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

New Delhi, the 9th September, 2014

ORDER

S.O.2292(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 revisions, if any, of drugs, monitor the prices and availability of scheduled and non-scheduled drugs and oversee the implementation of the provisions of the Drugs (Price Control) Order (DPCO); and

2. 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; and

3. And whereas the Ministry of Chemicals and Fertilizers vide S.O.1394(E) dated the 30th May, 2013, in exercise of the powers conferred by Section 3 and 5 of Essential Commodities Act, 1955 has delegated the powers in respect of specified paras of the DPCO, 2013, including para 21(1) and para 29 of the said order to be exercised by the NPPA on behalf of the Central Government.

4. And whereas para 21(1) of DPCO inter alia authorises that the Government, shall monitor the production and availability of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulation and the manufacturer of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulation shall furnish the information as stated in Form-III of schedule-II of this Order quarterly.

5. And whereas para 29 of DPCO provides that every manufacturer shall maintain records relating to the sales of individual active pharmaceutical ingredients or bulk drugs manufactured or imported and marketed by him, as the case may be, and the sales of formulations units and packs and also such other records as may be directed from time to time by the Government and the Government shall have the power to call for any record and to inspect such records at the premises of the manufacturer.

6. And whereas the NPPA, which has been delegated with the powers of the Government in this regard, is of the considered view that every manufacturer shall maintain the production level and adequate supply of the medicines and also ensure submission of the information in Form- III of the Schedule -II of the DPCO, 2013 quarterly. Further the manufacturer shall keep the records ready for producing before the Government and / or inspection thereof.

7. And whereas the scarcity of certain essential medicines, namely, Anti-Snake Venom, Rabies vaccine, Rabies Immunoglobulin, Albumin Injection and Anti-malarial combination of Sulfadoxine + Pyrimethamine Tablets has been reported to the NPPA and in absence of regular reporting under DPCO, 2013 by the manufacturers it appears that the concerned manufacturers are not maintaining normal supplies of these medicines in domestic market and / or Institutions. Hence, the availability of such vital and essential drugs has been affected many parts of the country.

8. Now, therefore, in exercise of the powers delegated under para 21(1) and para 29 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, in exercise of powers conferred by section 3 and 5 of the Essential Commodities Act, 1955, the National Pharmaceutical Pricing Authority after being satisfied that it is necessary in the public interest so to do, hereby direct that all the concerned manufacturers / importers shall comply with the requirements contained in para 21(1) and provide the month-wise production and sale figures for the last 12 months under para 29 of the said Order immediately to the NPPA. All the manufacturers / importers of the essential medicines specified in para 7 above shall also submit a compliance report of resolving the shortage of these drugs in the country immediately but not later than 96 hours from the date of issuance of this notification to NPPA.

9. In case of failure / non-compliance of para 8 above, the manufacturer / marketer / importer shall be liable for penal action under the relevant provisions of Essential Commodities Act, 1955.

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

PN/150/18/2014/F

F. No. 15(3)/2014/Div-III/NPPA

(Injeti Srinivas)
Chairman
National Pharmaceutical Pricing Authority