

National Pharmaceutical Pricing Authority

Subject: Minutes of the 19th meeting of Multidisciplinary Committee of Experts held on 17.06.2020 at 12:00 noon in NPPA

19th meeting of the “Multidisciplinary Committee of Experts” was held on 17.06.2020 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. Dr. Vijay Kumar, Scientist-G and Head (BMS), ICMR, New Delhi
3. Shri A. K. Pradhan, Dy. Drugs Controller, CDSCO
4. Dr. Pooja Gupta, Assoc. Prof., Pharmacology, AIIMS, New Delhi

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

1. Sh. S. S. Ojha, Jt. Director (Pricing), NPPA
2. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA
3. Sh. Prakash Hemani, Assistant Director (Pricing), NPPA

1. Agenda No. 1 - Retail price fixation of each film coated tablet containing Capecitabine IP 700 mg and Cyclophosphamide IP 32.1 mg eq. to Anhydrous Cyclophosphamide 30 mg under Para 5 of DPCO, 2013 for M/s Intas Pharmaceuticals Ltd (manufacturer and marketer).

1.1 The Committee deliberated upon the matter in detail and noted that in the subject Fixed Dose Combination (FDC), the strength of cyclophosphamide is lower and the strength of Capecitabine is higher as compared to the strength of their respective single drug formulations mentioned in the National List of Essential Medicines 2015 (NLEM 2015). The Committee observed that the FDC needs to be assessed from the pharmacoeconomics point of view. Accordingly, the Committee directed that the applicant company may be requested to furnish evidence based data regarding the scientific rationality, therapeutic justification and cost effectiveness for the change in the strength of these drugs in the FDC as compared to their respective single drug formulations mentioned in NLEM 2015.

2. Agenda No. 2 - Retail price fixation of each film coated tablet containing Capecitabine IP 400 mg and Cyclophosphamide IP 21.4 mg eq. to Anhydrous Cyclophosphamide 20 mg under Para 5 of DPCO, 2013 for M/s Intas Pharmaceuticals Ltd (manufacturer and marketer).

2.1 The Committee deliberated upon the matter in detail and noted that in the subject Fixed Dose Combination (FDC), the strength of Cyclophosphamide and Capecitabine are lower as compared to the strength of the respective single drug formulations mentioned in the National List of Essential Medicines 2015 (NLEM 2015). The Committee observed that the FDC needs to be assessed from the pharmacoeconomics point of view. Accordingly, the Committee directed that the applicant company may be requested to furnish evidence based data regarding the scientific rationality, therapeutic justification and cost effectiveness for reducing the strength of the active ingredients in

the FDC as compared to their single drug formulations mentioned in NLEM 2015. The Committee further directed to obtain scientific justification for the changing the ratio of the strength in the FDC as compared with the FDC mentioned in para 1.1 above.

3. Agenda no. 3 Retail price fixation of each soft gelatin capsule containing Methylcobalamin IP 1500 mcg , Alpha Lipoic Acid USP 100 mg , Pyridoxine Hydrochloride IP 3 mg and Folic Acid IP 1.5 mg under Para 5 of DPCO, 2013 for M/s Mylan Pharmaceuticals Pvt. Ltd (marketer) and M/s Akum Drugs & Pharmaceuticals Ltd (manufacturer/ importer).

3.1 The Committee deliberated upon the matter in detail and noted that Methylcobalamin is the main ingredient in the Fixed Dose Combination (FDC). The Committee also observed that therapeutic rationale for the strength of other components in the FDC needs to be examined from the pharmacoeconomics point of view. Accordingly, the Committee directed that the company may be requested to furnish evidence for the therapeutic rationale of other components and justification for strength added in the FDC.

4. Agenda no. 4 Application for upward price revision under para 19 of DPCO 2013

Record note of discussion to be circulated separately to the members.

Sd/-
(P. Das)
Asst. Director (Pricing)

Copy to:
All members of the Committee.