

National Pharmaceutical Pricing Authority

Subject: Minutes of the 15th meeting of Multidisciplinary Committee of Experts held on 08.01.2020 at 10:30 AM in NPPA

15th meeting of the “Multidisciplinary Committee of Experts” was held on 08.01.2020 under the Convenorship of the Sh. Kalyan Nag, Adviser (Cost), in the Conference Room of NPPA. The following members attended the meeting:-

1. Prof. Y. K. Gupta, Principal Scientific Advisor (Projects), THSTI-DBT, Gol & Ex-HoD, Pharmacology & Dean, AIIMS, New Delhi
2. Dr. Vijay Kumar, Scientist-G and Head (BMS), ICMR, New Delhi
3. Dr. K. Bangarurajan, JDC(I), CDSCO

The following members could not attend the meeting:

1. Dr. C.D.Tripathi, Head Department of Pharmacology, VMMC & Safdarjung Hospital.
2. Dr. Jai Prakash, Sr. Principal Scientific Officer, IPC,
3. Dr. Pooja Gupta, Asso. Professor, Deptt of Pharmacology, AIIMS, New Delhi
4. Dr. Ujwal Kolhe, Asstt Professor, NIPER, Rae Bareilly

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

1. Sh. Amarpal Singh Sawhney, Director (Pricing), NPPA
2. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA
3. Sh. Prakash Hemani, Assistant Director (Pricing), NPPA

Agenda No. 1 - Retail price fixation of each uncoated tablet containing Paracetamol IP 500 mg + Caffeine Anhydrous IP 50 mg under Para 5 of DPCO, 2013 for M/s Dabur India Ltd (marketer) and M/s Rivpra Formulations Pvt. Ltd (manufacturer/ importer)

The Committee deliberated upon the matter in details and observed as follows:

- a) NPPA has earlier fixed retail price of Paracetamol IP 650 mg + Caffeine Anhydrous IP 50 mg tablet vide SO. 3984(E) dated 13.08.2018 at Rs. 2.36 per tablet ex. GST.
- b) Present applicable ceiling price of Paracetamol IP 650 mg tablet is Rs. 1.80 per tablet (ex. GST) vide SO. 1485(E) dated 29.03.2019.
- c) Derived price of caffeine IP 50 mg tablet is Rs. 0.56 per tablet [(a)-(b)]
- d) Present applicable ceiling price of Paracetamol IP 500 mg tablet is Rs. 0.89 per tablet (ex. GST) vide SO. 1485(E) dated 29.03.2019.
- d) Derived price of Paracetamol IP 500 mg + Caffeine Anhydrous IP 50 mg tablet is Rs. 1.45 per tablet (ex. GST) [(c)+(d)]
- e) Price claimed by the company Rs. 1.25 per tablet (ex. GST)

Accordingly, the Committee recommended the retail price of each uncoated tablet containing Paracetamol IP 500 mg + Caffeine Anhydrous IP 50 mg under Para 5 of DPCO, 2013 for M/s Dabur India Ltd (marketer) and M/s Rivpra Formulations Pvt. Ltd (manufacturer/ importer) at Rs. 1.25 per tablet excluding GST.

Agenda No. 2 Retail price fixation under Para 5 of DPCO, 2013 - Rabies Human Monoclonal Antibody (rDNA) Inj. 1.25ml injection for M/s Serum Institute of India Private Limited (Manufacturer and Marketer)

The Committee deliberated upon the matter in details and observed as follows:

