India’s drug trial industry: regulation and challenges

By Dr Rachna Bharadwaj,
Krishna & Saurastri Associates

India is the world’s most favoured destination for pharmaceutical R&D and clinical research. The key reasons are a 100 million-plus English-speaking population, over 2 million science postgraduates, a large pool of treatment-naïve patients from multi-ethnic and multiracial backgrounds, easy patient recruitment, robust IT Industry, 30 million patients with cardiovascular disease, 25 million with type 2 diabetes, 10 million with psychiatric disorders, 2 million cases of cancer with 500,000 cases detected every year, 600,000 practising physicians, 17,000 medical graduates per year, 14,000 hospitals and 700,000 specialty beds.

PricewaterhouseCoopers expects the total market value to rise to about US$50 billion by 2020, and R&D costs are 50% to 75% lower than in the US and EU.

Regulation

The onus is on regulatory bodies to ensure well regulated clinical trials and a healthy supply of quality drugs. Regulations for drug trials in India are being transformed to ensure more transparent and ethical clinical trials conforming to international standards. This is evidenced by the new regulations on compulsory registration of all clinical trials with the Clinical Trials Registry of India and by guidelines for calculating compensation for adverse drug events based on age, income, severity of the disease the person was suffering prior to participation in the trial and the percentage of permanent disability. Also, persons with adverse drug reactions will be treated for as long as required.

The Central Drugs Standard Control Organization, under the Ministry of Health and Family Welfare, prescribes standards and measures for ensuring safety, efficacy and quality of drugs, cosmetics, diagnostics and medical devices in the country, and regulates the market authorization of new drugs and clinical standards.

The Drugs and Cosmetics Act, 1940, Schedule Y, specifies guidelines for clinical trials, and the import and manufacture of new drugs. The act provides for a system of dual regulatory controls at both the central and state government level.

Under the Drugs and Cosmetic Rules, 1945, the Drugs Controller General of India must be informed of drug trials concerning children, pregnant or nursing women, elderly patients, patients with renal or other organ system failure, and those on specific medication.

For a child, consent should be obtained from the parent or legal guardian. The reviewing ethics committee should include members who are knowledgeable about paediatric, ethical, clinical and psychological issues.

Pregnant or nursing women should be included in clinical trials only when the drug is intended for use by pregnant/nursing women or foetuses/nursing infants and where the data generated from women who are not pregnant or nursing are not suitable.

Clinical trials in the geriatric population are to be conducted only when the new drug is likely to alter the geriatric patients’ response compared with that of the non-geriatric patient.

For drugs approved elsewhere in the world and absorbed systemically, bioequivalence with the reference formulation should be carried out wherever applicable. All bioavailability and bioequivalence studies should be conducted according to the guidelines for bioavailability and bioequivalence studies as prescribed.

Stem cell research

Stem cell therapy is being billed as the next panacea for treatment of diseases traditionally considered degenerative, incurable and irreversible such as diabetes, heart disease, spinal cord injuries, Parkinson’s disease and Alzheimer’s.

There are new Indian Council of Medical Research-Department of Biotechnology draft guidelines on stem cell research. These however are non-binding.

The growing global interest in stem cell research and therapy calls for robust regulation. In addition, intellectual property regimes for stem cell research should set conditions that do not restrict basic research or delay future product development.

Patent linkages

The Ministry of Health and Family Welfare is responsible for drug regulation, while the IP rights fall under the Ministry of Commerce and Industry and the Ministry of Health. The drug approval authority functions independently, with no linkages to the patent authorities.

Patent linkages refers to the practice of linking drug marketing approval to the status of the patent of the originator’s product and not allowing the grant of marketing approval to any third party prior to the expiration of the patent term, unless the patent owner consents. The Supreme Court in December 2010 dismissed Bayer Corporation’s appeal against a Delhi High Court decision refusing its plea for patent linkages for its cancer drug Nexavar.

Providing affordable innovator drugs to the masses and creating a favourable environment for drug trials are major challenges. Drug developments in the areas of stem cells and biosimilars will be a challenging area for regulators and the regulations will remain in a state of flux.

Dr Rachna Bharadwaj is an associate at Krishna & Saurastri Associates and an advocate registered with the Bar Council of India.