CDSCO guidance document on grant of licence for drugs import for test purposes

On May 30, 2011, the Central Drugs Standard Control Organization (CDSCO) came with a Guidance Document on grant of licence for drugs to be imported into India for test purposes. The purpose of this guidance document, which will be effective from June 15, 2011, is to harmonize the submission documents for applications for test licence for drugs and to facilitate the examiners to take uniform and expeditious decisions. The focus of this CDSCO Guidance Document is only drugs for human use which undergo systemic circulation and is not applicable to import of diagnostic kits, veterinary drugs, medical devices, and drugs of biological origin.

Test license is given for small quantities of drugs proposed to be imported for the purpose of examination, test or analysis. Section 10 of the DCA prohibits import of drugs which are misbranded, adulterated, spurious, not of standard quality etc. into India. However, the proviso to Section 10 permits import of small quantities of any drug for the purposes of examination, test or analysis or for personal use. Import of such drugs is permitted only under a test license in Form 11 of Schedule A of the DCR and application for such test licence is made in Form 12 by the head of the institution in which the examination, test or analysis will be conducted, or by a proprietor or director of the company or firm by which the examination, test or analysis will be conducted. Other documents which are required to be filed along with the application is the Bank's receipt for the payment of requisite fees by way of TR-6 Challan and justification and utilization break-up, detailing the test parameters visà-vis quantities of the drugs, batch manufacturing plan. DCR is silent on as to what constitutes "small quantity" as per Rule 33 (on import of drugs for examination, test or analysis) and interpretation of this term hither to may have remained rather subjective. As per this new guidance document, test license for import of large quantities of drugs may be granted subject to the applicant justifying test parameters, batch sizes, no. of batches, categories of batches etc in a notarized undertaking or affidavit. Addressing this issue by CDSCO is undoubtedly a step in the right direction. However, the Ministry of Health may also consider bringing about appropriate amendment to the DCR to avoid any conflict between the guidance document and the DCR and to provide an importer a legal basis to import larger quantities of drugs for test purposes.

For purposes of bio-equivalence (BE) studies, the new guidelines require an applicant to submit BE protocol along with his application for test licence. For BE studies on new drugs, a copy of BE NOC for those drugs firm are required to be submitted and in case of drug, which is not a new drug, regulatory status of drug (strength and dosage form) in India along with the year of its approval is required to be indicated. Applicant is also required to submit a copy of approval certificate from Dept of Scientific and Industrial Research.

Test licences are subject to certain conditions - drugs imported under such licences are to be used exclusively for purposes of examination, test or analysis; such exam, test or analysis is to be carried out only at such places as specified in the license; licensee should allow the licensing authority or his authorized representative to investigate and inspect premises and to take samples of the substances and licensee is required to keep a record of substances imported under the license and report about the same to the licensing authority along with the details of quantities imported, date of importation and name of the manufacturer. These test licenses remain in force for a period of one year and may be cancelled by the licensing authority for breach of any of the conditions subject to which the license is issued. For renewal of this license, an applicant is required to file fresh application.

This Guidance document is a positive move on the part of the CDSCO for facilitating research and development activities and boosting up scientific and technological activities in the pharmaceutical sector. ◆

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FinMin approves Health Ministry's proposal to set up 'National Health Portal

Our Bureau, Mumbai

The union health ministry's proposal to set up a 'National Health Portal,' a database for the medical records of all citizens and other health related issues, has received the approval of the union finance ministry.

Union minister of state for health and family welfare Dinesh Trivedi said that the expenditure finance committee of the union ministry of finance has given its nod to the health ministry's proposal to set up a 'National Health Portal.' The proposal will now go to the Union Cabinet for approval. Trivedi was inaugurating FICCI's 'International Conference on Medical Electronics: Partnering for Access and Affordability' in New Delhi.

The Health Ministry adopted a three-pronged initiative two years ago to put in place a National Health Portal, a 24-hour, 3-digit National Emergency Media Service Number and an Indian Health Information Network, he said.

The National Health Portal, recommended by the National Knowledge Commission, would make the optimum use of technology for establishing a database for the medical records of all citizens and other health related issues. The portal would put information on standardization and protocols in the public domain. The effort would also be to ensure that the medical records of all citizens are electronically stored for ease of access by pathologists and doctors for diagnosis and treatment of patients. ◆