F.No. 20(8)/2013/Div-III/NPPA
Government of India
Ministry of Chemical and Fertilizers
National Pharmaceutical Pricing Authority
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3rd & 5th Floor
YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi-110001.

Dated: 23rd February, 2017.

OFFICE MEMORANDUM

Subject: - Compliance and enforcement of coronary stent price cap notification No. 8(41)/2017/DP/NPPA/Div-II dated 13th February, 2017

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It has been brought to the knowledge of NPPA through its helpline and Pharma Jan Samadhan that certain hospitals (doctors) are refusing to use certain categories of coronary stents on the ground that respective company has asked them to 'hold' such (high priced) stents and not to make those available to the patients on demand. Some doctors have gone on record having said so in media. NPPA has also been informed by companies during a meeting held on 22nd February, 2017 that few hospitals are refusing to raise requirements/orders for coronary stents which were hitherto being put to use by them. Some distributors have also been quoted to have talked about shortage of stents to the press. Probability of an 'understanding' between companies, the distributors and hospitals under such a situation cannot be ruled out.

In order to curb such attempts of misinformation generation and to ensure the uninterrupted supply and usage of coronary stents of all makes on patients' demands within the ceiling price fixed and notified by NPPA, irrespective of its past MRP, the manufacturers/the importers, hospitals and cardiac care centres (as well as doctors) are reminded of the following provisions of law as provided for under DPCO, 2013 and the Essential Commodities Act, 1955 and the intent of the NPPA to ensure compliance of the same in public interest.

1. Under Para 21 of Drugs (Prices Control) Order 2013 (DPCO 2013), it is the responsibility of the Government to monitor the production and availability of scheduled drugs (coronary stents) and no manufacturer/importer/marketing company can withdraw any product from the market without following the due procedure under Para 21(2) of the Order and also the guidelines issued by NPPA dated 23rd January, 2017 in this regard.

   State Drug Controllers have already been requested to exercise the powers of entry, search and seizure under Para 30 of DPCO, 2013 based on verifiable and actionable complaints in their States.

2. Government has already invoked its powers under Para (3) of DPCO, 2013 and directed all manufacturers/importers/ marketing companies to not only maintain existing level of stocks of all brands of coronary stents but also to maintain the 'pre price capping' level and ensure its availability in future as well. NPPA will monitor the stock availability being submitted in this regard by companies.

3. Under Para 28 of the DPCO 2013, the manufacturers/importers, the distributor or dealers (for coronary stents, hospitals billing the patients as dealers), the provisions of the law are as follows: -

'(a) No manufacturer (importer) or distributor shall withhold from sale or refuse to sell to a dealer (hospitals, if billing the patients) any drug (coronary stents) without good and sufficient reasons.

(b) No dealer (hospitals if billing patients) shall withhold from sale or refuse to sell any drug (coronary stent) available with him to a customer (patient) intending to purchase such drug.'

4. NPPA has already issued instructions that recall of coronary stents from distributors or hospitals by stent companies or distributors from hospitals for the purposes of relabeling or repackaging is not mandatory if the revised price lists have been issued (as provisioned) and manufacturer/importer ensures that no patient is charged above the maximum ceiling price notified by NPPA (plus VAT/ local taxes as applicable).

5. Any hospital having a situation where stocks of any brand of any company have been exhausted and require to be replenished, is expected to have issued a written demand/ communication to the company. Without having done so, talking of shortage of stents on record is misinformation which needs to be stopped in public interest. All hospitals are advised to raise demand and mail a copy of the same to: chairman.nppa@nic.in or msecy.nppa@nic.in . NPPA will ensure the lawful compliance by companies for meeting such demands. Under no circumstances, however, any hospital (doctor) will refuse to provide any stent for whatever reason, if it has, in its inventory.

6. Similarly, if a stent company finds that any hospital or distributor has refused to take supply of stents of certain brand which it used to take during the pre-price capping period, such companies are advised to write to concerned distributor/hospital and mail a copy of the same to NPPA. Such hospitals will face inspection of its records by NPPA/SDCs. Such statement of the companies about hospitals without having issued such communication is 'misinformation'

7. In order to dispel any fear/doubt creating misinformation in the minds of the people, all manufacturers/importers are being directed to issue the above instructions and also any other

clarification to their distributors and the hospitals (stocking their stents) and to send a copy of such communication to NPPA within 72 hours of issue of this notification.

8. In case of non-compliance of these instructions, NPPA may be constrained to invoke the provisions of legal prosecution under Essential Commodities Act, 1955 , apart from other provisions under DPCO, 2013.

23/2/17

(Roshni Sohni)
Director (Monitoring & Enforcement)

Copy to –

1. All manufacturers/importers of coronary stents
2. All State Drug Controllers with a request for firm implementations of these instructions