F. No. 12(7)/2021/DP/NPPA/Div.II/ Vol-VI

National Pharmaceutical Pricing Authority

Subject: Minutes of the 62nd meeting of the Multidisciplinary Committee of Experts held on 25.09.2024 at 03:30 PM.

62nd meeting of the Multidisciplinary Committee of Experts was held on 25.09.2024 at 03:30 PM under the convenorship of Shri Sanjay Kumar, Adviser (Cost). The following members attended the meeting: -

1. Shri Ranga Chandrashekar, Joint Drugs Controller, CDSCO
2. Dr. Rakesh Kr. Singh, Associate Professor, NIPER Raebareli, through Video Conferencing
3. Prof. Y. K. Gupta, Principal Scientific Adviser (Projects), THSTI-DBT, GoI & Ex-HoD, Pharmacology & Dean (Academics), AIIMS, New Delhi - Co-opted member
4. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia – Co-opted member, through Video Conferencing

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

a. Ms. Rashmi Tahiliani, Director (Pricing)
b. Shri Mahaveer Saini, Deputy Director (Pricing)
c. Ms. Yuvika Panwar, Assistant Director (Pricing)

Agenda Item No. 1: Application by M/s Pulse Pharmaceuticals Private limited for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (iii) for the formulation "Paracetamol Oral solution (taste masked) 125mg/5ml and 250mg/5ml produced utilizing indigenously developed innovative LYOMATRIX Technology offering Novel Drug Delivery System".

1.1 The Committee noted that M/s Pulse Pharmaceuticals Private Limited has submitted application for exemption under Paragraph 32 (iii) for their formulation, "Paracetamol Oral Solution (taste masked) 125mg/5ml and 250mg/5ml," which utilizes the indigenously developed LYOMATRIX Technology, offering a Novel Drug Delivery System.

1.2 The Committee noted the applicant has claimed exemption under Para 32(iii) citing various benefits like unmet medical need, the innovative LYOMATRIX technology, faster absorption indicated by bioequivalence studies, clinical trial demonstrating quicker temperature reduction, and higher acceptability compared to existing products in terms of taste, smell, and mouthfeel. It was also noted that the applicant claimed high efficacy, reduced dosage frequency for pharmacoeconomic advantages and has submitted approval from the DCGI.

1.3 The committee deliberated upon the claim submitted by M/S Pulse Pharmaceuticals Private limited and directed to invite the company to make presentation in the next MDC meeting.

Agenda Item No. 2: Application for grant of separate price/special price for 'Synchrobreathe Inhaler device' under the provision of Para 11(3) of DPCO, 2013 by M/s Cipla Ltd.

2.1 The Committee noted that M/s Cipla Limited has applied for a separate ceiling price for the 'Synchrobreathe Inhaler device' under the provisions of Paragraph 11(3) of the DPCO 2013 in relation to following scheduled formulations: (i) Budesonide 100mcg-200 MDI, (ii) Budesonide 200mcg-200 MDI, and (iii) Formoterol 6mcg + Budesonide 100mcg-120 MDI.

2.2 It was noted that the company mentioned that 'Synchrobreathe inhaler device' is a cutting-edge, novel device developed through incremental innovation to benefit patients. It represents a significant advancement over existing market options, offering an innovative delivery mechanism, ease of use, suitability for various age groups, and enhanced effectiveness. The Committee noted that the applicant has provided a pharmacoeconomic analysis highlighting the benefits of the device, along with a study report and published journal articles supporting their claim.