- a) M/s Serum Institute of India applied for retail price fixation of Rabies Human Monoclonal Antibody (rDNA) Inj. 1.25ml injection (40IU/ml) vide its letter dated August 2019 and claimed retail price of Rs. 4835.00 per 1.25 ml pack.
 - b) The data of the subject formulation is not available in AIOCD-Pharmatrac and therefore, M/s Serum Institute of India was requested to provide the data of Rabies Human Monoclonal Antibody (rDNA) Inj. 2.5ml injection (40IU/ml) for the month of January 2019.
 - c) The company provided the Price To Retailer (PTR) and Moving Annual Turnover (MAT) of Rabies Human Monoclonal Antibody (rDNA) Inj. 2.5ml injection (40IU/ml) at Rs. 1476.98 and Rs. 13,46,96,000.00 respectively.
 - d) The data provided by the company was used in the calculation.
 - e) PTR of 2.5 ml Rabies Human Monoclonal Antibody (rDNA) Injection is Rs. 1476.98
 - f) Therefore, PTR of 1 ml Rabies Human Monoclonal Antibody (rDNA) Injection is Rs. 590.79 [(e)/2.5]
 - g) Retailer margin @ 16% of (f) is Rs. 94.53
 - h) Derived retail price of 1 ml Rabies Human Monoclonal Antibody (rDNA) Injection is Rs. 685.32 [(f)+(g)]
 - i) Derived retail price of 1.25 ml Rabies Human Monoclonal Antibody (rDNA) Injection is Rs. 856.65 [((h)X1.25]
 - j) Price claimed by the company is Rs. 4835.00 (per 1.25 ml pack)
- Accordingly, the Committee recommended the retail price of Rabies Human Monoclonal Antibody (rDNA) Inj. 1.25ml injection (40IU/ml) for M/s Serum Institute of India Private Limited (Manufacturer and Marketer) at Rs. 856.65 per pack of 1.25ml (excluding GST).

Agenda no. 3 Retail price fixation of each film coated bilayered tablet containing Evogliptin Tartrate eq. to Evogliptin 5mg + Metformin Hydrochloride IP 1000mg (As sustained release) (Valera-M 1000 Tablet) under Para 5 of DPCO, 2013 - for M/s Alkem Laboratories Limited (marketer and Manufacturer).

The Committee deliberated upon the matter in details and observed as follows:

- a. The retail price of Evogliptin 5 mg tablet as per para 4 of DPCO 2013 based on Pharmatrac data (May 2019) is Rs. 15.58 per tablet (ex. GST).
- b. Present applicable ceiling price of Metformin HCL (Controlled release) 1000mg is Rs. 3.57 per tablet (ex. GST) vide SO. 1485(E) dated 29.03.2019.
- c. Derived retail price of each film coated bilayered tablet containing Evogliptin Tartrate eq. to Evogliptin 5mg + Metformin Hydrochloride IP 1000mg (As sustained release) is Rs. 19.15 per tablet (ex. GST) [(a)+(b)].
- d. 20% of the lowest of (a) and (b) based on formula recommended in the Pronab Sen Committee report is Rs. 0.71
- e. Derived net retail price of each film coated bilayered tablet containing Evogliptin Tartrate eq. to Evogliptin 5mg + Metformin Hydrochloride IP 1000mg (As sustained release) is Rs. 18.44 per tablet (ex. GST) [(c) -(d)].
- f. Company claimed price is Rs. 20.24 per tablet

Accordingly, the Committee recommended the retail price of each film coated bilayered tablet containing Evogliptin Tartrate eq. to Evogliptin 5mg + Metformin Hydrochloride IP 1000mg (As sustained release) (Valera-M 1000 Tablet) under Para 5 of DPCO, 2013 - for M/s Alkem Laboratories Limited (marketer and Manufacturer) at Rs. 18.44 per tablet excluding GST.

Agenda no. 4 Retail price fixation of each hard gelatin capsule containing Amoxicillin Trihydrate IP eq. to Amoxicillin 250mg + Cloxacillin Sodium IP eq. to Cloxacillin 250mg + Lactic Acid Bacillus 2 billion spores under Para 5 of DPCO, 2013 for M/s Skymap Pharmaceuticals Private Limited (marketer and Manufacturer).

The Committee deliberated upon the matter in details and observed as follows:

- a) Present applicable ceiling price of Amoxycillin 250mg capsule is Rs. 2.16 per capsule (ex. GST) vide SO. 1485(E) dated 29.03.2019.
- b) Present applicable ceiling price of Cloxacillin 250mg Capsule is Rs. 1.11 per capsule (ex. GST) vide SO. 1485(E) dated 29.03.2019.
- c) Price of Lactic Acid Bacillus 2 Billion Spores is Rs. 0.34 (based on SO. 2458(E) of 24.09.2009 of DPCO 1995 in which Lactic Acid Bacillus is Rs. 0.017/- per 10 million spores for 10 capsules)
- d) Worked out retail price is Rs. 3.61 per capsule [(a)+(b)+(c)]
- e) 20% of the lowest of (a), (b) and (c) based on formula recommended in the Pronab Sen Committee report is Rs. 0.07.
- f) Derived net retail price of each hard gelatin capsule containing Amoxicillin Trihydrate IP eq. to Amoxicillin 250mg + Cloxacillin Sodium IP eq. to Cloxacillin 250mg + Lactic Acid Bacillus 2 billion spores under Para 5 of DPCO, 2013 for M/s Skymap Pharmaceuticals Private Limited is Rs. 3.54 per capsule (ex. GST) [(d) -(e)].
- g) Company claimed price is Rs. 12.00 per capsule
- Accordingly, the Committee recommended the retail price of each hard gelatin capsule containing Amoxicillin Trihydrate IP eq. to Amoxicillin 250mg + Cloxacillin Sodium IP eq. to Cloxacillin 250mg + Lactic Acid Bacillus 2 billion spores under Para 5 of DPCO, 2013 for M/s Skymap Pharmaceuticals Private Limited (marketer and Manufacturer) at Rs. 3.54 per capsule excluding GST.

