

F. No. 8(64)/2019/DP/NPPA/Div.II  
भारत सरकार  
Government of India  
रसायन और उर्वरक मंत्रालय  
Ministry of Chemicals & Fertilizers  
औषध विभाग  
Department of Pharmaceuticals  
राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण  
National Pharmaceutical Pricing Authority

तीसरी/पांचवीं मंजिल 5<sup>th</sup> / 3<sup>rd</sup> Floor,  
वाई.एम.सी.ए. सांस्कृतिक केन्द्र बिल्डिंग  
YMCA Cultural Center Building,  
1, जय सिंह रोड, नई दिल्ली-110001  
1, Jal Singh Road, N. Delhi – 110001.  
दिनांक :- 08.03.2019

**OFFICE MEMORANDUM**

**Subject : Trade Margin Rationalisation of select Non-scheduled Anti-Cancer Drugs under paragraph 19 of DPCO, 2013.**

National Pharmaceutical Pricing Authority (NPPA) vide Order SO No. 1041(E) dated 27.02.2019 put a cap of 30% Trade margin on Selling Price for the non-scheduled Anti-Cancer formulations containing any of the 42 drugs listed therein by invoking paragraph 19 of DPCO, 2013.

2. The NPPA directed manufacturers to fix their retail price based on price at first point of sale of product (referred as Price to Stockist), as per formula in Table A of aforesaid Order, of the non-scheduled formulations containing any of the 42 Non-Scheduled anti cancer drugs listed in the aforesaid Order (whether individual or in combination, irrespective of dosage strength, dosage form and /or route of administration).

3. The NPPA also directed manufacturers to provide the revised MRP of their formulations in Annexure I (details of PTS and MRP arrived for formulations by using the formula prescribed) of Order dated 27.02.2019 in respect of all non-scheduled formulations containing drugs as per Table B, irrespective whether there was any change in MRP or not, by 6<sup>th</sup> March, 2019, under paragraph 9(2) of the DPCO, 2013.

4. Further, information was also sought from 10 hospitals regarding these 42 drugs, to capture institutional data.

5. The revised MRP in respect of formulations arrived from these 42 drugs as per data provided by manufacturers, is at Annexure-X.
6. The revised prices shall come into effect from 8<sup>th</sup> March, 2019.
7. The onus of providing correct information rests with the manufacturer. The manufacturer will be liable for any aberration arising out of incorrect information or withholding correct information from NPPA.
8. It is further reiterated that the trade margin cap notified by S.O. No. 1041(E) dated 27.02.2019 is applicable on All the brands containing any of the 42 drugs listed in aforesaid Order, irrespective of whether the brand/ formulation is included in the Annexure attached herewith.
9. All other conditions for non-scheduled formulations as per the provisions of DPCO, 2013 shall be applicable to the 42 drugs under reference.
10. The manufacturers not complying with the price arrived at through S.O. No. 1041(E) dated 27.02.2019 and notes therein, are liable to be acted against, under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.



(Amarपाल Singh Sawhney)  
Director (Pricing)

## Revised MRP of Non-Scheduled Anti-Cancer Medicines w.e.f. 08.03.2019

(Based on data received till 07.03.2019)

Annexure : X

Sl. No	Medicine	Strength & Dosage Form	Brand Name	OLD MRP	Revised MRP	Reduction %
1	Azacitidine	100mg Injection	MDS Plus	8900.00	4367.07	50.93%
2	Azacitidine	100mg inj	Azactiv	7800.00	2221.00	71.53%
3	Azacitidine	100mg Injection	Azatend	7600.00	2980.05	60.79%
4	Azacitidine	100 mg injection	HEMAZIDE INJ	8900.00	3840.00	56.85%
5	Azacitidine	100mg Injection	Azadine	8900.00	3951.10	55.61%
6	Azacitidine	100mg Injection	AZASHINE	9000.00	4068.00	54.80%
7	Azacitidine	100 mg Injection	Azatirel	8900.00	4265.60	52.07%
8	Azacitidine	100mg vial	AZALIVE 100MG per Vial	10044.08	5043.11	49.79%
9	Azacitidine	100mg Injection	Azacytin 100mg Injection	8995.00	5079.50	43.53%
10	Azacitidine	100mg Injection	MYAZA	4950.00	3201.00	35.33%
11	Azacitidine	100mg 1 Vial	Azafab Inj.	4590.00	2978.50	35.11%
12	Azacitidine	100mg Injection	AZZURE INJECTION	9000.00	7701.56	14.43%
13	Azacitidine	100mg Inj. (Powder)	Mylotex 100mg	5150.00	4748.15	7.80%
14	Azacitidine IP	100 mg Injection	ATSA	8750.00	4514.00	48.41%
15	Azacitidine IP 100 Mg	100mg Injection	AZAPLAST 100MG Inj	8500.00	3373.00	60.32%
16	Bendamustin Hcl	100mg Powder	Ribomustin	11000.00	5500.00	50.00%
17	Bendamustin HCL	100mg Inj.	Adben-100	8000.00	4001.00	49.99%
18	Bendamustin Hcl+ Mannitol	100+170 mg Vial	Lymphfor 100	8572.20	4051.80	52.73%
19	Bendamustine	100mg Injection	LEUBEN	8200.00	1811.00	77.91%
20	Bendamustine	100mg Single Dose Vial	Bendamax	7542.00	2267.00	69.94%
21	Bendamustine	100mg Injection	Bizisa	7000.00	2561.49	63.41%
22	Bendamustine	100mg Injection	Benzz	7848.00	4007.36	48.94%
23	Bendamustine	100mg Injection	Maxtorin Injection 100mg (Inj.)	11144.70	9503.18	14.73%
24	Bendamustine	180mg Injection	Benzz	5000.00	4776.89	4.46%
25	Bendamustine	45mg Injection	Benzz	1250.00	1194.56	4.44%
26	Bendamustine	100 mg Injection	BIMODE	7683.00	1951.00	74.61%
27	Bendamustine	100 mg Injection	ZUMUSTIN	8121.75	2028.00	75.03%
28	Bendamustine Hydrochloride	100mg Injection	NEOMUSTIN INJ	7304.66	2666.00	63.50%
29	Bendamustine Hydrochloride	100mg Injection (1vial*1)	Bemustin	6950.00	2684.00	61.38%
30	Bendamustine Hydrochloride	100mg Injection	Purplz Injection 1's	7830.00	3981.00	49.16%
31	Bevacizumab	100mg Injection	Bevatas	25990.00	9500.00	63.45%
32	Bevacizumab	100mg Injection	CIZUMAB	31200.00	11838.00	62.06%
33	Bevacizumab	100 mg Inj	KRABEVA 100 MG	26376.00	12214.14	53.69%
34	Bevacizumab	100 mg Injection	BEVAREST	28500.00	13223.00	53.60%
35	Bevacizumab	100mg Injection	ABEVMY	24000.00	13451.00	43.95%
36	Bevacizumab	100mg/4ml Injection	Bryxta	27000.00	16059.00	40.52%
37	Bevacizumab	100mg/4ml Injection	Zybev	27000.00	17470.43	35.29%
38	Bevacizumab	100mg Injection	Bevazza Inj.	24181.00	18247.00	24.54%
39	Bevacizumab	400mg Injection	CIZUMAB	52000.00	43859.00	15.66%

