मिसिल स.- 8(83)/2021/डी.पी/एनपीपीए-डीवी-II
F. No. 8(83)/2021/DP/NPPA-Div. II

कार्यवाहीस. : 215/83/2021/F
Proceeding No: 215/83/2021/F

Minutes of the 215th (overall) and 83rd meeting of the Authority under DPCO, 2013 held on 27.01.2021 at 11:30 AM

The 215th meeting of the Authority (overall), which is the 83rd meeting under the DPCO, 2013, was held on 27th of January 2021 at 11:30 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following Authority members of the NPPA were present:

(i) Dr. Vinod Kotwal, Member Secretary
(ii) Shri A. K. Saha, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

Ms. A. Srija, Economic Advisor, Department of Economic Affairs had requested for leave of absence.

Shri A. K. Pradhan, Deputy Drug Controller, CDSCO, Ministry of Health & Family Welfare was also present.

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

(i) Shri N. I. Chowdhury, Advisor
(ii) Shri S. S. Ojha, Jt. Director (Pricing)
(iii) Shri Prasenjit Das, Deputy Director (Pricing)
(iv) Shri Prakash Hemani, Asstt. Director (Enforcement)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 82nd meeting held on 23.12.2020.

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 82nd meeting dated 23.12.2020

2.1 The Authority noted that due action has been taken.

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

3.1 Noted. It was noted with satisfaction by the Authority that all cases are being processed in a time-bound manner and even the seven pending applications are within the time-frame of the ecosystem guidelines.

3.2 The Authority noted that the most of the retail price applications of new drugs mainly consist of Fixed Dose Combinations (FDCs) of two or more drugs. It was discussed and felt that undertaking a 'prescription audit' may throw light on the prescription patterns of various drugs & their usage. The Authority was of the view that NPPA may undertake 'prescription audit' as the findings can be of help for decision making.

3.4 The Authority noted with satisfaction that with the implementation of ecosystem guidelines w.e.f. August 2020 most of the new drug applications are received online which has helped in their faster processing in a time bound manner. The Authority deliberated upon the matter in detail and desired that the same be made mandatory w.e.f 1st April, 2021.

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

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4(xxii) (total 22 Form I applications containing retail price fixation of 22 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 21 (twenty one) new drugs [except 1 formulation as per agenda no. 4(xi)] under Para 5 and 15 of the DPCO 2013, as detailed below:

A. Retail price fixed under Para 5 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)	Rosuvastatin + Aspirin Capsule	**Each Capsule contains:** Rosuvastatin Calcium IP eq.	1 Capsule	M/s Sun Pharma Laboratories	8.33

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		to Rosuvastatin 20mg Aspirin IP 75mg (as enteric coated)		Limited	
4(ii)	Rosuvastatin + Aspirin Capsule	**Each Capsule contains:** Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg Aspirin IP 150mg (as enteric coated)	1 Capsule	M/s Sun Pharma Laboratories Limited	8.09
4(iii)	Escitalopram + Clonazepam Tablet	**Each film coated tablet contains:** Escitalopram Oxalate IP eq. to Escitalopram 20mg, Clonazepam IP 0.5mg	1 Tablet	M/s Sun Pharma Laboratories Limited	18.19 (Note 2)
4(iv)	Amlodipine & Extended Release Metoprolol Succinate tablet (AMLONG MT 5/25)	**Each film coated bilayered Tablet contains:** Amlodipine Besilate IP eq. to Amlodipine 5mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (As Extended Release form)	1 Tablet	M/s Micro Labs Limited	6.15
4(v)	Remogliflozin Etabonate and Metformin hydrochloride tablet	**Each film coated Tablet contains:** Remogliflozin Etabonate 100mg Metformin hydrochloride IP 1000mg	1 Tablet	M/s Glenmark Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.	13.18
4(vi)	Remogliflozin Etabonate and Metformin hydrochloride tablet	**Each film coated Tablet contains:** Remogliflozin Etabonate 100mg Metformin hydrochloride IP 500mg	1 Tablet	M/s Glenmark Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.	11.44
4(vii)	Azathioprine Tablet	**Each film coated Tablet contains:** Azathioprine IP 100mg	1 Tablet	M/s RPG Life Sciences	8.69
4(viii)	Moxifloxacin Eye Drops	**Composition:** Moxifloxacin hydrochloride	1 ML	M/s East African (India) Overseas	21.87

