PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Business Standard, Delhi
Tuesday, 27th July 2010, Page: 17
Width: 20.74 cms Height: 10.20 cms, Ref: pmin.2010-07-27.52.59

Govt.

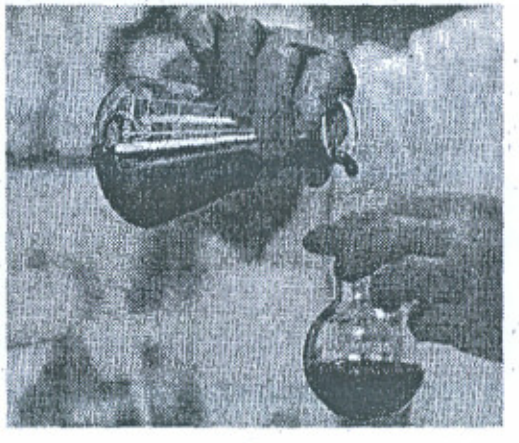
DCGI sets stringent rules for clinical trials

JOE C MATHEW
New Delhi, 26 July

The country's apex pharmaceutical regulator — the Drugs Controller General of India (DCGI) — has tightened the approval mechanism for clinical trials and marketing licenses for biotechnology drugs, medical devices and vaccines in the country.

Following the DCGI move on July 12, four marketing approval applications for vaccines were cleared, while four others, from well known names such as Johnson & Johnson, Panacea, and GlaxoSmithKline were returned with attached deficiency letters.

On July 9, all 14 applicants for marketing approvals for diagnostic kits were issued deficiency letters that essentially pointed out the gaps the companies need to fill. The same day, leading players Wyeth and Serum Institute of India found their vaccine approval applications being returned with deficiency letters for "post approval changes".



A similar pattern was seen on most days in July, where bulk of the applications were not cleared due to "deficiencies".

Medical devices, biotechnology and vaccine manufacturing and marketing firms – both domestic as well as multinationals – are facing intense regulatory heat these days in India after the country's drug regulator decided to act tough.

Lengthy delays are the result and a fuming industry is complaining about the sudden "bureaucratic" hurdles that are posed before them. "The department is aware of the complaints," said DCGI Surinder Singh, adding that the delays are caused because of the "incomplete" applications that are forwarded by the companies.

"In the past, the scrutiny was not so rigorous, as the applications relating to biotechnology products were less. Today, the companies are trying to introduce hundreds of products that belong to the biotech, vaccine, medical device categories," a senior health ministry official said.

The most serious of all complaints, Singh said, is the practice of "post approval changes" where companies tweak the biotechnology products which were not part of the early disclosure. "We cannot allow such changes."

The office of the DCGI is planning to call a meeting of the industry on July 19 or 20 to make them aware of the seriousness of the issue. "If an application is incomplete, or there are post-approval changes, the marketing approval for the specific product gets rejected in most developed countries. Here we are only issuing deficiency letters and allowing companies to rectify their mistakes and approach us again. This is why there is a delay. The industry should appreciate this," the DCGI said.

The regulatory tightening over biotech products has come at a time when the biopharmaceutical market is expected to turn major revenue driver for most global drug firms.

According to the Association of Biotechnology Led Enterprises (ABLE) and Pricewaterhousecoopers, the domestic biologics market was worth $ 1.9 billion (about Rs 8,900 crore) in 2009-10. With over 20 companies that are already producing biosimilars or low-cost versions of patented biotechnology products sold globally, India is already in a growth mode, an ABLE-PWC report released today said.