मिसिल स.- 8(152)/2026/डी.पी/एनपीपीए-डीवी-II
F. No. 8(152)/2026/DP/NPPA-Div. II

कार्यवाही स. : 284/152/2026/F
Proceeding No: 284/152/2026/F

Minutes of the 284th (overall) and 152nd meetings of the Authority under DPCO, 2013 held on 16.10.2026 at 04:30 PM and 17.10.2026 at 12:30 PM.

The 284th (overall) and 152nd meetings of the Authority under DPCO, 2013 were held on 16.10.2026 at 04:30 PM and 17.10.2026 at 12:30 PM under the Chairmanship of Shri Manoj Joshi, Secretary, D/o Pharmaceuticals & Chairman, NPPA. The following Authority members were present during the meeting:

(i) Ms. Sai Ahlladini Panda, Member Secretary, NPPA
(ii) Shri Rajesh Yadav, Adviser (Cost), O/o Chief Adviser Cost, Department of Expenditure

Shri Arvind Kukrety, Deputy Drugs Controller, CDSCO, M/o Health & Family Welfare.

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

(i) Shri Rajiv Wadhawan, Adviser (Cost)
(ii) Ms. Priyanka Sachdeva, Joint Director (Pricing)
(iii) Shri Bhiva Ram Yadav, Assistant Director (Pricing)

At the outset, Member Secretary, welcomed all the participants.

Agenda: Trade Margin Rationalisation of Non-Scheduled Anti-Cancer Drugs under Paragraph 19 of DPCO, 2013

1. The Authority considered the matter relating to Trade Margin Rationalisation (TMR) of non-scheduled anti-cancer drugs under Paragraph 19 of the Drugs (Prices Control) Order, 2013 (DPCO, 2013), in continuation of its deliberations in the 283rd (overall) and 151st Authority meeting held on 08.10.2026.

2. The Authority recalled that in its 283rd (overall) and 151st meeting held on 08.10.2026, it had deliberated on the need to address excessive trade mark-ups in non-scheduled anti-cancer drugs and observed that extraordinary circumstances warranted intervention under Paragraph 19 of DPCO, 2013 in public interest. Wherein, after considering the market evidence, the public-health concerns and the precedent of 2019, the Authority agreed that the extraordinary circumstances and public interest considerations justified invoking Paragraph 19 of DPCO, 2013 in respect of the identified non-scheduled anti-cancer formulations. The Authority considered it necessary to cap the trade margin at 30% of MRP, excluding GST, corresponding to a mark-up of 42.86% on the Price to Stockist/Price to Distributor (PTS/PTD), to retain a reasonable trade margin while preventing excessive mark-ups.

3. The Authority noted that the Expert Committee of Ministry of Health and Family Welfare (MoHFW) after examining in detail, deliberating and considering all available information/data/viewpoints and all relevant options for ensuring affordability of essential drugs to the patients, in case of Anti-cancer medicines, has recommended 137 Anti-Cancer

drugs for coverage under the TMR exercise. The Authority noted that the list would provide a defined scope for the intervention and could be updated periodically, as warranted by market developments and public-health considerations. Considering all these, in order to bring in regulation of trade margins in the 'non-scheduled' segment, the Authority agreed to undertake the exercise of Trade Margin Rationalisation of Anti-Cancer drugs, identified by MoHFW as being essential for the treatment of this disease.

4. The Authority approved the mechanism for calculation of the revised MRP based on price at first point of sale (PTS/PTD) for March 2026 as the reference month, as per formula in table A. The PTS/PTD is to be determined based on the manufacturer's net sales realization for the relevant product during March 2026 divided by the total quantity sold during that month. Where there were no sales during March 2026, the PTS/PTD is to be determined based on net sales realization and total quantity sold during April 2025 to March 2026. All categories of sales are to be considered for this purpose, except Government sales.

Table A

Maximum Retail Price of the product =	Price to Stockist/Price to Distributor (PTS/PTD) × { 1 + (TM / (100 − TM)) } + Applicable GST
Where TM = Trade Margin not exceeding 30 Where PTS/PTD = PTS/PTD for the month of March 2026	

Table B (enclosed as **Annexure II**)

5. The Authority further decided that:

(i) where any non-scheduled anti-cancer formulation containing a drug listed in Table B has been launched after 31.03.2026, the MRP shall be fixed using the formula in Table A on the basis of the current PTS/PTD.

