DCGI'S SUB-COMMITTEE TO FRAME GUIDELINES ON REGULATION OF ONLINE PHARMACIES

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With the recent surge in e-commerce permeating into the drugs and pharmaceutical industry, state food and drugs administration ("FDA") authorities are frowning upon online pharmacies. The Maharashtra FDA had initiated action against online marketplaces like SnapDeal and Amazon while the Gujarat FDA too had registered a case against certain online pharmacies. Realizing the need for constituting guidelines for online pharmacies, the DGCI has formed a sub-committee under the chairmanship of Harshadeep Kamble, Commissioner Food and Drug's Administration & Food Safety Commissioner, Maharashtra, to assess the feasibility of online pharmacies. The sub-committee is also in consultation with state drug controllers, trade bodies, pharmacy chains, e-tailers, states chemists and druggists associations, and consumer forums. The sub-committee is seeking to allow online sale of drugs while putting in place additional safeguards for pharmacy licensing and sale of over the counter drugs, and recognition of electronic record of prescriptions in terms of the Rules.

PSA View: The Drugs and Cosmetics Rules, 1945 require a pharmacist to stamp the prescription after dispensing the medicine. In case of online pharmacy this mandate cannot be met with. This is precisely the reason why the authorities get a reason to frown upon online pharmacies. But the question here is, do the brick and mortar pharmacies adhere by this rule? The answer is "No". Let us wait and watch and see what the guidelines will offer.

FSSAI scraps product approval advisory after Supreme Court decision

The FSSAI had introduced the product approval advisory on May 11, 2013 to streamline the product approval procedure for food products for which the standards are not specified under Food Safety Standards Act, 2006 ("Act"), rules and regulations made thereunder. In August, 2014, Vital Neutraceuticals Private Limited and lobby group Indian Drug Manufacturers' Association challenged the FSSAI's product approval advisory, on the grounds that it involved arbitrary and non-scientific criteria for product approval and was beyond its powers as provided by the Act, which was upheld by the Bombay High Court. The Supreme Court, in September, 2015 has dismissed the appeal against the Bombay High Court order, following which the FSSAI has issued a notification withdrawing its product approval advisory.

PSA View: The controversy has arisen in the wake of the product approval advisory extending to food items/ingredients/additives covered within Section 22 of the Act, which also includes "proprietary foods". This was posing additional delay in launch of packaged foods for the manufacturers, who are already burdened

with pre-marketing FSSAI compliances involving labeling, manufacturing license, good manufacturing practices (GMPs), advertisements and import licenses. However, the FSSAI is in the process of notifying guidelines for proprietary foods, health supplements and additives, which were not covered earlier under the Food Safety and Standards Regulations of 2011. These guidelines have been put up on the FSSAI website for inviting comments from the public and the stakeholders. This move furthers the FSSAI's efforts to bring domestic food safety and security standards in line with the international standards prescribed under the Codex.

DTAB has ruled out double animal testing for approval of new drugs and clinical trials in India

The DTAB recently recommended that repeated animal testing by the Central Drugs Standard Control Organization was not required for permission for a new drug or clinical trial. This ruling was based on the fact that India is a signatory to the Organisation for Economic Co-operation and Development ("OECD") agreement on "mutual acceptance of data" since 2011, which mandates that "test data generated in any member country in accordance with OECD Test Guidelines and Principles of Good Laboratory Practice ("GLP") shall be accepted in other member countries". The committee deliberated and agreed that "for drugs approved in other countries where complete toxicological data generated in a GLP certified laboratory and in alignment with the requirements prescribed under the Drugs and Cosmetics Act, 1940 and Rules, 1945 (Schedule Y), further toxicity study may not be required if complete data as per prescribed requirements is submitted during application for new drug approval."

PSA View: This ruling not only appeals to the organizations lobbying for animal rights but also eases the burden on the pharmaceutical industry by reducing their expenditure on such tests and eliminating one step in the process for the launch of new drugs in the Indian market.

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