COMPLIANCE TO PRICING REGULATIONS IN THE PHARMACEUTICAL INDUSTRY: A SHARED RESPONSIBILITY

Introduction

In a complex landscape of pharmaceutical regulations, compliance with drug pricing regulations remains paramount. This article provides a detailed exploration of the Drug Price Control Order (DPCO), 2013, its implications for pharmaceutical manufacturers, and the roles and responsibilities of various stakeholders in ensuring compliance with government-notified ceiling prices.

Background

The prices of various drug products in India are regulated by the government through its regulatory agency, i.e., National Pharmaceutical Pricing Authority (NPPA), Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers, Government of India. The NPPA regularly publishes lists of medicines and their maximum selling prices[1], which all parties, including manufacturers, distributors, wholesalers, and retailers, involved in the manufacture, sale, and distribution of such drugs, are required to adhere to.

The regulation of drug prices in India falls under the purview of the Drug and Cosmetics Act, 1940, and its associated rules, alongside Section 3 of the Essential Commodities Act (EC Act). These legal frameworks grant the Central Government authority to control the prices of essential commodities, including pharmaceuticals, ensuring accessibility and affordability.

HISTORICAL CONTEXT

To address concerns about pharmaceutical pricing practices, the Hathi Committee was appointed, submitting its report in April 1975. The report, comprising 224 recommendations across 8 chapters, emphasized the need for rationalizing drug prices to benefit consumers, highlighting issues such as aggressive marketing tactics.

In response, the government formulated the Drug Price Control Order (DPCO), 1979, marking a significant regulatory shift aimed at curbing pricing distortions in the pharmaceutical sector. Subsequent iterations of the DPCO, including versions in 1987, 1995, and ultimately 2013, reflected evolving industry dynamics and aimed to strengthen regulatory mechanisms for fair pricing and accessibility.

PRACTICAL CHALLENGES AND NPPA CLARIFICATIONS

Conflicts between pharmaceutical companies and the National Pharmaceutical Pricing Authority (NPPA) frequently arise over the implementation and enforcement of revised drug prices. Show cause notices issued by the NPPA allege violations or non-implementation of revised prices, posing challenges for pharmaceutical companies in adjusting prices promptly, especially with large inventories or complex distribution networks.

To resolve practical challenges, NPPA has issued clarification vide Office Memorandum O.M. No. 25(5)/2014/DivV/ NPPA dated 13th April, 2016 and O.M. No. 25(5)/2014/Div-V/NPPA dated 10th May, 2016, which contain detailed guidelines for compliance of prices fixed and notified under the provisions of DPCO,2013 by the manufacturers/marketing companies.

LEGAL FRAMEWORK AND COMPLIANCE

To have the proper perspective of the issue, it is necessary that certain provisions of the DPCO, 2013 are surveyed. Paragraph 2 is an interpretation clause; it defines certain expressions occurring in DPCO as under:2. ...

(d) "ceiling price" means a price fixed by the Government for Scheduled formulations in accordance with the provisions of this Order;