40	Bevacizumab	400mg Injection	ABEVMY	39990.00	35120.00	12.18%
41	Bevacizumab	400mg/16ml Injection	Bryxta	48999.00	43369.40	11.49%
42	Bevacizumab	400mg Injection	Bevazza Inj.	43900.00	38915.00	11.36%
43	Bevacizumab	400 mg Inj	KRABEVA 400 MG	39990.00	35777.44	10.53%
44	Bevacizumab	400mg Injection	Bevatas	39995.00	36061.64	9.83%
45	Bevacizumab	100 mg Injection	Bevacirel	31196.55	12356.89	60.39%
46	Bevacizumab	400 mg Injection	Bevacirel	49990.00	38856.34	22.27%
47	Bortezomib	2.5mg Injection	Proteoz	18133.50	3415.14	81.17%
48	Bortezomib	3.5 mg Injection	Bortiad	17140.00	4001.20	76.66%
49	Bortezomib	2.5 mg injection	BORTECAD 2.5 MG INJ	12929.00	3180.00	75.40%
50	Bortezomib	2mg Single Dose Vial	Botiva	12495.00	3268.00	73.85%
51	Bortezomib	3.5 mg Injection	Brortezomib	14000.00	3678.93	73.72%
52	Bortezomib	2.5mg Injection	Brorviz	12929.03	4522.23	65.02%
53	Bortezomib	3.5mg Injection	Zortemib	13500.00	6057.82	55.13%
54	Bortezomib	3.5mg Injection	Brorviz	12499.00	6245.39	50.03%
55	Bortezomib	3.5 mg Powder	Velcad	60360.00	54350.00	9.96%
56	Bortezomib	1 mg Powder	Velcad	19850.00	18060.00	9.02%
57	Cabazitaxel	60mg Inj.	Arbaz	48000.00	12552.40	73.85%
58	Cabazitaxel	60mg Injection	Cabaxan	11999.00	11041.92	7.98%
59	Cabazitaxel	60 mg Inj.	Procabazi	20000.00	11100.00	44.50%
60	Carfilzomib	60mg Injection	Kyprolis 60mg	49500.00	47325.00	4.39%
61	Clofarabine	20mg Injection	Farabine	15000.00	11119.55	25.87%
62	Clofarabine	20mg Injection	Cfara	15000.00	14503.90	3.31%
63	Cloforabine	20mg inj	Colymph	15000.00	13800.00	8.00%
64	Crizotinib	200mg Capsules	Crizalk 200mg 60's Caps(capsule)	106698.00	100177.53	6.11%
65	Crizotinib	250mg Capsules	Crizalk 250mg 60's Caps(capsule)	106698.00	106270.25	0.40%
66	Cytarabin	100mg Injection	Biobin	288.70	50.74	82.42%
67	Cytarabin	100mg Injection	Arasid	195.79	117.85	39.81%
68	Cytarabine	100 MG/1ML Injection	CYTANEON 100 MG./1ML.	91.50	45.73	50.02%
69	Cytarabine	100 mg/5ml. Injection	CYTANEON 100 MG./5ML.	99.00	77.76	21.45%
70	Cytrabine	100mg Single Dose Vial	Cytramax	167.00	98.00	41.32%
71	Decitabine	50mg inj	Deczuba	7800.00	3401.00	56.40%
72	Decitabine	50mg Injection	Decitas	8501.00	4250.50	50.00%
73	Decitabine	30mg Injection	Decitas	5900.00	3562.52	39.62%
74	Decitabine	50mg Injection	Xalibo(Injection)	8100.00	5187.00	35.96%
75	Decitabine	50 mg Powder	Dacogen IV	80000.00	61430.00	23.21%
76	Decitabine	50mg Injection	DECITEX 50 MG INJECTION	7973.05	6229.39	21.87%
77	Decitabine	30mg Injection	DECITEX 30 MG INJECTION	5980.00	5546.43	7.25%
78	Doxarubicin Hcl	2 mg Peg Liposomal Con. For soln	Caelyx	49427.00	48850.00	1.17%
79	Doxorubicin	20mg Injection	Pegadria	7848.00	2879.50	63.31%
80	Doxorubicin	50mg Injection	Pegadria	20056.00	7827.52	60.97%
81	Doxorubicin	20mg Injection	Tadro	7290.00	2977.30	59.16%
82	Doxorubicin	20mg Injection	Nudoxa	9650.00	4353.04	54.89%
83	Doxorubicin	50mg Injection	Nudoxa	20490.00	12000.00	41.43%
84	Doxorubicin	50mg Injection	Tadro	14147.00	8435.64	40.37%



85	Doxorubicin (Liposomal)	20mg Injection	LIPODOX 20 MG INJECTION 10 ML	8040.00	3893.95	51.57%
86	Doxorubicin (Liposomal)	50mg Injection	LIPODOX 50 MG INJECTION 25 ML	18400.00	11797.26	35.88%
87	Doxorubicin HCL	50mg Injection	DOXOREX 50	943.60	262.10	72.22%
88	Doxorubicin HCL	2mg Injection	ONCODEX	9350.00	3166.97	66.13%
89	Doxorubicin HCL	10mg Injection	DOXOREX 10	188.71	128.86	31.72%
90	Doxorubicin HCL Pegylated Liposomal Injection	20mg Injection	LIPOPEG INJECTION	7000.00	3395.00	51.50%
91	Doxorubicin hydrochloride	2 mg injection	CADRIA I INJ.	8500.00	6766.00	20.40%
92	Enzalutamide	40mg Capsule	Azel Capsules	27500.00	18081.00	34.25%
93	Enzalutamide	40mg capsule	Glenza	27500.00	18600.00	32.36%
94	Enzalutamide	40 mg capsule	ENZUTA	27500.00	20059.00	27.06%
95	Enzalutamide	40mg Capsule	Encrpc	27500.00	20298.72	26.19%
96	Enzalutamide	40mg Capsule	Enzamide	27500.00	20298.72	26.19%
97	Epirubicin	50mg Injection	Biorubin	3551.30	900.85	74.63%
98	Epirubicin	50mg Powder to Injection	EPIDOX-50	3954.33	1171.36	70.38%
99	Epirubicin	50mg Injection	Epixtra	3079.90	1036.56	66.34%
100	Epirubicin	10mg Inj.	Adricin 10	950.00	339.64	64.25%
101	Epirubicin	10mg Injection	Biorubin	723.40	264.15	63.48%
102	Epirubicin	10mg Powder to Injection	EPIDOX-10	941.35	355.74	62.21%
103	Epirubicin	50mg Inj.	Adricin 50	3200.00	1370.48	57.17%
104	Epirubicin	50mg Injection	EPITERO	2000.00	978.00	51.10%
105	Epirubicin	50 MG/ VIAL Injection	EPINEON-50	1080.00	637.63	40.96%
106	Epirubicin	10mg Injection	Epixtra	735.60	448.32	39.05%
107	Epirubicin	10 MG/ VIAL Injection	EPINEON-10	268.00	169.77	36.65%
108	Epirubicin	100mg Injection	Epitaz	4360.00	2890.49	33.70%
109	Epirubicin	100mg Single Dose Vial	Epiget	2250.00	1530.00	32.00%
110	Epirubicin	50mg Injection	Epitaz	2235.00	1573.80	29.58%
111	Epirubicin	100mg Injection	Zepirubin	4800.00	3526.06	26.54%
112	Epirubicin	10mg Injection	Epitaz	600.00	454.12	24.31%
113	Epirubicin	50 mg inj	Epribenz	2500.00	1935.50	22.58%
114	Epirubicin	50mg Injection	Zepirubin	2600.00	2025.60	22.09%
115	Epirubicin	50mg Single Dose Vial	Epiget	495.00	412.00	16.77%
116	Epirubicin	10 mg inj	Epribenz	600.00	540.00	10.00%
117	Epirubicin	10mg Injection	Zepirubin	640.00	577.67	9.74%
118	Epirubicin	50mg Injection	Farmorubicin RTU 50mg/25ml Injection (injection)	3813.70	3589.82	5.87%
119	Epirubicin	50mg Injection	Farmorubicin RD 50mg Injection (injection)	3318.42	3250.95	2.03%
120	Epirubicin	10mg Injection	Farmorubicin RTU 10mg/5ml Injection (injection)	805.20	799.34	0.73%
121	Epirubicin	50 mg Injection	EPICURE	2390.00	1113.00	53.43%
122	Epirubicin	100 mg Injection	EPICURE	4132.00	2229.00	46.06%

