

'Ensuring data protection is crucial for clinical activity'

Incorporated in India in 1994, Roche Scientific Company (India), is a wholly owned subsidiary of the Basel (Switzerland)-based F Hoffmann LA Roche (FHLR). In 1993, FHLR entered into an agreement with Nicholas Piramal India to market and manufacture some of its products, but this was terminated in 2003. Roche is now going on its own, and launching Avastin, its cancer drug, here, just a few months after its global launch. Dr G Telang, the company's managing director, spoke to MG Arun on the new patent scenario and Roche's future plans in India.

There was much euphoria that with the heralding of product patents in India, global pharma companies would step up their activities in the country in a big way, be it in product launches, clinical trials, or research & development. Do you see this happening?

It is a really welcome step that the government has introduced patents in the country. The pharmaceutical fraternity has now been asked by the authorities to give their views on the draft patent law. In general, the industry feels that more clarity is needed in two areas: the definition of 'patentability' as per the Draft, and the issue of pre-grant opposition. I feel that the issue of data protection also needs to be addressed, since that is essential for MNCs to do their clinical studies with confidence in the Indian market. Now, even if the regulatory norms are in place, implementing them becomes an issue. It is doubtful whether the office of the Drug Controller General of India (DCGI) has the necessary infrastructure to ensure

efficient implementation.

Of course, it's true that all these issues will not be addressed overnight. Roche has a faith in the Indian regulatory environment, and we were confident the system would change for the better over time. The amendment to the Schedule Y of the Drugs and Cosmetics Act is welcome, whereby international drug companies can now conduct multi-centre phase I and phase II throughout the country. This is a very strong step to show the world that the country is globalising.

Roche India has a strong portfolio in oncology, transplantation and virology. But our main thrust is the area of oncology. We have received the DCGI approval and would be soon launching Avastin, a product that has emerged through biotechnological research. Avastin is the first anti-angiogenic drug in the world and is the result of Roche-Genentech research. Another drug we have applied for approval and are looking for a 2006 launch is in the area of lung cancer.

What is your marketing model for these new products, considering that they are highly priced?

The marketing model that we follow is one of outsourcing distribution and keeping the core competence of research and medical informatics within the organisation. We closely monitor the distribution network of our drugs since the drugs are distributed via a cold chain and therefore need to be maintained at particular temperatures. We support our distributors by providing them the necessary infrastructure for the same.

We follow the practice of therapy management, whereby we identify patients, see where the drug fits. We use the service of scientifically skilled persons, comprising pharmacists, microbiologists and biotechnologists, who will be able to explain the technical aspects of the molecule to the doctors. They track patients' progress and make sure drugs are administered as per the defined, customised portfolio. We have a team of 50 trained personnel, out of which 18 are dedicated to the oncology portfolio.

F Hoffmann - LA Roche has identified India as a major outsourcing hub for its activities. What are your outsourcing plans on the clinical trials front?

Roche's outsourcing to India are in the areas of IT, development work, drug safety, and purchase of intermediates. In 2004, Roche's outsourcing here was to the tune of more than seven million Swiss francs. In the area of clinical trials, we are in the process of recruiting more and more professional clinical research associates (CRAs). We are also identifying clinical research organisations (CROs) to whom we can outsource clinical activity. The clinical trials that will soon be conducted are mainly for rheumatoid arthritis, and gastric cancer.

The sites for the study are awaiting evaluation. Patients for these are to be recruited by October this year. The extended access programme (EAP) for Avastin is going on, and we have already recruited 18 patients for this ambitious project. Roche has received approval from the DCGI for its study assessing MabThera for non-



Dr G Telang, managing director, Roche

Hodgkin's lymphoma, and for another study assessing Pegasys in end-stage renal disease.

The prima study in non-Hodgkin's lymphoma has a follow up period of six years which makes it the longest trial in India. This is being done across three centres in Delhi, Bangalore and Pune.

However, we do not envisage a research centre in India in the near future, although Roche had set up a research facility in China. ◆