

Pharma & Healthcare Update

November 15, 2003

SHOULD PHASE 1 TRIALS BE PERMITTED IN INDIA? - DEBATE CONTINUES

India is fast evolving as a favored clinical trial location due to the varied gene pool resource and a well-trained medical workforce.

The initial safety trials of a new medicine in which investigators attempt to establish the dose range tolerated by about 20-30 healthy volunteers for single or multiple doses is termed as a Phase 1 trial. Although Phase 1 trials are usually conducted on healthy volunteers, these trials are sometimes conducted even on severely ill patients, for example those with cancer or AIDS.

The present Schedule Y of the Rules framed under the Drugs and Cosmetics Act, 1940 of India allows Phase I trials of new drug substances discovered in other countries to be conducted in India if data of the Phase I trials in other countries is available. However, the authorities retain a right to waive this requirement if the drug tested was of special relevance to the health problem in India. India is in the process of establishing and amending existing guidelines, regulations and legislations to address various technical, moral and ethical issues involved in conducting clinical trials. One such move is the proposed amendment of Schedule Y of the Drugs and Cosmetics Rules. Schedule Y deals with requirements and guidelines on clinical trials for Import and Manufacture of new drugs.

The Mashelkar panel has recommended allowing conducting Phase 1 trials in India at the same time as they are being carried on abroad. As per the Mashelkar panel report, these trials would work for the betterment of India. According to the report, the pros of permitting the trials would lead to:

- New drugs, which have already been tested abroad, would be directly accessible to the people, facilitating greater and faster access to latest drugs.
- Conducting these trials on Indians would prove to be beneficial for testing the applicability to Indian patients, considering that medical and genetic profiles of Indians could be substantially different from the profiles used for trials abroad.
- Costs of conducting the trials in India is significantly lower than other countries which would cause global pharmaceutical majors to shift their operations of conducting trials to India, and in turn produce more revenue for India.

However, despite all these pros, the cons, at present, seem to attract more attention and unless legal provisions are well in place, Phase 1 trials would raise a lot of ethical concerns.

For example, the lack of accountability in India proves to be a major problem. India lacks the appropriate provisions to ensure that human subjects used for the trials are volunteers and not people compelled by poverty to offer themselves as 'guinea pigs'. This was made apparent by the case on sale of body organs for money. Additionally, since India does not have high literacy levels, there is no system in place to ensure that volunteers have been adequately informed about the risk they would be undertaking. Informed consent is just a matter of obtaining a thumb impression on a piece of paper.

On a separate note, the Mashelkar panel has also suggested introduction of provisions for data exclusivity, preventing reliance on the original inventor's data by others. Article 39.3 of Trade Related aspects of Intellectual Property rights (TRIPS) provides as following:

"Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

When the Indian government was in the process of introducing the 2nd Amendment to the Patents Act, 1970 in 2002, the MNCs had approached the Government with the recommendation to introduce a data exclusivity provision in the same. However, the Government had refused to accede to such a request.

FIRST PHARMACEUTICAL COMPANY GRANTED EXCLUSIVE MARKETING RIGHTS ('EMR') IN INDIA

Novartis became the second company (after United Phosphorous) and the first pharmaceutical company to be granted an EMR. The Controller-General of Patents and Trademarks of India on Tuesday, November 11, 2003 granted Novartis India, an Indian subsidiary of Swiss drug manufacturer Novartis, an EMR on Glivec, its breakthrough anti-cancer drug to tackle certain types of chronic myeloid leukaemia (CML) and stomach cancers. The EMR grants Novartis, rights to market the drug in India for a period of five years, or until a product patent supersedes

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Although Glivec costs USD 27,000 a year to the patient, Novartis, under a worldwide programme, provides the drug free of cost to patients who cannot afford it. The programme hopes to help 10,000 people a year in 45 countries including India and the granting of such an EMR facilitates the success of their programme.

Out of the fifteen applications for EMR filed till date, the Controller has approved two while rejecting six on the ground that they failed to comply with the conditions under Patents Act, 1970 (the "**Act**"). The conditions can be found [here](#). GlaxoSmithKline's anti-diabetic drug Rosiglitazone, Swiss company Hoffmann-La Roche's application on HIV protease inhibitor Saquinavir, etc. are some drugs that were rejected for the grant of EMR in India. Such rejections had created scepticism among drug companies about India's policy in respect of grant of EMRs. The granting of the EMR to Novartis signifies India's commitment of moving towards the product patent system and establishing a fully functional regime to comply with the obligations under Trade Related aspects of Intellectual Property rights (**'TRIPS'**). The process to draft a third amendment to the Act to introduce product patents by 2005 is underway. The details of the provisions introduced by Second Amendment to the Act can be found [here](#).

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