Pharma & Healthcare Update

September 14, 2012

PHARMA UPDATE - I

Between the last week of August, 2012 and the date of publication of this update, numerous important amendments have been implemented or proposed to the law, regulation and practice governing the health and pharmaceutical industries. These changes have the potential to impact the industries significantly.

Nishith Desai Associates, continuing with its practice to document all current and future regulatory changes, is bringing you this three part update- document which aims to provide a brief overview of these regulatory changes with our comments.

DCGI tightens post- market surveillance of new drugs, declares deadline for submission of PSUR

In the past few months, the Central Drugs Standard Control Organisation ("**CDSCO**") has notified numerous draft modifications to regulations governing conduct of clinical trial of new drugs in India. The Drugs Controller General of India ("**DCGI**") is also tightening its surveillance over manufactures / importers of new drug who have received marketing approval for new drugs.

Under the Drugs and Cosmetics Rules, 1945 ("**Rules**"), a new drug is defined as a drug which is yet to approved by DCGI, or a new drug which has received approval from DCGI for certain claims, but now is proposed to be marketed for different claims (indication, dosage, dosage form etc.), or a fixed dose combination of two or more drugs, which have been individually approved by DCGI earlier for certain claims, but now are being proposed to be combined for the first time in a fixed ratio or if the ratio of ingredients in an already marketed combination is proposed to be changed, with certain claims. Once a new drug gets approval from DCGI, it continues to be considered a new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, which is earlier.

Under Schedule Y of the Rules which regulates conduct of clinical trial of new drugs in India, it is mandatory Periodic Safety Update Reports ("**PSUR**") are submitted every six months for the first two years after receipt of marketing approval, and should be submitted annually for the subsequent two years. PSURs must be submitted within 30 calendar days of the last day of the previous reporting period. If, for some reason, there is some delay in marketing of new drug then the six month period for marketing the drug will trigger from the day of start of marketing of the new drug in India. The ingredients and structure of a PSUR has been specified under Schedule Y.

In spite of the existence of this provision it was noticed by the DCGI that the manufacturer / importer of the new drug have failed to submit such reports. Therefore, the DCGI issued an order on August 28, 2012 directing all manufacturers / importers to submit PSUR to do so 'in totality' within three weeks of the date of the order. A failure to submit the PSURs within the deadline may result in suspension / cancellation of the permission to market the new drug within India.

Union Government issues 4th edition of National Formulary of India

The Indian Pharmacopoeia Commission ("**IPC**") has published the 4th edition[1] of National Formulary of India ("**New NFI**") on behalf of the Central Government. The publication follows announcement in 2010 about a pre- print publication of the national formulary.[2]

A formulary is a document which provides basic drug information and their right doses, and is meant for the guidance of the members of the medical profession such as medical students, nurses and pharmacists working in hospitals and in sales establishments. The New NFI lists indications for which the drug may be used, and provides information about form and availability of the drug in Indian market, correct dosage, contraindications, precautions, adverse effects and proper method of storage. It is expected to assist medical professional in rational and economic prescribing.

For the preparation of the New NFI, it is reported that expert opinion of medical practitioners, teachers in medicine, nurses, pharmacists and Pharmaceutical manufacturers has been obtained.[3] It is further

reported that the New NFI represents a broad consensus of medical opinion in respect of drugs and their formulations and provides the physician with carefully selected therapeutic agents of proved effectiveness which form the basis of national drug therapy.[4]

However, the NFI is not a mandatory document but only a reliable reference document. Physicians are expected to use their professional judgment while prescribing drugs.

Drug Inspectors in various states to carry out surprise inspections of chemist shops to check licenses and compliance

The Drugs and Cosmetics Rules, 1945 regulate sale of drugs in India. The Rules require that separate licenses are required to sell drugs depending upon system of medicine (allopathic or homeopathic), type of business model (wholesale or retail sale), nature of drugs sold (whether drug sold are part of Schedule X, Schedule C or Schedule C1), mode of sale (through a permanent physical location or through a motor car) and whether services of with an 'registered pharmacist' will be engaged to effect the sale. All the licenses which are issued are conditional licenses and their validity depends upon meeting of requirements prescribed in the Rules as well as in the license.

It is the responsibility of the state- level Drug Inspectors to ensure that drugs are not sold without valid license in their jurisdictions and all conditions prescribed in the Rules as well as the license are met by the licensee. If it is found that a person has engaged in sale of drugs without valid license, then it may lead to imprisonment as well as pecuniary penalty as per the Rules. The DCGI has the power to co- ordinate and guide State Drug Controllers, who in turn can issue directions to Drug Inspectors.

In furtherance of its powers, DCGI has requested all Drug Controllers of all States and Union Territories to issue a direction to Drug Inspectors to conduct surprise checks of chemist shops to ensure compliance with condition of license. Further, DCGI has requested that all chemists and druggist associations should sensitize their members to comply with the Rules. With a culture of surprise checks in place, it is hoped that the malpractises such as sale of drugs (including psychotropic drugs) without prescription or compounding of drugs without supervision of a registered pharmacist will be checked and brought under control.

DCGI to increase representation on Advisory Committees

The Drugs Controller General of India issued a notice on August 28, 2012 inviting participation of experts of certain disciplines working in Government medical colleges / institutions for advice on matters related to regulatory approval of new drugs, medical device, fixed dose combination and clinical device.

DCGI is the licensing authority under the Drugs and Cosmetics Act, 1940 which grants approval for clinical trial / manufacture / import / marketing of drugs, fixed dose combination and medical devices in India. To aid DCGI in process of approval, numerous New Drug Advisory Committees ("**NDACs**") and Medical Devices Advisory Committee ("**MDAC**") are constituted which scrutinize proposals submitted by applicants.

The notice lays down the terms of reference, details of honorarium, duration of office and obligations of membership. However, there is no clarity about the process of selection of experts- whether it will be done by nomination / industry representation / unilateral decision of DCGI. Further, it has not been clarified why DCGI limited the invitation to experts from certain disciplines only.

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You can direct your queries or comments to the authors

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[1] Available at http://cdsco.nic.in/NFI_2011.pdf

[2] "The experts are working to publish the pre-print version of the 4th edition of NFI by end of July 2010." Indian Pharmacopoeia Commission, available at http://www.ipc.gov.in/index1.asp?linkid=211

[3] Id.

[4] Supra note 2.

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