



DYNAMICS IN DPCO 2017: A BOON TO LIFE SAVING MEDICINES

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ABSTRACT

National Pricing Pharmaceutical Authority of India has initiative in revising the retailing drug price on pharmaceuticals all over India. This article will help to know the new prices according categories of drug and its impact with GST. To achieve the main objective of DPCO, to achieve the drugs at reasonable prices, the regulations assigned on framing of ceiling price with new dynamic changes in DPCO pharmaceutical world.

Key words: DPCO, GST, NPPA, CGST, SGST, IGST.

INTRODUCTION

It is to make Indian pharmaceutical companies globally competitive, amendments were made to DPCO, from time to time, and several concessions were offered for promotion of indigenous R&D efforts. DPCO is a Government Order notified by Ministry of Chemicals and Fertilizers, Department of Chemicals, dated 6.1.1995 for regulating the price structure of certain [1]. The retail price of a formulation shall be calculated by the Government in accordance with the following formula namely: $R.P. = (M.C. + C.C. + P.M. + P.C.) \times (1 + MAPE/100) + ED$ [2-4]

Where *R.P.* means retail price;

M.C means material cost and includes the cost of drugs and other pharmaceutical aids used including overages, if any, plus process loss There on specified as a norm from time to time by notification in the Official Gazette in this behalf;

C.C means conversion cost worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf;

P.M. means cost of the packing material used in the packing of concerned formulation, including process loss, and shall be fixed as a norm every year by, notification in the Official Gazette in this behalf;

P.C. means packing charges worked out in accordance with established procedures of costing and shall be fixed as a norm every year by notification in the Official Gazette in this behalf; "MAPE" (Maximum Allowable Post-manufacturing Expenses) means all costs incurred by a manufacturer from the stage of ex-factory

cost to retailing and includes trade margin and margin for the manufacturer and it shall not exceed one hundred per cent for indigenously manufactured Scheduled formulations

E.D. means excise duty, Provided "landed cost" means the cost of import of formulation inclusive of customs duty and clearing charges.

MATERIALS AND METHODS

Average Price to Retailer, P(s)

= (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)

Procedure For Calculation of Ceiling price According to new DPCO with impact of GST: The authority in its 46 th meeting held on 08.06.2017 has decided to notify ceiling prices of scheduled formulations, exclusive applicable GST rates, after the GST rates are notified by the Government, as detailed below:

In case of scheduled formulation, were presently excise duty is levied on MRP, the revised ceiling price exclusive of applicable GST rates would be calculated by applying a factor of 0.95905 to the existing notified ceiling price. The factor has been implanted in following way: Accordingly the impact of the above may be summarized as below:

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In case of schedule formulations, which are exempted from excise duty, no multiplication factor would be applicable. The existing notified ceiling price would be the ceiling price exclusive of gst rates are applicable. In case of nonscheduled formulations, paragraph 20 of DPCO, 2013 need to be followed irrespective of any change in the tax rates, the companies will have no option but to absorb the net increase, if anything the incidence of tax on implementation of GST within the permissible limit of 10% for increase of MRP compared to MRP of preceding 12 months as prescribed under paragraph 20 of DPCO, 2013 [3].

Effect of GST On Ceiling Price

Drug price regulator NPPA has declared a provisional ceiling prices of 761 medicines, including anti-cancer, HIV, diabetes and antibiotic, with a majority being reduced ahead of the GST implementation.

The actual price increase or decrease in drug prices post GST is nominal ranging between 2-3 percent. As per the provisional list, ceiling price of various cancer drugs like Bortezomib, Docetaxel and Gemcitabine have been reduced. Ceiling price of Bortezomib has been fixed at Rs 11,160.08 per pack, down from Rs 11,636.60 at present while that of a pack of Docetaxel has been fixed at Rs 10,326.94 from Rs 10,767.88 currently. Similarly,

