DCGI ISSUES NOTICES TO STREAMLINE GRANTING OF LICENSES

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The first notice was a direction under section 33(P) of the Drugs and Cosmetics Act, 1940 ("Act") for grant/renewal of manufacturing license of drug formulations in proper generic names only. The DCGI has pointed out that the current practice of granting license by endorsing trade name as submitted by the applicant is not in compliance with the Act. What the Act prescribes is mentioning the name of the drug and not the brand or trade name. So, it has been instructed to the state licensing authorities that the licenses should be granted to generic/proper names only and in case of drug formulations containing multiple ingredients, license should be granted under the name of the categories of products. The composition of such product should also mention the name of active ingredients and the strength. The second notice from DCGI was concerning the cancellation of license to manufacture drug formulations falling under the purview of "new drugs." As defined under Rule 122E of the Rules, it is mandatory to procure prior approval of DCGI before granting license under this category but the state licensing authorities were granting licenses without prior approval of the DCGI. Therefore, the DCGI has instructed the state authorities to follow the law and the procedure prescribed under the Rules.

PSA view – The above notices are an attempt to make the procedures followed in the state authorities more efficient and in compliance with the Act and Rules. The notices do not suggest what would happen to the existing licenses which have been granted by the state authorities in the name of the brand or without seeking the prior approval of DCGI. As the notices are silent on this front it can be safely assumed that currently the licenses already granted by the state authorities will not be questioned and shall remain valid. The notices will be followed henceforth.

Schedule K of Rules to be amended to curb marketing of food supplements

The Health Ministry has proposed to amend item no. 1 of the Schedule K of the Rules, which provides exemption from all provisions of Chapter IV of the Act and Rules to the drugs falling under section 3(b)(i) of the Act that are not intended for medicinal use and such products are conspicuously labeled with the words "NOT FOR MEDICINAL USE." This proposal will be a step towards controlling the marketing of vitamin preparations as food supplements. A large number of non pharmaceutical units manufacture and sell products containing vitamins in quantities which fall either into prophylactic category or therapeutic category as specified under Schedule V of the Rules. If examined carefully it would be abundantly clear that such products are indiscriminately licensed under Food Safety and Standards Act, 2006 as "dietary supplements" or "nutritional supplements" or "nutraceuticals," whereas medicinal claims are made in them.

PSA view – This measure will ensure that the drug substances manufactured for even non-medicinal use should be with the permission of the concerned licensing authority under the Rules. Though it will deeply impact the prevailing neutraceutical market but adhering to the changing law is the only option that the manufacturers will ultimately have.

Inadmissibility of expenses incurred in providing freebees to Medical Practitioner

Income Tax Department took cognizance of the prevailing practice of providing freebees to medical practitioners and their professional associations by pharmaceutical and allied health sector industries in violation of the Medical Council of India guidelines and issued a circular (Circular No. 5/2012 [F. No. 225/142/2012-ITA.II], dated 1-8-2012) to include freebees as taxable income. Section 37(1) of Income Tax Act provides for deduction of any revenue expenditure (other than those failing under sections 30 to 36) from the business income if such expense is laid out/expended wholly or exclusively for the purpose of business or profession. However, the explanation appended to this sub-section denies claim of any such expense, if the same has been incurred for a purpose which is either an offence or prohibited by law. Thus, the claim of any expense incurred in providing above mentioned or similar freebees in violation of the provisions of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 shall be inadmissible under section 37(1) of the Income Tax Act being an expense prohibited by the law. This disallowance shall be made in the hands of such pharmaceutical or allied health sector industries or other assessee which has provided aforesaid freebees and claimed it as a deductable expense in its accounts against income. It is also clarified that the sum equivalent to value of freebees enjoyed by the aforesaid medical practitioner or professional associations is also taxable as business income or income from other sources as the case may be depending on the facts of each case.

PSA view – This is a crucial step to end the unethical drugs marketing practice. The Medical Council of India amended the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 (the regulations) on December 10, 2009 imposing a prohibition on the medical practitioner and their professional associations from taking any gift, travel facility, hospitality, cash or monetary grant from the pharmaceutical and allied health sector industries. Samples were the most widely prevalent brand promotional exercise of the pharma companies. If doctors will be taxed for sample medicines, they will refrain from taking such samples.

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