2.3 The Committee recalled that MDC in it's 14th meeting held 04.12.2019 recommended a separate price under Para 11(3) of DPCO 2013 for "Synchrobreathe inhaler" for the formulations "Formoterol 6mcg + Budesonide 200mcg 120MDI" and "Formoterol 6mcg + Budesonide 400mcg 120MDI of M/S Cipla Ltd. The price was considered @ 20% of the average of then prevailing ceiling price of these two formulations. The price was approved in 71st Authority meeting held on 09.12.2019. It was also recalled that the same separate price was extended to 'Synchrobreathe inhaler device' for Tiotropium 9 mcg/ dose in 23rd MDC held on 20.10.2020 and was approved in 80th Authority meeting held on 26.10.2020. Further, Authority in its 84th meeting held on 10.03.2021 allowed the company to avail WPI on the price of 'Synchrobreathe inhaler device' for the above formulations w.e.f. 1.4.2021. The Committee noted that the applicant has now requested a separate price for the same device i.e., the 'Synchrobreathe inhaler device', for three formulations as mentioned in point 2.1 above.

2.4 The Committee noted that the company has provided a study report and published journal literature in support of the price. The committee deliberated upon the matter and in line with previous practice of granting 20% additional price in case of innovation being supported by published literature, recommended that a separate price may be granted for "Synchrobreathe inhaler" @ 20% of the prevailing ceiling price of (i) Budesonide 100mcg-200 MDI, (ii) Budesonide 200mcg-200 MDI, and (iii) Formoterol 6mcg + Budesonide 100mcg-120 MDI.

Agenda Item No. 3: Application for extension of ceiling price of IV fluids (Double Port) under (JEDUX DOUBLE PORT WITH EURO HEAD, JPORT PLUS) with packaging in non-glass with special feature filed by M/s Jedux Parenteral Private Limited.

3.1 The Committee noted that M/s Jedux Parenteral Private Limited has requested for extension of ceiling price for their IV fluids (Double Port) under the names JEDUX DOUBLE PORT WITH EURO HEAD and JPORT PLUS, with packaging in non-glass with special features for sixteen formulations.

3.2 The committee deliberated upon the matter and directed to invite the applicant for demonstration of special features in the next MDC meeting. The Committee also directed to seek the following documents from the applicant:

(a) Test report of three consecutive batches for plastic granules used as per IP standards
(b) Detailed flow rate analysis of more than one bottle from each batch along with standard deviation, if any, in data in respect of each formulation
(c) Report on residual quantity after administration in respect of the IV fluids applied in respect of each formulation

Agenda Item No. 4: Request for consideration of Price Fixation under Para 11(3) of DPCO-2013 for "Each 100ml contains: Potassium Chloride IP 150mg + Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 900 mg- in 500ml pack" with pack of non-glass container in plastic bottle with Euro head having special features filed by M/s Otsuka Pharmaceutical India Pvt. Ltd.

4.1 The committee noted that the matter was deliberated in 60th MDC held on 26.06.2024 and 61st MDC held on 14.08.2024 wherein, the committee had recommended a price of Rs.45.51 per pack of 500 ml. The committee was informed that the M/S Otsuka Pharmaceutical India Pvt. Ltd. had represented against the recommended price vide email dated 27.08.2024.

4.2 The recommendation of the 61st MDC, representation dated 27.08.2024 along with the examination was discussed before the Authority in its 126th meeting held on 09.09.2024. The Authority noted that the application for the formulation was filed in Form I without any mention of seeking special price under Para 11(3), DPCO, 2013. Hence, the application was treated as normal retail price application by MDC. The Authority deliberated upon the matter in detail and decided that the company may be asked to resubmit the application under Para 11(3).

4.3 Subsequent to the decision of the Authority, the applicant vide letter dated 12.09.2024 requested that it may be granted separate price based on their initial application and letter dated 27.08.2024.

4.4 Accordingly, the matter was placed before the Committee to examine the claim under Para 11 (3) of DPCO, 2013. The committee noted that the company has claimed special features like (a) self- seal ability (b) self collapsibility (c) no air vent requirement and (e) No chances of contamination during manufacture, infusion and admixing level.