Agenda no. 5 Representation of M/s Biological E. Ltd. for separate pricing of vaccines having new drug delivery system- Pre filled Syringe (PFS) packs.

The Committee deliberated the matter in details and observed that M/s Biological E. Ltd had applied for higher price for Pre-filled syringes (PFS) and claimed additional price of Rs. 115.00 per PFS for its formulation (I) Liquid Pentavalent vaccine (DPT-Hep B-Hib) and (ii) Inactivated Japanese Encephalitis. The committee noted that the company in further submission has not brought any new fact on the clinical outcome of using PFS to support their claim for additional price for their scheduled formulations (vaccines) formulation in PFS. Accordingly, the Committee recommended its earlier recommendation taken on the subject in its 10th meeting dated 21.05.2019 and recommended that the prefilled syringe is a minor modification which will ease the drugs administration and have no significant clinical advantage and recommended that no separate price be given for PFS.

Agenda no. 6 Sub: Review application against ceiling price fixation of Ringer lactate Injection fixed vide S.O. 2401(E) dated 28.07.2017 filed by

- (i) M/s Albert David Ltd
- (ii) M/s Aculife healthcare Pvt. Ltd
- (iii) M/s B. Braun Medical (india) Pvt. Ltd
- (iv) M/s Fresenius Kabi India Pvt. Ltd
- (v) M/s Ostuka Pharmaceuticals India Pvt. Ltd.

The Committee deliberated the matter in details and is of the view that further examination is required and decided to invite the following officials/ associations in the next meeting

- a. Dr. Pravin Agarwal, AIIMS
- b. A nephrologist from Safdarjung Hospital
- c. A nephrologist from RMI Hospital
- d. Vice Chancellor, University of Rohtak
- e. Dr. Bhiu or Dr. Sanjay Agarwal, Nephrologist, AIIMS
- f. Representative from Critical care Association

Agenda no. 7 Overcharging cases in respect of the formulation (1) “Cloxacillin based formulations Klox Injection 500mg, (2) Baxin Inj 1gm (1000 mg), (3) Baxin Inj 500mg, (4) Baxin Inj 250mg, (5) Baxin Kid Tab”reg.

The Committee perused the paper in details and noted as follows:

A. The matter is essentially administrative in nature and does not have any issues for technical consideration.

B. On quick perusal of the documents, the consideration of the Committee is summarised below (subject to critical evaluation of administrative nature).

i. The overcharging (OC) notice was issued on the premise that the single vial of the medication was sold at higher price than ceiling price approved by NPPA.

ii. The manufacturer M/s Lyka Labs Ltd responded to this OC notice stating that the price list given (which was the basis of Overcharging by NPPA) was in fact for double ampoule pack containing one vial for medicine and the other is ampoule for water for injection.

iii. In support of the submission, the company also provided the photocopy of the carton (copy available in the file).

iv. The company also provided the copy of the manufacturing license issued by State Drug Controller (copy available in the file)

v. NPPA office, however, did not agree/ pay attention to this submission and continued to ask for the Overcharge amount. This, inter alia, implies that NPPA did not agree to the submission made by the company.

vi. However, company continued to make the same submission, while, NPPA did not accepted their contention and continued with OC case.

vii. Personal hearing was also granted to the Company. Based on the Company's oral as well as written submissions made, the divisions has evaluated the submissions in detail and proposed to not proceed further in case of Baxin based formulations. However, competent authority decided that the case may be referred to committee of experts. The Committee of experts has deliberated on the matter in its 9th meeting held on 15.04.2019 and directed to refer the matter to SDC, Gujarat to verify the documentary evidence from the records of the company and submit a report directly to NPPA.

viii. NPPA vide its letter dated 06.05.2019 referred the matter to SDC, Gujarat to certify the following: (copy available in the file)

(a) to certify that the formulations at S.no. 1 to 4 were actually manufactured and sold in twin packs in the year 1997 and onwards as is being claimed by the company.

