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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:

(Sum of Net sales realization of product by the manufacturer as the case may be for the sales during June-2018)

**Price to Stockist (PTS) =** -----  
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

(Sum of Net sales realization of product by the manufacturer as the case may be for the sales during 2018)

**Price to Stockist (PTS) =** -----  
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: