.00 |
| 4(x) | Rabeprazole Sodium + Ondansetron Hydrochloride Tablet | Each Enteric coated tablet contains: Rabeprazole Sodium IP 20mg Ondansetron Hydrochloride eq. to Ondansetron IP 4mg | 1 Tablet | M/s Dallas Drugs Pvt. Ltd. / M/s Alkem Laboratories Limited | 10.00 (Note 2) |

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| S. No. | Name of the Formulation / Brand Name | Strength | Unit | Manufacturer & Marketing Company | Retail Price (Rs.) |
|---------|--|--|----------|--|--------------------|
| (1) | (2) | (3) | (4) | (5) | (6) |
| 4(xi) | Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine Maleate, Sodium Citrate and Menthol Syrup | Each 5ml contains: Paracetamol IP 125mg Phenylephrine Hydrochloride IP 5mg Chlorpheniramine Maleate IP 0.5mg Sodium Citrate IP 60mg Menthol IP 1mg | 1 ML | M/s Shiv Industries / M/s Profic Organic Limited | 0.64 |
| 4(xii) | Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet | Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 500mg (As Extended release form) | 1 Tablet | M/s Synokem Pharmaceuticals Ltd. / M/s Lupin Limited | 6.25 (Note 3) |
| 4(xiii) | Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet | Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 1000mg (As Extended release form) | 1 Tablet | M/s Synokem Pharmaceuticals Ltd. / M/s Lupin Limited | 7.54 (Note 3) |
| 4(xiv) | Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet | Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form) | 1 Tablet | M/s Synokem Pharmaceuticals Ltd. / M/s Lupin Limited | 9.65 (Note 3) |
| 4(xv) | Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet | Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form) | 1 Tablet | M/s Synokem Pharmaceuticals Ltd. / M/s Lupin Limited | 11.17 (Note 3) |
| 4(xvi) | Methylcobalamin, Alpha Lipoic Acid, Vitamin D3, Pyridoxine Hydrochloride & Folic Acid Tablet | Each film coated tablet contains: Methylcobalamin IP 1500mcg, Alpha Lipoic Acid USP 100mg, Vitamin D3 IP 1000 IU, Pyridoxine Hydrochloride IP | 1 Tablet | M/s Akums Drugs & Pharmaceuticals Limited / M/s Abbott Healthcare Pvt. | 10.97 |

| S. No. | Name of the Formulation / Brand Name | Strength | Unit | Manufacturer & Marketing Company | Retail Price (Rs.) |
|---------------|--|---|-------------|--|----------------------|
| (1) | (2) | (3) | (4) | (5) | (6) |
| | | 3mg Folic Acid IP 1.5mg | | Ltd. | |
| 4(xvii) | Methylcobalamin, Alpha Lipoic Acid, Vitamin D3, Pyridoxine Hydrochloride & Folic Acid Tablet | Each film coated tablet contains: Methylcobalamin IP 1500mcg, Alpha Lipoic Acid USP 100mg, Vitamin D3 IP 1000 IU, Pyridoxine Hydrochloride IP 3mg & Folic Acid IP 1.5mg | 1 Tablet | M/s Unison Pharmaceutical s Pvt. Ltd. | 10.97 |
| 4(xviii)) | Diclofenac Diethylamine, Methyl Salicylate, Capsaicin, Menthol & Linseed Oil Gel | Composition: Diclofenac Diethylamine IP 1.16% w/w eq. to Diclofenac Sodium 1.0% w/w, Methyl Salicylate IP 10%w/w, Capsaicin USP 0.025% w/w, Menthol IP 5.0% w/w & Linseed Oil BP 3.0% w/w | 1 GM | M/s Hetero Healthcare Ltd. | 2.70 (Note 2) |
| 4(xix) | Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet | Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 500mg (As Extended release form) | 1 Tablet | M/s Synokem Pharmaceutical s Ltd. / M/s Primus Remedies Pvt Ltd | 6.25 (Note 3) |
| 4(xx) | Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet | Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form) | 1 Tablet | M/s Synokem Pharmaceutical s Ltd. / M/s Primus Remedies Pvt Ltd | 9.65 (Note 3) |
| 4(xxi) | Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet | Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form) | 1 Tablet | M/s Synokem Pharmaceutical s Ltd. / M/s Primus Remedies Pvt Ltd | 11.17 (Note 3) |
| 4(xxii) | Dapagliflozin + Metformin Hydrochloride (As Extended release form) | Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg, | 1 Tablet | M/s Synokem Pharmaceutical s Ltd. /M/s Indoco Remedies | 9.65 (Note 3) |