(b) to certify that the formulations at S.no. 5 was actually manufactured and sold in aluminium strip pack and not in blister pack in the year 1997 and onwards as is being claimed by the company.

ix. SDC, Gujarat has submitted a copy of inspection report dated 02/07/2019. On physical verification of records of the company, SDC, Gujarat has observed that formulations from S.no. 1 to 4 were mfg at this site while S.no. 5 was not mfg at this site. So, SDC have done verification of subjected products of S.no. 1 to 4 and submitted the same. The Inspection report of SDC, Gujarat includes the following:

Klox Inj 500mg - It is observed on physical verification that Klox Inj 500mg was manufactured in **twin pack**, with sterile water for injection.

Baxin Inj 250mg -It is observed on physical verification that Baxin Inj 250mg was manufactured in **twin pack**, with sterile water for injection

Baxin Inj 500mg -It is observed on physical verification that Baxin Inj 500mg was manufactured in **twin pack**, with sterile water for injection

Baxin Inj 1gm (1000mg) -It is observed on physical verification that Baxin Inj 1gm was manufactured in **twin pack**, with sterile water for injection

The SDC, Gujarat, in its report, has also submitted their final conclusion as follows:

Product From S.no. 1 to 4 were mfg as twin packs from 1997 onwards. Product Baxin cap 500mg was not mfg at that company's site . So, SDC can't give any comment related to this product.

ix. It is further noticed that in his report submitted by SDC, i.r.o medicine at S.no. 5, they had wrongly reported upon 'Baxin Cap 500mg' instead of report asked for the formulation 'Baxin

Kids Tab'. NPPA has already requested SDC, Gujarat to submit the inspection report in respect of correct formulation 'Baxin Kids Tab'.

x. The Committee has not gone to the details to the process of verification

C. On the basis of the above facts, the Committee came to the following conclusion:

On the face of it on the basis of above information / evidence i.e (1) the photocopy of the cartoon (2) Manufacturing license (3) the SDC report, it appears that NPPA might have done an oversight in reporting overcharging case based on single ampoule which actually could have been twin pack. Therefore, in case the evidence provided by the company (which has been vetted by SDC) is accepted by NPPA, the case of OC may not be considered sustainable.

Agenda no. 8 Review against ceiling price fixation of Paclitaxel Injection made by M/s Fresenius Kabi India Pvt. Ltd – regarding nano based formulation

The Committee deliberated upon the matter in details and observed that the matter was referred by Department of Pharmaceuticals to DCGI. Accordingly, the Committee is of the opinion that the matter would be deliberated after receipt of reply from DCGI.

Agenda no. 9 Representations of M/s Emcure Pharmaceuticals Ltd regarding retail price fixation of Darunavir 800 mg + Ritonavir 100 mg tablet.

The agenda was deferred due to paucity of time.

Agenda no. 10 Retail price fixation under Para 5 of DPCO, 2013 - KOLQ Plus Suspension for M/s Blue Cross Laboratories Private Limited (marketer) and M/s Akums Drugs & Pharmaceuticals Limited (Manufacturer).

The agenda was deferred due to paucity of time.

Agenda no. 11 Price Fixation of Human Normal Immunoglobulin 10% solution

The Committee deliberated the issue in details and observed that M/s Paviour Phamaceuticals Pvt. Ltd could not furnish data for the required month and recommended rejection of the representation of the company being devoid of merit.

Agenda no. 12 Fixation of ceiling price of scheduled formulation

The Committee deliberated the matter in details and of the view that more due-diligence is required towards obtaining data for fixation of the ceiling price of the remaining scheduled formulations. Dr. Y. K. Gupta, further stated that he would utilize the service of Standing National Committee on Medicine (SNCM) for obtaining the requisite data for fixation of ceiling price of the remaining scheduled formulations in a weeks time.

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

Sd/-
(Prasenjit Das)
Asstt. Director (Pricing)

Copy to:
All members of the Committee.