VALIDITY OF LICENSE TO MANUFACTURE/IMPORT DRUGS FOR EXAMINATION, TEST AND ANALYSIS INCREASED TO 3 YEARS

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DTAB has recently approved a recommendation to increase the validity of the license to import drugs for test and analysis under Form 11 and license to manufacture drugs for test and analysis under Form 29 from one year to three years. The Drugs and Cosmetics Rules, 1945 ("Rules") permit the manufacture as well as the import of small quantities of drugs for test and analysis purposes, which is otherwise prohibited under the Drugs and Cosmetics Act. The validity period of such licenses was one year from the date of issue.

This move has come in light of concerns raised by various drug manufacturers associations regarding the hassle of seeking a fresh license every year, to import drugs for the purpose of clinical trials and drug development. The department of commerce has also made similar recommendations to the health ministry in order to aid the business of such drug manufacturers.

PSA view: This would be an important move on the DTAB's part to ease the process for import and manufacture of drugs for clinical trials and testing purposes, a process which sometimes takes more than a year to conclude.

New draft standards for milk and milk products proposed by FSSAI

In a much awaited move, the FSSAI also brought out standards for milk and milk products and guidance on the use of 'dairy terms' in relation to foods to be offered to the consumer or for further processing. These draft standards also cover cream; malai, curd, paneer, cheese, dairy-based desserts or confection, evaporated or condensed milk and milk products, butter, ghee and milk fats, chakka, shrikhand, fermented milk products, whey and edible casein products. The standards prescribed include requirements for heat treatments, pasteurisation, boiling and sterilisation, along with packaging and labeling requirements, including order of listing ingredients and their ratio of usage.

This move has come in light of an FSSAI survey conducted across states on milk from different animal sources, where majority of the milk samples collected from 19 states and union territories were found to be adulterated with agents like skimmed milk powder, glucose, fat, solid-not-fats and water, and non-compliant with existing food safety standards.

The draft standards prepared by a FSSAI technical committee is up for public comments within the next 60 days, which would be taken into account before the final milk standards are notified.

PSA view: Concerns regarding adulteration of milk and milk products have been echoing across the country for several years now. Moreover, milk and dairy products are consumed on a large scale in India round the year, and especially during festival seasons. Therefore, there is a dire need to regulate the standards of milk and milk products in light of public health and safety. Once notified, these standards would help ensure quality control and prevent adulteration in manufacture and processing of milk and milk products.

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