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

New Delhi, the 10th July, 2014

ORDER

S.O. 1765(E) - Whereas the National Pharmaceutical Pricing Authority (NPPA) was established vide the Resolution of the Government of India in the Ministry of Chemicals and Fertilizers No. 33/7/97-PI.I dated 29th August, 1997 inter alia, to fix prices and notify the changes therein, if any, of bulk drug and formulations, monitor the prices of decontrolled drugs and formulations and oversee the implementation of the provisions of the Drugs (Price Control) Order (DPCO).

2. And whereas the aim of the DPCO is to ensure that essential drugs are available to all at affordable prices, and the Hon'ble Supreme Court of India vide their Order dated 12.11.2002 in SLP no. 3668/2003 (Union of India vs K.S. Gopinath & others) have directed the Government to ensure that essential and life saving drugs do not fall out of the price control, which has the force of law.

3. And whereas the Ministry of Chemicals and Fertilizers vide S.O.1394(E) dated the 30th May, 2013, in exercise of the powered conferred by Section 3 and 5 of Essential Commodities Act, 1955 has delegated the powers in respect of specified paragraphs of the DPCO,2013, including paragraph 19 of the said order to be exercised by the NPPA on behalf of the Central Government.

4. And whereas paragraph 19 of DPCO *inter alia* authorises the Government, in extraordinary circumstances, if it considers necessary so to do in public interest, fix the ceiling price or retail price of any drug for such period as it deems fit.

5. And whereas the NPPA, which has been delegated with the powers of the Government in this regard, is of the considered view that there exist huge inter-brand price differences in branded-generics/ off patent drugs, which is indicative of a severe market failure, as different brands of the same drug formulation, including the off patent drug, which are identical to each other in terms of active ingredient(s), strength, dosage, route of administration, quality, product characteristics, and intended use, vary disproportionately in terms of price.

6. And whereas it is observed that, the different brands of the drug formulation may sometimes differ in terms of binders, fillers, dyes, preservatives, coating agents, and dissolution agents, but these differences are not significant in terms of therapeutic value.

7. And whereas the market failure in respect of pharmaceuticals in the context of India can be attributed to several factors, but the main reason is that the demand for medicines is largely prescription driven and the patient has very little choice in this regard.

8. And whereas market failure alone may not constitute sufficient grounds for government intervention, but when such failure is considered in the context of the essential role of pharmaceuticals play in the area of public health, which is a social right, such intervention becomes necessary, especially when exploitative pricing makes medicines unaffordable and beyond the reach of most and also puts huge financial burden in terms of out-of-pocket expenditure on healthcare.

9. And whereas the NPPA has considered this matter in detail at its 147th meeting held on 16.05.2014 and approved objective guidelines for fixation/ revision of price of non-scheduled drugs showing extreme inter-brand price differences, under paragraph 19 of DPCO 2013. It has decided that, to start with inter-brand price variation will be examined in respect of single ingredient formulations in eight therapeutic groups, namely, anti-cancer, HIV/ AIDS, anti-TB, anti-malaria, cardiovascular, anti-diabetics, anti-asthmatic, and immunological (sera/ vaccines); and wherever the maximum retail price (MRP) of the brand(s) of medicine of a particular formulation exceeds 25 per cent of the simple average price the same will be capped at the 25 per cent level.

10. And whereas the Authority noted that there is very high incidence of cardiovascular disease (CVD) in the country, which is estimated to affect around 10 per cent of the population and is responsible for 25% of the deaths in the age group of 25-69

11. Whereas the National Pharmaceutical Pricing Authority monitors the prices of decontrolled (non-scheduled) formulations on regular basis and wherein, from the data obtained from IMS Health, it was observed that prices of Nebivolol Tablets in the strength of 2.5mg manufactured / marketed in brand name by the respective company namely M/s.Micro Labs were found exceeding the limit of simple average price of the medicine plus 25% as per market based data provided by M/s IMS-Health for the month of April, 2014. In accordance with the guidelines issued by the NPPA, after approval of the Competent Authority, in respect of price fixation of non-scheduled formulations under para 19 of DPCO, 2013, prices of such formulations, as specified in the table below, manufactured / marketed by the above mentioned company(ies) were unjustified and against public interest as much as it puts an unreasonable burden on the consumers without sufficient justification.

12. Now, therefore, in exercise of the powers delegated under para 19 of the Drugs (Prices Control) Order, 2013 vide S.O. No. 1394(E) dated 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and thereafter, the National Pharmaceutical Pricing Authority being satisfied that it is necessary in the public interest to do so, hereby notifies the maximum retail price including excise duty and local taxes, of the following formulation pack

manufactured / marketed in brand name by M/s.Micro Labs as applicable, as per the details herein under:-

TABLE

Sl. No.	Name of the Formulation	Strength	Unit	Maximum Retail Price (including excise duty* and local taxes). In Rs.
(1)	(2)	(3)	(4)	(5)
1	Nebivolol Tablets	Each Tablet contains Nebivolol 2.5mg	One Tablet	5.64

*** subject to actual payment of excise duty + local taxes.**

13. The maximum Retail Price fixed as above shall be implemented by the concerned companies named above as per the provision of the DPCO, 2013 by issuing a price list in form V in accordance with the provisions of paragraph 25 of the said order.

14. The maximum price fixed as above under paragraph 19 of DPCO,2013 shall be maintained for a period of one year from the date of notification after which annual price increase not exceeding 10% of the maximum retail price will be permissible under paragraph 20 (1) of the said order.

15. In case of failure / non-compliance of para 5 and 6 above, the manufacturer /marketer shall be liable to deposit the overcharged amount alongwith the interest thereon from the date of notification and / or date of price increase beyond 10%, as the case may be.

16. The manufacturer / marketing company for the above said formulation shall be jointly and severally responsible to comply with this order and conditions mentioned herein above.

PN/148/2014/NPPA

F. No. 23(1)/2014/Div-III/NPPA

(Injeti Srinivas)
Chairman
National Pharmaceutical Pricing Authority