

Draft Minutes of the 236th(overall) and 104thmeeting of the Authority under DPCO, 2013 held on 23.11.2022 at 11:00 AM

The 236thmeeting of the Authority (overall), which is the 104thmeeting under the DPCO, 2013 was held on 23rdNovember at 11:00AM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The following Authority members of NPPA were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri G. Venkatesh, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
- (iii) Shri Saikat Sarkar, Economic Adviser, Department of Economic Affairs

Shri A. K. Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare also was present and joined through video-conferencing.

1.1 The following officers of NPPA attended the meeting and assisted the Authority in its deliberations:

- (i) Shri Manmohan Sachdeva, Advisor (Cost-I)
- (ii) Shri Sanjay Kumar, Advisor (Cost-II)
- (iii) Ms. Rashmi Tahiliani, Joint Director (Pricing)
- (iv) Shri Mahaveer Saini, Deputy Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 103rdMeeting held on 10.11.2022

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 - (a) Action Taken Report (ATR) on decisions taken by NPPA in its 103rdMeeting held on 23.11.2022

2.1 Noted.

3. Agenda item no. 3 - Status of New Drug applications

3.1 Noted.

4. Agenda item no. 4 – New Drug applications for Price fixation under Para 5 and Para 15 of DPCO, 2013

4.1 The Authority discussed the following case of retail price fixation of new drugs as presented in Agenda no. 4 (i) (total 1 Form I applications containing retail price fixation of 1 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 1(One) new drug under Para 5 and 15 of the DPCO 2013, as detailed below:

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Amoxicillin and Potassium Clavulanate Oral Suspension IP	Each 5ml of the reconstituted suspension contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 600mg Potassium Clavulanate diluted IP eq. to Clavulanic Acid 42.09mg	Per Vial (50ml)	M/s Sun Pharmaceutical Industries Limited	168.43

5. Agenda item no. 5 – Status of implementation of Review cases

5.1 Noted.

6. Agenda item no. 6 – Fixation of Ceiling Price of scheduled formulations under Revised Schedule-I (NLEM, 2022)

6.1 The Authority was apprised of the revised Schedule-I of DPCO, 2013 (i.e. NLEM, 2022) notified by Department of Pharmaceuticals (DoP) vide SO No. 5249 (E) dated 11.11.2022 and about the methodology and approximate number of formulations for which ceiling prices are to be fixed under revised Schedule-I.

6.2 It was informed that the number of formulations covered in revised Schedule – I are as follows:

S.No	Particulars	Number of formulations
1.	Approximate number of formulations	954 (388 Medicines)
2.	Duplicate formulations under various sections	135
3.	Unique formulations, including:	
a.	Formulations of newly added drugs	56
b.	Formulations continued from NLEM, 2015 drugs	763 (approx.)
	Total Unique formulations for which ceiling prices are to be fixed.	819 (approx.)

However, in view of explanations to the revised Schedule I and Para 11(3) of DPCO, 2013 number of formulations may increase beyond 954 formulations to approximately 1000 formulations.

6.3 The authority was appraised that as per Para 17 (1) of DPCO, 2013, the ceiling prices for the medicines in the Schedule-I has to be fixed within 60 days of the notification of Schedule-I.

6.4 The following methodology of fixation of Ceiling prices of medicines in revised Schedule-I was agreed upon by the Authority after deliberation:

1. The ceiling prices shall be calculated as per the formula prescribed under Para 4 and Para 6 of DPCO, 2013, as the case may be.
2. The Authority observed that as per provisions of Para 9 (5) "the market-based data for fixing the ceiling price of schedule formulation due to revision in the First schedule shall be the data available for the month ending immediately before six months of notification of revision in the first schedule."
3. Authority was informed about the representations received from some of the industry associations requesting not to consider the data of April, 2022, viz., 6 months prior to date of issue of notification by DoPi.e. Notification No. SO 5249(E) dated 11.11.2022. Industry associations further contended that it may not completely reflect the current PTR/MRP of formulations as revised in pursuance of revision of ceiling price based on WPI Notification S.O.1499(E) to 1508(E) dated 30.03.2022 for scheduled formulations. It has been further stated by them that market-based data to be considered for ceiling price fixation should be post implementation of revised prices for products considering the potential time lag for implementation with regard to imported

formulations. Industry Associations have requested to consider the latest month data i.e. October 2022/September 2022.