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		IP eq. to Moxifloxacin 0.5%w/v		/ M/s Alkem Laboratories Ltd.	
4(ix)	Paracetamol + Mefenamic Acid Suspension	**Each 5ml contains:** Paracetamol IP 125mg, Mefenamic Acid IP 50mg	1 ML	M/s Aristo Pharmaceuticals Pvt. Ltd.	0.58 (Note 2)
4(x)	Paracetamol + Mefenamic Acid Suspension	**Each 5ml contains:** Paracetamol IP 250mg, Mefenamic Acid IP 100mg	1 ML	M/s Aristo Pharmaceuticals Pvt. Ltd.	0.66 (Note 2)
4(xi)	Ciprofloxacin + Dexamethasone Eye Drops	**Each ml Contains:** Ciprofloxacin Hydrochloride IP Eq. to Ciprofloxacin 0.3% w/v, Dexamethasone IP 0.1% w/v	1 ML	M/s AXA Perentals Ltd. / M/s Sun Pharmaceutical Industries Limited	Deferred (Note 3)
4(xii)	Ascorbic Acid (Vitamin C) + Zinc Chewable Tablet	**Each uncoated Chewable tablet contains:** Ascorbic Acid IP 100mg Sodium Ascorbate IP 450mg eq. to Ascorbic Acid 400mg Zinc Citrate USP eq. to Elemental Zinc 5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Koye Pharmaceuticals Pvt. Ltd.	3.82 (Note 2)
4(xiii)	Telmisartan, Cilnidipine and Chlorthalidone Tablet	**Each film coated tablet contains:** Telmisartan IP 40mg, Cilnidipine IP 10mg, Chlorthalidone IP 6.25mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Obsurge Biotech Ltd.	11.36
4(xiv)	Pantoprazole Dual-Release Gastro-Resistant Tablet	**Each Dual-release Gastro-resistant tablet contains:** Pantoprazole Sodium IP eq. to Pantoprazole 80mg	1 Tablet	M/s Alkem Healthscience / M/s Alkem Laboratories Ltd.	16.48
4(xv)	Rosuvastatin + Clopidogrel Tablet	**Each Film coated tablet contains:** Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg, Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Sun Pharma Laboratories Limited	16.97
4(xvi)	Rosuvastatin +	**Each Film coated tablet**	1 Tablet	M/s Pure and	

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Clopidogrel Tablet	**contains:** Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg, Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg		Cure Healthcare Pvt. Ltd. / M/s Sun Pharmaceutical Industries Ltd.	16.97
4(xvii)	Mefanamic Acid+ Paracetamol Suspension (Pyremol-MF)	**Each 5ml contains:** Mefanamic Acid IP 100mg Paracetamol IP 250mg	1 ML	M/s Vivimed Labs Ltd. /M/s Alembic Pharmaceuticals Limited	0.66 (Note 2)

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

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xviii)	Vildagliptin + Metformin Hydrochloride (SR) Tablet	**Each uncoated bilayered tablet contains:** Vildagliptin 50mg, Metformin Hydrochloride IP 500mg (As sustained release form)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Torrent Pharmaceuticals Limited	6.86 (Note 4)
4 (xix)	Vildagliptin + Metformin Hydrochloride (SR) Tablet	**Each uncoated bilayered tablet contains:** Vildagliptin 50mg, Metformin Hydrochloride IP 1000mg (As sustained release form)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Torrent Pharmaceuticals Limited	7.51 (Note 4)
4(xx)	Vildagliptin + Metformin Hydrochloride (SR) Tablet	**Each uncoated bilayered tablet contains:** Vildagliptin 50mg, Metformin	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Alkem Laboratories	6.86 (Note 4)

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Hydrochloride IP 500mg (As sustained release form)		Limited	
4(xxi)	Vildagliptin + Metformin Hydrochloride (SR) Tablet	**Each uncoated bilayered tablet contains:** Vildagliptin 50mg, Metformin Hydrochloride IP 1000mg (As sustained release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Alkem Laboratories Limited	7.51 (Note 4)
4 (xxii)	Azathioprine Tablet	**Each film coated Tablet contains:** Azathioprine IP 75mg	1 Tablet	M/s RPG Life Sciences	14.17