(ii) where a formulation is supplied directly by the manufacturer to a hospital or medical institution, the hospital or medical institution shall be treated as the stockist/distributor and the manufacturer's invoice data to that institution shall be considered for calculation of MRP.

(iii) Patient Assistance Programmes (PAP) quantities may be excluded from the calculation of PTS/PTD and MRP for trade-margin capping only where the drugs are supplied free of cost to patients under the manufacturer's PAP. The manufacturer shall furnish an undertaking to NPPA in line with extant Customs notifications issued by the Department of Revenue from time to time, and maintain patient name, age, gender, residence and contact details; valid identity and residence proof of the patient and caregiver, if any; details of the diagnosed disease and prescribed dosage; and records of drugs imported or received and consumed. The drugs shall be used only for the specified purpose. The manufacturer shall also undertake that the information furnished is true and correct and shall be liable for consequences arising from false, misleading or incorrect declarations under DPCO, 2013 and the Essential Commodities Act, 1955. NPPA shall retain the right to seek further information or clarification, conduct audits or inspections, and verify PAP implementation through third-party agencies or other appropriate means. Failure to comply with any condition shall render the relevant PAP quantities liable to be excluded from the exemption.

(iv) Manufacturers shall submit the revised MRP information in **Annexure I** to NPPA and the State Drug Controller concerned within seven days from publication of the Order in the Official Gazette, whether or not there is change in MRP. Non-submission shall be construed as non-reduction of MRP and shall result in initiation of action for recovery of the overcharged amount under the applicable provisions of DPCO, 2013.

(v) Manufacturers shall also issue and submit the price list in Form V under Paragraph 25 of DPCO, 2013 through IPDMS and furnish copies to the State Drug Controller, dealers and other entities as required within the same seven-day period. Documentary evidence of adequate dissemination of the price to be furnished upon demand. Retailers, dealers, hospitals and institutions shall display the price list and supplementary price list prominently in accordance with Paragraph 25(3) of DPCO, 2013.

6. The Authority further decided that manufacturers selling branded or generic versions, or both, at an MRP higher than the MRP computed under Table A shall reduce the price so that it does not exceed the computed MRP. Where the existing MRP is lower than the computed MRP, the existing lower MRP shall be maintained. The revised prices shall come into effect from 09.11.2026 and shall remain in force until further orders. Manufacturers may avail annual price increases in accordance with Paragraph 20(1) of DPCO, 2013, subject to continued compliance with the maximum permissible trade margin specified in the Order.

7. The Authority emphasized the need to ensure uninterrupted availability of the covered formulations. Manufacturers shall maintain the present production levels. Any manufacturer intending to reduce average monthly production levels shall obtain prior permission from NPPA. Any manufacturer intending to discontinue production or import shall furnish the prescribed information in Form IV of Schedule II of DPCO, 2013 at least six months before the intended date of discontinuation.

8. The Authority noted that the MRP formula shall apply to non-scheduled formulations containing any drug listed in Table B, whether the drug is present individually or in combination, irrespective of strength, dosage form or route of administration, even where the formulation is used for another therapeutic indication. Consequent to the publication of TMR notification in the Official Gazette, earlier price orders fixing ceiling prices under Paragraph 4 or retail prices under Paragraphs 5 and 15 of DPCO, 2013, if any, shall stand superseded as provided in the Order.

9. The Authority noted that there is no restriction on the price fixation of the patented drugs except if exemption has been approved under Paragraph 32 of the DPCO, 2013. Therefore, the Authority decided that patented medicines shall also be covered under the Order.

10. The Authority noted that, since substantial supplies of anti-cancer medicines are made directly to hospitals and medical institutions, these institutions shall monitor the MRPs and bring violations to NPPA's notice. State Drug Controllers shall monitor compliance by manufacturers, dealers, hospitals and medical institutions, and the concerned entities shall assist them in verification. In cases of violation, NPPA shall initiate action for recovery of the overcharged amount in accordance with DPCO, 2013.

