

Pharma & Healthcare Update

February 08, 2011

PHARMA REGULATORY UPDATE 2010

The Government of India has over the last few months proposed various guidelines, regulations and amendments to regulate the Pharma and Healthcare industry in India. We have discussed below some of the key developments in relation to the same.

MORE STRINGENT MEASURES TO IMPROVE CLINICAL TRIALS IN INDIA:

All the stake holders involved in the conduct of clinical trials in India, be it sponsor pharma company, Contract Research Organization ("CRO"), institution, investigator or independent ethics committee, shall now be subject to detailed inspection by the drug authorities in India.

To ensure safety of the study subject, which is of utmost importance, the Central Drugs Standard Control Organization ("CDSCO")¹ and the Drug Controller General of India ("DCGI") have recently issued guidelines regarding inspection of clinical trials being conducted in India under the clinical trial inspection program ("Program")². The main objective of the Program is to verify GCP compliances, the safety and well being of the subjects involved in clinical trial, the credibility and integrity of clinical trial data generated and the compliance of various regulatory provisions as per the Drugs & Cosmetics Rules. The Program will cover all clinical trial sites and sponsor / CRO's facilities which are involved in the clinical trial of drugs including biological and medical device as identified under the Drugs & Cosmetics Act 1940

Inspection can be conducted any time before, during or even after the trial is completed on the instruction by DCGI and will include verification of all the documents related to the trial, study site, protocol and other documents including informed consent forms, case records etc. Further, the inspection will also verify and examine details regarding independent ethics committee.

THE SALIENT FEATURES OF THE PROGRAM, INTER ALIA, ARE AS FOLLOWS:

- It provides guidance to the inspectors or CDSCO officers who would be conducting inspection of the clinical trial site, sponsor / CRO's facilities and their scope, power and responsibilities.
- The inspector is conferred with the power to verify and assess all the documents related to the sponsor, CRO, institution and the investigator.
- Inspector will also verify record keeping, process of managing database, implementation of SOP. After verifying all the documents, compliances and other details, inspector will be submitting the report to CDSCO.
- It also provides information to investigators, sponsor/ CRO'S about procedures for inspection and follow up of action etc.

Though it is a common practice to have sponsor's own audit procedures regarding the conduct of clinical trials in India along with corrective measures, this move by the regulators is welcomed as it will ensure further safety of the study subjects along with the authenticity of the data generated during the clinical trials conducted in India.

Medical Devices on way to better regulations in India:

Until 2005, Medical device industry was not regulated in India, which led to import and manufacturing of substandard devices leading to possible hazards to patients.

The Central Government of India in the year 2005 issued notifications for regulating the manufacture, sale and distribution of the 10 sterile medical devices,³ as "drugs" within Section 3(b) of the Drugs and Cosmetic Act, 1940 ("Drugs Act")⁴. In March 2006, the government issued guidelines for the Import and Manufacture of Medical Devices ("Guidelines"). Thereafter in the year 2010, 4 more devices were added to the list of "drugs" within Section 3(b) of the Drugs Act. Apart from the herein mentioned 14 notified medical devices ("Regulated Devices"), other medical devices, still remain unregulated.

The Ministry of Health and Family Welfare has in the month of August, 2010, approved certain procedures to be adopted in respect of licensing of import as well as manufacture of these Regulated Devices in the country. DCGI office had uploaded the proposed requirements for the regulatory control of medical devices on the website www.cdscn.org.in for information and comments of all stakeholders. The following guidance documents have been uploaded -

1. Guidance document on application for grant of licence in Form-28 for manufacture of medical devices in India under Central Licensing Approval Authority (CLAA) Scheme;

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2. Guidance document on common submission format for registration of medical devices in India;
3. Guidance document on common submission format for import licence in form 10 of medical devices in India;
4. Requirements for conducting clinical trial(s) of medical devices in India.

The above uploaded documents describe in detail the process that needs to be followed by the applicant which includes submission of forms, various letters, certificates, details of the devices, details of site and undertakings that are required to be submitted to the relevant authorities mentioned in the guidance notes for either manufacture, registration, import or conduct of clinical trials, in India. Government has received the comments and inputs but final guidelines are not issued.

A REASON TO BLOW THE WHISTLE AGAINST FAKE/SPURIOUS DRUGS

Considering the gravity of the situation of fake and spurious drugs in India, the Government of India recently amended the Drugs & Cosmetics Act, 1940 by the Drugs & Cosmetics (Amendment) Act, 2008 for providing more stringent and stricter penalties to the offenders who trade in spurious drugs. (Please refer to our earlier [hotline](#).)

To beef up the war against the menace of spurious and misbranded drugs, the authorities have recently launched a scheme for whistle blowers. Under this scheme whistleblowers would be given monetary rewards for taking the risk of providing the information to the officers leading to seizures of spurious, adulterated, misbranded and not of standard quality drugs, cosmetics and medical devices. This reward scheme will be applicable to both the informers as well as the officers of CDSCO.

Some of the important features of the scheme are as follows;⁵

- (i) Reward is to be given to the whistleblowers i.e. the informers / officials only when there is a confirmation of the seizure of spurious, adulterated and misbranded drugs, cosmetics and medical devices by the designated officers of the CDSCO.
- (ii) The reward of maximum of up to 20% of the total cost of consignments seized will be payable to the informer / officials *[NO, Scheme mentions official, this is generic statement and mentions total amount for reward]* which should not in any case exceed Rs. 25,00,000 (USD 55000 approximately) in each case.
- (iii) In respect of an officer of the Government / CDSCO, the reward should not in any case exceed Rs 500,000 (USD 11000 approximately) for one case and a maximum of Rs 3000000 (USD 55000 approximately) in his / her entire service.
- (iv) With a view to ensure that the informers are not made to wait till the final disposal of the matter, 25% of the amount will be given at the time of filing of the charge sheet in the court of law.
- (v) Further, with a view to ensure that the informers do not turn hostile during the trial of the case and continue to assist the court in deciding the matter in favor of the Government, 25% of the amount will be given to them at the time of disposal of the case in favour of the Government in the first court of law.
- (vi) The remaining 50% amount will be paid only when the case has been finally disposed of in favour of the Government and no appeal with respect to the matter is pending in any other Court of Law in the country.

The whistle blower scheme by the Government is a welcome initiative and is expected to encourage the officers and public at large to assist government to curb the menace of counterfeit and spurious drugs in India.

- **Dr. Milind Antani & Gowree Gokhale**

- 1 The apex regulatory authority regulating pharma industry in India,
- 2 Guidance note under this Program is posted on the website of CDSCO. <http://www.cdsco.nic.in/>
- 3 The list of these devices is available on the website www.cdsco.nic.in
- 4 The Drugs Act is the relevant legislation that regulates the manufacture, sale, distribution and import of pharmaceutical products in India.
- 5 As posted on the website www.cdsco.nic.in

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