MONOGRAPHS FOR RADIOCEUTICALS TO BE ADDED SOON

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The Indian Pharmacopeia Commission (**"IPC"**), which is an autonomous institution under the Ministry of Health & Family Welfare, has initiated efforts to include monographs of radiopharmaceuticals, which are used in the field of nuclear medicine, as tracers in the diagnosis and treatment of various diseases including cancer, in India for the first time. The IPC, after holding a meeting in July 2010, plans to add a general chapter covering approximately 25 monographs of radiopharmaceuticals which are widely used for diagnostic and therapeutic use in India. The commission has formed an expert committee consisting of eminent scientists from the field and is expected to complete its job within a period of six months. The IPC proposes to publish the general chapter on radiopharmaceuticals in the 6th edition of Indian Pharmacopeia under the Second Schedule of the Drugs and Cosmetics Act, 1940.

PSA view – The effort of IPC is to keep pace with emerging and contemporary areas for addressing the issues of healthcare requirements, in tandem with the regulatory developments in global pharmaceutical sector. Radioceuticals are drug formulations which are used for diagnosis and therapy for various diseases and at various stages of treatment. These drug formulations contain radioactive isotopes and are already used in many developed countries. The efforts of the IPC will definitely benefit India as an emerging market for drug manufacture, by bringing India at par with global accepted standards for the manufacture of such drug formulations.

Cosmetic imports registration to be made mandatory from April 2011

The Drugs and Cosmetics Rules (**"Rules"**) have been amended to make registration of all imported cosmetics mandatory. The notification dated May 19, 2010 will come into effect on April 1, 2011. The new rules (Rule 129 to 129H) pertaining to import and registration of imported cosmetics shall substitute the existing rule 129 of the Rules. The heading in Part XIII of the Rules has also been changed from "Import of Cosmetics" to "Import and Registration of Cosmetics". According to the new rule,

"No cosmetic shall be imported into India unless the product is registered under the rules by the licensing authority appointed by the Central Government under Rule 21 or by a person to whom such powers may be delegated under Rule 22." Further, sub-sections have been included, which stipulate the procedure and formalities for the registration of the imported cosmetics as given below:

Rule 129A prescribes the form and manner of application for registration certificate. **Rule 129B** deals with registration certificate for the import of cosmetics manufactured by one manufacturer. The registration authority will issue the certificate in form 43 subject to conditions. Under **Rule 129C**, the licensing authority

has the power to grant the registration certificate, which, as per Rule **129D,** is valid for a period of three years. **Rule 129E** of the amendment deals with suspension and cancellation of the registration certificate.

Rule 129F prohibits import of cosmetics into the country, which are banned in the country of origin unless it is only for the purpose of examination, test or analysis. Finally, while **Rule 129** G talks about the standards for imported cosmetics, **Rule 129F** stipulates the labeling and packaging of cosmetics, which ought to be in accordance with Part XV of the Rules.

PSA view – These rules had been in the offing for a long time. The Ministry of Health and Family Welfare had proposed the amendment and published it in February 2007 for suggestions from the public and the concerned stakeholders. It is a good move and will keep a check on imported cosmetics. It will ensure regulation and maintenance of a database with the licensing authority and, simultaneously, attempt to protect interests of consumers.

New Food Regulations

The Prevention of Food Adulteration (3rd Amendment) Rules, 2010 as released by the Ministry of Health and Family Welfare was notified in the official gazette. This amendment amends the proportion of **usage of various food additives, especially polyols, in food products. Further,** in terms of section 92 (1) of the Food Safety and Standards Act, **the** Food Safety and Standards Authority of India (**"FSSAI"**) has sent a draft Food Safety and Standards Regulations, 2010 for the approval of the Government. The Food Safety and Standards Authority of India has integrated the erstwhile acts/rules/orders in line with the mandate of the Act. The present FSSAI regulations will enable introduction of the new food law in the States and UTs after final notification of these regulations.

PSA view – Along with FSSA Rules, and Licensing Regulations, the present regulations cover all the legal requirements for transition from PFA to FSSAI. The unified licensing procedures will be implemented by the FSSAI, Food Safety Commissioners in the States and the officers working under the Commissioner. This regulation has brought a distinction between "Registration" and "Licensing" and also has proposed their cut off limits. The sectors which have high potential for food contamination and hazard have been brought under central licensing. Finally, all labeling, prohibitions, laboratory, residues & contaminants, additives related provisions have been grouped separately under respective chapters so that future amendments can be easily introduced and revision made at the appropriate places.

Health ministry to allow drug imports through ICD of Tuticorin seaport soon

The Union Ministry of Health & Family Welfare (**"MHFW"**) may soon allow imports of medicines and related products through one more Inland Container Depot (ICD), at Tuticorin, Tamil Nadu, by including the Depot as a clearance point in the Drugs and Cosmetics (2nd Amendment) Rules, 2010 .The MHFW issued a draft notification announcing its proposal to include the ICD to Rule 43-A of Drugs and Cosmetics Rules, 1945, in respect of drugs imported by sea in India. In addition to this, the notification has made further amendments in the Form 45 and 46 under the Schedule A of the Drugs and Cosmetics Rules, 1945, by updating the norms of post marketing surveillance with details on submission of Periodic Safety Update Reports (**"PSUR"**). The earlier form 45 and 46 only mandated post marketing surveillance during the initial period of two years of marketing of a new drug formulation. Now, as per the amendments, an applicant will be required to submit PSUR every six months for the first two months, and annually for the subsequent two years.

PSA view –

The decision to approve a new drug is based on it having a satisfactorily balance of benefits and risks. A strong and constant “pharma-vigilance” is required to ensure the continuous monitoring and evaluation of new safety data generated under the real-world conditions on the effect, side effects, etc. At present, the legislative requirements of “pharma-vigilance”, in India, are guided by specifications of “Schedule Y” of Drugs and Cosmetics Rules, 1945. The amendment will be a positive move by the MHFW as the draft notification, when published, will ensure stricter “pharma-vigilance” on pharmaceutical companies, as there will be a constant check on whether the imported drugs meet the required safety standards and thus, will better define the responsibilities of pharmaceutical companies.

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