



## SUPREME COURT DIRECTS THE DEPARTMENT OF PHARMACEUTICALS TO REVISE THE NATIONAL PHARMACEUTICAL PRICING POLICY AND THE DRUGS PRICE CONTROL ORDER 2013

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Under the Drug Price Control Order 2013 (“DPCO”), the Government controls prices of 348 drugs listed in the National List of Essential Medicines. In a PIL filed by an NGO, All India Drug Action Network (“AIDAN”) it was alleged that the regulation of prices under the DPCO has actually resulted in rendering medicines costlier for the consumer, contrary to the National Pharmaceutical Pricing Policy (“NPPP”) which aims to make medicines affordable for the people. AIDAN also sought inclusion of more life-saving medicines for diseases like diabetes and tuberculosis in the list of drugs whose prices would be regulated by the Government, and to extend the price control to various dosages, strength and combinations. The Court observed that the existing prices charged by pharmaceutical companies in certain states was up to 5000 times their production cost, which when taken into account to determine the average market based price under the DPCO rendered such average even higher than the price charged by the market leader for such medicines. The Court, however, expressed reluctance to delve further into what it termed as a “policy matter” and has asked AIDAN to make representation to the Department of Pharmaceuticals under the Union Ministry of Chemicals and Fertilizers within six weeks and asked the Department to respond to the same within six months thereafter.

**PSA View:** The NPPP was formulated to further the Government’s objective of improving access to medicines in India. Since one of the main observations of the Court in this order was that the existing prices charged by pharmaceutical companies in certain states was already multiple times the production cost, a market based pricing would not be sustainable in such circumstances. We hope that the Department of Pharmaceuticals takes into consideration the interest of all stakeholders in revising the price regulation under the DPCO.

### **Demand for contaminated product insurance grows among food and beverage manufacturers in India**

With the recent fiasco over Nestle’s Maggi and certain other consumable goods being declared unfit for consumption, insurance companies are witnessing a surge in demand for contaminated product insurance policies. Such contaminated product insurance covers all food and agricultural products, juices, soft drinks, cosmetics, pharmaceutical products and broadly anything that can be consumed or applied and that poses a potential threat to health. Whereas, existing product liability insurances only cover losses incurred by the

manufacturer in third party litigation claims, contaminated product policies cover all issues related to recall, mislabeling, business interruption, loss of the gross profit, money spent on the rehabilitation, loss of brand value, and even for malicious contamination by employees' conducts. The cost of the premium for such insurance covers varies depending on the kind of the product, turnover of the company, whether it is exported overseas or sold in the domestic markets.

**PSA View:** In light of the recent embargoes imposed on various food products, this appears to be a wise move on part of food and beverage manufacturers to boost their product liability insurance with such added covers which widen the product liability to include expenses incurred in recall of contaminated products, mislabeling and losses suffered due to impairment of business in lieu thereof.

### **DCC to deliberate on online pharmacy norms soon**

Considering the new e-retail culture for pretty much everything in market, the DCC too now has felt the need to deliberate on the norms that must be devised for regulating online pharmacies. The Drugs Controller General of India ("DCGI"), Mr. Singh, is scheduled to take up this agenda in a meeting scheduled for July 24, 2015 at New Delhi. The focus of the meeting will be on key licensing norms for online pharmacies.

The current drug rules do not permit online pharmacy services and there is an urgent need to frame regulations for the same. As of date, there are already a handful of players who have delved into e-space for drugs retailing. However, there are a lot of illegalities in their business models. For instance, drugs which cannot be sold without prescription are being sold online without one. Further, there are certain mandates to be followed by pharmacists/druggists at the time of selling drugs, but they are being flouted blatantly. Some online pharmacists have been encouraging self medication which is a dangerous trend. While some online pharmacy operations were stalled by the state drugs control departments, there are many which are seen to continue this activity. Since the DCGI office is cognizant of this disturbing trend, issuing a set of norms for online pharmacies is their top priority.

With the team from the DCGI office examining the US FDA's Verified Internet Pharmacy Practice and European Union's norm, the issue will be taken up in the forthcoming meeting.

**PSA View:** There is a legal vacuum when it comes to regulating online sale of drugs. The Drugs and Cosmetics Act is an old legislation and it contains provisions with respect to sale of drugs and brick and mortar pharmacy shops. Online drug sale could not have been anticipated long back. Now that it is the need of the hour, appropriate regulations must be devised at the earliest to regulate sale of drugs via online medium. Aspects such as authenticity of prescription, sale of scheduled drugs, delivery of well packaged and unexpired drugs, maintenance of records by druggists etc. must be looked into. Further, since sale of spurious Kerala based drugs has recently come into picture, we are of the view that sale of ayurvedic products online must be regulated as well.

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