



FSSAI LAUNCHES NEW MOBILE APPLICATION

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The FSSAI has launched a new mobile application (“App”) which allows food business operators to check their compliance and allows customers to raise complaints regarding food safety. This App is available on android platform, with built-in geolocation function which allows all android device users to automatically detect their location. While food business operators (“FBOs”) can use this for registration and to check compliance of multiple outlets, customers can use the same to file complaints regarding quality of packaged food and ready-to-eat food served in outlets along with photos. The App also allows FBOs to use the food safety inspection tool to either self-check compliance or seek expert inspection and generate automated reports for multiple locations. At the same time it also has provision for the customers to enter the license/registration number of the FBO to submit information about manufacturing date, expiry date and general adherence to food safety standards by any food business operator. The customer is also given the option of rating the overall hygiene of the food serving establishment. The App also provides access to regular updates about new FSSAI guidelines and directives along with webinars for online training in license/registration process, packaging and labeling and food product approval to help FBOs as well as customers understand the regulatory parameters better.

PSA view: The App is one of the recent moves by the sectoral regulator, FSSAI to revamp its image among consumers as well as food business operators. It will serve as an important and convenient tool for the consumers to report contravention of food safety standards and at the same time allow food business operators to ensure compliance to such standards and prepare for inspections and approvals.

Ban on 344 fixed dose combination drugs

Vide a series of standing orders published by a notification dated March 10, 2016, the Ministry of Health and Family Welfare (“MoHFW”) banned “the manufacture for sale, sale and distribution for human use” of 344 different fixed dose combinations drugs (“FDC Drugs”). FDC Drugs, which are made by combining two or more approved drugs in a fixed ratio into a single dosage, require the prior approval of Central Drugs Standard Control Organization (“CDSCO”). These include several common cough syrup solutions, analgesics and antibiotic combinations, many of which are sold over the counter. This move comes after an expert committee formed to examine the efficacy of these drug combinations recommended that certain fixed dose combinations had no therapeutic justification and were likely to pose risk to humans. The MoHFW highlights that the banned drugs have safer alternatives available in the market. Several manufacturers of affected products, including Pfizer, Abbott, Macleods Pharma and Glenmark Pharmaceuticals have appealed to the courts and received interim injunctions against these standing orders.

PSA view: This move has hit the revenue and sales of the over the counter drugs in India. However, the bigger picture suggests that this would also result in improving the regulation of FDC drugs. India has several such FDC Drugs which are unavailable in other states like UK and the USA. The Expert Committee recommendation indicates that some of these fixed dose combinations might pose certain risks in the long term which required attention from the CDCSO. With a stay on the ban obtained by various leading drug manufacturing companies, we have to await a final decision on the validity of these standing orders to see its long term effect on the over the counter drug market in India.

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