

Pharma & Healthcare Update

May 15, 2009

PHASE I TRIALS FOR DRUGS DISCOVERED OUTSIDE INDIA TAKE A BACKSEAT YET AGAIN

The Union Health Ministry ("Ministry") has, temporarily, decided against allowing phase I trials in India for new drug substances discovered outside India. The Drug Technical Advisory Board ("DTAB"), back in 2007, had provided recommendations to the Ministry for allowing such trials in India. Currently, only Phase II and Phase III clinical trials of drugs discovered outside India are permissible in India.

Under Schedule Y of the *Drugs and Cosmetics Rules, 1945*¹, the Phase I trials involve the estimation of safety and tolerability with the initial administration of an investigational new drug into humans after it is successfully tried on animals. Currently, as the legislation stands, Phase I trials cannot be initiated in India for new drug substances discovered in other countries unless Phase I data from such country is presented to the appropriate Indian drug authority, the Drug Controller General of India ("DCGI"). However, in relation to new drugs discovered in India, all stages of trials including Phase-I are allowed to be conducted.

According to an article that recently appeared in the **Economic Times**, a Health and Family welfare ministry official stated that, "Analysis of these drugs, setting up stringent monitoring systems, registering the clinical trial organizations and maintaining a database of people who volunteer for these drug trials are some of the key issues to be resolved before the phase-I trial for molecules developed outside the country could be allowed."

There are several other concerns that need to be addressed prior to allowing Phase I trials. For instance, establishments carrying out these trials need to have manpower with the required skill-set and expertise and be fully equipped infrastructure. In addition, to the legislative changes, a stringent monitoring system should also be put in place. Moreover, making registration of clinical trial organizations mandatory and maintaining a registry of trial subjects will help bring in a transparent system and aid in regulating the clinical trials space. The process of mandatory registration of the clinical trials organizations the Clinical Trials Registry is likely to begin from June this year.

The Government of India has announced plans to amend the *Drugs and Cosmetics Act, 1940* to impose imprisonment (up to 10 years) and cancellation of licenses for companies that violate norms for testing drugs on humans in India.² Under the current regulations the DCGI does not have statutory power to penalize companies that do not follow guidelines.

The Ministry is expected to reconsider the proposal of the DTAB for permitting Phase I trials in India of drugs discovered abroad once the relevant ethical and regulatory requirements are enacted in order to ensure a safer environment for clinical trials, which in turn, will make India a credible and safe destination for clinical trials.

- **Khushboo Baxi, Nirva Patel & Gowree Gokhale**

Source: <http://economictimes.indiatimes.com/News/News-By-Industry/Healthcare--Biotech/Pharmaceuticals/Pharma-MNCs-cant-experiment-with-India-yet/articleshow/4497457.cms>

1 The Drugs and Cosmetics Rules, 1945 was framed under the Drugs and Cosmetics Act, 1940 and is the governing regulation for clinical research conducted in India

2 "Unethical clinical trials may invite painful penalty." **Economic Times**. 15 Apr 2009

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