

## Pharma & Healthcare Update

January 14, 2011

### INDIAN DRUG AUTHORITIES TO NOW VISIT AND INSPECT FOREIGN MANUFACTURERS' FACILITIES

In a recent development, the office of the Drug Controller General of India ("DCGI") has decided that it will soon start inspection of the manufacturing facilities located in foreign countries from where Indian companies are importing active pharmaceutical ingredients ("APIs"), intermediates and finished products. This move will enable the Indian drug authorities put a quality check on the products coming into India.

#### BACKGROUND:

The import, manufacture, distribution and sale of 'drugs' are governed by the Drugs and Cosmetics Act, 1940 ("Drugs Act") and the Drugs and Cosmetics Rules, 1945 ("Drugs Rules"). The licensing authority for import under the Drugs Act is the DCGI. The company intending to import drugs into India needs to obtain an import license and a product registration certificate from DCGI, which also registers the manufacturing site from where the product (finished or API) is proposed to be imported. The Drugs Rules provide a process of inspection of foreign manufacturing sites prior to the grant of the product registration certificate. However, due to lack of trained resources, the inspection process was not being followed. This caused some concerns over the quality of the drug being imported to India.

#### RECENT DEVELOPMENT:

The current DCGI, Dr. Surinder Singh, has recently expressed his intention of soon commencing the audit and inspection of the foreign manufacturing sites. The DCGI, as part of its pilot project, proposes beginning the process of inspections with manufacturing facilities in Europe and China towards the end of January this year, and then accordingly implement globally.

To accomplish this, the Central Drugs Standard Control Organization ("CDSCO") has selected a group of drug inspectors who will be trained as per international standards. These trained inspectors will be sent to various manufacturing sites overseas for audit and inspection.

#### KNOWLEDGE OF THE INDIAN ACT AND RULES:

One issue that is of relative concern is the lack of understanding of the Indian laws on the part of the foreign manufacturers. The office of the DCGI has observed that the foreign manufacturers are not particularly familiar with the provisions of the Drugs Act and Drugs Rules and its interpretation. In fact, at times, their submissions to the drug authorities do not include complete details, which may lead to non-compliance of the applicable laws in India.

As a result, the foreign manufacturers are reluctant to provide undertakings as is the mandatory requirement under the Drugs Rules prior to them exporting products to India. The forms prescribed under the Drugs Rules require the foreign manufacturers to provide undertakings that they have knowledge of the Drugs Act and the Drugs Rules and that they will comply with the same. The stand taken by some of the foreign manufacturers is that they have no knowledge of the Indian laws and therefore cannot give such undertakings.

According to the office of the DCGI, it is the responsibility of the importers (who register the product locally) to make the manufacturers aware of the rules and regulations of the country and also to ensure that the manufacturer follows the Indian law.

#### WAY FORWARD:

The process of inspection, under the current law, forms part of the compliances for import and product registration in India, and every manufacturer will need to co-operate with the DCGI. This move will definitely clear the concerns over the quality of the drugs imported into India. The applicability, however, of certain provisions under the Drugs Rules in relation to certain products remains unclear. The DCGI should consider coming up with manuals that may be referred to as guidance documents and can be followed by foreign manufacturers for compliance with Indian laws, as is already done for certain other processes (for instance, guidance documents are available for procedures to be followed in the case of importing, distributing and selling medical devices in India). The manuals could clarify the applicability of the Drugs Rules, which will aid in providing comfort to the foreign manufacturers while giving undertakings that are required under the Drugs Rules in India.

- Dr. Milind Antani & Gowree Gokhale

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