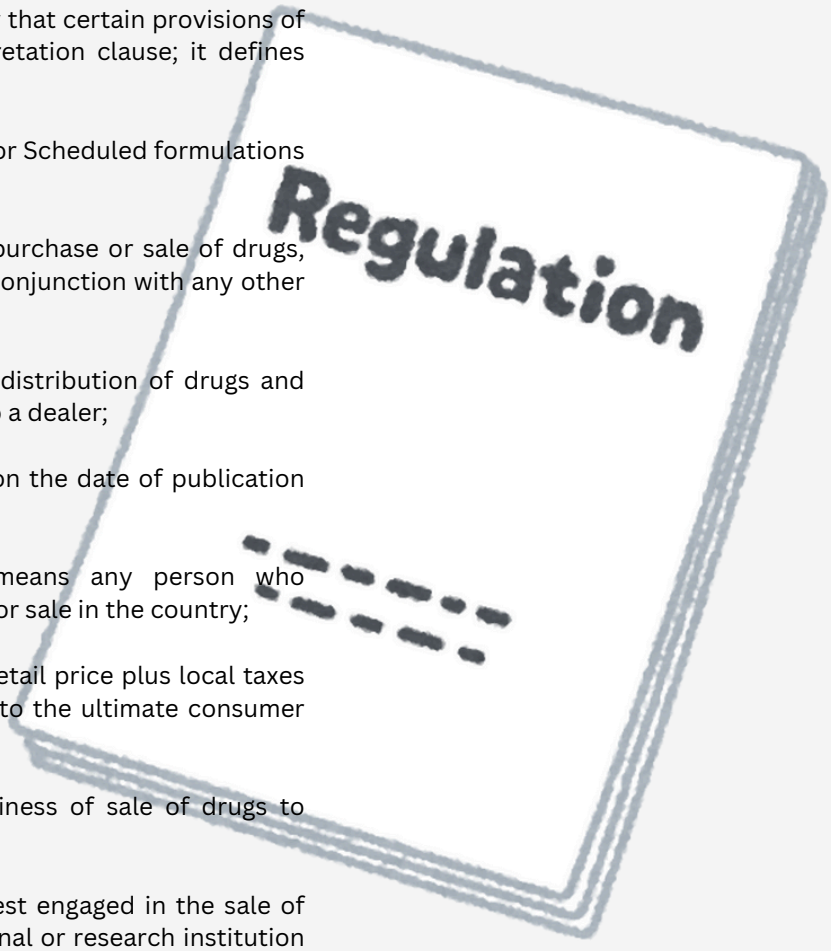
(e) "dealer" means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer and whether or not in conjunction with any other business and includes his agent;

(f) "distributor" means a person engaged in the work of distribution of drugs and includes an agent or a stockist for stocking drugs for sale to a dealer;

(g) “existing manufacturer” means manufacturer existing on the date of publication of this order in the Official Gazette.
....
(n) "manufacturer" for the purpose of this Order means any person who manufactures or imports or markets drugs for distribution or sale in the country;
....
(r) “maximum retail price” means the ceiling price or the retail price plus local taxes and duties as applicable, at which the drug shall be sold to the ultimate consumer and where such price is mentioned on the pack;

(za) "retailer" means a dealer carrying on the retail business of sale of drugs to customers;

(zd) "wholesaler" means a dealer or his agent or a stockiest engaged in the sale of drugs to a retailer, hospital, dispensary, medical, educational or research institution or any other agency;



Para 14 of DPCO 2013 grants the Central Government the authority to establish prices for bulk drugs to ensure fair distribution and maximum sale prices. These prices, specified in the First Schedule, are enforced through official gazette notifications. Manufacturers must adhere to the maximum sale price set by the government, along with local taxes. If a manufacturer or importer labels a price exceeding the notified ceiling price, they are subject to liability for the recovery of the overcharged amount, along with accrued interest and/or penalty. This liability is stipulated in Paragraph 14(2) or Paragraph 23 of the DPCO, 2013.

IMPLEMENTATION TIMELINE FOR REDUCED CEILING PRICE ("NOTIFIED PRICE")

Para 13 of DPCO 2013 mandates existing manufacturers of scheduled formulations to lower their prices if they are currently selling above the ceiling price set by the government. The proviso to para 13(1) specifically warrants that the existing manufacturers must ensure that within forty-five days of the notification, the maximum retail price of such formulations does not exceed the ceiling price, including local taxes.

Para 24 of DPCO 2013 outlines the procedure for implementing the prices fixed or revised by the Government. In the case of scheduled formulations where the maximum retail price (MRP) exceeds the ceiling price (plus local taxes), manufacturers are required to revise the MRP, ensuring it does not surpass the ceiling price (plus local taxes). Proviso to Para 24(1) specifies that, for scheduled formulations already in the market before the notification of the ceiling price, manufacturers must ensure within forty-five days of the notification that the MRP does not exceed the ceiling price (plus local taxes).

