

**F.No. 19(837)/2016/NPPA/Div-II
National Pharmaceutical Pricing Authority
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India**

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YMCA Cultural Centre Building,
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Dated: 16th February, 2017

Office Memorandum

Sub: Implementation of Coronary Stents prices fixed and notified under the provisions of DPCO, 2013 - reg.

Under the provisions of the DPCO, 2013, ceiling prices of coronary stents are fixed and notified by the National Pharmaceutical Pricing Authority (NPPA). All the manufacturers are required to implement the prices fixed by the NPPA as per paragraph 24 of the DPCO, 2013. Some queries have been received from stents manufacturer associations, drugs distributors, dealer associations, etc. in NPPA in respect of captioned matter. There is also some 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 date of notification. In this connection, one may like to refer to NPPA's O. M. Nos. 25(5)/2014/Div-V/NPPA dated 13.4.2016 and 10.5.2016. In case of coronary stents, it is stated that -

1. 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 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.
 - (a) 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.
 - (b) The manufacturers and retailers are responsible to comply with notified prices from 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 thereof, *whichever is less*.
 - (c) In this context, the Hon'ble Supreme Court in GlaxoSmithKline Pharmaceuticals limited versus Union of India and others, case reported in 2014 SCC vol. II 753 has held that the current price list is simply the price reflecting the currently operating notified price under the DPCO and once a price is notified for a formulation, it takes effect immediately and sale of the formulation to the consumer has only to be at the price specified in the current price list or price indicated on the label of the container or pack thereof, *whichever is less*".
2. 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 notifications, 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. hospital/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.

3. The Hon'ble Supreme Court in aforesaid GlaxoSmithKline Pharmaceuticals Limited case *supra* in para 51 has held that, *"the ultimate object of the DPCO is that there is no deception to a consumer and he is sold the formulation at a price not exceeding the price specified in the current price list or price indicated on the label of the container or pack thereof, whichever is less. Logically it follows that there cannot be two prices at the end point of the distribution chain depending on the batch number. A consumer approaching a chemist/retailer can hardly be offered two prices for the very same product based only on the difference in batch numbers. Consumer must get the benefit of the notified price. That is the ultimate objective of DPCO. The batch number cannot override the benefit to which a consumer is entitled on price reduction of a formulation. A fair reading of DPCO leaves no manner of doubt that a formulation cannot be sold to the consumer at the higher price (for earlier batch numbers). In this view of the matter, we find merit in the submission of the learned Additional Solicitor General that the provisions of DPCO requires not just the end point sale to be at the notified price, but also every sale within the distribution chain must be at the notified price, if such sale is made after the date on which sale price is operative"*.

The Hon'ble High Court of Delhi in its judgment dated 24.11.2015 passed in Writ Petition Civil 4374/2013, Cipla Ltd. vs UOI with connected cases on similar issue has referred and relied upon the aforesaid decision of the apex court.

4. The manufacturers recalling or re-labelling or re-stickering on the label of container or pack of 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.
5. It has also been informed to the NPPA that some manufacturers/importers/distributors are trying to create artificial shortage of stents. NPPA has advised all State Govts. and State Drug Controllers to proceed under para 30 of DPCO, 2013, if required.
6. 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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