

F.No: 37(01)/2016 / Div-III / NPPA
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

the 26th May, 2017

OFFICE MEMORANDUM

Sub: - Violation of different provisions under DPCO, 2013 by pharma companies.

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Based on the analysis of data provided by 'AIOCD PharmaTrac' and its verification from partial IPDMS data submitted by pharma companies, NPPA had uploaded the lists of pharma companies on the following: -

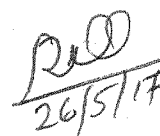
- a) For violation of ceiling price by O.M. No.35(01)/2017/Div-III/NPPA dated 20.2.2017 and 7.4.2017
- b) For violation of Para 15 of DPCO, 2013 i.e launching of 'new drugs' without prior price approval vide O.M No: 37(01)/2016/Div-III/NPPA dated 17.5.2017

2. In the light of large number of cases (634+ 612 (19 additional) + 201), it was found that sending individual preliminary notices was not feasible because of shortage of manpower in NPPA and the huge efforts and paper work involved in the process apart from precious time spent in the process. The intention of NPPA was not to create 'discomfort' for the pharma companies as it is being felt. Examination of the replies received from the pharma companies and sample purchased from market in some cases have proved that in most of the cases, NPPA database is correct and violation has taken place. Remaining replies being received from the companies are being examined. This proves the extent of non-compliance of the different provisions of DPCO, 2013 by several manufacturers. NPPA has enough database to monitor such violations and so manufacturers are requested to comply with all the provisions of DPCO, 2013 in letter and spirit.

3. However in the light of 'discomfort' of the pharma companies, the lists have been taken off from the NPPA website with a hope that the companies will now be sensitized enough to comply with different provisions of DPCO, 2013.

4. The pharma companies which have not yet submitted their replies with reference to above three lists are requested to submit the same at the earliest. NPPA has list of more such violations which has been kept on hold. It is requested that all the pharma companies on their own must check their entire portfolio and see whether the prices of all scheduled/non-scheduled and new drugs have been fixed correctly, as per provisions of DPCO,2013 and take necessary action by 30th June,2017. In case of new drugs, the prior price approval wherever required must have been taken and if not, companies are advised to complete their IPDMS filing and submit their applications to NPPA in Form I for price approval. The NPPA will publish the name of the companies where after examinations, the violation was not established.

5. The Pharma Associations are also requested to contemplate the reasons for such violation and complete their database of IPDMS as soon as possible which has not yet been done in most of the cases in spite of constant reminders, meetings, notices and untiring efforts on the part of the NPPA.


26/5/17

(Roshni Sohni)

Director (Enforcement)

Copy to:

- a) All Pharma Companies
- b) IDMA, OPPI, IPA and other Pharma Associations
- c) Department of Pharmaceuticals