ACTIONS EXPECTED FROM MANUFACTURERS TO ENSURE COMPLIANCE WITH THE REDUCED CEILING PRICE.

Para 24 and 25 of the DPCO 2013 mandate that manufacturers must prominently display the maximum retail price (MRP) of both scheduled and non-scheduled formulations on the container labels and minimum pack offered for retail sale. This requirement includes clear labeling indicating "Maximum Retail Price" and "inclusive of all taxes." Para 26 emphasizes that no person is permitted to sell any formulation to consumers at a price exceeding the MRP specified in the current price list or indicated on the packaging.

Para 29 requires manufacturers to maintain sales records in accordance with the DPCO 2013 guidelines, ensuring transparency and accountability in sales practices. Furthermore, manufacturers and importers are obligated to issue price lists for each drug, whether scheduled or non-scheduled, in Form V under Schedule II. This requirement ensures that consumers and regulatory authorities have access to comprehensive pricing information, facilitating compliance and transparency within the pharmaceutical industry.

If the DPCO provisions are to be read verbatim, it indicates that a massive relabeling activity has to be undertaken by most drug companies to implement provisions of DPCO, 2013 involving relabeling batches of products existing at the manufacturer's/trader's premises. The old stock of finished products lying at various stock points also needs to be recalled for the relabeling process. All this practically cannot be done in the limited time frame of forty-five days. Considering the amount of time these products will be in transit during the entire process, the products remain exposed to a high risk of spoilage or damage. This process will also have a severe impact on drugs with a low shelf life. Because of these reasons, there is a huge logistical challenge in the execution of DPCO, 2013.

To resolve practical challenges, NPPA has issued clarification vide Office Memorandum O.M. No. 25(5)/2014/DivV/ NPPA dated 13th April, 2016 and O.M. No. 25(5)/2014/Div-V/NPPA dated 10th May, 2016, which contain detailed guidelines for compliance of prices fixed and notified under the provisions of DPCO,2013 by the manufacturers/marketing companies. Point No. 2 of O.M. dated 13.04.2016 is reiterated as below:

"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 herein above 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."

Further, Para 4 of O.M. No. 25(5)/2014/Div-V/NPPA dated 10th May 2016 states:
"It has also been informed to the NPPA that some Stockists/Trade Associations are showing resistance in selling the products without stickering/re-labelling. The dealers including Stockists/Retailers may not return any stocks in case current price list as per revised notified price has been made available. In this connection, attention is drawn to paragraph 28 of the DPCO, 2013 which states as under-
"28. Manufacturer. distributor or dealer not to refuse sale of drug Subject to the provisions of the Drug and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder, -
(a) no manufacturer or distributor shall withhold from sale or refuse to sell to a dealer any drug without good and sufficient reasons;
(b) no dealer shall withhold from sale or refuse to sell any drug available with him to a customer intending to purchase such drug".

All the manufacturers and retailers shall make sure that prices fixed/notified by the NPPA for essential medicines are duly implemented and benefit of price is made available to the consumers."

With aforesaid clarifications of NPPA it can be safely concluded that for implementation of the revised prices notified by the NPPA in accordance with Para 24, the recalling, re-labelling, or re-stickering of containers or packs of products already released into the market before the date of notifications is not obligatory. This exemption applies if manufacturers can guarantee price compliance at the retailer level by issuing a revised price list.[1]

The NPPA OM dated 13th April 2016 also states:

"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
[1]Office Memorandum No. 12(90) /2022/DP/NPA/JIVAN-II dated 19.12.2022
Management System (IPDMS) of the National Pharmaceutical Pricing Authority (NPPA) as proof thereof."