123	Epirubicin	50 mg Injection	ZUVICIN	2392.00	1298.00	45.74%
124	Epirubicin	100 mg Injection	ZUVICIN	4130.00	2335.00	43.46%
125	Epirubicin	10 mg Injection	EPICURE	478.00	333.00	30.33%
126	Epirubicin	10 mg Injection	ZUVICIN	526.00	405.00	23.00%
127	Epirubicin 10mg	10mg Injection	ERUBIN 10MG(Injection)	500.00	258.00	48.40%
128	Epirubicin 50mg	50mg Injection	ERUBIN 50MG(Injection)	2000.00	597.00	70.15%
129	Epirubicin Hydrochloride	10mg inj	Epithra	551.00	230.00	58.26%
130	Epirubicin Hydrochloride	50mg inj	Epithra	2270.00	971.00	57.22%
131	Epirubicin Hydrochloride	100mg inj	Epithra	4277.00	1916.00	55.20%
132	Epirubicin Hydrochloride	50 mg injection	CADRUBIN 50 MG	3300.00	1568.00	52.48%
133	Epirubicin Hydrochloride	10 mg injection	CADRUBIN 10 MG	1030.00	569.00	44.76%
134	Eribulin Mysylate	0.44 mg/ml Parentral Preparation	Halaven	32860.00	31885.00	2.97%
135	Erlotinib	150mg Tablet	Zycev	13078.10	3330.00	74.54%
136	Erlotinib	100mg Tablet	Zycev	10880.10	2860.30	73.71%
137	Erlotinib	150mg Tablet	ERLOTERO	9900.00	3990.00	59.70%
138	Erlotinib	100mg tablet	Erlotiva	2250.00	1004.00	55.38%
139	Erlotinib	150mg Tablet	ERLOMY	11900.00	6106.00	48.69%
140	Erlotinib	150mg Tablet	Tyrokinin 250mg	5580.00	2918.00	47.71%
141	Erlotinib	150mg tablet	Erlotiva	4143.00	2251.00	45.67%
142	Erlotinib	100mg Tablet	ERLOMY	9990.00	6490.00	35.04%
143	Erlotinib	100 mg Tablet	Erlotad	7500.00	1638.89	78.15%
144	Erlotinib	150 mg Tablet	ERTINIB	8550.00	2080.00	75.67%
145	Erlotinib	150 mg Tablet	ERTINIB	16500.00	6400.00	61.21%
146	Erlotinib	100 mg Tablet	ERTINIB	10500.00	4679.11	55.44%
147	Erlotinib	150mg Tablet	Erlotib	6666.00	2975.24	55.37%
148	Erlotinib	150 mg Tablet	ERTINIB	9500.00	4469.00	52.96%
149	Erlotinib 100mg	100mg tablet	Erlotad 100	7500.00	1164.27	84.48%
150	Erlotinib 150mg	100mg tablet	Erlotad 150	11000.00	2996.10	72.76%
151	Erlotinib Hcl	150 MG/TAB Tablet	ERLIB	270.00	112.67	58.27%
152	Erlotinib HCL	100mg Tab	Erlonon	5000.00	2640.79	47.18%
153	Erlotinib HCL	150mg Tab	Erlonon	6200.00	3721.12	39.98%
154	Erlotinib HCL	100mg Tablet	ERLOCIP	7326.00	4690.24	35.98%
155	Erlotinib HCL	150mg Tablet	ERLOCIP	10989.00	7479.00	31.94%
156	Erlotinib HCL 100mg	100mg Tablet	LORTNIB 100MG (Tablet)	7900.00	1026.00	87.01%
157	Erlotinib HCL 150mg	150mg Tablet	LORTNIB 150MG (Tablet)	11159.85	1535.00	86.25%
158	Erlotinib hydrochloride	100mg Tablet	Erleva	6392.51	3222.00	49.60%
159	Erlotinib hydrochloride	150mg Tablet	Erleva	9688.65	5280.00	45.50%
160	Estramustine Phosphate	140mg Capsule	ESTRAMIN	4263.00	3573.96	16.16%
161	Everolimus	10 mg Tablet	Afinitor	53400.00	19882.43	62.77%
162	Everolimus	5 mg Tab	EVERTOR 5 MG	21735.60	9644.90	55.63%
163	Everolimus	10 mg Tab	EVERTOR 10 MG	32603.60	14690.87	54.94%
164	Everolimus	10mg Tablet	Volantis 10s tablet 10mg	20020.00	9837.50	50.86%
165	Everolimus	0.5 mg Tab	ADVACAN 0.5	1595.70	825.59	48.26%

