

Subject: Minutes of the 38th meeting of the Multidisciplinary Committee of Experts held on 24.01.2022 at 3:30 PM.

38th meeting of the "Multidisciplinary Committee of Experts" was held on 24.01.2022 at 3.30 P.M. under the convenorship of Dr. Vinod Kotwal, Member Secretary, through video-conferencing. The following members attended the meeting through video conferencing:-

1. Prof. Y. K. Gupta, Principal Scientific Advisor (projects), THSTI-DBT, GoI & 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
4. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission
5. Dr. J. J. Cherian, Scientist-D, ICMR

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

1. Sh. Prasenjit Das, Deputy Director (Pricing), NPPA

1. Agenda No. 1 - Retail price fixation under Para 5 of DPCO, 2013-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%lg G3, 10% Ig G4 for M/s Intas Pharmaceuticals Ltd. (manufacturer and marketer).

1.1 The Committee noted the representation dated 10th December 2021 of M/s Intas Pharmaceuticals Ltd wherein they have made a submission that formulation for which retail price is sought is different from Normal Human Immunoglobulin Infusion 5%. It was noted by the committee that company has given some references in their representation but has not submitted any published clinical studies showing significant therapeutic advantage/ clinical efficacy of the formulation. The Committee deliberated upon the matter in detail and decided that M/s Intas Pharmaceuticals be directed to submit the following:

- Published clinical studies demonstrating the significant therapeutic effect/ clinical efficacy of the formulation over Normal Human Immunoglobulin 5%
- Safety concerns, if any on increasing the levels of IgA & IgM

The Committee further decided that M/s Intas Pharmaceuticals Ltd be directed to make presentation on their application before the Committee in the next meeting.

1.2 The Committee also observed that launch of the same formulation by M/s Paviour Pharmaceutical Pvt. Ltd and requested that necessary action may be initiated as per the provisions of DPCO 2013.

2. Agenda No. 2 - Retail price fixation under Para 5 of DPCO, 2013- Each hard gelatin capsule contains Tacrolimus IP 3 mg for M/s Cadila Healthcare Ltd. (manufacturer and marketer).

2.1 The Committee noted the application for retail price fixation of Tacrolimus 3mg prolonged release capsule. The Committee deliberated upon the matter in detail and decided that M/s Cadila Healthcare Ltd. be directed to provide published clinical trial data in indexed journal showing the significant therapeutic advantage/ clinical efficacy of Tacrolimus prolonged release capsule over conventional Tacrolimus capsules.

3. Agenda No. 3 Fixation of Ceiling Price of Clotrimazole 1% mouth paint under DPCO 2013 (NLEM 2015).

3.1 The Committee examined the representation of M/s Zydus healthcare Ltd and noted Clotrimazole 1% drops, Clotrimazole 1% cream and Clotrimazole 100 mg pessery are scheduled formulations and ceiling price has been given for Clotrimazole 1% lotion also. Explanation I of DPCO Schedule-I of DPCO 2013 provides for inclusion in DPCO in respect of formulations which have no significant difference in terms of Pharmacokinetics (PK) or Pharmacodynamics (PD). With regard to the point made in the representation that PK or PD or efficacy profile of any mouth paint including Clotrimazole 1% mouth paint is significantly different from that of a cream including Clotrimazole 1% cream or for that matter a drop including Clotrimazole 1% drop, the company may be requested to provide published literature on significant difference in PK or PD of Clotrimazole 1% mouth paint viz a viz other formulations that leads to different outcomes.

3.2 The Committee further noted that Clotrimazole is a very old drug and the formulation Clotrimazole 1% mouth paint is in the market for a long time. Accordingly, the Committee desired that clarification of approval of license status may be obtained from the manufacturer(s)/ marketer(s) of Clotrimazole 1% mouth paint for further deliberation in the matter.

4. Agenda no. 4 - Retail price fixation under Para 5 of DPCO, 2013- Each film coated tablet containing Calcium Carbonate IP 1250 mg eq. to Elemental Calcium 500 mg + Vitamin D3 IP 2000 IU + Methylcobalamin IP 1500 mcg + L-Methyltetrahydrofolate Calcium 1 mg + Pyridoxal-5-Phosphate 20 mg for M/s Akums Drugs & Pharmaceuticals Ltd. (manufacturer) and M/s Mankind Pharma Ltd. (marketer)

4.1 The Committee noted that the retail price of the subject formulation has been given to various companies and the companies have submitted their Form-V data to NPPA. The Committee deliberated upon the matter in detail and decided to recommended the retail price of each film coated tablet containing Calcium Carbonate IP 1250 mg eq. to Elemental Calcium 500 mg + Vitamin D3 IP 2000 IU + Methylcobalamin IP 1500 mcg + L-Methyltetrahydrofolate Calcium 1 mg + Pyridoxal-5-Phosphate 20 mg for M/s Akums Drugs & Pharmaceuticals Ltd. (manufacturer) and M/s Mankind Pharma Ltd. (marketer) based on Form-V data.