price of Gemcitabine will come down to Rs 4,813.94 per pack from the current Rs 5,019.49. Also, breast cancer treatment medicine Trastuzumab injection pack has been fixed at Rs 54,582.25 post July 1, down from Rs 56,912.83 earlier. Ceiling price of HIV combination drug of Tenofovir (300mg), Lamivudine (300mg) and Efavirenz (600mg) has been fixed at Rs 89.69 per tablet, down from Rs 93.52 per tablet earlier. Price of one tablet of HIV treatment drug Darunavir has been fixed at Rs 151.4, down from Rs 157.93. Besides cost of one tablet of Lamivudine and Zidovudine combination has been reduced to Rs 18.20 from Rs 18.98 currently. Ceiling price of Eplilepsy drug Levetiracetam reduced. Price of single tablet of Diabetes drug Metformin has come down to Rs 3.31 from Rs 3.45 currently. Paracetamol 500 mg tablet cost has been fixed at Re 0.82 from Re 0.85. Ceiling price of drug eluting stents will however remain unchanged at Rs 30,180. Ceiling price of Atorvastatin tablets, used to treat hypertension, has also been reduced. Similarly, the ceiling prices of various antibiotics like Azithromycin, Ciprofloxacin, Clarithromycin, Ampicillin, Amoxicillin have also been lowered. Ibuprofen and Imatinib prices are also fixed at a lower slab Price of one tablet of Entecavir, used to treat Hepatitis B, has come down to Rs 69.44 from Rs 72.40 [2].

Table 1. Methods for Calculation of Ceiling Price OF Scheduled medicines

Steps involved	Formula	Condition
I	Average Price to Retailer, P(s)	ceiling price of a scheduled formulation.
II	$P(c) = P(s).(1+M/100),$	
I	$P(s) = Pm\{1-(P_1+P_2+\dots)/(N*100)\}$	Ceiling price of a scheduled formulation in case of no reduction in price due to absence of competition ceiling price of a scheduled formulation [4].
II	$P(c) = P(s).(1+M/100),$	
Maximum Retail Price	Maximum Retail Price = Ceiling price + Local Taxes as applicable	Max.retail price of scheduled formulations
	Maximum Retail Price = Retail Price + Local Taxes as applicable	maximum retail price of a new drug

Table 2. List of schedules medicines by DPCO

Schedule	Contents in schedule
I	List of 76 drugs
II	forms to be submitted
III	maximum pre-tax return on sales turnover:
	Category A more than 6 crores per annum
	Category B turnover between Rs. 1 crore to Rs.6 crores per annum
	Category C turnover of less than 1 crore per annum.

Table 3. Computation of the factor to arrive at the revised ceiling prices

computation of the factor to arrive at the revised ceiling prices		(Rs.)
a	Ceiling price fixed before 30.6.2017(Incl.Excise Duty)	100
b	Add: Local Taxes/VAT on above (@5%)	5
c	MRP (inclusive of all taxes)	105
d	Less: Excise Duty of the 6% on 65% of MRP	4.095
e	Less: Local taxes /VAT as applicable	5
f	Revised Ceiling price to be re-notified (excluding GST)	95.905
	FACTOR(f/a)	0.95905

Table 4. Existing MRP structure of Scheduled Formulation

Existing MRP structure of Scheduled Formulation		(Rs.)	GST MRP structure of Scheduled Formulation	(Rs.)
A	Ceiling price fixed before 30.6.2017(Incl.Excise Duty)	100	Ceiling Price to be notified Conversion Factor.95905	95.905
b	Add: Local Taxes/VAT on above (@5%	5	Add: GST on above (@12%)	11.509
c	MRP (inclusive of all taxes)	105	MRP (inclusive of all taxes	107.41
d			Impact (Increase% /Decrease %) 2.30	2.30

Table 5. Difference of between Pre-GST & Post GST

Particulars	Pre-GST	Post GST
Job Work and Loan License Model	Supplies to loan licensee: No VAT Formulations cleared by job-worker to loan licensee is subject to excise based on MRP minus abatement. Processing charges paid to loan licensee: no service tax.	Special provisions for movement of goods without payment of GST subject to permission
Stock transfer and supply chain issue	No tax on stock transfer MRP-based valuation	GST on inter-state stock transfer. No clarity on intra-state stock transfer. Stock transfer between two business segments/verticals having different GST.Registrations in same state subject to CGST and SGST. Valuation will be based on the transaction value [5]

CONCLUSION

The implementation of GST on pharmaceuticals finished products has played a crucial and beneficial to cure the chronic to acute diseases in India.GST is more effective on reducing the prices of life saving drugs.It has also a optimistic effect on following:

ACKNOWLEDGEMENT

Nil

CONFLICT OF INTEREST

No interest

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