166	Everolimus	0.25 mg Tab	ADVACAN 0.25	797.80	439.97	44.85%
167	Everolimus	5mg Tablet	Volantis 10s tablet 5mg	10010.00	6438.50	35.68%
168	Everolimus	10mg Tablet	ROLIMUS	12839.67	9000.00	29.90%
169	Everolimus	5mg Tablet	ROLIMUS	7133.15	5250.00	26.40%
170	Everolimus	0.25mg Tablets	EverGrafo.25	696.25	579.00	16.84%
171	Everolimus	0.75 mg Tablet	Certican	2760.00	2320.00	15.94%
172	Everolimus	0.25 mg Tablet	Certican	920.00	789.00	14.24%
173	Everolimus	0.5 mg Tablet	Certican	1840.00	1615.00	12.23%
174	Everolimus	0.50mg Tablets	EverGraf 0.50	1392.50	1298.35	6.76%
175	Evrolimus	10mg Tablet	Evermil	15000.00	6835.00	54.43%
176	Evrolimus	5mg Tablet	Evermil	10000.00	5168.00	48.32%
177	Exemestane	25mg 10 tabs	Exeget	850.00	511.00	39.88%
178	Exemestane	25mg Tablets	Aromasin 25mg Tablet	5284.40	4867.77	7.88%
179	Fulveser	250mg Injection	FULVESER	21000.00	7920.99	62.28%
180	Fulvestrant	250 mg Inj	FASNORM	24727.50	15054.45	39.12%
181	Fulvestrant	250 mg injection	FUVESTROL INJ	22000.00	13511.00	38.59%
182	Fulvestrant	250mg Injection	Strantas	20000.00	13300.08	33.50%
183	Fulvestrant	250mg Single Dose	Faslomax	18500.00	12521.00	32.32%
184	Fulvestrant	250 mg Injection	FULVIRA	44000.00	21342.00	51.50%
185	Fulvestrant	250 mg Injection	FULVIRA	22000.00	11109.00	49.50%
186	Fulvestrant	250mg inj	Fulviglen	20700.00	11365.00	45.10%
187	Fulvestrant PFS	5ml Injection	Fistent	24500.00	16516.95	32.58%
188	Irinocetan	100mg Injection	Campto 100mg/5ml (injection)	22651.20	18151.11	19.87%
189	Irinocetan	40mg Injection	Campto 40mg/2ml (injection)	9059.60	7628.31	15.80%
190	Irinotecan	100mg Injection	IRITERO	4100.00	1000.00	75.61%
191	Irinotecan	40mg Injection	IRITERO	1800.00	617.00	65.72%
192	Irinotecan	40mg Injection	Zinotecan	1800.00	1576.48	12.42%
193	Irinotecan	100mg Injection	Zinotecan	2200.00	2160.65	1.79%
194	Irinotecan	40 mg Injection	IMTUS	1969.00	322.00	83.65%
195	Irinotecan	100 mg Injection	IMTUS	4610.00	1267.00	72.52%
196	Irinotecan Hcl Trihydrate	100 MG/ 5 ML Injection	INTENSIC	850.00	517.82	39.08%
197	Irinotecan Hcl Trihydrate	40 MG/ 2mL Injection	INTENSIC	486.00	472.78	2.72%
198	Irinotecan Hydrochloride Trihydrate	20mg Injection	Irnocam 100Inj	4084.00	1566.00	61.66%
199	Irinotecan Hydrochloride Trihydrate	20mg Injection	Irnocam 40Inj	1825.50	777.50	57.41%
200	Lapatanib	250mg Tablet	Abnib Tablet 30mg	12990.00	8403.76	35.31%
201	Lapatanib	250mg Tablet	Lupidoc Tab	11952.00	10305.00	13.78%
202	Lapatinib	250mg Tablet	HERLAPSA	9750.00	8057.00	17.36%
203	Lapatinib	250mg Tablet	HERTAB	6995.00	5950.00	14.94%
204	Lapatinib	250mg Tablet	HERTAB	32995.00	28160.00	14.65%
205	Lapatinib	250mg Tablet	LapaHope	10000.00	8750.00	12.50%
206	Lapatnib Ditosylate	250 mg Tablet	LAPATEM	11000.00	6745.00	38.68%
207	Lapatnib Ditosylate	250 mg Tablet	LAPATEM	29500.00	28384.00	3.78%
208	Lenalidomide	25mg Capsules	Lenomust-25	18000.00	4601.95	74.43%
209	Lenalidomide	10mg Capsules	Lenomust-10	8700.00	2454.25	71.79%

210	Lenalidomide	5 mg Capsule	Relidomide	4000.00	1259.00	68.53%
211	Lenalidomide	10mg Capsule	Lenangio 10	2821.70	1013.00	64.10%
212	Lenalidomide	25mg Capsule	Lenangio 25	7400.00	2759.00	62.72%
213	Lenalidomide	10mg Capsule	LENDOMY	9000.00	3408.00	62.13%
214	Lenalidomide	25 mg Capsule	Relidomide	16000.00	6400.00	60.00%
215	Lenalidomide	25mg Capsule	LENDOMY	18000.00	7700.00	57.22%
216	Lenalidomide	5mg Capsule	LENDOMY	4400.00	1887.00	57.11%
217	Lenalidomide	5mg Capsule	Lenangio 5	1410.80	632.00	55.20%
218	Lenalidomide	10mg Capsule	LENMID	2051.79	998.61	51.33%
219	Lenalidomide	10 mg Capsule	Relidomide	7500.00	4080.00	45.60%
220	Lenalidomide	25mg Capsule	LENMID	4409.02	2796.72	36.57%
221	Lenalidomide	5mg Capsule	LENMID	1024.10	795.73	22.30%
222	Lenalidomide-10mg	10mg Caps	Adlinod-10	2660.00	1852.76	30.35%
223	Lenalidomide-25mg	25mg Caps	Adlinod-25	6650.00	3680.00	44.66%
224	Lenalidomine	5mg Capsule	Lenome	2180.00	948.87	56.47%
225	Lenalidomine	10mg Capsule	Lenome	3815.00	1691.13	55.67%
226	Lenalidomine	25mg Capsule	Lenome	6540.00	3040.93	53.50%
227	Lenalidomine	10mg Capsule	Laviat	2400.00	1220.12	49.16%
228	Lenalidomine	25mg Capsule	Laviat	4800.00	2447.32	49.01%
229	Lenalidomine	5mg Capsule	Laviat	1200.00	734.65	38.78%
230	Leuprolide	3.75 mg Injection	Leuprorel	4400.00	2224.20	49.45%
231	Leuprolide	3.75mg Injection	Luprorin Depot	4634.00	2351.12	49.26%
232	Leuprolide	22.5mg Injection	Leupo	21000.00	16893.51	19.55%
233	Leuprolide	22.5mg Injection	Luprotas	21000.00	16893.51	19.55%
234	Leuprolide	4mg Injection	Luprorin	560.00	478.58	14.54%
235	Leuprolide	11.25mg Injection	Leupo	11500.00	10167.27	11.59%
236	Leuprolide	11.25mg Injection	Luprotas	11500.00	10167.27	11.59%
237	Leuprolide	22.5 mg Injection	ELIGARD DEPOT	24000.00	22650.00	5.62%
238	Leuprolide	45 mg Injection	ELIGARD DEPOT	38350.00	36357.00	5.20%
239	Leuprolide Acetate	3.75mg Injection	EUROLIDE-DEPOT	5072.76	1772.10	65.07%
240	Leuprolide acetate	3.75 mg Injection	MATERNA	4395.00	2203.00	49.87%
241	Leuprolide Acetate	3.75mg Inj. (Powder)	Luprodex 3.75mg Depot	4095.00	2257.07	44.88%
242	Leuprolide Acetate	22.5mg Inj	Glerelin	19990.00	12210.00	38.92%
243	Leuprolide Acetate	22.5mg Inj. (Powder)	Luprodex 22.5mg	20100.00	12552.85	37.55%
244	Leuprolide Acetate	11.25mg Inj. (Powder)	Luprodex 11.25mg depot	11576.00	7339.71	36.60%
245	Leuprolide Acetate	1mg Injection	EUROLIDE	304.37	196.45	35.46%
246	Leuprolide Acetate	11.25mg Inj. (Powder)	Luprodex 3M(11.25mg)	11576.00	7500.00	35.21%
247	Leuprolide Acetate	4mg Injection	EUROLIDE	795.96	527.92	33.68%
248	Leuprolide Acetate	4mg Multidose Vial	Luprodex MD 4mg	510.00	439.17	13.89%
249	Leuprolide Acetate	1mg/0.5 ml inj	Luprofact	233.50	155.50	33.40%
250	Leuprolide Acetate	1 mg/ml inj	Luprofact	727.00	566.25	22.11%



251	Leuprolide Acetate Depot for Inj.	11.25mg Injection	LUPRIDE 11.25 MG INJECTION	11500.00	10137.88	11.84%
252	Leuprolide Acetate Depot for Inj.	3.75mg Injection	LUPRIDE 3.75 MG INJECTION	4200.00	3917.36	6.73%
253	Leuprolide Acetate Depot for Inj.	22.50mg Injection	LUPRIDE 22.50 MG INJECTION	18700.00	17466.04	6.60%
254	Leuprolide depot In	3.75mg Single Dos	Prolimax	4646.00	2349.00	49.44%
255	Linalidomide	10mg 10caps	Lenaget	3293.00	1451.00	55.94%
256	Linalidomide	5mg 10caps	Lenaget	1476.00	805.00	45.46%
257	Mitomycin	40mg Injection	Mitomycin C	2879.40	2245.69	22.01%
258	Mitomycin	2mg Injection	Mitomycin C	216.20	172.23	20.34%
259	Mitomycin	10mg Injection	Mitomycin C	556.60	491.69	11.66%
260	Mitomycin	10 mg/Vial Injection	MITO-10	529.00	472.34	10.71%
261	Mitomycin	40 mg/Vial Injection	MITO-40	2140.00	1924.00	10.09%
262	Mitomycin	2 mg/vial Injection	MITO-2	168.00	164.56	2.05%
263	Mitoxantrone	20 MG/ 10ML Injection	NITROL	433.00	427.17	1.35%
264	Nilotinib	200 cap	Tasigna	8768.00	8507.57	2.97%
265	Paclitaxel	100 mg Injection	AB-Pacli	12160.00	6563.58	46.02%
266	Paclitaxel	6mg Injection 43.4ml*1	PacliTrust 260	9000.00	1781.60	80.20%
267	Paclitaxel	260 mg injection	PACLICAD 260MG INJ	10182.03	2775.00	72.75%
268	Paclitaxel	100mg Injection (100mg/vial)	PacliAll	12697.74	5242.90	58.71%
269	Paclitaxel	100mg Injection	Petaxel	13056.48	5946.24	54.46%
270	Paclitaxel	100mg Injection	Taxonab	14058.70	6739.83	52.06%
271	Paclitaxel	100mg Vial	Nab Tortaxel	12737.40	7918.20	37.84%
272	Paclitaxel	100mg Injection	DUTAXEL	3917.90	508.72	87.02%
273	Paclitaxel	260mg Injection	DUTAXEL	8800.00	1203.28	86.33%
274	Paclitaxel	30mg Injection	DUTAXEL 30	1173.03	423.01	63.94%
275	Paclitaxel (Protein bound particle)	100mg Injection	NABPAC 100 MG (Injection)	12333.00	4628.00	62.47%
276	Paclitaxel (Protein Bound particles)	100mg vial	NANOPACLI 100MG	11957.22	7256.63	39.31%
277	Paclitaxel (Proteinbound particle)	100mg Injection	NAB PACLITERO	10900.00	4622.00	57.60%
278	Paclitaxel (Proteinbound particle)	100mg Injection	NABTOXOL	11543.00	6418.00	44.40%
279	Paclitaxel IP 100, Humen albumin IP	100 mg injection	PACLICAD N INJ	12169.50	5138.00	57.78%
280	Paclitaxel Nanopart	100mg Injection	PACLITAX	13172.50	6803.88	48.35%
281	Peg L Asperginase Inj	750/IU injection	LAGIPEG INJECTION	43378.43	34560.00	20.33%
282	Peg L-Asparaginase	5ml Injection	PEG L-ASPATERO	43370.00	25536.00	41.12%
283	Peg r-humen G-CSF	6mg inj	Glenstim	11997.00	3665.00	69.45%
284	Peg-Asparaginase	750IU Inj.	Peg-Lasgen	59990.00	29448.83	50.91%
285	Pegasperagase	3750IU Injection	Asviia	24990.00	20383.71	18.43%

286	Pegfilgrastim	6 mg Injection	Pegreligrast	12000.00	2919.14	75.67%
287	Pegfilgrastim	6mg Injection	Pegasta	11227.00	2958.93	73.64%
288	Pegfilgrastim	6mg Injection	PEGFRASTIM(Injection)	14500.00	4016.00	72.30%
289	Pegfilgrastim	6mg Injection	Peg-grafeel 6mg	10790.00	3010.00	72.10%
290	Pegfilgrastim	6mg Injection	Pegstim	12078.00	3592.93	70.25%
291	Pegfilgrastim	6mg Injection	Pegheal	10990.00	3420.34	68.88%
292	Pegfilgrastim	6mg Injection	Neupeg	18530.00	6849.99	63.03%
293	Pegfilgrastim	6 mg Injection	PEGEX	9340.00	3455.00	63.01%
294	Pegfilgrastim	6 mg Injection	PEGEX	9340.00	3455.00	63.01%
295	Pegfilgrastim	6 mg/ 0.6 ml. PFS Injection	PEGNEON	7200.00	2882.30	59.97%
296	Pegfilgrastim	6mg Injection	LUPIFIL-P	8930.00	4172.00	53.28%
297	Pegfilgrastim	6mg Injection	CIPLASTIM	12000.00	6399.99	46.67%
298	Pegfilgrastim	0.06mg PFS	Imupeg Injection (Prefilled Syringes)	12023.06	6984.45	41.91%
299	Pegfilgrastim	6 mg Injection	PEGLAST	10870.00	6400.00	41.12%
300	Pegfilgrastim	6 mg Injection	PEGLAST	10870.00	6400.00	41.12%
301	Pegfilgrastim	6 mg prefilled syringe	Fillif-peg	10352.60	7086.40	31.55%
302	Pegfilgrastim	6mg Injection	Pegstim	5500.00	3894.46	29.19%
303	Pegfilgrastim	6mg Injection	Pegasta	3900.00	2958.93	24.13%
304	PEG-FILGRASTIM	6mg Injection	PEG XPHIL 6MG(0.6ml) INJECTION	11000.00	6334.13	42.42%
305	Pegfilgrastin	6mg Injection 6mg/0.6ml	Peg Trust	13233.00	4992.10	62.28%
306	Pegylated Liposomal Doxorubicin	2 mg Injection	RUBILONG	9898.00	3918.00	60.42%
307	Pegylated Liposomal Doxorubicin Hydrochloride	10 ml Injection	PIGLIT	8353.00	3158.00	62.19%
308	Pemetrexed	500mg Injection	Pexe trust 500	20394.00	2745.20	86.54%
309	Pemetrexed	100mg Injection	Pexe trust 100	5150.00	740.75	85.62%
310	Pemetrexed	100mg Injection	Pempro	5500.00	936.79	82.97%
311	Pemetrexed	500mg Powder to Injection	PEMAXAM-500	13200.00	2259.95	82.88%
312	Pemetrexed	100mg Injection	PEMETA	4950.00	862.78	82.57%
313	Pemetrexed	500mg Injection	Pempro	18000.00	3224.76	82.08%
314	Pemetrexed	500mg Injection	PEMETA	21450.00	4071.70	81.02%
315	Pemetrexed	500mg Injection	PEMETERO	13200.00	2673.00	79.75%
316	Pemetrexed	500 mg Injection	PEMCURE	16500.00	3431.00	79.21%
317	Pemetrexed	100mg Injection	MY TREX	4500.00	957.00	78.73%
318	Pemetrexed	500mg Injection	MY TREX	12000.00	2691.00	77.58%
319	Pemetrexed	500 mg injection	PEMECAD 500MG	19255.27	4349.00	77.41%
320	Pemetrexed	500mg Injection	Pemgem 500mg inj	21215.00	5123.50	75.85%
321	Pemetrexed	100mg Injection	Pemmet	5450.00	1344.18	75.34%
322	Pemetrexed	500mg Vial	Pemotide 500	21403.00	5346.80	75.02%
323	Pemetrexed	100mg Injection	Pemgem 100mg inj	5373.00	1378.50	74.34%
324	Pemetrexed	100mg Powder to Injection	PEMAXAM-100	3080.00	801.84	73.97%
325	Pemetrexed	100 mg Injection	PEMCURE	3800.00	1034.00	72.79%
326	Pemetrexed	500mg Injection	Pemmet	19075.00	5467.60	71.34%