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 noted that representation has been received from M/s Sun Pharmaceutical Industries Ltd. Accordingly, the Authority decided to examine the same and deferred its decision.*

Note 4. *The Authority deliberated upon the matter in detail and decided to approve the retail price in line with the decision as recorded in Note 6 of Para 4.1 of the Minutes of the 80th Authority meeting dated 26.10.2020, based on the recommendation of Multidisciplinary Committee of Experts.*

5. 1 Agenda item no. 5 – Status of implementation of Review cases

5.1.1 Noted.

5.2 Agenda item no. 5 (i) - Review order no. 31015/05/2020-Pricing dated 14.12.2020 relating to application filed by M/s Bharat Serums and Vaccines Ltd for ceiling price fixation of Human normal Immunoglobulin 16.5% vide SO. 1241(E) dated 03.04.2020.

5.2.1 The Authority noted that Department of Pharmaceuticals vide its review order no. 31015/05/2020-Pricing dated 14.12.2020 directed to revise the ceiling price of Human Normal Immunoglobulin 16.5 % after verifying the applicability of GST factor in view of the fact that the formulation attracts nil rate of excise duty. The Authority also noted the documents submitted by the company. The Authority deliberated upon the matter in detail and decided to obtain clarification from Central Board of Indirect Taxes & Customs, Department of Revenue, Ministry of Finance, Government of India, as to whether the formulation Human Normal Immunoglobulin 16.5 % attracts nil rate of excise duty.

6. Agenda item no. 6 - Application for extension of ceiling price for I.V. Fluids with packaging in Non-glass with special feature

6.1 The Authority deliberated upon the matter in detail and noted that two companies namely, M/s Puniska Healthcare Pvt. Ltd and M/s Realcade Lifesciences Pvt. Ltd have applied for separate ceiling price of I.V. Fluids for packages in non-glass having special features. The Authority noted that the matter was deliberated in the 26th meeting of the Multidisciplinary Committee of Experts held on 18.01.2021 and the two companies namely, M/s Puniska Healthcare Pvt. Ltd and M/s Realcade Lifesciences 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.1215(E) dated 25.03.2020 to the two companies namely, M/s Puniska Healthcare Pvt. Ltd [for M/s M/s Puniska Healthcare Pvt. Ltd, the product mentioned in Sl. No. 5,6,7 and 8 of S.O. 1215(E) dated 25.03.2020] and M/s Realcade Lifesciences Pvt. Ltd for 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.

6.2 Accordingly, the Authority decided to extend the ceiling prices and the formulations mentioned in S.O.1215(E) dated 25.03.2020 to the two companies namely, M/s Puniska Healthcare Pvt. Ltd [for M/s M/s Puniska Healthcare Pvt. Ltd, the product mentioned in Sl. No. 5,6,7 and 8 of S.O. 1215(E) dated 25.03.2020] and M/s Realcade Lifesciences Pvt. Ltd for the products "non-PVC bag" and "Euro head bottle" respectively 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.

7. Agenda item no. 7 – Application for extension of ceiling price for Ringer Lactate Injection with packaging in Non-glass with special feature

7.1 The Authority deliberated upon the matter in detail and noted that one company namely, M/s Realcade Lifesciences Pvt. Ltd had applied for separate ceiling price of ringer lactate injection in packages having special features. The Authority further noted that the matter was deliberated in the 26th meeting of the Multidisciplinary Committee of Experts held on 18.01.2021 and M/s Realcade Lifesciences 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.1216(E) dated 25.03.2020 to M/s Realcade Lifesciences Pvt. Ltd 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.

7.2 Accordingly, the Authority decided to extend the ceiling prices and the formulations mentioned in S.O.1216(E) dated 25.03.2020 to M/s Realcade Lifesciences Pvt. Ltd 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.