| S. No. | Name of the Formulation / Brand Name | Strength | Unit | Manufacturer & Marketing Company | Retail Price (Rs.) |
|----------|---|--|----------|--|--------------------|
| (1) | (2) | (3) | (4) | (5) | (6) |
| | Tablet | Metformin Hydrochloride IP 500mg (As Extended release form) | | Limited | |
| 4(xxiii) | Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet | Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form) | 1 Tablet | M/s Synokem Pharmaceuticals Ltd. / M/s Indoco Remedies Limited | 11.17 (Note 3) |
| 4(xxiv) | Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet | Each film-coated bilayered tablet contains: Dapagliflozin Propanediol monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 1000mg (As Extended release form) | 1 Tablet | M/s Synokem Pharmaceuticals Ltd. / M/s Primus Remedies Pvt Ltd | 7.54 (Note 3) |
| 4(xxv) | Calcium Carbonate + Vitamin D3 Methylcobalamin + Calcium L-5-Methyltetrahydrofolate & Pyridoxal - 5- Phosphate Tablet | Each Film coated tablet contains: Calcium Carbonate IP 1250mg eq. to Elemental Calcium 500mg, Vitamin D3 IP 2000IU Methylcobalamin IP 1500mcg, Calcium L-5-Methyltetrahydrofolate USP 1mg, Pyridoxal - 5- Phosphate 20mg | 1 Tablet | M/s Unison Pharmaceuticals Ltd. | 17.12 (Note 2) |

Note 1. The retail prices are to be notified after 10 working days from uploading of draft working sheet/Minutes of the Multidisciplinary Committee of Experts/ Minutes of the Authority Meeting on NPPA's website, as applicable.

Note 2. The representative of DCGI present in the meeting confirmed that the formulations are approved by DCGI.

Note 3. The Authority deliberated upon the matter in detail and decided to approve the retail price in line with the decision as recorded in Note 2 of Para 4.1 of the Minutes of the 82nd Authority meeting dated 23.12.2020, based on the recommendation of Multidisciplinary Committee of Experts.



4.1.2 Agenda item no. 4(xix): The Authority noted that the application of M/s Manas Pharma Mfg for retail price fixation of orodispersible Lorazepam IP 1mg & 2 mg tablet was placed before the Multidisciplinary Committee of Experts in its 34th meeting dated 26.07.2021 in which the Committee recommended that since there is no significant therapeutic advantage of 'orodispersible' variants of Lorazepam from the conventional variants, the retail price application of M/s Manas Pharma Mfg for orodispersible Lorazepam IP 1mg & 2 mg tablet be treated as closed and that the ceiling price of Lorazepam 1mg & 2 mg tablet are applicable to the orodispersible tablets too containing Lorazepam IP 1mg & 2 mg respectively. The Authority accepted the recommendation of the Committee and decided to close the application of M/s Manas Pharma Mfg for retail price fixation of orodispersible Lorazepam IP 1mg & 2 mg tablet. The Authority further decided that the company be directed that the ceiling price of Lorazepam 1mg & 2 mg tablet are applicable for orodispersible tablets containing Lorazepam IP 1mg & 2 mg respectively.

4.2 The Authority noted that in respect of retail price of new drugs which were earlier approved based on the recommendation of the Multidisciplinary Committee of Experts, the same are again placed before the Multidisciplinary Committee for subsequent application since the market based data is not available even after approval of the retail price of the formulation earlier. The Authority took cognizance of Para 15(2)(i) of DPCO 2013 in which it provides for fixation of retail price on the principles of 'Pharmacoeconomics' in respect of those new drugs which are not available in domestic market. The Authority deliberated upon the matter in detail and opined that options may be explored for rationalizing the issue.

