NATIONAL POLICY FOR ANTIBIOTICS IN THE OFFING

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India is set to have a policy on the rational use of antibiotics the need for which got heightened because of the recent "super bug" study on antibiotic resistance that stirred a hornet's nest. In a recently concluded study on the 'Emergence of a new antibiotic resistance mechanism in India, Pakistan and the UK' published in an online edition of the Lancet Infectious Diseases, the drug-resistant "super-bug" strain of bacteria was traced to New Delhi, and even cautioned people coming to India for medical tourism.

PSA view – Considering the fact that the irrational use of antibiotics have resulted in strains of bacteria increasingly becoming resistant to antibiotics – thus requiring newer, stronger generations of antibiotics to quell an illness, it becomes all the more crucial to have a policy framework for antibiotics usage. The government is keen to have a framework of the policy within three months as the recent "super bug" issue has the capacity to upset the increasing flow of people coming to India for medical treatment.

*** Cold chain storages for drugs to be set up at Mumbai and Delhi airports in first phase**

The government is planning to enhance the drug storage facilities at airports by creating additional cold chain capacities. In the first phase, cold chain storages will be set up at Mumbai and Delhi airports. In the next two to three years, the facilities will be extended to Hyderabad and Bangalore. Mumbai International Airport Private Limited has already created four new cold rooms for pharma products. The Delhi International Airport Limited has also planned to create additional cold room facilities for pharma products at the new cargo terminal. The Central Drugs Standard Control Organization eventually intends to create full-fledged dedicated pharma zones at airports and seaports in line with good manufacturing practices and good distribution practices to assure quality, safety and efficacy of drugs meant for export/import.

***PSA view* –** Lack of proper storage system affects the quality of medicines. Drugs require specific temperatures and storage conditions. Facilities for storage of drugs are available at some of the airports. In the absence of such facilities owing to space constraints or other reasons, the consignments are released on priority basis to avoid any deterioration in the quality of the drugs. Setting up of new cold chain storage facilities will contribute to maintaining the quality and efficacy of the exported and/or imported drugs. But, it is important that over the time the facilities are evenly spread across the country and not limited to a few areas.

*** No provision for issue of GMP certificates: DCGI**

In response to an RTI application by a pharmaceutical company, the Drug Controller General of India's office (**"DCGI"**) has clarified that there is no provision for the issue of GMP certificates under the Drugs and Cosmetics Rules (**"DCR"**). The RTI was filed to clarify whether any provision exists under the DCR for

issuance of a GMP certificate and if yes, then in what form can an application be made. This clarification was sought by the pharma manufacturer due to inconvenience faced while supplying to the various drug procurement agencies that ask for a GMP certificate for participating in tenders. The DCGI in reply to the RTI further replied that a drug manufacturing unit which has a valid license, is considered automatically GMP compliant.

PSA view – The incessant demand by drug procurement agencies seeking a GMP certificate as a pre-requisite for participating in tenders is detrimental to the interests of small and medium scale pharma companies. Though it is logical to ask for a GMP certificate if the procurement is from a foreign company, companies that have been set up and regulated under the Drugs and Cosmetics Act should be considered GMP compliance. Following the clarification by the DCGI, drug procurement agencies should cease asking for GMP certificates, to allow small and medium scale manufacturers a fair chance. However, despite the fact that there are no legal provisions requiring a drug manufacturer to procure a GMP certificate which has been clarified by the RTI, there is no bar on procurement agencies providing this condition as a pre-requisite for participating in a tender. The DCGI needs to notify the fact that being a licensed manufacturer in India implies GMP certification to put the controversy at rest.

*** Industries to move SC for notifying guidelines on spurious drugs**

The Pharmaceutical industry is moving the SC for immediate notification of guidelines for taking action on samples of drugs declared spurious or not of standard quality**.** Manufacturers are concerned that the genuine drug manufacturers and traders could be harassed by the drug inspectors under the new system under the Drugs and Cosmetics (Amendment) Act, 2008 (**"The Act"**). The guidelines were issued in August 2009 by the Ministry which seeks forming of screening committees in every state comprising of at least three senior officers to examine investigation reports of the cases where prosecutions are proposed to be launched. The committee would then submit written comment on the investigation reports regarding the feasibility of legal action. Manufacturers fears that the implementation of the act in its present form can be misinterpreted and misused by the drug inspectors to harass them.

PSA view – Though the guidelines are quite fair and the Ministry has committed to adopt them while implementing the amended Act, the hitch seems to be the industry's lack of trust on the ministry. Industry representatives want these guidelines to be made mandatory and legally binding, as this would insure that the genuine manufacturers are not harassed. Though the ministry of health did assure that it will make the guidelines mandatory and legally binding, a notification is still to be released. The government, to ensure that genuine manufacturers are not harassed, must immediately notify the guidelines.

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