

National Pharmaceutical Pricing Authority

Subject: Minutes of the 37th meeting of Multidisciplinary Committee of Experts held on 25.11.2021 at 3:00 PM in NPPA

37th meeting of the "Multidisciplinary Committee of Experts" was held on 25.11.2021 under the Convenorship of Sh. N.I. Chowdhury, Adviser (Cost), in NPPA. The following members attended the meeting through video conferencing:-

1. Prof. Y. K. Gupta, Principal Scientific Advisor (projects), THSTI-DBT, Gol & Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi
2. Shri A. K. Pradhan, Jt. Drugs Controller, CDSCO
3. Dr. Rakesh K. Singh, Assoc. Professor, NIPER, Raebareli

The following officers of NPPA attended and presented the cases to the Committee

1. Mr. S. S Ojha, Jt. Director (Pricing), NPPA
2. Sh. Prasenjit Das, Deputy Director (Pricing), NPPA

1. Agenda No. 1 - Retail price fixation under Para 5 of DPCO, 2013- Each 5ml of the reconstituted suspension containing Amoxicillin Trihydrate IP eq. to Amoxicillin 600 mg+ Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9 mg for M/s Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketer).

1.1 The Committee noted that as per the provisions of DPCO 2013, the retail price of each 5ml of the reconstituted suspension containing Amoxicillin Trihydrate IP eq. to Amoxicillin 600 mg+ Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9 mg for M/s Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketer) is required to be calculated based on the market data for the month of February 2021. The Committee further noted that data of the formulation is not available in Pharmatrac database for the month of February 2021, however, the data of the formulation started appearing from April 2021. The Committee also noted that the applicant company has claimed retail price of Rs. 4.00 per ml excluding GST. The Committee deliberated upon the matter in detail and decided to fix the retail price of the subject formulation by calculating as per the formula provided in DPCO 2013 for calculating retail price of new drugs based on April 2021 data as available in Pharmatrac database. Accordingly, the Committee recommended the retail price of each 5ml of the reconstituted suspension containing Amoxicillin Trihydrate IP eq. to Amoxicillin 600 mg+ Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9 mg for M/s Alkem Healthscience (manufacturer) and M/s Alkem Laboratories Ltd. (marketer) at Rs. 3.36 per ml excluding GST.

2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013- Each 100 ml contains Povidone Iodine IP 1.0g (Available Iodine 0.1 g) + 2-Propanol IP 50 mg in 500 ml pack for M/s G.S. Pharmbutor Pvt. Ltd. (manufacturer) and M/s Win Medicare Pvt. Ltd. (marketer).

2.1 2.1 The Committee deliberated upon the matter in detail and recommended the retail price of Betadine Alcoholic Handrub in which each 100 ml contains Povidone

Iodine IP 1.0g (Available Iodine 0.1 g) and 2-Propanol IP 50 mg for M/s Win Medicare Pvt. Ltd (marketer) and M/s G.S. Pharmbutor Pvt. Ltd (manufacturer/ importer). at Rs. 230.00 per 500 ml pack excluding GST as detailed below:

Computation of Retail Price per ml	Source/Method	Rs.
Composition – Each 100 ml containing Povidone Iodine IP 1.0g (Available Iodine 0.1 g)+ 2-Propanol IP 50 mg		
a. Povidone Iodine *	Retail Price as per Pronab Sen Committee Report	0.17 per ml
b. 2-Propanol IP Solution	Ceiling Price of Ethyl Alcohol 50% (Data of Isopropyl Alcohol not available)	0.34 per ml
Worked out Retail Price		0.51 per ml
c. Less 30% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		0.05 per ml
Net Retail Price (a+b-c)		0.46 per ml
Retail price for 500ml pack		Rs. 230
Company Claimed Price for 500ml pack		Rs. 279.02 excluding GST
Recommended price for 500 ml pack		Rs. 230.00 excluding GST

Derived retail price as per recommendation of Pronab Sen committee :

$$P(s) = P^* \cdot [1 + a \cdot \{(s - s^*) / s^*\}]$$

Where : P(s) = Price ceiling of the strength s

P* = price ceiling for reference strength s*

s = strength in terms of API content

s* = reference strength

a = 0.8 for tablet / capsule and 0.7 for injectables.

