NPPA CLARIFIES IMPLEMENTATION OF PRICES FIXED UNDER DPCO 2013

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The NPPA has recently issued an office memorandum to clarify the doubts raised by manufacturers and retailers regarding implementation of prices of drugs revised in accordance with the DPCO from time to time. Para 24 of the DPCO requires manufacturers to comply with the revised prices notified under the DPCO with immediate effect from the date of notification by issuing a revised/supplementary price list to the retailers and dealers. The office memorandum issued by the NPPA on April 13, 2016 allows manufacturers to circulate the revised/supplementary price list to the dealers and retailers by means of e-mail, WhatsApp, etc. to save time and submit the price list online on the NPPA website as proof thereof. The office memorandum also clarifies that re-calling/re-labelling/re-stickering of pre-manufactured batches of drugs is not mandatory to implement the revised prices. However, if the manufacturers choose to do so, they are advised to do it in a phased manner so that it does not cause excessive shortage of the concerned drugs in the market.

PSA view: This clarification not only helps to resolve practical difficulties faced by manufacturers in implementing revised prices as soon as they are notified, but also ensures that the customer gets the benefit of revised prices with immediate effect, irrespective of the batch number of the drugs purchased. The revised prices have to be implemented by manufacturers from the date of notification itself, and as per para 26 of the DPCO, drugs have to be sold at the current notified price or the price printed on the label of the pack, whichever is less. Therefore, even if the stock already released into the market prior to date of notification reflects a price more than the revised prices that have been communicated to dealer and retailers, they will be bound to sell it at the revised prices to customers.

Setting up pharmacovigilance departments to be made mandatory for companies

The MoHFW has proposed a draft amendment to Schedule Y of the Drugs and Cosmetics Act, 1940 (“Act”) to add a new provision making it mandatory for companies to set up a pharmacovigilance department for the post marketing surveillance of new drugs manufactured or imported by them. This move comes as a result of the Drug Testing and Advisory Board’s (“DTAB”) recommendation for improving involvement of drug companies in testing the Adverse Drug Reaction (“ADR”) of drugs sold in the Indian market. As per the DTAB, ADR is primarily reported by hospitals and very few companies are actively involved in it. Once this proposed amendment comes into effect, it will be compulsory for all drug manufacturing companies to have a pharmacovigilance department in place, to collect, assess and formulate periodic reports regarding the clinical safety of the drugs being manufactured and marketed by them.

PSA view: This is a welcome move as it will not only ensure safety and quality control for drugs being manufactured and sold in the Indian market, but also create more job opportunities as the proposed pharmacovigilance departments would require qualified and trained pharmacists to collect and process ADR data.

Katoch Committee's recommendations finally inspires action from the Government

India's drug market is very weak from a regulatory standpoint. There are various drugs such as Deanxit (a drug which is exported from Denmark but not permitted to be sold in the country) which have been sold in India without conducting any clinical trials. The proposed ban on 344 fixed-dose combinations only highlights the weak drug approval system of our country. In the month of September last year, a committee headed by Dr. V.M Katoch, ex-Secretary, Department of Health Research ("Committee") made several recommendations on formulation of policy on drugs manufacture system of the country. The recommendations included providing state of the art facilities of bulk drugs' intermediates and manufacturers at subsidized rates and setting up state established drug manufacture zones to boost local production of bulk drugs. The Committee also suggested that the Department of Pharmaceuticals should facilitate a single window clearance from Ministry of Revenue, Ministry of Environment, etc. for drug manufacturers. Setting up of advanced labs at all major airports and sea ports to check the quality of imported drugs was a noteworthy recommendation of the Committee. At present, more than 75% of India's bulk drug imports come from China.

PSA view: With the Government finally taking cognizance of the Katoch Committee's recommendations, the scenario must improve. Stricter implementation of clinical trial laws, sophisticated implementation of pharmacovigilance practices and local production of drugs is the need of the hour.

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