**By Fax / E-mail**

F.No. 20(8)/2013/Div-III/NPPA
Government of India
Ministry of Chemicals & Fertilizers,
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority

3rd & 5th Floor
YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi
**Dated: 05.12.2014**

To,

M/s Abbott Healthcare Pvt. Ltd.,
M/s Boston Scientific India Pvt. Ltd.
M/s Zimmer India Pvt. Ltd.,
M/s Edwards Life Sciences Pvt Ltd.,
M/s Johnson & Johnson Limited.
**And all concerned**

M/s India Medtronic Corporate
M/s B. Braun Medical India Pvt. Ltd.,
M/s 3M India Limited.,
M/s Harsoria Healthcare Pvt. Ltd.,
M/s Roche Products India Pvt. Ltd.,

**Subject: - Monitoring of price movement of notified medical devices as drugs under DPCO, 2013.**

Sir,

There have be en reports in certain sections of print media that the prices of medical devices, regulated as 'drugs' under Drugs & Cosmetics Act & Rules there under, are sold at exorbitant price with high profit / trade margin in particular Cardiac Stents, Drug Eluting Stents, Orthopedic Implants etc. The news reports also mention that prices of such medical devices notified as 'drugs' have increased significantly during the recent past. In this regard, it may be noted that these medical devices are categorized as non scheduled formulations barring the two medical devices viz., Intra Uterine Devices (Cu-T) and Condoms falling in the scheduled category of DPCO, 2013. NPPA has already fixed and notified the prices of these two medical devices under DPCO, 2013.

Para 20 of the DPCO, 2013 provides for monitoring the prices of non scheduled formulations and to ensure that no manufacturer / importer / distributor is allowed to increase the MRP of a non scheduled drug more than ten percent of MRP during preceding twelve months and where the increase is beyond ten percent, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months. The manufactures / importer / distributor shall be liable to deposit the overcharged amount along with interest thereon, form the date of increase in price in addition to the penalty.

Further, Para 25 of DPCO, 2013 provides that every manufacture / importer shall issue a price list and supplementary price list in Form V to the dealer, State Drugs Controller and the Government from time to time. As provided in Para 26 of the said order, no person is authorized to sell any formulation including medical devices regulated as drugs to any consumer at a price exceeding the price specified in the current price list or price indicated on the label of the container or pack thereof, whichever is less.

In this regard, it has been decided to seek the following information / documents in order to examine price violation, if any, in respect of notified medical device, manufactured / imported / marketed by the company:

1. Product specification with brief description / Literature for different types of notified medical devices manufactured / imported by the company.

2. A copy of current price list in Form-V under provision of DPCO, 2013.

3. Details of price revision carried out during the last two years for each type of medical device.

The above information / document may be furnished urgently, not later than 3 days from the date of issue of this letter, as it is required in connection with issues raised during the ongoing parliament session.

Yours faithfully,

(Babita Singh)
Assistant Director (Enf.)