Calculation of price of Povidone Iodine IP 1.0g solution

Ceiling Price for Povidone Iodine 5% = Rs. 0.39 per ml

Derived Retail price for Povidone Iodine Solution = $0.39[1 + 0.70\{(1-5)/5\}] = \text{Rs. } 0.17$ per ml

Calculation of price for 2-Propanol IP solution

Ceiling Price of Ethyl Alcohol (denatured) 70% = Rs. 0.42 per ml

Derived Retail price for Ethyl Alcohol 50% = $0.42[1+0.70\{50-70\}/70]$ = Rs. 0.34 per ml.

3. Agenda No. 3 Retail price fixation under Para 5 of DPCO, 2013- Composition: - Diclofenac Diethymine IP 2.32% w/w + Menthol IP 5 % w/w + Methyl Salicylate IP 10% w/w for M/s. Tuton Pharmaceuticals (manufacturer) and M/s. Unison Pharmaceuticals Pvt. Ltd. (marketer).

3.1 The Committee noted the retail price of the subject formulation has been given to M/s Sun Pharmaceutical Industries Ltd and the company has submitted the Form-V data. The Committee deliberated upon the matter in detail and decided to recommended to retail price of gel containing Diclofenac Diethymine IP 2.32% w/w + Menthol IP 5 % w/w + Methyl Salicylate IP 10% w/w for M/s. Tuton Pharmaceuticals (manufacturer) and M/s. Unison Pharmaceuticals Pvt. Ltd. (marketer) based on the Form-V data submitted by the company. Accordingly, the Committee recommended the retail price of gel containing Diclofenac Diethymine IP 2.32% w/w + Menthol IP 5 % w/w + Methyl Salicylate IP 10% w/w for M/s. Tuton Pharmaceuticals (manufacturer) and M/s. Unison Pharmaceuticals Pvt. Ltd. (marketer) at Rs. 3.69 per gm excluding GST as detailed below:

Sl. No.	Company	Unit	PTR	PTR per gm
1	M/s Sun Pharmaceutical Industries Ltd (as per Form-V data)	20 gm	63.57	3.18
2	Add: Retailer margin @16% (16% of sl. No. 1)			0.51
3.	Proposed Retail Price based on submitted Form-V by the companies (excluding GST) (sl. No. 1+ sl. No. 2)			Rs. 3.69 (Retail price per gm ex. GST)
4.	Retail price claimed			Rs. 6.25 per gm excluding GST
5.	Recommended retail price			Rs. 3.69 per gm excluding GST

4. Agenda no. 4 - Retail price fixation under Para 5 of DPCO, 2013- Each hard gelatin capsule contains Atorvastatin Calcium IP eq. to Atorvastatin 40 mg (as coloured pellets) + Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg (as two brown coloured film coated tablets each containing 37.5 mg Clopidogrel tablet IP) + Aspirin IP 75 mg (as enteric coated white-coloured pellets) for M/s. Windlas Biotech Ltd. (manufacturer) and M/s. Torrent Pharmaceuticals Ltd. (marketer).

4.1 The Committee noted that as per the provisions of DPCO 2013, the retail price of each hard gelatin capsule contains Atorvastatin Calcium IP eq. to Atorvastatin 40 mg (as coloured pellets) + Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg (as two brown coloured film coated tablets each containing 37.5 mg Clopidogrel tablet IP) + Aspirin IP 75 mg (as enteric coated white-coloured pellets) for M/s. Windlas Biotech Ltd. (manufacturer) and M/s. Torrent Pharmaceuticals Ltd. (marketer) is required to be calculated based on the market data for the month of March 2021. The Committee further noted that data of the formulation is not available in Pharmatrac database for the month of March 2021, however, the data of the formulation started appearing from April 2021. The Committee also noted that the applicant company has claimed retail price of Rs. 18.00 per capsule excluding GST. The Committee deliberated upon the matter in detail and decided to fix the retail price of the subject formulation by calculating as per the formula provided in DPCO 2013 for calculating retail price of new drugs based on April 2021 data as available in Pharmatrac database. Accordingly, the Committee recommended the retail price of each hard gelatin capsule contains Atorvastatin Calcium IP eq. to Atorvastatin 40 mg (as coloured pellets) + Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg (as two brown coloured film coated tablets each containing 37.5 mg Clopidogrel tablet IP) + Aspirin IP 75 mg (as enteric coated white-coloured pellets) for M/s. Windlas Biotech Ltd. (manufacturer) and M/s. Torrent Pharmaceuticals Ltd. (marketer) at Rs. 12.92 per capsule excluding GST.

