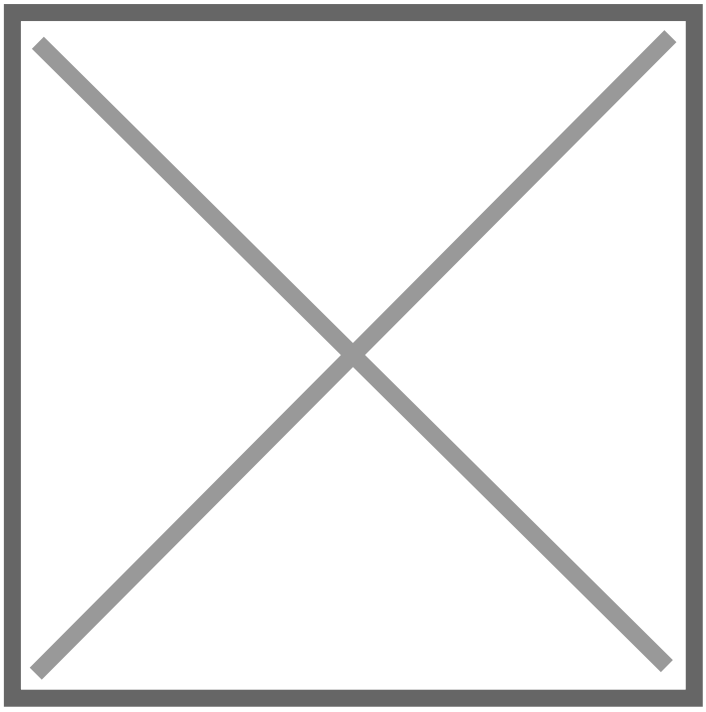
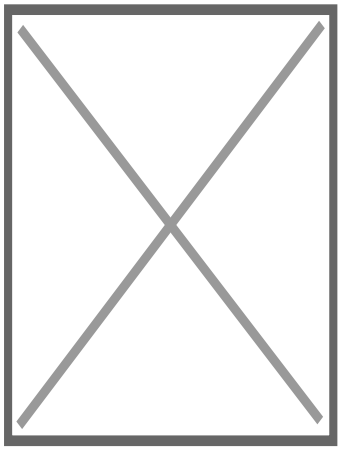
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Vaccines Alive

05 November 2008 | News



Vaccines Alive



India's Rs 2,000 crore vaccine industry can now breathe easy till March 31, 2009. The World Health Organization (WHO) has given India's drug regulator, DCGI, an extension to its October 31, 2008 deadline by five months to upgrade its testing laboratories. The October 31 deadline was hanging like a Damocle's Sword over the vaccine industry who were caught in the cross fire between the Indian regulator and WHO over some quality issues.

Vaccine industry leaders had vented their fury at the regulatory set up during a special meeting organized by BioSpectrum in Mumbai on August 28 for threatening their existence. Hopefully, the government will speed up its publicized plans to quickly upgrade the three de-recognized public sector vaccine manufacturing units to international standards. The quality issues plaguing these century-old manufacturing units which were also used by the DCGI for conducting drug tests had come in the way of WHO certification for new India-made vaccines.

Another good news is that there has been some more forward movement in the enactment of India's own Bayh-Dole Act which will spur innovation in the country's government-run laboratories and research institutions. The Federal cabinet, on October 31, has approved the draft of the Protection and Utilization of Publicly Funded Intellectual Property Bill, 2008. The legislation can now be introduced in Parliament for its approval.

Though this is a good development, there are some misgiving in the industry and scientific committee about some of its provisions.

Concerns have been raised about the provision which seeks to provide exclusive marketing rights with royalty for patented products developed in public institutions. With the country's leading industrial research network, CSIR, championing the cause of Open Source Drug Discovery, there is a strong case for only allowing non-exclusive licensing arrangements for products developed with public funding. Science and Technology Minister Kapil Sibal had recently promised to look into some of these concerns raised by experts.

It will be in public interest if the draft of the legislation that will go to the Parliament for approval is released for suggestions and comments. The Department of Biotechnology (DBT), under Sibal's watch, has won wide acclaim for its wide-ranging consultations on the new Biotech Policy as well as the proposals for setting up a National Biotechnology Regulatory Authority (NBRA) in the last two years. The DBT's example should be followed in the case of the public R&D Bill too.

Prime Minister Manmohan Singh has called industry leaders for consultations to revive the sentiments of the economy, impacted by the bad news coming from the global banking sector. The biotechnology sector was hit by the Rupee appreciation last year and the export-oriented sector can look forward to the depreciating Rupee with some cheer. However, how the recessionary trends in the global markets will have its immediate impact on the industry is not clear. Experts have indicated that due to the essential nature of life sciences, the industry's prospects may not be dented too much. Anyway, the industry has its wish list to the Finance Minister P Chidambaram for his Union Budget 2009. The list is not too long and industry hopes the Finance Minister will continue his biotech-friendly initiatives for one more time.

BioSpectrum too is starting two new initiatives in 2009. First, there is a plan to bring out a comprehensive Education and Careers Resource Guide (ECRG) in early 2009 to answer almost all the queries biotech students and future industry professional have about the industry. BioSpectrum is also planning to organize, Navigate 2009, the first Life Sciences Business Convention (February 18-19, Mumbai) to bring together the community on a common platform to address the future challenges and opportunities together.

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