327	Pemetrexed	500mg Single Dose	Giopem	13125.00	4074.00	68.96%
328	Pemetrexed	100 mg injection	PEMECAD 100 MG	6080.61	1909.00	68.61%
329	Pemetrexed	100mg Injection	PEMETERO	2750.00	1014.00	63.13%
330	Pemetrexed	100mg Vial	Pemotide 100	5268.40	2140.90	59.36%
331	Pemetrexed	100mg Injection	Antifol	2300.00	936.29	59.29%
332	Pemetrexed	500mg Injection	Antifol	8500.00	3905.17	54.06%
333	Pemetrexed	100 mg inj	Benzpee	2100.00	1024.00	51.24%
334	Pemetrexed	100mg Inj	Pexotra	2000.00	1050.00	47.50%
335	Pemetrexed	500 mg inj	Benzpee	8100.00	4289.00	47.05%
336	Pemetrexed	100mg Injection	PEXITAZ 100 MG INJECTION	2516.75	1339.88	46.76%
337	Pemetrexed	100mg Single Dose	Giopem	2990.00	1606.00	46.29%
338	Pemetrexed	500mg Injection	PEXITAZ 500 MG INJECTION	12785.05	7115.23	44.35%
339	Pemetrexed	500 mg/ vial Injection	PEMEPLAST-500	4299.00	2506.02	41.71%
340	Pemetrexed	500mg Inj	Pexotra	8000.00	4690.00	41.38%
341	Pemetrexed	100 mg /vial Injection	PEMEPLAST-100	904.00	634.53	29.81%
342	Pemetrexed	100 mg Injection	ZUPEMED	4550.00	960.00	78.90%
343	Pemetrexed	100 mg Injection	Relitrexed	5500.00	1272.46	76.86%
344	Pemetrexed	500 mg Injection	Relitrexed	20900.00	5461.33	73.87%
345	Pemetrexed	500 mg Injection	ZUPEMED	14900.00	4246.00	71.50%
346	Pemetrexed 100mg	100mg Inj.	Adpem 100	5350.00	1014.00	81.05%
347	Pemetrexed 500mg	500mg Inj.	Adpem 500	19500.00	4416.00	77.35%
348	Pemetrexed Disodium 100mg+mannitol 106mg(Per Vial)	100mg Injection	PEMEXAR (Injection)	5000.00	1141.00	77.18%
349	Pemetrexed Disodium 500mg+mannitol 500mg(Per Vial)	500mg Injection	PEMEXAR (Injection)	19000.00	4249.00	77.64%
350	Plerixafor	24 mg Inj	IRANSEZE	75000.00	45685.99	39.09%
351	Plerixafor	20mg Injection	Stemfor	39950.00	33222.97	16.84%
352	Pomalidomide	2mg Capsules	Pomavia	9980.00	5748.00	42.40%
353	Pomalidomide	4mg Capsule	POMALONG	20000.00	12000.00	40.00%
354	Pomalidomide	1mg Capsule	POMALONG	5000.00	3000.00	40.00%
355	Pomalidomide	1mg Capsule	POMAHOPE 1MG	5500.00	3680.02	33.09%
356	Pomalidomide	4mg capsule	Pomacel	20000.00	14200.00	29.00%
357	Pomalidomide	4mg Capsule	MYHB	20000.00	14201.00	29.00%
358	Pomalidomide	1mg Capsule	MYHB	5000.00	3590.00	28.20%
359	Pomalidomide	1 mg capsule	Pomacel	5000.00	3600.00	28.00%
360	Pomalidomide	4mg Capsule	IBIPOLID 4	20000.00	14400.00	28.00%
361	Pomalidomide	4mg Capsule	Pomiat	20000.00	14868.00	25.66%
362	Pomalidomide	2mg Capsule	MYHB	10000.00	7497.00	25.03%
363	Pomalidomide	4mg Capsules	Pomavia	21880.00	16432.00	24.90%
364	Pomalidomide	4mg Capsule	Pomired 4mg capsule	21000.00	16021.00	23.71%
365	Pomalidomide	3mg capsule	Pomacel	15000.00	11650.00	22.33%
366	Pomalidomide	4mg Capsule	Pomyelo	20000.00	15805.22	20.97%
367	Pomalidomide	2mg Capsule	POMAHOPE 2MG	10000.00	7916.21	20.84%
368	Pomalidomide	2 mg capsule	Pomacel	10000.00	8100.00	19.00%
369	Pomalidomide	1 mg Capsule	IBIPOLID 1	5000.00	4176.00	16.48%
370	Pomalidomide	4mg Capsule	POMAHOPE 4MG	21000.00	17955.74	14.50%

371	Pomalidomide	2mg Capsule	Pomiat	10000.00	8800.00	12.00%
372	Pomalidomide	2mg Capsule	Pomyelo	10000.00	9047.77	9.52%
373	Pomalidomide	1mg Capsule	Pomyelo	5000.00	4586.70	8.27%
374	Pomalidomide	2 mg Capsule	IBIPOLID 2	10000.00	9219.28	7.81%
375	Pomalidomide	1mg Capsule	Pomiat	5000.00	4640.00	7.20%
376	Pomalidomide	3mg Capsule	POMAHOPE 3MG	16000.00	15199.99	5.00%
377	Pomalidomide	2mg Capsule	Pomired 2mg capsule	10500.00	10371.50	1.22%
378	Pomalidomine	1mg Capsule	POMIDE	5040.00	3084.00	38.81%
379	Pomalidomine	2mg Capsule	POMIDE	9975.00	7572.00	24.09%
380	Pomalidomine	4mg Capsule	POMIDE	19740.00	16567.00	16.07%
381	Regorafenib	40 mg tab	Nublexa	59294.00	36965.00	37.66%
382	Regorafenib	40mg Tablet	Resihance	42385.10	42194.57	0.45%
383	Sunitinib	25mg Capsules	Sutent 25mg Capsules (Capsules)	30501.71	29204.51	4.25%
384	Sunitinib	12.5mg Capsules	Sutent 12.5mg Capsules (Capsules)	15250.52	14786.42	3.04%
385	Triptorelin	11.25mg Injection	Pamorelin LA 11.25	20055.00	17876.50	10.86%
386	Triptorelin	3.75mg Injection	Pamorelin LA 3.75	8137.50	7506.00	7.76%
387	Triptorelin	22.5mg Injection	Pamorelin LA 22.5	38000.00	36409.00	4.19%
388	Triptorelin Acetate Injection	3.75mg Injectable	Decapeptyl Depot	7259.85	6231.17	14.17%
389	Triptorelin Acetate Injection	50mg Injectable	Gonapeptyl	10145.00	9581.10	5.56%
390	Triptorelin Acetate Injection	0.1mg/ml Injectable	Decapeptyl 0.1mg	2454.76	2361.62	3.79%



(Published in Part II, Section 3, Sub Section (ii) of the Gazette of India Extraordinary)