5. Agenda no. 5 - Retail price fixation under Para 5 of DPCO, 2013- Each hard gelatin capsule contains Atorvastatin Calcium IP eq. to Atorvastatin 40 mg (as white coloured pellets) + Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg (as two reddish brown coloured film coated tablets, each containing 37.5 mg Clopidogrel tablet IP) + Aspirin IP 75 mg (as enteric coated white coloured pellets) for M/s. Windlas Biotech Ltd. (manufacturer) and M/s. USV Pvt. Ltd. (marketer).

5.1 The Committee noted that as per the provisions of DPCO 2013, the retail price of each hard gelatin capsule contains Atorvastatin Calcium IP eq. to Atorvastatin 40 mg (as coloured pellets) + Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg (as two brown coloured film coated tablets each containing 37.5 mg Clopidogrel tablet IP) + Aspirin IP 75 mg (as enteric coated white-coloured pellets) for M/s. Windlas Biotech Ltd. (manufacturer) and M/s. USV Pvt. Ltd (marketer) is required to be calculated based on the market data for the month of March 2021. The Committee further noted that data of the formulation is not available in Pharmatrac database for the month of March 2021, however, the data of the formulation started appearing from April 2021. The Committee also noted that the applicant company has claimed retail price of Rs. 14.88 per capsule excluding GST. The Committee deliberated upon the matter in detail and decided to fix the retail price of the subject formulation by calculating as per the formula provided in DPCO 2013 for calculating retail price of new drugs based on April 2021 data as available in Pharmatrac database. Accordingly, the Committee recommended the retail price of each hard gelatin capsule contains Atorvastatin Calcium IP eq. to Atorvastatin 40 mg (as coloured pellets) + Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg (as two brown coloured film coated tablets each containing 37.5 mg Clopidogrel tablet IP) + Aspirin IP 75 mg (as enteric coated

white-coloured pellets) for M/s. Windlas Biotech Ltd. (manufacturer) and M/s. USV Pvt. Ltd (marketer) at Rs. 12.92 per capsule excluding GST.

6. Agenda no. 6 - Retail price fixation under Para 5 of DPCO, 2013- Human Normal Immunoglobulin for Intravenous use IP 5% solution (ig M enriched) in which each vial contains Total Protein 50g/L + Immunoglobulin M 6g/L + Immunoglobulin A 6g/L + Immunoglobulin G 38g/L + Glucose Monohydrate (as stabilizer) 27.5 g/L + Sodium Chloride 4.56 g/L + Water for injection, Distribution of Ig G subclass is approx. 62% IgG1, 27% IgG2, 1% Ig G3, 10% Ig G4 for M/s Intas Pharmaceuticals Ltd. (manufacturer and marketer).

6.1 The Committee noted the application submitted by M/s Intas Pharmaceuticals Ltd for retail price fixation of Human Normal Immunoglobulin for Intravenous use IP 5% solution (ig M enriched) in which each vial contains Total Protein 50g/L + Immunoglobulin M 6g/L + Immunoglobulin A 6g/L + Immunoglobulin G 38g/L + Glucose Monohydrate (as stabilizer) 27.5 g/L + Sodium Chloride 4.56 g/L + Water for injection, Distribution of Ig G subclass is approx. 62% IgG1, 27% IgG2, 1% Ig G3, 10% Ig. The Committee also noted Human Normal Immunoglobulin 5% solution for infusion is a scheduled formulation and its ceiling price is notified. The Committee deliberated upon the matter in detail and decided to close the retail price application of M/s Intas Pharmaceuticals Ltd since it is a scheduled formulation and directed the company to follow the ceiling price of Human Normal Immunoglobulin 5% solution for infusion.

7. Agenda no. 7 - Retail price fixation under Para 5 of DPCO, 2013- Each ml solution containing Cyclosporine IP 0.9 mg for M/s Sun Pharmaceutical Industries Ltd. (manufacturer and marketer).

