India One Step Closer to Amending Phase I Rules

01/08/2007 - **India could be a step closer to allowing first-in-man trials on 'foreign' new drugs.**

According to local media reports the Drugs Technical Advisory Board (DTAB) has recommended to the government's Health Ministry to change the current regulation preventing such studies.

Such as move would bring India in line with other emerging markets.

According to an *Economic Times* report this week, DTAB's advice "would weigh heavily on the government", although the latter does not have to accept the recommendations.

Currently, first-in-man trials of 'foreign made' new drugs are not permitted in India, while other Phase I studies of drugs developed abroad are only allowed once the drug has completed Phase I and moved to Phase II in other countries.

According to official sources, the reasons why the DTAB made his recommendation include the need for the country to participate in the 'global trials' of drugs, the ET reported. In addition, it said, another reason for the decision is that the thinking behind the present policy that drugs discovered in India are safer than those discovered overseas is misleading.

Other media reports suggest the DTAB's move was driven by the progress made by the contract research organisation (CRO) industry in the last few years.

The CEOs of Laurus Labs, an Indian CRO, recently told Outsourcing-Pharma.com that it was expected that within the next 18 months the Indian drug regulatory authority will have new guidelines in place for the conducting of Phase I studies on foreign drug compounds and that it will open the doors to much more of this type of research in the country.

The clinical trial industry in India in general has been shaping up in the past few months, while the government has been tightening the regulation of clinical research activities. The Health Ministry recently proposed a draft bill, under which the Central Drugs Authority (CDA) would have the power to prosecute CROs, investigators and pharma companies who violate rules of clinical trials.

Meanwhile, India's first official Clinical Trials Registry (CTRI) was launched last month. Any company or CRO conducting a clinical study involving human subjects now has to register the trial before enrolling the first participants.