5. Agenda item no. 5 – Status of implementation of Review cases

5.1 Noted.

6. Agenda item no. 6 – Review application under Para 31 of DPCO, 2013 against S.O. 1724(E) dated 30.04.2021 for the formulation Vitamin D3 (Cholecalciferol) 60000 IU orally disintegrating strips (Marketer- M/s Cadila Pharmaceuticals Ltd.)- regarding.

6.1 The Authority noted that based on the application of M/s Cadila Pharmaceuticals Ltd, the retail price of Vitamin D3 (Cholecalciferol) 60000 IU orally disintegrating strips was calculated and the draft working sheet was uploaded on the NPPA's website on 07.04.2021, so as to enable the company to make representations, if any, within 10 working days. However, the Company has neither raised any objection nor submitted any document at that time in support of their claim. Accordingly, the Authority in its 86th meeting held on 28.04.2021 fixed the Retail Price of Vitamin D3 (Cholecalciferol) 60000 IU orally disintegrating strips and notified the same vide S.O. 1724(E) dated 30.04.2021 at Rs. 20.16 per strip excluding GST. Thus, M/s Cadila Pharmaceuticals Ltd did not submit its representation to NPPA subsequently.



6.2 Based on the notification, M/s Cadila Pharmaceuticals Ltd filed a review application before Department of Pharmaceuticals (DoP) stating that erroneous data was used in the calculation of the retail price. DoP vide letter dated 30.06.2021 requested NPPA to '*complete their first hand re-verifications of basic data and calculations based there upon before any decision about reviewing the case.*'

6.3 The Authority also noted that based on the corrected data submitted by the AIOCD-AWACS Pharmatrac, the revised retail price of Vitamin D3 (Cholecalciferol) 60000 IU orally disintegrating strip M/s comes to Rs. 30.39 per strip excluding GST.

6.4 The Authority deliberated upon the matter in detail and decided to re-fix the retail price of Vitamin D3 (Cholecalciferol) 60000 IU orally disintegrating strips for M/s Zim Laboratories Ltd (manufacturer)/M/s Cadila Pharmaceutical Ltd (marketer) which was earlier fixed vide SO. 1724(E) dated 30.04.2021 [Sl. No. 20] and approved the revised price at Rs. 30.39 per strip excluding GST based on corrected data.

7. Agenda item no. 7 - Intimation of Minutes of 34th meeting of Multidisciplinary Committee of Experts held on 26.07.2021.

7.1 Noted.

8. Agenda item no. 8 - Application for extension of ceiling price for I.V. Fluids with packaging in Non-glass with special feature

8.1 The Authority deliberated upon the matter in detail and noted that M/s Rusoma Laboratories Pvt. Ltd have applied for separate ceiling price of I.V. Fluids for packages in non-glass having special features i.e. i.e eurohead bottles with brand name 'Dewdrip'. The Authority noted that the matter was deliberated in the 34th meeting of the Multidisciplinary Committee of Experts held on 26.07.2021 and M/s Rusoma Laboratories Pvt. Ltd made demonstration before the Multidisciplinary Committee of Experts. The Authority further noted that the Committee recommended to extend the ceiling prices and the formulations mentioned in SO.1332(E) dated 25.03.2021 to M/s Rusoma Laboratories Pvt. Ltd for I.V. fluids in packages in non-glass with special features as (i) Self Collapsibility and selfseal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels.

8.2 Accordingly, the Authority decided to extend the ceiling prices and the formulations mentioned in S.O.1332(E) dated 25.03.2021 to M/s Rusoma Laboratories Pvt. Ltd for the products "eurohead bottles with brand name 'Dewdrip'" in respect of I.V. fluids in packages in non-glass with special features as (i) Self Collapsibility and self-seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels.



9. Agenda item no. 9 - Application for extension of ceiling price for Ringer Lactate Injection in packaging with special feature.