4. In this context Authority was informed that amendment in DPCO has been made on dated 3.1.2019 by adding Para 9 (7) as below:

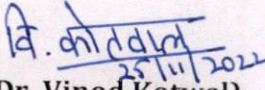
“Notwithstanding anything contained in this paragraph, for fixing or revising the ceiling price for formulations, the Government may, if it is necessary so to do, consider market based data available for any month, as deemed fit.”

5. Authority was further informed that NLEM, 2022 was notified on 13.09.2022 and the latest database available with NPPA as on date of release of NLEM, 2022 was that of July 2022. The impact of ceiling prices revision based on WPI notification dated 30.03.2022 expected to have captured in Pharmatrac database by July, 2022. Since effect of WPI increase on market price should be reflected in the ceiling prices to be fixed, the data of April, 2022 may result in fixation of ceiling prices without capturing the effect of WPI increase. Also, it may not be appropriate to use the data of March, 2022 and apply the WPI increase on it as all manufacturers may not avail the full WPI increase.
6. The issue was deliberated and it was agreed that looking at the complexity of the supply chain, there may be some time lag to reflect/capture the price changes carried out due to revision in WPI. Therefore, the authority agreed that data for the month of July, 2022 and Pharmatrac database for July 2022 be considered for calculation of ceiling prices.
7. The Authority reviewed the explanations to the revised Schedule I of DPCO and it was deliberated that the fixation of ceiling prices may be carried out as per DPCO 2013 provisions read with explanations to revised schedule I. Further, the Authority was also apprised of the methodology for data selection for fixation of ceiling prices.
8. In case of common formulations, the ceiling price as fixed under the earlier Schedule-I of DPCO, 2013 i.e. NLEM, 2015 may be taken as the base price while fixing ceiling price under the revised Schedule-I of DPCO, 2013 and in case the present PTR of any line item is found to be in excess of the Maximum Permissible PTR (Ceiling Price Net of Retailer Margin i.e. 16% as per the

earlier Schedule-I of DPCO, 2013 i.e. NLEM, 2015) then the same may be restricted to the such Maximum Permissible PTR.

9. As per para 18(i) Ceiling prices needs to be revised in every five years. In case of drugs for which prices were increased under Para 19 vide S.O. 4461(E) dated 13.12.2019 and S.O. 2654(E) dated 01.07.2021, the cutoff date for 5 years may be calculated from original fixation of ceiling price under DPCO, 2013. However, in respect of such formulations, no differentiation in data selection may be considered and data as appearing for July 2022 may be considered for pricing.
10. Further, in compliance to O.M. No. F. NO. 31015/44/2016-PI.I dated 11.07.2016 issued by Department of Pharmaceuticals, the Authority approved uploading of the draft working sheets for fixation of ceiling prices of formulations on NPPA website for 10 working days to invite comments, if any. Companies may submit their representations to NPPA on the draft working sheets supported their Price to Retailer (PTR) and Moving Annual Turnover (MAT) data along with supporting documents like copies of invoices to retailer and samples of July, 2022 in order to take necessary action in this regard. Such representations should reach NPPA within 10 working days of the upload of draft worksheet. It is proposed that an office memorandum may be issued in this respect.
11. The authority also noted that further issues regarding methodology that are likely to come up during price fixation may be taken up for deliberation in the subsequent meetings of the Authority.

The meeting ended with a vote of thanks to the Chair and all the participants in the meeting.


(Dr. Vinod Kotwal)
Member Secretary