Government of India  
Ministry of Chemicals and Fertilizers  
Department of Pharmaceuticals  
National Pharmaceuticals Pricing Authority

New Delhi, 27th Feb 2019

**ORDER**

SO. 1041(E) Whereas the National Pharmaceutical Pricing Authority (NPPA) was established vide Resolution No. 33/7/97-PI.I dated 29<sup>th</sup> August 1997 of the Government of India in the Ministry of Chemicals and Fertilizers to fix/revise, monitor prices of drugs/formulations and oversee the implementation of the Drugs (Prices Control) Order (DPCO); and whereas the Government of India by S.O. 1349(E) dated 30<sup>th</sup> May 2013 in exercise of the powers conferred by Section 3 and 5 of the Essential Commodities Act, 1955 (10 of 1955) has delegated the powers in respect of paragraphs 4,5,6,7,8,9,10,11,12,13,14,15,16,18,19, 20,21,23,24,25,26,27,28,29,30 and 32 of the DPCO, 2013 to the NPPA to exercise the functions of the Central Government;

02. And whereas the aim of the DPCO, 2013 issued under section 3 of Essential Commodities Act, 1955, is to ensure that essential drugs are available to all at affordable prices.

03. And whereas, the Hon'ble High Court of Karnataka by judgment dated 12<sup>th</sup> November 2002 in WP no. 21618/2002 (*K.S.Gopinath & others vs. Union of India*) directed the Government to ensure that lifesaving drugs do not fall out of price control, which was reiterated by the Hon'ble Supreme Court of India in its order dated 31.03.2011 in CA No. 9218/2003.

04. And whereas, the Indian pharmaceutical industry is valued at US \$ 34 billion, about 50 percent of which is exported to other countries. India is called the Pharmacy of World. However, due to prevalent inequalities, out of pocket expenditure on medicines is the single largest contributor to pushing families beyond poverty threshold in the country. Thus, ensuring affordable drugs is a necessary pre-requisite for bringing down the overall healthcare expenses and to achieve the overall goal of affordable healthcare for all.

05. *And whereas, the judgment dated 19.03.2013 of the Hon'ble High Court of Punjab & Haryana in CRL Misc. No. M-14171 of 2008 (Ranbaxy Laboratories Limited vs. The State of Haryana & ors.) noted as under:*

*"Before parting the judgment it has been noticed that although the petitioner is allegedly selling the drug in question to the consumers at about 900% of reasonable price of drug, but there appears to be no legal provision in force to save the consumer from such naked fleecing of consumers by the petitioner or other drug manufacturers by – pricing the drug to such an extent. It is surprising no remedial or ameliorating step*

*has been taken either by State or by Union of India in this regard. The court hopes that now at least the concerned authority shall wake up and shall take some remedial step to save the consumers from such fleecing.”*

06. And whereas, the Authority noted that while the scheduled formulations currently under price cap form 16-17 percent of the pharma industry, the only control on the remaining non-scheduled drugs is by ensuring that the annual price increase is not more than 10 percent. The Government has been examining options for rationalisation of prices in this segment in a graded manner. *One major factor that contributes to high drug prices in India, is the unreasonably high trade margins.* Trade margin is the difference between the price at which the manufacturers sell the drugs to stockist / distributors (price to stockist) and the final price to patients (maximum retail price).

07. And whereas the Authority noted that the matter with regard to regulation of Trade Margin has been under discussion since a long time. The matter pertaining to trade margins had been discussed in the interim Report of Sandhu Committee constituted by Department of Chemical and Petrochemicals submitted in November, 2004. Subsequently, the *Committee on ‘High Trade Margin in the sale of drugs’ submitted a Report on 09.12.2015, after holding large scale consultation with various stakeholders.* Representations received by the Committee along with drug name alleged that Trade Margin allowed to retailers goes upto even 1800% or more. This Report inter-alia stated that ‘It is neither the desire nor is it possible for the government to interfere in the day to day business activities of the industry. Government is, however, committed to saving the consumers from such naked fleecing as rightly pointed out by the Hon’ble Punjab & Haryana High Court. Consumer protection is, however, an area where the Government has to regulate especially in the knowledge based industry like drugs where the consumer has little choice. The consumer is guided by the prescription / medicine dispensed by a doctor. He has to pay as per MRP, with or without discount. None of the DPCOs had capped MRP which is the guiding factor / purchase price for the consumer. There are no laws which control MRP / trade margin. Capping of trade margins is therefore necessary. The Committee recommends that intra trade margins could be decided by the industry subject to a cap to be notified by the Government from time to time.’

08. And whereas, the Competition Commission of India (CCI) in its policy note titled ‘Making Market Work for Affordable Healthcare’ (October 2018) has observed that ‘the pharmaceutical sector is characterized by information asymmetry and supplier-induced demand that significantly circumscribes consumer choice, a condition necessary for well-functioning markets. In the absence of agency with the consumer, various industry practices flourish which do not allow markets to work effectively and efficiently. One major factor that contributes to high drug prices in India is the unreasonable high trade margin. The high margins are in form of incentive and an indirect marketing tool employed by drug companies.

09. *And whereas, considering the High trade margin in sale of drugs leading to high out of pocket expenses on healthcare, the Government hereby, seeks to undertake the matter of price control through a ‘Trade Margin Rationalisation Approach’. And therefore, in order to bring in regulation of drugs in the ‘non-scheduled’ segment the Government*

*hereby seeks to undertake a Pilot for Proof of Concept by capping prices of select Anti-Cancer drugs, identified by the MoHFW as being essential for the treatment of this disease.*

10. And whereas, the Authority noted that 'Cancer is one of the leading causes of adult illness and death due to chronic and non-communicable diseases (NCD) in India. As per WHO estimate, there are approximately 18 million cases globally and 1.5 million in India alone. There were 8 lakhs cancer deaths in India in 2018. The number of new cases are estimated to rise to double in India in 2040. The financial burden associated with cancer can force patients and households to acute misery and even insolvency. It is also noted that out of pocket (OOP) expenditure on cancer hospitalization is about 2.5 times of overall average hospitalization expenditure. While catastrophic expenditure on cancer inpatient treatment is highest among all NCDs, poor health financing mechanisms and heavy reliance on out-of-pocket healthcare payments compels several cancer patients to resort to distressed means for treatment financing. *In fact, some studies on India suggest that about 60 and 32 percent households resort to borrowings and contributions (from friends and relatives) respectively for cancer hospitalization. It is estimated that almost more than 50% cancer patients avail the private sector facilities and out of pocket expenses in the Health care including cancer care is about around 65%.*

11. And whereas, a disease centric approach on cancer assumes salience because of specific national policy commitments to ensure universal access to healthcare at affordable prices. Although, provisioning and access to cancer treatment has been an important item on the public health agenda but the policy intent cannot proceed very far without understanding the socioeconomic pattern in cancer prevalence, treatment-seeking and financing. Cancer patients in India incur heavy out-of-pocket expenditures. The cancer drugs needs to be affordable so that whenever required the treatment can be provided at the earliest in the early stages when the cancer treatment is curable. The Authority noted that availability and affordability of cancer drugs will give impetus to treatment outcomes and will bring down the cost of common anti-cancer drugs will increase affordability and accessibility of these drugs.