9.1 The Authority deliberated upon the matter in detail and noted that M/s Rusoma Laboratories Pvt. Ltd have applied for separate ceiling price of ringer lactate injection in packages having special features i.e eurohead bottles with brand name 'Dewdrip'. The Authority further noted that the matter was deliberated in the 34th meeting of the Multidisciplinary Committee of Experts held on 26.07.2021 and M/s Rusoma Laboratories Pvt. Ltd had made demonstration before the Multidisciplinary Committee of Experts. The Authority further noted that the Committee recommended to extend the ceiling prices and the formulations mentioned in SO.1333(E) dated 25.03.2021 to M/s Rusoma Laboratories Pvt. Ltd [for product mentioned in Sl. No. 2, 3 and 4 of S.O. 1333(E) dated 25.03.2021] for ringer lactate injection in packages with special features as (i) Self Collapsibility and self-seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels.

9.2 Accordingly, the Authority decided to extend the ceiling prices and the formulations mentioned in S.O.1333(E) dated 25.03.2021 to M/s Rusoma Laboratories Pvt. Ltd [for product mentioned in Sl. No. 2, 3 and 4 of S.O. 1333(E) dated 25.03.2021] for ringer lactate injection in packages with special features "eurohead bottles with brand name 'Dewdrip'" as (i) Self Collapsibility and selfseal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels.

10. Agenda item no. 10 - Review application of M/s Emcure Pharmaceuticals Ltd against retail price fixation of Darunavir 800mg + Ritonavir 100 mg tablet vide S.O. 4062(E) dated 08.11.2019

10.1 The Authority noted the review order no. 31015/16/2019-Pricing dated 25.06.2021 issued by Department of Pharmaceuticals (DoP) wherein NPPA was directed to "*fix the retail price of the formulation Darunavir 800 mg + Ritonavir IP 100 mg for M/s Emcure Pharmaceuticals Limited strictly as per provisions of para 5(1) read with para 9(4) of DPCO, 2013 and consider the PTR of available drugs in the market, take simple average of all those who have more than 1% market share and consider the fixation of drug price as per the simple average formula contained in para 4(1) of DPCO, 2013.*"

10.2 The Authority further noted that M/s Emcure Pharmaceuticals Limited had applied for retail price fixation of Darunavir 800 mg + Ritonavir 100 mg tablet in the month of June, 2019. As per the provisions of DPCO, 2013, the data of six month earlier than the month of receipt of the application was to be considered for calculation of retail price (i.e. November 2018) under Para 9(4) of DPCO 2013. From analysis of latest Pharmatrac data available at that time, it was noted that the data for the month of November, 2018 was not available. Further, the market based data of Darunavir 800 mg + Ritonavir 100 mg tablet was not even available for twelve month before November 2018 in AIOCD-AWACS Pharmatrac database.

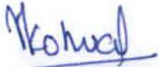
Hence, the matter was referred to Multi-disciplinary Committee of experts. The Multidisciplinary Committee of Experts in its 13th meeting recommended the retail price of each film coated tablet contained Darunavir 800 mg + Ritonavir 100 mg for M/s Emcure Ltd. (marketer) and M/s Hetero Labs Ltd., (manufacturer/Importer) at Rs. 197.55 per tablet excluding GST based on the latest PTR as submitted by M/s Hetero Healthcare Ltd in Form-V. The Authority noted that the retail price had been recommended based on Form-V data which is in line with the data as per Para 9(2) of DPCO 2013. Hence, the Authority in its 70th meeting dated 20.10.2019 fixed the retail price based on the recommendation of Multidisciplinary Committee of Experts,

10.3 The Authority deliberated upon the matter in detail and observed that since the data is not available, the retail price could not be calculated as per Para 5(1) read with para 9(4) of DPCO 2013 towards implementation of the review order. Accordingly, the Authority decided to refer the matter to DoP.

11. Agenda item no. 11 - To discuss Form-IV Intimation submitted by M/s Neon Laboratories Limited for discontinuation of scheduled formulation Tropine 1ml Injection (Atropine Sulphate Injection 0.6mg/ml) under para 21(2) of DPCO, 2013

11.1 The Authority deliberated upon the matter in detail and decided that M/s Neon Laboratories Ltd be directed under Para 3 of DPCO 2013 to continue production of Atropine 0.6mg/ml injection for six month from the date of issue of direction.

The meeting ended with a vote of thanks to the Chair and all the participants in the meeting.


(Dr. Vinod Kotwal)
Member Secretary