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

SAI AHLLADINI PANDA

Digitally signed by SAI AHLLADINI PANDA
Date: 2026.10.17 18:31:48 -07'00'

(Sai Ahlladini Panda)
Member Secretary

Annexure I

Format for submission of revised MRP by the manufacturer

1. Name and address of the manufacturer/importer.

2. Name and address of the marketing company, if any.

Sl. No	Formulation				Composition approved by Drug Control Authorities	Pack Size	Price to Stockist/Price to Distributor (PTS/PTD) (excl. of GST) as in **March-2026** (₹)	Applicable GST Rate (%)	Maximum Retail Price Arrived by applying the formula in Table A (incl. of GST) (₹)	Pre-revised Maximum Retail Price (incl. of GST) (₹)
(1)	(2)				(3)	(4)	(5)	(6)	(7)	(8)
	Drug	Strength	Dosage Form	Brand Name						

*Formula to arrive MRP = Price to Stockist/Price to Distributor (PTS/PTD) x $\left\{1 + (\frac{TM}{100-TM})\right\}$ + Applicable GST

Where TM = Trade margin not exceeding 30

The information furnished above is correct and true to the best of my knowledge and belief.

(Signature and stamp)

Place:……

Date: ……

Name of authorized person:

Designation:

Name of the Organization:

Annexure II

Sr. No	Name of the Drug	Sr. No	Name of the Drug
1	Abemaciclib	70	Lenvatinib
2	Abiraterone acetate	71	Lomustine
3	Acalabrutinib	72	Lorlatinib
4	Afatinib	73	Lymphoseek kit
5	Alectinib	74	Megestrol
6	Alpelisib	75	Midostrurin
7	Amivantamab	76	Mirvetuximab soravtansine
8	Anastrazole	77	Mitomycin
9	Apalutamide	78	Mitoxantrone
10	Asciminib	79	Nelarabine
11	Atezolizumab	80	Netupitant
12	Avelumab	81	Nilotinib
13	Axitinib	82	Nimotuzumab
14	Azacitidine	83	Nintedanib
15	Belantamab Mafodotin	84	Niraparib
16	Bevacizumab	85	Nivolumab
17	Bosutinib	86	Obinutuzumab
18	Brentuximab Vedotin	87	Ofatumumab
19	Brigatinib	88	Olaparib
20	Busulfan	89	Osimertinib
21	Cabazitaxel	90	Palbociclib
22	Cabozantinib (S) – Maleate	91	Panitumumab (Vectibix)
23	Capmatinib	92	Pazopanib (as Hydrochloride)
24	Carfilzomib	93	Pegasparginase
25	Carmustine	94	Pegfilgrastim
26	Ceritinib	95	Pegylated interferon Alpha 2B
27	Cetuximab	96	Pembrolizumab
28	Cladribine	97	Pemetrexed
29	Clofarabine	98	Pertuzumab
30	Crizotinib	99	Pertuzumab + Trastuzumab
31	Cytarabine	100	Plerixafor
32	Dabrafenib	101	Polatuzumab Vedotin
33	Dacomitinib	102	Pomalidomide
34	Daratumumab	103	Ramucirumab
35	Darolutamide	104	Regorafenib
36	Dasatinib	105	Relugolix
37	Datopotamab Deruxtecan	106	Ribociclib
38	Decitabine	107	Rucaparib
39	Degarelix	108	Ruxolitinib
40	Denosumab	109	Selpercatinib
41	Dostarlimab	110	Selumetinib
42	Durvalumab	111	Serplulimab
43	Elranatamab	112	Sotorasib
44	Enfortumab vedotin	113	Sunitinib
45	Entrectinib	114	Talquetamab
46	Enzalutamide	115	Teclistamab
47	Epirubicin	116	Tegafur + Uracil
48	Erdafitinib	117	Tegafur, Gimeracil and Oteracil
49	Eribulin mesylate	118	Temsirolimus
50	Erlotinib	119	Tepotinibe

51	Estramustine	120	Thiotepa
52	Everolimus	121	Tislelizumab
53	Exemestane	122	Tocilizumab
54	Fludarabine	123	Topotecan
55	Fulvestrant	124	Toripalimab
56	Gilteritinib	125	Trabectedin
57	Goserelin acetate	126	Trametinib
58	Ibritumomab	127	Tremelimumab
59	Ibrutinib	128	Treosulfan
60	Idelalisib	129	Trifluridine + Tipiracil
61	Ifosfamide & Mesna	130	Triptorelin
62	Nivolumab and Relatimab	131	Tucatinib
63	Pegylated Liposomal Irinotecan	132	Vemurafenib
64	Inotuzumab Ozogamicin	133	Venetoclax
65	Interferon Alpha 2B	134	Vinorelbine tartrate
66	Ipilimumab	135	Vorasidenib
67	Ivosidenib	136	Zanubrutinib
68	Lapatanib	137	Zolbetuximab
69	Lazertinib		