4.5 The Committee deliberated up on the matter and decided to invite the applicant in next MDC meeting to demonstrate their product w.r.t. special features claimed. The Committee also directed to seek the following documents from the applicant:

(a) Test report of three consecutive batches for plastic granules used as per IP standards
(b) Detailed flow rate analysis of more than one bottle from each batch along with standard deviation, if any, in data
(c) Report on residual quantity after administration in respect of the IV fluids applied

Agenda Item No. 5: Request for consideration of Price Fixation under Para 11(3) of DPCO-2013 for "Each 100ml contains: Potassium Chloride IP 150mg + Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 450mg- in 500ml pack" with pack of non-glass container in plastic bottle with Euro head having special features filed by M/s Otsuka Pharmaceutical India Pvt. Ltd

5.1 The committee noted that the matter was deliberated in 60th MDC held on 26.06.2024 and 61st MDC held on 14.08.2024 wherein, the committee had recommended a price of Rs. 33.81 per pack of 500 ml. The committee was informed that the M/S Otsuka Pharmaceutical India Pvt. Ltd. had represented against the recommended price vide email dated 27.08.2024.

5.2 The recommendation of the 61st MDC, representation dated 27.08.2024 along with the examination was discussed before the Authority in its 126th meeting held on 09.09.2024. The Authority noted that the application for the formulation was filed in Form I without any mention of seeking special price under Para 11(3), DPCO, 2013. Hence, the application was treated as normal retail price application by MDC. The Authority deliberated upon the matter in detail and decided that the company may be asked to resubmit the application under Para 11(3).

5.3 Subsequent to the decision of the Authority, the applicant vide letter dated 12.09.2024 requested that it may be granted separate price based on their initial application and letter dated 27.08.2024.

5.4 Accordingly, the matter was placed before the Committee to examine the claim under Para 11 (3) of DPCO, 2013. The committee noted that the company has claimed special features like (a) self- seal ability (b) self collapsibility (c) no air vent requirement and (e) No chances of contamination during manufacture, infusion and admixing level.

5.5 The Committee deliberated up on the matter and decided to invite the applicant in next MDC meeting to demonstrate their product w.r.t. special features claimed. The Committee also directed to seek the following documents from the applicant:

(a) Test report of three consecutive batches for plastic granules used as per IP standards
(b) Detailed flow rate analysis of more than one bottle from each batch along with standard deviation, if any, in data
(c) Report on residual quantity after administration in respect of the IV fluids applied

Agenda Item No. 6: Request for consideration of Price fixation for Multiple electrolytes and 5% Dextrose injection Type I USP for pack of non-glass container in plastic bottle with Euro Head and Non-PVC bag having special feature under Para 11(3) of DPCO, 2013 as applied by M/s Otsuka Pharmaceuticals India Pvt. Ltd. (Manufacturer & Marketer).

6.1 The Committee noted that M/s Otsuka Pharmaceuticals India Pvt. Ltd. has submitted a Form I application dated 01.08.2024 for the retail price fixation of a Multiple Electrolytes and 5% Dextrose Injection in non-glass containers in plastic bottles with Euro heads and non-PVC bags. It was also noted that the company has requested for price fixation under Paragraph 11(3) of the DPCO 2013 vide emails dated 5.08.2024, 21.08.2024 and 12.09.2024.

6.2 It was observed that the applicant has claimed special features such as self collapsibility, self seal ability, no air vent requirement and minimized contamination risks during manufacture, infusion and admixing.

6.3 The Committee deliberated up on the matter and decided to invite the applicant to the next MDC meeting to demonstrate their product w.r.t. special features claimed. The Committee also directed to seek the following documents from the applicant:

(a) Test report of three consecutive batches for plastic granules used as per IP standards
(b) Detailed flow rate analysis of more than one bottle from each batch along with standard deviation, if any, in data
(c) Report on residual quantity after administration in respect of the IV fluids applied

The meeting ended with a vote of thanks to all.

27/9/24

(Rashmi Tahiliani)
Director (Pricing)

Copy to:
All members of the Committee.