The suggestion to issue price lists via email, WhatsApp, etc., alongside traditional methods, is aimed at facilitating the rapid dissemination of information to a wider audience of dealers and retailers. By adopting these electronic communication channels, manufacturers can ensure that price updates reach their intended recipients promptly, enabling swift compliance with regulatory requirements. Moreover, electronic submission of price lists to the Integrated Pharmaceutical Database Management System (IPDMS) of the National Pharmaceutical Pricing Authority (NPPA) will serve as concrete evidence of compliance by manufacturer demonstrating commitment to regulatory adherence and establishing a clear record of their efforts to comply with pricing revision. In the event of any default by retailers or other parties in the distribution chain, having a documented trail of electronic communication and submission can serve as valuable defense evidence for manufacturers. It provides them with the means to demonstrate that they took necessary steps to inform stakeholders of price updates and fulfill their obligations.

RESPONSIBILITY FOR THE SALE OF DRUGS AT PRICES EXCEEDING THE NOTIFIED PRICE

Para 26 underscores that the responsibility for controlling sale prices of formulations extends to all individuals involved in the distribution chain, emphasizing the phrase "no person." It mandates that no entity, including manufacturers and retailers, may sell a formulation to any consumer at a price surpassing the amount specified in the prevailing price list or indicated on the container or pack label, selecting the lesser of the two. This provision ensures accountability across the distribution network, compelling all stakeholders to adhere to pricing regulations to safeguard consumer interests.

> Para 26. Control of sale prices of formulations:– No person shall sell any formulation 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.

The aforesaid provision has also been discussed in Cipla Ltd. Vs Union of India[1] wherein the and the Hon'ble Delhi High Court in para 6 has taken note of the particular provisions providing the intent of DPCO as under:-

[1]Judgement dated 24.11.2015 in W.P.(C) 4374/2013 along with connected matters

> "...We may also point out that the proviso to paragraph 24(1) of DPCO, 2013 requires a manufacturer to ensure that within a period of forty-five days of the date of the notification, the maximum retail price of the concerned formulation does not exceed the ceiling price (plus local taxes as applicable). But, paragraph 26 also makes it clear that no person, which includes the manufacturer, wholesaler, dealer and retailer, shall sell any formulation 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."

The judicial pronouncements, particularly the Delhi High Court's observation, underscore the collective responsibility of all stakeholders in ensuring compliance with the Notified Price. Retailers, being the frontline interface with consumers, bear a significant burden to sell formulations at prices not exceeding the ceiling price (Para 26).

It is evident that while manufacturers are mandated to implement and communicate the Notified Price, the ultimate responsibility for adherence rests with all parties involved in the sale chain. Retailers, in particular, are obligated to ensure compliance with the Notified Price, notwithstanding the actions taken by manufacturers.

Therefore, in the event of non-compliance or sale at prices exceeding the Notified Price, the retailer shall be held accountable alongside other relevant stakeholders. Manufacturers, having fulfilled their obligations under the DPCO, cannot be deemed responsible for subsequent violations by retailers. It is imperative for all stakeholders to cooperate and uphold the regulatory framework to ensure equitable access to essential medications at controlled prices.

IMPACT OF GLAXOSMITHKLINE CASE

The Hon'ble Supreme Court, in the judgement of GlaxoSmithKline Pharmaceuticals Limited Vs. Union of India (UOI) and Ors; 2013/INSC/813, in para 51 has held:

"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".

Add a littleThough the said judgement discards the argument of practical difficulties in implementing the price revisions on existing stocks in the market, the court does not delve into redressing such impediments. Pertinently, the said judgment takes note that "the DPCO defines 'dealer', 'distributor', 'manufacturer', 'retailer' and 'wholesaler'. ...provisions of DPCO effectively covers the chain from manufacture of the bulk drug by the manufacturer to sale of formulation to consumer though there may be several persons in the distribution chain." The ratio of the judgment is limited to the extent of implementation of the price revisions within 15 days of notification under DPCO 1995 (now revised to 45 days under DPCO 2013) and availability of the drug at such revised/lower price to the end consumer.

