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Indian drugmakers shifting R&D to South East Asia

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Singapore: Many leading Indian drug makers, that comprise a core part of the country's $1,000 bn worth pharmaceutical industry, are soon shifting their research and development operations and clinical trials to South East Asian countries, concluded a survey by ASSOCHAM.

The Associated Chambers of Commerce and Industry of India (ASSOCHAM) concluded the survey stating that red tapism has been pushing the country's pharma industry in peril as most operations get shifted to countries like Cambodia, Korea, Philippines, Singapore, Thailand, Vietnam and other South East Asian countries.

These countries share similar patient population, disease profile and also have a conducive environment for operations like easy market approach without any regulatory uncertainity, the survey highlighted.

"Various South East Asian countries are wooing India's R&D industry by offering sops and transparent regulations as regulatory bottlenecks and a plethora of committees have slowed permissions/approvals for trials or marketing drugs to more than 12-15 months back home in India while such permissions are given by the USFDA, EU and Singapore within a month's time," the survey by the industry body pointed out.

The survey covered about 250 top officials and representatives from India's pharma industry from five states - Andhra Pradesh, Gujarat, Karnataka, Maharashtra and Tamil Nadu between March-June, 2013 to identify their problem areas and come up with solutions.

"Flight of operations by India's pharma majors will surely hit India's image as a fast-growing, low-cost hub for medical research," said Mr D S Rawat, national secretary general of ASSOCHAM while releasing the findings of the chamber's survey.

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ASSOCHAM officials believed that the gazette notification issued by the department of Health, Ministry of Health & Family Welfare has put a 'full stop' to the research and development (R&D) in India, triggering serious concerns amid entire pharma

industry.

ASSOCHAM has further written to the Indian Prime Minister regarding the issue. "This notification is not in line with the established international standards and is likely to have a cascading effect on the future of clinical trials in India as the flaws in the gazette could negatively impact the future growth of R&D as well as development of low cost high quality medicines in the country," ASSOCHAM wrote on behalf of India's pharma majors.

ASSOCHAM claimed that the controversial gazette notification prescribed stringent laws that are not in line with the established regulations, making it almost impossible for the R&D based industry to comprehend it and provides compensation for investigational new drug studies (IND), even if a patient is taking (placebo) sugar pills, or other concomitant medication. The gazette also makes it mandatory for a study drug to be efficacious - a condition that is nearly impossible to meet since most drugs approved globally are not 100% efficacious every time a patient takes them.

The Health Ministry too has been approached by ASSOCHAM through a letter to immediately take action to prevent slowdown of clinical R&D in India while adding that global trials have almost come to a grinding halt in India over the past six months, consequently denying patients suffering from life threatening conditions access to brand new drugs.