WHO ISSUES DRAFT GUIDELINES ON GOOD PHARMACOPOEIAL PRACTICES

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The WHO has issued draft guidelines on Good Pharmacopoeial Practices and is looking for the industry to comment before March 10, 2015. This move by WHO is being appreciated widely. Pharmacopoeias are embedded in almost every country's national or regional regulatory environment. The Indian Pharmacopoeia ("IP") is published in fulfillment of the requirements of the Drugs and Cosmetics Act, 1940 and Rules thereunder. Also, in several other Indian laws, the IP is recognized as the standard book. A first initiative to reopen the discussion on international harmonization of quality control specifications on a global scale was taken in a side meeting of the 10th International Conference of Drug Regulatory Authorities ("ICDRA") entitled: 'Pharmacopoeial Specifications – Need for a Worldwide Approach?' in Hong Kong in June 2002. This further led to discussions among regulators during the 11th ICDRA meeting held in Madrid in 2004.

PSA view – The Indian Pharmacopoeia Commission ("IPC") formed under the aegis of the Health Ministry has issued the IP which serves as a standard document prescribing standards for identity, purity and strength of drugs essentially required from health care perspective of human beings and animals. IPC keeps on updating the existing monographs. With the release of WHO's draft guidelines, we must revise our approach and policies towards pharmacopoeial standards in India so as to harmonize the same, to a great extent, with the international standards. It would be interesting to see the comments from IPC and other industry players on the draft guidelines.

NPPA Clarifies Labelling Requirement For Scheduled Drugs

The NPPA has decided to abort its initial proposal to implement new labelling requirements such as including distinguishing marks and ceiling prices on the labels of every scheduled medicine under the Drugs (Prices Control) Order, 2013, (the "DPCO 2013"). The industry stakeholders were discontent with the proposal as it imposes upon them additional labelling requirements, increases their cost of production and is likely to cause confusion among the consumers. Thus, it was alleged that the proposal negates the NPPA's objective to ensure effective implementation of DPCO guidelines and empower the consumers.

Adhering to the stakeholder's suggestion, NPPA has decided to revamp the existing reporting and labelling requirements under DPCO and has cast certain obligations on the manufacturers and retailers of scheduled or non-scheduled medicine in compliance with DPCO 2013: (i) price list issued to the dealers must be in Form V; (ii) the invoices issued by retailers to consumers must include all the information prescribed under Form V; (iii) the manufacturer and retailer must give details regarding the medical composition, pack size and price; and ; (iv) must disclose whether the medicine is a scheduled or non-scheduled drug under DPCO 2013 and if it is scheduled drug must also mention the current notified ceiling price per unit (inclusive of local

taxes). As regards to implementing the distinguishing marking requirements on labels, NPPA proposes to convene a meeting with the pharmaceutical trade associations to design a feasible method.

PSA view – The NPPA's move is quite praise-worthy as it aids to strike a balance between ease of implementation for the industry and consumer education. However, it will not be easy to ensure effective implementation of consumer interest unless a robust information dissemination mechanism is established. The NPPA's initiative to launch a comprehensive in-house market database i.e., Integrated Pharmaceutical Database Management System and Online Grievance Redressal System is still in a nascent stage. Therefore, effectiveness of the proposal can be decided only in times to come.

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