8. Agenda item no. 8 - Ceiling price fixation of Pheniramine Maleate Injection 22.75 mg/ ml in 33 ml and 100 ml pack.

8.1 The Authority noted that the Multidisciplinary Committee of Experts in its 26th meeting dated 18.01.2021 recommended the ceiling price of Pheniramine Maleate Injection 22.75 mg/ ml in 33 ml and 100 ml pack at Rs. 0.66 per ml (excluding GST) and Rs. 0.53 per ml (excluding GST) subject to confirmation of the availability of manufacturing/ marketing license from the M/s Intervet India Pvt. Ltd/ Central Drugs Standard Control Organisation (CDSCO) regarding the pack size of 33ml and 100 ml.

8.2 The Authority deliberated upon the matter in detail and accepted the recommendation of the Multidisciplinary Committee of Experts and decided to approved the ceiling price of Pheniramine Maleate Injection 22.75 mg/ ml in 33 ml and 100 ml pack at Rs. 0.66 per ml (excluding GST) and Rs. 0.53 per ml (excluding GST) subject to confirmation of the availability of manufacturing/ marketing license from the M/s Intervet India Pvt. Ltd/ Central Drugs Standard Control Organisation (CDSCO) regarding the pack size of 33ml and 100 ml.

9. Agenda item no. 9 - Status of drugs exempted under para 32 of DPCO, 2013

9.1 The Authority noted the status report of the exemption granted under para 32 of DPCO 2013 to various companies.

10.1 Agenda item no. 10 (i) - Retail price fixation for M/s Torrent Pharmaceuticals Ltd in respect of formulations to which exemption granted under para 32 of DPCO 2013 has expired.

10.1.1 The Authority noted that the exemption granted under para 32 of DPCO 2013 to M/s Torrent Pharmaceuticals Ltd for Fixed Dose Combination (FDC) of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated) vide SO 2110(E) dated 21.08.2014 and for Olanzapine Pamoate Prolong Release Powder for suspension for IM Injection (Olanzapine Pamoate Monohydrate eq. to Olanzapine 210mg/ vial, 300 mg/vial and 405 mg/vial) vide SO 856(E) dated 25.03.2015 has expired.

10.1.2 The Authority further noted that Acetylsalicylic (Aspirin) 75mg tablet is a scheduled formulation, included in revised schedule I of DPCO'13. Accordingly, FDC of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg is a new drug for the existing companies as per the provisions of DPCO 2013. Further, Olanzapine Pamoate Prolong Release Powder for suspension for IM Injection (Olanzapine Pamoate Monohydrate eq. to Olanzapine 210mg/ vial, 300 mg/vial and 405 mg/vial) is a non-scheduled formulation under DPCO 2013.

10.1.3 The Authority also noted that the matter was referred to the Multidisciplinary Committee of Experts in its 26th meeting held on 18.01.2021 in which the Committee noted that for the formulation "Fixed Dose Combination (FDC) of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated)" M/s Torrent Pharmaceuticals Ltd is an existing manufacturer/ marketer and needs to have price approval for marketing/ manufacturing of the formulation after the expiry of the exemption granted under para 32(iii) of DPCO 2013. However, the company did not seek any price approval. Accordingly, the Committee directed that explanation may be sought from the company for non-compliance and that the reply received from the company may be examined and placed in its next meeting.

10.1.4 The Authority deliberated upon the matter in detail and observed that M/s Torrent Pharmaceuticals Ltd, being an existing manufacturer/ marketer is required to apply for retail price fixation of "Fixed Dose Combination (FDC) of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated)" after the expiry of the exemption granted under para 32(iii) of DPCO 2013. Accordingly, the Authority decided that the retail price for the new drug "Fixed Dose Combination (FDC) of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated)" is to be fixed for M/s torrent Pharmaceuticals Ltd and overcharging notice, as applicable, is to be issued for the non-compliance. In this regard, the Authority directed that the matter regarding retail price fixation of "Fixed Dose Combination (FDC) of Prasugrel Hydrochloride 10 mg (as film coated) plus Aspirin 75 mg (as enteric coated)" for M/s Torrent Pharmaceuticals Ltd be

placed before the Multidisciplinary Committee of Experts for its recommendation and place in the next Authority meeting.