12. And whereas, it is also noted that the list of medicines specified in the National List of Essential Medicines (NLEM) which are included in the First Schedule of Drug Pricing Control Order (DPCO), 2013 also contain drugs used for the treatment of Cancer. NLEM has 376 medicines out of which 59 drugs are already under the category of Anti-neoplastic/immunosuppressive, Hormones & Antihormones and medicines used for palliative care. Pricing of these medicines are controlled through Drug Pricing Control Order (DPCO) 2013 as amended from time to time.

13. And whereas, 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 43 Anti-Cancer medicines for price control on pilot basis, Imatinib mesylate being scheduled is already under price cap, hence excluded from the current exercise.

14. Now, therefore, in the exercise of the powers vested by the Government of India in the Ministry of Chemicals and Fertilizers, having been satisfied that in view of the extraordinary circumstances in public interest, as explained above, the Government hereby decides to invoke the provisions of paragraph 19 of the DPCO, 2013.

15. ***And whereas, invoking paragraph 19 of DPCO, 2013, the Government hereby puts a cap on trade margin of 30% and directs manufacturers to fix their retail price based on price at first point of sale of product (hereinafter referred as Price to Stockist), as formulated in Table A, of the non-scheduled formulations containing any of the 42 drugs listed in Table B (whether individual or in combination, irrespective of dosage strength, dosage form and /or route of administration):***

**Table A**

<p><b>Retail price of the product = Price to Stockist (PTS) x <math>\left\{1 + \left(\frac{TM}{100-TM}\right)\right\}</math></b></p> <p><b>Where TM = Trade Margin not exceeding 30</b></p> <p><b>Where PTS = PTS for the month of June, 2018</b></p>
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**Table B**

Sl. No.	Name of the Drug
1	Azacitidine
2	Bendamustine Hydrochloride
3	Bortezomib
4	Crizotinib
5	Cytarabine
6	Dasatinib
7	Decitabine
8	Doxorubicin HCl Pegylated Liposomal Injection
9	Enzalutamide
10	Epirubicin
11	Eribulin mesylate
12	Erlotinib HCl
13	Estramustine phosphate
14	Everolimus
15	Exemestane
16	Fulvestrant
17	Irinotecan HCl Trihydrate
18	Lapatinib
19	Leuprolide acetate depot for Inj.
20	Lomustine
21	Mitoxantrone
22	Nilotinib
23	Plerixafor



24	Carfilzomib
25	Cladribine
26	Triptorelin
27	Pomalidomide
28	Osimertinib
29	Pegasperagase
30	Regorafenib
31	Ribociclib
32	Clofarabine
33	Sunitinib
34	Olaparib
35	Olaratumab
36	Paclitaxel (Protein-bound particles)
37	Cabazitaxel
38	Bevacizumab
39	Lenalidomide
40	Pegfilgrastim
41	Mitomycin
42	Pemetrexed

16. Further, in the exercise of the powers vested by the Government of India in the Ministry of Chemicals and Fertilizers under paragraph 9(2) of the DPCO, 2013, hereby directs manufacturer to provide the information in **Annexure I** in respect of the non-scheduled formulations containing drugs as per Table B, irrespective whether there is any change in MRP or not, by 6<sup>th</sup> March, 2019.

**Notes:**

a) Every manufacturer shall recalculate its MRP as stated above for its product based on the average first point of sale computed on the basis of PTS for the month of June-2018 as follows:

$$\text{Price to Stockist (PTS)} = \frac{\text{(Sum of Net sales realization of product by the manufacturer as the case may be for the sales during June-2018)}}{\text{Total Quantity of such product sold in June-2018}}$$

b) In case there is no sale during the month of the June-2018, the Price to Stockist (PTS) shall be

$$\text{Price to Stockist (PTS)} = \frac{\text{(Sum of Net sales realization of product by the manufacturer as the case may be for the sales during 2018)}}{\text{Total Quantity of such product sold in the 2018}}$$

- c) The manufacturers may add Goods and Services Tax (GST), as applicable to arrive at the MRP.
- d) For the purpose of this Order any formulation being supplied by the manufacturers directly to the hospitals, in such case, hospital will be treated as stockist.
- e) The revised prices shall come into effect from 8<sup>th</sup> March, 2019 based on the information available / provided by manufacturers as per paragraph 16 of this Order.
- f) Annexure I contains details of PTS and MRP arrived for formulations by using the formula prescribed in Table A, to be submitted by the manufacturers to NPPA with copy to concerned State Drug Controller.
- g) The manufacturers of non-scheduled formulations, selling branded or generic or both the versions of formulations at MRP higher than the retail price (plus goods and services taxes as applicable) so computed as per Table A, shall revise the prices of such formulations downward not exceeding the retail price computed by above formula plus goods and services taxes as applicable, if any.
- h) All the existing manufacturers of formulations having MRP lower than the retail price (plus goods and services taxes as applicable) so computed as per Table A, shall maintain the MRP and not increase any price based on the basis of formula as per Table A.
- i) The manufacturer shall issue a price list in Form-V as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS not later than 06.03.2019 and submit a copy to State Drug Controller and dealers.
- j) As per para 24(4) of DPCO 2013, every retailer, dealer, hospital and institution shall display price list and the supplementary price list, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.
- k) The manufacturers of the formulations are required to maintain the present production levels. Any manufacturer intending to lower the average monthly production levels will seek prior permission from NPPA. Further, any manufacturer intending to discontinue production of above said formulations shall furnish information to the NPPA, in respect of discontinuation of production and / or import of said formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.
- l) The manufacturers not complying with the retail price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955. The overcharged amount shall be the difference between MRP (excluding taxes) less retail price computed as per Table A in respect of sale.
- m) The price so fixed shall be valid for one year from the date of notification.
- n) The price computed for non-scheduled formulations (all strengths and doses form) (whether individual or in combination, irrespective of dosage strength, dosage form and /or

route of administration) under this Order containing any of the drugs listed in Table A shall be applicable even if the formulation is being used for other therapeutic uses.

o) Consequent to the issue of retail price formula in the Table A, of such formulations as specified in Table B in this notification, the price order(s) fixing ceiling under para 4, or retail price under para 5 & 15, if any, issued prior to the above said date of notification, stand(s) superseded.

p) Henceforth, all the manufacturers are required to compulsorily report PTS and MRP of their formulations in the SUGAM portal of The Central Drugs Standard Control Organisation (CDSCO).

q) Since substantial supply of cancer drugs is directly made to Hospitals, the Superintendents of Hospitals and Medical Institutions are required to monitor the MRP's of formulations, as per this Order, and to ensure compliance. Any violation of this Order is required to be brought to the notice of NPPA.

r) State Drug Controllers shall monitor the compliance of this Order by the manufacturers / dealers / Hospitals / Medical Institutions and the manufacturers / dealers / Hospitals / Medical Institutions shall assist the State Drug Controllers in verifying the compliance to this order. Any violation of this Order is required to be brought to the notice of NPPA.

PN/196/64/2019/F

F. No. 8(64)/2019/D.P./NPPA-Div.-II

(Shubhra Singh)  
Chairperson

ANNEXURE : I

Format for submission of Revised MRP by the manufacturer

1. Name and address of the manufacturer / importer / distributor.

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

Sl. No	Formulation				Composition approved by Drug Control Authorities	Pack Size	Price to Stockist (excl. of GST) (Rs.) as in June, 2018	Applicable GST Rate	Maximum Retail Price Arrived by applying the formula in Table A (incl. of GST) (Rs.)
(1)	(2)				(3)	(4)	(5)	(6)	(7)
	Drug	Strength	Dosage Form	Brand Name					

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

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 Organisation/person: