F. No. 37 (1)/2016/Div-III/NPPA
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

5th/3rd Floor,
YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi-110001

Date: 17.5.2017

OFFICE MEMORANDUM

During the monitoring of compliance of various provisions of Drug (Prices Control) Order, 2013 (DPCO 2013) by drug manufacturers, it is seen that the provisions related to 'new drugs' have not been followed by some pharmaceutical companies. These companies have launched formulations [new drugs as defined under Para 2 (u) of DPCO 2013)] by altering a scheduled formulation i) with strength/dosage other than as specified in DPCO, 2013 and/or (ii) in combination with other non-scheduled medicines without even applying for price approval from NPPA as required under Para 15 (2) of DPCO, 2013. List of such formulations/companies is attached. It is also not clear whether these formulations have the approval of CDSCO and whether these are rational or irrational combination drugs, as many of these are fixed dose combinations(FDCs).

2. DPCO, 2013 has been issued by the Central Government in exercise of the powers conferred by Section 3 of the Essential Commodities Act, 1955. Any contravention of the provisions of the DPCO, 2013 is punishable in accordance with the provisions of the Essential Commodities Act, 1955.

3. Accordingly, it has been decided to take action against these pharmaceutical companies under provisions of para 15(5) of DPCO,2013 which reads as:

"Where existing manufacturer of scheduled formulation fails to apply for prior approval of the price of the new drug in Form-I, such manufacturer shall be liable to deposit the overcharged amount over and above such price fixed and notified by the

Government, if any, along with interest thereon from the date of launch of the new drug, in addition to the penalty."

4. The concerned companies are required to furnish batch wise production and sales details along with the corresponding MRP duly certified by a Chartered / Cost Accountant for the formulations indicated in the list, from the date of launch of production till date, along with reasons for non-compliance of the provisions related to new drug, to this office positively by 15th June 2017. If the replies are not received by the stipulated date, NPPA will proceed for taking further action in the matter as per DPCO,2013 and Essential Commodities Act,1955.

5. The Pharma Industry Associations are also requested to sensitize their members to obtain prior approval of prices from this office, before launching any formulation that may be categorized as 'new drug'.

6. As the number of cases identified is high, NPPA is not in a position to issue individual 'Show Cause Notice' in all these cases because of paucity of manpower in NPPA. This O.M accordingly is deemed as Show Cause Notice as per NPPA's overpricing guidelines for dealing with such cases. On receipt of satisfactory representations, names of those companies shall be dropped from the list.

Yours faithfully

17/5/17

(**Roshni Sohni**)

Director (Enforcement)

To,

1. The Pharmaceutical Companies as per Annexure
2. All Industry Associations
3. All State Drug Controllers to monitor the issue of such 'unauthorized' launches of 'new drugs' under DPCO,2013.
4. Drug Controller General of India, with a request to verify the licences of these drugs and also the drug's 'rationality' as the case may be.
5. Department of Pharmaceuticals, for information.