10.1.5 The Authority further observed that the formulation Olanzapine Pamoate Prolong Release Powder for suspension for IM Injection (Olanzapine Pamoate Monohydrate eq to Olanzapine 210mg/ vial, 300 mg/vial and 405 mg/vial) is a non-scheduled formulation under DPCO 2013 and accordingly directed that the formulation be monitored as per the applicable provisions of DPCO 2013.

10.2 Agenda item no. 10 (ii) - Retail price fixation for M/s Wockhardt Ltd in respect of formulations to which exemption granted under para 32 of DPCO 2013 has expired.

10.2.1 The Authority noted that the exemption granted under para 32 of DPCO 2013 to M/s Wockhardt Ltd for (i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml vide SO 3131(E) dated 20.11.2015 had expired.

10.2.2 The Authority further noted that Insulin 40IU/ml is a scheduled formulation, included in revised schedule I of DPCO'13. Accordingly, (i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml are new drugs for the existing companies as per the provisions of DPCO 2013.

10.2.3 The Authority also noted that the matter was referred to the Multidisciplinary Committee of Experts in its 26th meeting dated 18.01.2021 in which the Committee noted that for the formulations (i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml, M/s Wockhardt Ltd is an existing manufacturer/ marketer and need to have price approval for marketing/ manufacturing of the formulation after the expiry of the exemption granted under para 32(iii) of DPCO 2013. However, M/s Wockhardt Ltd did not seek any price approval. Accordingly, the Committee directed that

explanation may be sought from the companies for the non-compliance and that the reply received from the company may be examined and placed in its next meeting.

10.2.4 The Authority deliberated upon the matter in detail and observed that M/s Wockhardt Ltd, being as existing manufacturer/ marketer is required to apply for retail price fixation of (i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml, after the expiry of the exemption granted under para 32(iii) of DPCO 2013. Accordingly, the Authority decided that the retail price for the new drug (i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml, is to be fixed for M/s Wockhardt Ltd and overcharging notice, as applicable, is to be issued for the non-compliance. In this regard, the Authority directed that the matter regarding retail price fixation of (i) Insulin Human Injection, 200IU/ml (ii) Isophane Insulin Human Suspension 200IU/ml and (iii) 70% Isophane Insulin Human Suspension and 30% Insulin Human Injection 200IU/ml, for M/s Wockhardt Ltd be placed before the Multidisciplinary Committee of Experts for its recommendation and place in the next Authority meeting.

11. Agenda item no. 11 - Action Taken Report in respect of 44 overcharging cases

11.1 The Authority deliberated upon the matter in detail and decided that in 44 overcharging cases, wherein statutory auditor certified data has been received by the companies, case may be processed further. The Authority further decided that Cost Auditor of the company appointed by the Board of Directors can also certify the data.

11.2 The Authority also decided that that in respect of other overcharging cases, NPPA may explore a new methodology/ procedure to ensure the veracity of the data provided by the company and if found feasible, appropriate changes in the existing internal guidelines be made.

12. Agenda item no. 12: Intimation of Minutes of 26th meeting of Multidisciplinary Committee of Experts held on 18.01.2021.

12.1 Noted.

13. Agenda item no. 13: Monitoring of MRPs of non-scheduled Medical Devices, notified as Drugs under D&C Act, 1940 under Para 20 of the DPCO 2013

13.1 The Authority deliberated upon the matter in detail and decided to collect the relevant information in respect of 24 non-scheduled medical devices for monitoring as per the provisions of DPCO 2013.

14. Agenda item no. 14: Upward revision of Ceiling Price of select Scheduled formulations under para 19 of DPCO, 2013

14.1 Deferred.

15. Agenda item no. 15: Agenda note in respect of 3 scheduled formulations of M/s Alkem Laboratories Limited (i) P-Carzine 50mg Capsule (Procarbazine Hydrochloride) (ii) Broadicillin 500mg Injection (Ampicillin) and (iii) Phenykem Injection 50mg/ml (Phenytoin) under para 21(2) of DPCO, 2013

15.1 Noted.

The meeting ended with a vote of thanks to the Chair.

Sd/-
(Dr. Vinod Kotwal)
Member Secretary