

F. No. 12(7)/2017/DP/NPPA/Div.II / Vol-IV
National Pharmaceutical Pricing Authority

Subject: Minutes of the 30th meeting of Multidisciplinary Committee of Experts held on 19.04.2021 at 12:00 noon in NPPA

30th meeting of the "Multidisciplinary Committee of Experts" was held on 19.04.2021 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. Dr. Rakesh K. Singh, Assoc. Professor, NIPER, Raebareli
3. Shri A. K. Pradhan, Dy. Drugs Controller, CDSCO
4. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission
5. Dr. J.J. Cherian, Scientist D, IMCR, 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, Deputy Director (Pricing), NPPA

1. Agenda No. 1 - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated extended release tablet containing Budesonide IP 9 mg for M/s Sun Pharmaceutical Industries Ltd. (manufacturer) and M/s Sun Pharma Laboratories Ltd. (marketer)

1.1 The Committee noted the reply received from the Office of the Central Drugs Standard Control Organisation (CDSCO). The Committee further noted that the data of Budesonide 3 mg capsule was available. Accordingly, the derived price of Budesonide 9 mg capsule was attempted based on the data of Budesonide 3 mg capsule and applying the recommendation of Pronab Sen Committee and it came to Rs. 41.34 per capsule excluding GST, as detailed below:

Derived 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 injectibles.

Price of Budesonide 3 mg capsule as per Para 4 of DPCO 2013 based on the data for the month of July 2020 = Rs. 15.90 per capsule excluding GST

Therefore, derived price of Budesonide 9 mg capsule Rs. 15.90 $[1 + 0.8 \cdot \{(9 - 3) / 3\}] =$ Rs. 41.34 per capsule excluding GST.

1.2 The Committee further decided that since the price of capsule is comparatively costlier than tablet, Rs.0.10 be deducted from the derived price of Budesonide 9 mg capsule i.e. Rs. 41.34 per capsule excluding GST so as to arrive

at the derive price of Budesonide 9 mg tablet. Accordingly, the derived price of Budesonide 9 mg tablet came to Rs. 41.24 per tablet excluding GST. The Committee also noted that M/s Sun Pharma Laboratories Ltd had claimed the retail price of Budesonide Extended Release tablet at Rs. 40.17 per tablet excluding GST.

1.3 The Committee deliberated upon the matter in detail and recommended the retail price of Budesonide IP 9 mg for M/s Sun Pharmaceutical Industries Ltd. (manufacturer) and M/s Sun Pharma Laboratories Ltd. (marketer) at Rs. 40.17 per tablet excluding GST as detailed below:

Sl.no	Particulars	Source/ Method	Price
1	Derived price of Budesonide 9 mg tablet	As mentioned in Para 1.2 above	Rs. 41.24 per tablet excluding GST
2	Price claimed by the applicant company		Rs. 40.17 per tablet excluding GST
3	Recommended price		Rs. 40.17 per tablet excluding GST

2. Agenda No. 2 - Application for extension of ceiling price for I.V. Fluids with packaging in Non-glass with special feature.

2.1 The Committee deliberated upon the matter in detail and noted that two companies namely, M/s Abaris Healthcare Pvt. Ltd and M/s Higgs Healthcare had applied for separate ceiling price for IV fluids with packaging in non-glass with special features in line with S.O. 1332(E) dated 25.03.2021 [M/s Abaris Healthcare Pvt. Ltd applied for product mentioned in Sl. No. 1 to 8 of S.O. 1332(E) dated 25.03.2021 and M/s Higgs Healthcare applied for product mentioned in Sl. No. 1,2,3,4,5,7 and 8 of S.O. 1332(E) dated 25.03.2021] . Both the companies namely, M/s Abaris Healthcare Pvt. Ltd and M/s Higgs Healthcare made demonstration before the members. The Committee observed that the non-glass packages of I.V. fluids of M/s Abaris Healthcare Pvt. Ltd and M/s Higgs Healthcare 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 SO. 1332(E) dated 25.03.2021 to M/s Abaris Healthcare Pvt. Ltd and M/s Higgs Healthcare [for M/s Higgs Healthcare product mentioned in Sl. No. 1,2,3,4,5,7 and 8 of S.O. 1332(E) dated 25.03.2021] for I.V. fluids in packages in non-glass with special features.

2.2 The Committee further noted that the non-glass packages of I.V. fluids having 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 have advantages over the normal IV fluids packages. The Committee further deliberated upon the matter in detail and opined that the packages of IV fluids having special features needs to be mentioned in the labels of the products so that it facilitates/ eases in the intended usage/ administration and also the information gets passed on the consumers. Accordingly, the Committee recommended that an Office

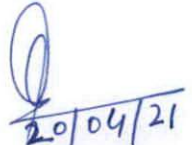
Memorandum be issued directing the manufacturers/ marketers of IV fluids having special features to make suitable modification in the labels by mentioning the details of special features.

3. Agenda No. 3 – Application for extension of ceiling price for Ringer Lactate Injection in packaging with special feature.

3.1 The Committee deliberated upon the matter in detail and noted that two companies namely, M/s Abaris Healthcare Pvt. Ltd and M/s Higgs Healthcare had applied for separate ceiling price for ringer lactate injection in packages with special features in line with S.O. 1333(E) dated 25.03.2021 [M/s Abaris Healthcare Pvt. Ltd applied for product mentioned in Sl. No. 2,3 and 4 of S.O. 1333(E) dated 25.03.2021 and M/s Higgs Healthcare applied for product mentioned in Sl. No. 3 and 4 of S.O. 1333(E) dated 25.03.2021] . Both the companies namely, M/s Abaris Healthcare Pvt. Ltd and M/s Higgs Healthcare made demonstration before the members. The Committee observed that the packages of ringer lactate injection of M/s Abaris Healthcare Pvt. Ltd and M/s Higgs Healthcare 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 SO. 1333(E) dated 25.03.2021 to M/s Abaris Healthcare Pvt. Ltd [for M/s Abaris Healthcare Pvt. Ltd product mentioned in Sl. No. 2,3 and 4 of S.O. 1333(E) dated 25.03.2021] and M/s Higgs Healthcare [for M/s Higgs Healthcare product mentioned in Sl. No. 3 and 4 of S.O. 1333(E) dated 25.03.2021] for ringer lactate injection for packages with special features.

3.2 The Committee further noted that the non-glass packages of ringer lactate having 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 have advantages over the normal ringer lactate injection packages. The Committee further deliberated upon the matter in detail and opined that the packages of ringer lactate having special features needs to be mentioned in the labels of the products so that it facilitates/ eases in the intended usage/ administration and also the information gets passed on the consumers. Accordingly, the Committee recommended that an Office Memorandum be issued directing the manufacturers/ marketers of ringer lactate injection having special features to make suitable modification in the labels by mentioning the details of special features.

The meeting ended with a vote of thanks to all.


20/04/21
(S. S. Ojha)
Director (Pricing)

Copy to:
All members of the Committee.

