



**What's New**

**16.02.2017**

**Implementation of Coronary Stents price fixed and notified under the provisions of DPCO,2013.**

NPPA has already fixed and notified the Ceiling prices of Coronary Stents under the provisions of DPCO 2013. All the manufacturers are required to implement the prices fixed by the NPPA as per Paragraph 24 of the DPCO 2013.

Clarifying the queries received from stents manufacturer associations, drug distributors, dealer associations etc. and misinformation as regards recalling or re-labelling or re-stickering on the label of container or pack of released stocks of Coronary stents in the market/distributor/Hospital prior to the date of the Notification, NPPA has advised to refer NPPA's O.M.Nos. 25(5)/2014/Div-V/NPPA dated 13.04.2016 and 10.05.2016.

In case of Coronary stents, it is stated that The provisions of paragraph 24 of the DPCO 2013 cast an obligation on the part of manufacturers to ensure compliance with the prices fixed or revised by the NPPA, from the date of price notification(s) by issuing a revised price list or supplementary price list, if required, in Form V to dealers, retailers and copy may be forwarded to State Drug Controllers and the Government within 15 days from the date of notification.

It is suggested that such price lists may be issued by e-mail, so as to reach dealers and retailers, quickly. The manufacturers are also required to follow electronic submission of such price list online through Integrated Pharmaceutical Database Management System (IPDMS) of the NPPA as proof thereof.

The manufacturers and retailers are responsible to comply with notified prices from the date of notification in sale of all available stocks including pre-manufactured batches of concerned formulation/ stents for which ceiling price has been fixed by the NPPA. As per paragraph 26 of the DPCO ,2013, no person shall sell any formulation to any consumer at a price exceeding the price specified in current price list or price indicated on label of the container or pack , whichever is less.

Recalling or re-labelling or re-stickering on the label of container or pack of released stocks of coronary stents in the market prior to date of notification, is not mandatory, if manufacturers are submitting revised price list, as stated in paragraph 1 hereinabove and are able to ensure price compliance at the institutions' (viz.hospitals/nursing homes/clinics etc.) retailers' level. However, the manufacturers, if they so desire in order to comply with notified prices, may re-label or re-sticker, as the case may be.

The manufacturers recalling or re-labelling or re-stickering on the label of container or pack pf released stocks in the market prior to date of notifications, shall ensure that adequate stocks are maintained to avoid shortage of such coronary stents. However, it does not mean that revised prices get deferred for the stock in circulation. The price change takes place with immediate effect.

NPPA has the information that some manufacturers/ importers/distributors are trying to create artificial shortage of stents. NPPA has advised all the State Drug Controllers to proceed under para 30 of DPCO,2013, if required.

All the manufacturers, distributors, institutions/ Hospitals and retailers shall make sure that prices fixed/ notified by the NPPA for coronary stents are duly implemented and benefit of price capping is made available to the consumers/ patients.

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