

F. No. 20(8)/2013/Div. III/NPPA
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority
Ph: 23746796, 23746652
Website: www.nppaindia.nic.in

5th / 3rd Floor,
YMCA Cultural Centre Building,
1, Jai Singh Road, N. Delhi - 110001
Date: 30.06.2015

To
The Managing Director/ Chief Executive Officer,
Pharma Associations
By Individual Names & also to be uploaded on website

Sub: Monitoring of price movement of notified Orthopaedic Implants as drugs under DPCO, 2013

Sir,

This is with reference to clarification sought by some companies regarding applicability of the provisions of DPCO, 2013 in the case of medical devices. In this regard, NPPA in its letter of even no. dated 15.05.2015 (copy enclosed) has clearly mentioned that Para 20 of DPCO, 2013 provides for monitoring of non-scheduled formulations. Orthopedic implants alongwith other medical devices are notified as 'Drug' under the Drugs & Cosmetic Act 1940 and rules thereunder. Therefore, your contention that the provisions of DPCO, 2013 are not applicable to the Medical Devices is totally incorrect.

It may also be noted that Para 25 of DPCO, 2013 requires every manufacturer / importer to issue a price list in Form-V. Further, Para 29 empowers the Government to call for any record and to inspect such report at the premise of the manufacturers relating to sales of the formulations, which include 14 notified "medical devices". Accordingly, 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:




- Product specification with brief description / Literature for different types of notified medical devices manufactured / imported by the company.
- Information / data in respect of Orthopaedic Implants in the following format :

S. No.	Ex-factory price / landed cost (including applicable duties)	Distributor Cost	Maximum Retail Price (MRP)	%age increase in MRP (year to year) in the last three years		Remarks, if any
				2013	2014	

You are requested to impress upon your concerned member companies to furnish the above information / document to NPPA within 7 days of receipt of this letter.

Yours faithfully,


 (Shyam S. Agrawal)
 Asst. Director (M&E)

30/06

Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
National Pharmaceutical Pricing Authority
Ph: 23345116, 23345118 & 23345122
Website: www.nppaindia.nic.in

5th / 3rd Floor,
YMCA Cultural Centre Building,
1, Jai Singh Road, N. Delhi – 110001
Date: 15.05.2015

To

The Managing Director/ Chief Executive Officer,
(To Mfrs of Orthopaedic Implants)

Sub: Monitoring of price movement of notified Orthopedic Implants as drugs under DPCO, 2013

Sir,

There have been reports in certain sections of print media that the prices of Orthopaedic Implants regulated as 'drugs' under Drugs & Cosmetics Act & Rules there under, are sold at exorbitant price with high profit / trade margin.

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 manufacturers / importer / distributor shall be liable to deposit the overcharged amount alongwith interest thereon, form the date of increase in price in addition to the penalty.

Further, Para 25 of DPCO, 2013 provides that every manufacturer / 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.



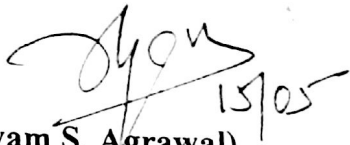
In this regard, it has been decided to seek the following information / documents in order to examine price violation, if any, in respect of notified medical device, manufactured / imported / marketed by the company:

1. Product specification with brief description / Literature for different types of notified medical devices manufactured / imported by the company.
2. Information / data in respect of Orthopedic Implants in the following format :

S. No.	Ex-factory price / landed cost (including applicable duties)	Distributor Cost	Maximum Retail Price (MRP)	%age increase in MRP (year to year) in the last three years			Remarks, if any
				2013	2014	2015	

The above information / document may be furnished urgently, not later than 7 days from the date of issue of this letter.

Yours faithfully,


(Shyam S. Agrawal)
Assistant Director (M&E)