DCGI'S PROPOSAL TO AMEND PHARMA MANUFACTURING LAWS

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DCGI has proposed to amend Drugs and Cosmetics Act, 1940, and Drugs and Cosmetics Rules, 1945 to bring the domestic drug manufacturing standards in line with those recommended by the World Health Organization ("WHO"). As per the WHO's website, good manufacturing practices includes factors such as sanitation and hygiene, qualification and validation, self-inspection, quality audits, suppliers' audits, prevention of cross-contamination and bacterial contamination during production, training of employees and personal hygiene. According to DCGI, a technical advisory board will be set up to recommend the proposed changes to the existing law. This amendment is sought to be brought about within the next six months.

PSA view: If the proposed amendments are effected, the small and medium scale pharmaceutical manufacturing units will have to meet the additional investment demands for establishment of new testing facilities and machine upgradation. However, this will bring our drug manufacturing standards at par with international standards. Recently, the FDA has issued an import alert banning the import of drugs manufactured at an Indian pharma company's plant in Maharashtra. In fact, the distributor had to recall three drugs. These incidents taint country's reputation as a reliable drug manufacturer and supplier. Once the proposed amendment is implemented, issues at drug manufacturing level should get sorted.

Multi-vitamins and health supplements: drugs or not?

The DCGI has set up an expert committee to validate labeling through sample testing of certain multi-vitamins and nutraceuticals. This move comes in the light of concerns raised by the National Pharmaceutical Pricing Authority, which regulates prices of medicines, and has urged the DCGI and the health ministry to check the practice of manufacturers effecting minute changes in the formulation of their products so that they qualify as a nutraceutical or a food supplement, thus evading price regulation and other stringent regulatory norms under the Drugs and Cosmetics Act. The eight-member committee appointed by DCGI has evaluated the ingredients of these multi-vitamins on parameters like composition, effect of each ingredient on the body, food safety and standard requirements as well as the indications claimed on their labels to determine if they fall under the category of 'drugs'. One critical recommendation the committee made was that if a multivitamin product claims that it treats, mitigates or prevents any disease or disorder then it should be classified as 'drug'.

PSA view: India's nutraceutical market is estimated to be close to USD 2 billion, with companies having a free hand in determining prices and marketing of such products. Given the burgeoning market for health

supplements and multivitamins, this is a welcome step in terms of quality control and marketing checks.

New Code for pharmaceuticals marketing practices introduced

The Code had been issued by the DoP from January 1, 2015 prescribing certain standard promotional and marketing practices. Initially implemented for a period of six months, the operation of the Code has now been extended till December 31, 2015. As of now it is voluntary for pharmaceuticals companies to follow the Code, however, the government is planning to make it mandatory. Apart from prescribing stringent measures for audio video promotional activities, the Code bars pharmaceutical companies from giving any gift, cash or other hospitality to doctors, or supplying physicians' samples of drugs which are used to treat depression or induce sleep such as hypnotic, sedative or tranquillizers. However, the pharmaceutical companies are allowed to extend funding for medical research and study through approved institutions with full disclosure. In this regard, the department has proposed to hold discussions with all stakeholders including members of the industry, Medical Council of India, DCGI, Health Ministry and non-governmental organizations.

PSA view: This proposal, if implemented, would narrow the scope of promotional measures for pharmaceutical companies, thereby encouraging more innovative marketing techniques in the industry, in compliance with the measures permissible under the Code.

Raging protests against internet pharmacy

These days lot of e-pharmacists are mushrooming up on the internet. However, there is a legal vacuum when it comes to regulating e-pharmacies in India. Basically, online sale of prescription drugs is not included as per the provisions of the Drugs and Cosmetics Act 1940. On the other hand, no law prohibits it either. With online shopping catching up, the health ministry recently took a befitting step to frame guidelines and mechanism to monitor online sale of drugs. While we await the regulations, chemists across the country have called for a nationwide strike to oppose online sale of drugs.

PSA view: There is no denying the fact that online sale is doing what ration shops did to the local kirana vendors! When the present legislation was brought in force in 1945, no one could foresee that going forward drugs would be sold online and precisely for that reason, the present legislation only has provisions to regulate sale of drugs in brick and mortar shops only. For instance, there is a mandate on pharmacists to sign the prescription after selling the drugs so as to ensure that the prescription is not used again or to say, abused. This is not possible when drugs are sold through e-pharmacies. Therefore, relevant provisions need to be introduced in the present law. Until then, the sale of drugs through online stores is indeed illegal.

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