

## 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*<sup>1</sup>, 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.<sup>2</sup> 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

### DISCLAIMER

The contents of this hotline should not be construed as legal opinion. View detailed disclaimer.

This Hotline provides general information existing at the time of preparation. The Hotline is intended as a news update and Nishith Desai Associates neither assumes nor accepts any responsibility for any loss arising to any person acting or refraining from acting as a result of any material contained in this Hotline. It is recommended that professional advice be taken based on the specific facts and circumstances. This Hotline does not substitute the need to refer to the original pronouncements.

This is not a Spam mail. You have received this mail because you have either requested for it or someone must have suggested your name. Since India has no anti-spamming law, we refer to the US directive, which states that a mail cannot be considered Spam if it contains the sender's contact information, which this mail does. In case this mail doesn't concern you, please unsubscribe from mailing list.

## Research Papers

### Little International Guide (India) 2024

November 08, 2024

### Unmasking Deepfakes

October 25, 2024

### Are we ready for Designer Babies

October 24, 2024

## Research Articles

### The Bitcoin Effect

November 14, 2024

### Acquirers Beware: Indian Merger Control Regime Revamped!

September 15, 2024

### Navigating the Boom: Rise of M&A in Healthcare

August 23, 2024

## Audio

### Digital Lending - Part 1 - What's New with NBFC P2Ps

November 19, 2024

### Renewable Roadmap: Budget 2024 and Beyond - Part I

August 26, 2024

### Renewable Roadmap: Budget 2024 and Beyond - Part II

August 26, 2024

## NDA Connect

Connect with us at events, conferences and seminars.

## NDA Hotline

Click here to view Hotline archives.

## Video

### "Investment return is not enough" Nishith Desai with Nikunj Dalmia (ET Now) at FI8 event in Riyadh

October 31, 2024

### Analysing SEBI's Consultation Paper on Simplification of registration for FPIs

September 26, 2024

