



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Set up by Ministry of Commerce, Govt. of India)

COPY

Date : 15-06-2010

News / Story reproduced with thanks:- **Pharmabiz**

Bio-pharma industry seeks faster regulatory clearances for new products

Tuesday, June 15, 2010 08:00 IST

Nandita Vijay, Bangalore

Direct link to the News/Story:-

<http://www.pharmabiz.com/article/detnews.asp?articleid=55943§ionid=>

India's bio-pharma sector is insisting that drug regulatory authorities in the country need to keep pace with the rapid technological developments in the industry so that it would enable them to grant speedy clearances for new products.

Bio-pharma sector which covers vaccines, therapeutic drugs, animal biologicals, statins and diagnostics has been on a product development spree. Among the recent launches includes the country's first indigenously developed H1N1 vaccine, Vaxiflu-S by Cadila Healthcare.

According to Dr Smita Singhania, head, regulatory affairs & project management, Cadila Healthcare Ltd, the regulatory authorities were quick to approve the influenza vaccine within one year of epidemic break out. "We could not have achieved this without the timely decisions and approvals by the regulators", she said.

In order to ensure speedy approvals from the regulatory authority, Dr K K Tripathi, advisor and member secretary, Review Committee on Genetic Manipulation (RCGM) of the Department of Biotechnology (DBT) said that it is vital for the industry to take an active role to bring their concerns to the regulatory authorities about the details of the drug which needs quick clearance.

In a fast changing scenario where advanced drugs are required to save patient lives, efficient and transparent working environment together with fast turnaround are the need of the hour. For instance in the area of clinical trials, present regulations do not permit phase-1 trials of any pharma product that is not developed in India. However, the regulators are seriously contemplating for a change in this regard and the industry can expect good news soon, stated Dr Tripathi who was recently here in Bangalore for discussion on "Regulatory Issues For Bio-pharma Industry".

"In order to facilitate quick positive approvals from the regulators, there was a need for a clear definition of 'bio-similar' drugs. There should be separate set of guidelines for bio-similars, strengthen the post marketing safety and monitoring. Currently, Department of Biotechnology and Drugs Control General of India are the advisory, monitoring and approval bodies, said Dr Vibha Ahuja, general manager, Biotech Consortium India Limited,

Providing a perspective from an international angle, Teresa Stanek Rea, partner, Crowell & Moring LLP, US, said that in the United States too, the legislations in bio-similars are not clear. Data exclusivity period for research in bio-similars vary across products.

Expressing similar concerns, Martin B Cox, business development manager, Faculty of Medical Sciences, New Castle University, UK, said that the regulatory and Intellectual Property lacked the clarity in Europe. "These issues are creating an obstacle for growth of regenerative medicine, which has huge potential to increase the quality of life of patients. For instance, the use of limbal cells from a healthy donor after culture and infusing into patient has proved to control diabetes, improve eyesight and treat various cancers," he added.

The biotech industry in the country accounts for earnings to the tune of Rs14,199 crore in 2009-2010. India accounts for 8 per cent of the world drug production and over a 1,000 clinical trials have been conducted here. This calls for the need for uniform regulations in Europe and India. As UK's regulations are valid in many European countries, there is scope for MHRA and Indian regulatory authorities to work in coordination, said Brijesh Patel, deputy manager, Licensing, Medicines and Healthcare Products Regulatory Agency, UK.