7.1 The Committee noted the representation made by M/s Sun Pharmaceutical Industries Ltd. The Committee further noted that the new drug for which application for retail price has been filed by M/s Sun Pharmaceutical Industries Ltd is a single use pack, whereas, the while recommended the price earlier in its 36th meeting dated 11.10.2021, the data of both single use and multiuse product was considered. The Committee deliberated upon the matter in detail and is of the view that single use vials are used one time and does not contain preservative. The Committee deliberated upon the matter in detail and decided to calculate the retail by considering the data of only single use pack. Accordingly, the Committee recommended the retail price of each ml solution containing Cyclosporine IP 0.9 mg per ml in 0.25 ml pack for M/s Sun Pharmaceutical Industries Ltd. (manufacturer and marketer) at Rs. 51.29 per 0.25 ml pack excluding GST as detailed below:

a. Calculation of retail Price of Cyclosporine IP 0.05% w/v drops based on Pharmatrac data for the month of February 2021 (by considering only single use pack) = Rs. 131.52 per ml

b. Derived Retail price for Cyclosporine IP 0.9 mg/ ml based on the recommendation of Pronab Sen Committee Report with respect to calculated retail price of Cyclosporine IP 0.05% w/v drops

$$P(s) = P^* \cdot [1 + a \cdot \{(s - s^*) / s^*\}]$$

Where : P(s) = Price ceiling of the strength s

P* = price ceiling for reference strength s*

s = strength in terms of API content

s* = reference strength

$$= 131.52[1+0.70\{0.9-0.5\}/0.5] = \text{Rs. } 205.17 \text{ per ml}$$

c. Therefore, the retail price of Cyclosporine solution 0.9 mg/ml in 0.25 ml pack = Rs. 205.17 x 0.25 = Rs. 51.29 (excluding GST)

8. Agenda no. 8 - Application by M/s Denis Chem Lab Ltd. for separate price under Para 11(3) of DPCO 2013 with respect to (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack

8.1 The Committee deliberated upon the matter in detail and noted M/s Denis Chem Lab Ltd. for separate price under Para 11(3) of DPCO 2013 with respect to (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack in line with S.O. 3939(E) dated 23.09.2021, S.O. 3938(E) dated 23.09.2021 and SO. 3937(E) dated 23.09.2021 respectively. M/s Denis Chem Lab Ltd made demonstration before the members. The Committee also noted the copy of the license submitted by Denis Chem Lab Ltd. The Committee observed that (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack of M/s Denis Chem Lab Ltd have 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. Accordingly, the Committee recommended to extend the ceiling prices and the formulations mentioned in S.O. 3939(E) dated 23.09.2021, S.O. 3938(E) dated 23.09.2021 and SO. 3937(E) dated 23.09.2021 to M/s Denis Chem Lab Ltd for (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack.

9. Agenda no. 9 - Application by M/s Rosuma Laboratories Pvt. Ltd. for separate price under Para 11(3) of DPCO 2013 with respect to (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack

9.1 The Committee deliberated upon the matter in detail and noted M/s Rosuma Laboratories Pvt. Ltd for separate price under Para 11(3) of DPCO 2013 with respect to (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack in line with S.O. 3939(E) dated 23.09.2021, S.O. 3938(E) dated 23.09.2021 and SO. 3937(E) dated 23.09.2021 respectively. M/s Rosuma Laboratories Pvt. Ltd made demonstration before the members. The Committee also noted the copy of the license submitted by M/s Rosuma Laboratories Pvt. Ltd. The Committee observed that (i) Dextrose Injection 25%w/v in Non-glass pack having

Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack of M/s Rosuma Laboratories Pvt. Ltd have 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. Accordingly, the Committee recommended to extend the ceiling prices and the formulations mentioned in S.O. 3939(E) dated 23.09.2021, S.O. 3938(E) dated 23.09.2021 and SO. 3937(E) dated 23.09.2021 to M/s Rosuma Laboratories Pvt. Ltd for (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack.

10. Agenda no. 10 - Application filed by M/s Abbott Healthcare Pvt. Ltd for differential pricing for a innovatively developed closed filled system to administer Sevoflurane under Para 11(3) of DPCO 2013

10.1 The Agenda item was deferred.

The meeting ended with a vote of thanks to all.



29/11/21

(S. S. Ojha)
Jt. Director (Pricing)

Copy to:
All members of the Committee.