Having considered the observation in the said judgement and representations by various stakeholders, NPPA has come up with the Office Memorandums[1] to resolve the practical impediments in recalling/ relabeling of the drugs already in distribution by clarifying that 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 able to ensure price compliance at the retailer level through issuance of a revised price list.

CONCLUSION

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In view of the aforesaid discussion, the issues arising qua implementation of price notification by NPPA could be concluded as under

a)Within how many days is the manufacturer required to implement the reduced ceiling price ("Notified Price")?

According to the proviso to paragraph 13(1) and paragraph 24(1) of the Drug Price Control Order (DPCO), 2013, the manufacturer must ensure within forty-five days of the notification that the maximum retail price (MRP) of the scheduled formulation does not exceed the ceiling price (plus local taxes as applicable).

b)What actions are expected from the manufacturer to implement the reduced ceiling price?

The actions expected from the manufacturer to implement the reduced ceiling price are outlined in various provisions of the DPCO, 2013:

- Revise the MRP of all the WIP (Work in Progress) and planned production of the drug to not exceed the Notified Price, with appropriate labeling indicating "Maximum Retail Price" and "inclusive of all taxes."
- Optionally, re-label or re-sticker the stock manufactured prior to the Notified Price or issue a price list or supplementary price list in Form V to dealers, state drugs controllers, and the government indicating the Notified Price for the stock manufactured before the Notified Price.
- Display the price list or supplementary price list prominently at the manufacturer's premises.
- File Form II with the Government within fifteen days from the date of the Notified Price.

c) Once all the expected, possible actions have been taken by the manufacturer, who shall be responsible for the chemist selling the drug at the pre-Notified Price?

Para 26 of the DPCO emphasizes that all individuals in the distribution chain, as denoted by "no person," bear responsibility for ensuring that drug sales do not exceed the specified prices. This includes manufacturers, wholesalers, dealers, and retailers. Judicial pronouncements, like the Delhi High Court's observation in Cipla Ltd. Vs Union of India, reiterate this shared responsibility, particularly highlighting the retailer's role as the frontline interface with consumers. While manufacturers must implement and communicate the Notified Price, ultimate compliance responsibility lies with all stakeholders. In cases of non-compliance or sales above the Notified Price, retailers, alongside other stakeholders, are held accountable. However, in situations where drug inspectors seize non-compliant products from retailers, they ought to assess whether manufacturers have fulfilled their obligations under the DPCO and NPPA guidelines. If manufacturers have complied, penalties should be directed solely at non-compliant retailers, considering the proportion of overcharged sales. Blanket penalties on manufacturers are unwarranted if they have adhered to regulatory requirements.

d) What is the impact of the decision made by the Hon’ble Supreme Court in the matter of Glaxosmithkline Pharmaceuticals Limited?

The decision of the Hon’ble Supreme Court in the matter of Glaxosmithkline Pharmaceuticals Limited could influence the determination of responsibility in cases where the manufacturer has taken all necessary actions to ensure compliance with the Notified Price. If the retailer sells the formulation at a price higher than the Notified Price despite being made aware of it by the manufacturer, the retailer would be held responsible. The Supreme Court's decision read with its interpretation by Delhi High Court in Cipla vs Union of India and the Office Memorandums dated 13.04.2016, 10.05.2016 and 19.12.2022 issued by NPPA emphasizes the importance of all parties involved in the supply chain adhering to pricing regulations and ensuring transparency in pricing for consumers.

Accordingly, it may be concluded that ensuring compliance with the Drug Price Control Order (DPCO), 2013, is a collective responsibility shared by manufacturers, distributors, wholesalers, and retailers. By adhering to these regulations and guidelines, the pharmaceutical industry can ensure that essential medications remain accessible and affordable to consumers while maintaining compliance with the legal framework.