4.2 Accordingly, the Committee recommended the retail price of each film coated tablet containing Calcium Carbonate IP 1250 mg eq. to Elemental Calcium 500 mg + Vitamin D3 IP 2000 IU + Methylcobalamin IP 1500 mcg + L-Methyltetrahydrofolate Calcium 1 mg + Pyridoxal-5-Phosphate 20 mg for M/s Akums Drugs & Pharmaceuticals Ltd. (manufacturer) and M/s Mankind Pharma Ltd. (marketer) at Rs. 15.55 per tablet excluding GST as detailed below:

S. No.	Company	Unit	PTR	PTR per tablet
1.	Torrent Pharmaceuticals Ltd. (As per Form-V data)	15 tablets	245.11	16.34
2.	Cadila Pharmaceuticals Ltd. (As per Form-V data)	15 tablets	211.07	14.07
3.	Cipla Ltd. (As per Form-V data)	15 tablets	213.32	14.22
4.	Intas Pharmaceuticals Ltd. (As per Form-V data)	10 tablets	144.14	14.41
5.	Unison Pharmaceuticals Ltd. (As per Form-V data)	1 tablet	8.00	8.00
6.	Average PTR (Av of sl. No. 1 to 5)			13.41
7.	Add: Retailer margin @16% (16% of sl. No. 6)			2.14
8.	Calculated Retail Price based on submitted Form-V by the companies (excluding GST) (sl. No. 7+ sl. No. 8)			15.55 (Retail price per tablet ex. GST)
9.	Retail price claimed			Rs.22.00 per tablet excluding GST
10.	Recommended retail price			Rs.15.55 per tablet excluding GST

5. Agenda no. 5 - Retail price fixation under Para 5 of DPCO, 2013- Each 37.5 sq.cm transdermal patch containing Diclofenac Diethylamine IP 100 mg for M/s Azista Industries Pvt. Ltd. (manufacturer) and M/s Hetero Healthcare Ltd. (marketer)

5.1 The Committee noted the retail price fixation of 37.5 sq.cm transdermal patch containing Diclofenac Diethylamine IP 100 mg and observed that the data of the patch having Diclofenac IP 100 mg (without mentioning the patch size) is available in Pharmatrac database and the proposed retail price based on the data for the month for the May 2021 came to Rs. 39.65 per patch excluding GST. The Committee further noted that M/s Hetero Healthcare Ltd has sought retail price of Rs. 31.25 per patch excluding GST.

5.2 The Committee deliberated upon the matter in detail and is of the opinion that the drug strength (i.e. Diclofenac 100mg) in the patch is to be considered for fixation of retail price. The size of the patch is not relevant as the therapeutic efficacy depends on the dosage strength of the drug. Accordingly, the Committee considered the retail price of Rs. 39.65 per patch excluding GST as worked out price and recommended the retail price of each 37.5 sq.cm transdermal patch containing Diclofenac Diethylamine IP 100

mg for M/s Azista Industries Pvt. Ltd. (manufacturer) and M/s Hetero Healthcare Ltd. (marketer) at Rs. 31.25 per patch excluding GST being lower than the worked out price.

**6. Agenda no. 6 - Retail price fixation under Para 5 of DPCO, 2013- Composition:-
Spray contains Diclofenac Diethymine IP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w) + Methyl Salicylate IP 10.00% w/w + Menthol IP 5.0 % w/w for M/s Pontika Aerotech Ltd. (manufacturer) and M/s. Intas Pharmaceuticals Ltd. (marketer)**

6.1 The Committee noted that the retail price of the subject formulation has been given to various companies and the companies have submitted the Form-V data to NPPA. The Committee deliberated upon the matter in detail and decided to recommended the retail price of Spray containing Diclofenac Diethymine IP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w) + Methyl Salicylate IP 10.00% w/w + Menthol IP 5.0 % w/w for M/s Pontika Aerotech Ltd.(manufacturer) and M/s. Intas Pharmaceuticals Ltd. (marketer) based on Form-V data. Accordingly, the Committee recommended the retail price of spray containing Diclofenac Diethymine IP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w) + Methyl Salicylate IP 10.00% w/w + Menthol IP 5.0 % w/w for M/s Pontika Aerotech Ltd. (manufacturer) and M/s. Intas Pharmaceuticals Ltd. (marketer) at Rs. 2.93 per gm excluding GST as detailed below:

S. No.	Company	Unit	PTR	PTR per gm
1.	M/s Sun Pharmaceutical Industries Ltd. (as per Form-V data)	55 gm	139.29	Rs. 2.53
2.	Add: Retailer margin @16% (16% of sl. No. 1)			Rs. 0.40
3.	Proposed Retail Price based on submitted Form-V by the companies (excluding GST) (sl. No. 1+ sl. No. 2)			Rs. 2.93 (Retail price per gm ex. GST)
4.	Retail price claimed			Rs. 6.36 per gm excluding GST
5.	Recommended retail price			Rs. 2.93 per gm excluding GST

The meeting ended with a vote of thanks to all.



(Prasenjit Das)

Deputy Director (Pricing)

Copy to:

All members of the Committee.

