‘Relax export norms to tap global clinical R&D market’

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Clinical studies outsourcing estimated at $1 b by 2010.

G. Naga Sridhar

Hyderabad, Sept. 27 There is a need to relax the norms pertaining to export of body fluids and test samples to cash in on the huge opportunity in contract research and clinical trails, according to Mr Tapan Ray, Director-General, Organisation of Pharmaceutical Producers of India.

“Pharma industry in India is over-regulated and there is a need for giving licences for export of body fluids and test samples. We have been requesting the Drug Controller General of India for this,” Mr Ray said on the sidelines of healthcare and pharma conclave at Indian School of Business here on Saturday.

India potential

Apart from tapping the potential in generics in view of many blockbuster drugs going off patent in the next few years, India could be a potential hub for contract research and development and outsourcing of clinical development, he said.

The market for clinical studies outsourcing is estimated to be at $1 billion by 2010 and outsourcing of clinical development to India would help in cost-cutting for global majors. “According to an estimate prepared last year, the savings could be over $350 million for a single molecule,” he said.

The time lags can also be brought down as clinical studies take 30-50 per cent of total R&D period for a new molecule. “This can be easier in India as we have a diversified patient profile and large number of specialty hospitals,” Mr Ray said.

The key drivers for tapping the opportunity, however, would be R&D collaborations between companies and addressing the need for skilled human resources, he added.

http://www.blonnet.com/2008/09/28/stories/2008092851170300.htm