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

5th / 3rd Floor,
YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi – 110 001
Dated: 10th March, 2017

OFFICE MEMORANDUM

Sub: Mandatory printing of Maximum Retail Prices (MRP) on notified medical devices as 'drugs' under the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 and other instructions.

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It has come to the knowledge of NPPA that several medical devices are available in the market and also being used in health care facilities where no MRP is printed on the package by manufacturers/importers. This is a blatant violation of law of the land.

1. The Government has notified 22 medical devices, as drugs under the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. Aforesaid medical devices/drugs are non-scheduled formulations as per para 2(v) of the Drugs Price Control Order(DPCO), 2013 issued under section 3 of Essential Commodities Act (E.C. Act), 1955. Accordingly, the sale of these medical devices(non-scheduled formulations) are governed by the provisions of DPCO, 2013. These devices classified as 'drugs' are as follows:

1) Disposable Hypodermic Syringes
2) Disposable Hypodermic Needles
3) Disposable Perfusion Sets
4) In vitro Diagnostic Devices of HIV, HBsAg and HCV
5) Catheters
6) Intra Ocular Lenses
7) I.V.Cannulae
8) Bone Cements
9) Heart Valves
10) Scalp Vein Set
11) Orthopaedic Implants
12) Internal Prosthetic Replacements
13) Blood Grouping Sera
14) Ligatures, Sutures and Staplers
15) Tubal Rings
16) Surgical Dressings
17) Umbilical Tapes
18) Blood/Blood Component Bags
19) Drug Eluting Stent
20) Cardiac Stents (BMS)
21) Condoms
22) Intra Uterus Devices

(Out of above list, Sl. 19 – 22 are 'scheduled drugs' under DPCO, 2013 and under price control of NPPA.)

2. Paragraph 25 of DPCO, 2013 casts an obligation on every manufacturer in respect of display of prices of non-scheduled formulations and pricelist thereof. As per paragraph 25(1), every manufacturer of aforesaid non-scheduled formulations intended for sale shall display indelible print mark, on the label of the container of the formulation and the minimum pack thereof offered for retail sale, the maximum retail price (MRP) with the word "Maximum Retail Price" preceding it and the words 'inclusive for all taxes' succeeding it. As per paragraph 25(2) of DPCO, 2013, every manufacturer shall issue a price list of the above non-scheduled formulations in Form – V to the Dealers, State Drug Controllers and the Government indicating changes, from time to time. Every retailer and dealer are required to display the price list under paragraph 25(3) of the DPCO, 2013.

3. As per paragraph 26 of DPCO, 2013, no person shall sell any formulation to any consumer at a price exceeding the price specified in the current price list of price indicated on the label of the container or pack thereof, whichever is less.

4. It is pertinent to mention here that, the prices of such non-scheduled formulations are monitored by the Government under paragraph 20 of DPCO, 2013. Every manufacturer is required to mandatorily comply with the provisions of paragraph 20(1) of the DPCO, 2013, by not increasing the MRP more than 10% of MRP during preceding twelve months, otherwise they shall be liable to deposit the overcharged amount with interest thereon from the date of increase in price addition to the penalty as per paragraph 20(2) of DPCO, 2013.

All the manufacturers are advised to ensure compliance of provisions of DPCO, 2013 in sale of aforesaid non-scheduled formulations to avoid action against any violation under the provisions of DPCO, 2013 read with E.C. Act 1955.

10/3/17

(**Roshni Sohni**)
Director (Enforcement)

Copy to:-

(1) All medical devices manufacturers and importers in Indian market.
(2) All medical devices Associations(CII, FICCI, ASSOCHAM, PHD Chamber of Commerce and Industry, AIMED, Medical Technology Association of India and Others).
(3) Chief Secretaries of all States & UTs for necessary instructions to healthcare institutions.
(4) State Drug Controllers of all States and UTs for enforcement of MRP and also to exercise powers under Para (30) of DPCO, 2013 wherever necessary.
(5) Drug Controller General of India for information and necessary action.