



F. No. 20(8)/46/2021/Div.VI/NPPA
भारत सरकार
Government of India
रसायन एवं उर्वरक मंत्रालय
Ministry of Chemicals & Fertilizers
औषध विभाग
Department of Pharmaceuticals
राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण
National Pharmaceutical Pricing Authority

तीसरी एवं पांचवी मंजिल,
वाई.एम.सी.ए. सांस्कृतिक केन्द्र बिल्डिंग,
1, जय सिंह रोड, नई दिल्ली-110001

3rd and 5th Floor,
YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi - 110001

दिनांक/ Dated: 30th September 2021

OFFICE MEMORANDUM

The undersigned is directed to refer to the queries from some of the manufacturers/marketing companies regarding implementation of MRP on the medical devices brought under price regulation through Trade Margin Rationalisation approach vide notification dated 03rd June 2021 and 13th July 2021 due to the withdrawal of GST rate concession for medical devices.

2. In this regard, reference is invited to the OM No. 25(5)/2014/Div V/NPPA dated 13th April 2016 (copy enclosed) issued by NPPA which contains detailed guidelines for compliance of revised prices by manufacturers/marketing companies.

3. In view of above, all the manufacturers and marketing companies may revise the MRP, up to the extent of increase in GST Rate, of the medical devices subject to actual payment of GST. Further, the Manufacturers and Marketing Companies are required to issue revised price list to all the participants in supply chain besides submitting the price list in Form VI to NPPA. It is further stated that these medical devices shall be monitored under Para 20 of the DPCO, 2013.

(Rajesh Kumar T)
Deputy Director

E-mail: medicaldevices-nppa@gov.in

☎ 011-23746794

Encl: As above

To,

1. All manufacturers/importers of Pulse Oximeter, Infrared thermometer, Digital Thermometer & Oxygen Concentrator
2. Medical Device Industry Associations to disseminate this information among its member companies and ensure compliance of the same

Copy to:

All Drug Controllers/ Food & Drug Administration of all the State/ UT Governments

F.No.25(5)/2014/Div-V/NPPA
National Pharmaceutical Pricing Authority
Department of Pharmaceuticals
Ministry of Chemicals & Fertilizers
Government of India

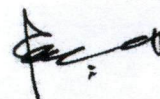
5th / 3rd Floor,
YMCA Cultural Centre Building,
1, Jai Singh Road, New Delhi – 110 001
Dated: 13th April, 2016

Office Memorandum

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

Under the provisions of the DPCO, 2013, ceiling prices or retail prices are fixed and notified by the NPPA, from time to time. All the manufacturers are required to implement the prices fixed or revised by the NPPA as per paragraph 24 of the DPCO, 2013. Some queries have been received from drugs manufacturer associations, drugs distributor and 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 in the market prior to date of notifications. In this connection, it is stated that -

1. The provisions of paragraph 24 of the DPCO, 2013 cast an obligation on the manufacturers to ensure compliance with the prices fixed or revised by the NPPA, from date of price notification by issuing a revised price list or supplementary price list, if required, in Form V to dealers, the retailers, State Drug Controllers and the Government.
 - (a) It is suggested that such price lists may be issued by e-mail, WhatsApp, etc. also apart from usual practices, so as to reach large number of dealers and retailers, quickly. The manufacturers are also advised to follow electronic submission of such price list in Integrated Pharmaceutical Database Management System (IPDMS) of the National Pharmaceutical Pricing Authority (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 stock including pre-manufactured batches of concerned formulation for which ceiling price or retail price has been fixed or revised 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 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 retailer level. However, the manufacturers, if they so desire in order to comply with notified prices, may re-label or re-sticker or recall the stocks, as the case may be. Putting the



stickers of revised prices is being practiced by many manufacturers which is the preferred option by retailers as intimated to NPPA by their associations. The printing of prices on the label of packs was earlier governed by Standard of Weights and Measures Act, 1976 and Rules made thereunder. However, now the said printing of prices is governed by Legal Metrology Act, 2009. Under Rule 26(c) of Legal Metrology (packaged commodity) Rules, 2011, formulations under the DPCO are exempted. However, the manufacturers, if recalling the stock, may ensure that recall is done in a phased manner so that it does not cause acute shortage of medicines in the market.

3. For the purpose of excise exemption for re-printing, re-labelling, re-packing or re-stickering of scheduled formulations under DPCO, 2013 the Department of Revenue vide notification no. 22/2013-Central Excise, dated 29.07.2013 and notification no. 29/2013-Central Excise dated 26.11.2013 has exempted levy of excise duty on re-printing, re-labelling, re-packing or stickering of the products in compliance with DPCO, 2013 for a period of 45 days and which may be further extended by a period of 90 days with the permission of the Department of Pharmaceuticals (DOP). The Drug Controller General of India has also issued a notification 26.06.2013 stating no objection for re-labelling/re-stickering of drugs under Rule 104 A of Drugs and Cosmetics Rules so that benefits of price reduction can be passed on to the consumers. Thus, there should not be any doubt or ambiguity in this regard.
4. 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.

5. In view of foregoing, all the manufacturers and retailers are required to comply with notified prices fixed or revised by the NPPA, in letter and spirit. NPPA, on its part, is committed to ensure compliance of such orders.



(Kalyan Nag)
Adviser