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WHO's 5-month booster shot for vaccine makers

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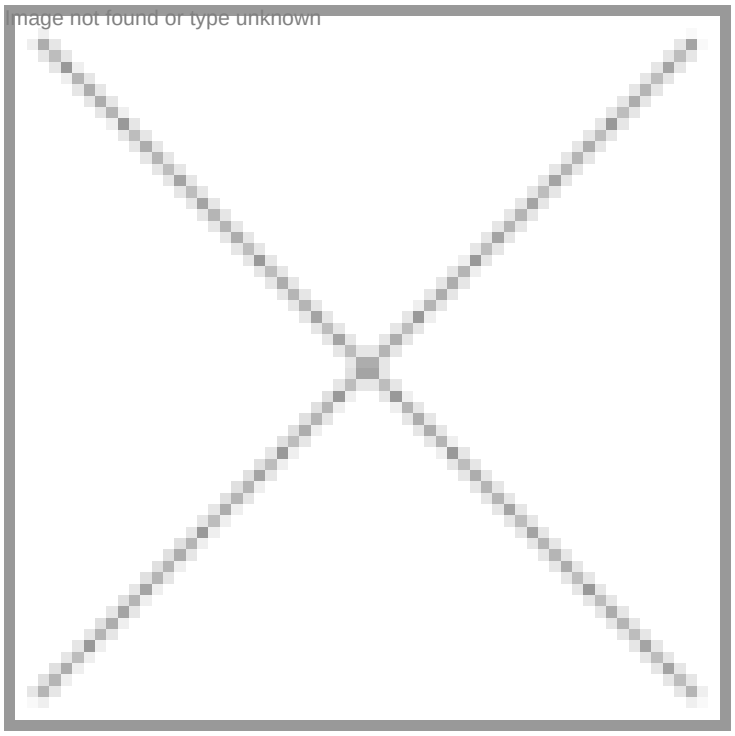

WHO's 5-month booster shot for vaccine makers

DCGI gets time till March 31 to upgrade regulator's labs

The World Health Organization (WHO) has given the Drugs Controller General of India (DCGI) five more months to improve its performance in accordance with international standards. The previous deadline of October-end was extended after a visiting WHO team was satisfied with the Indian drug regulator's modernization programs.

The Indian vaccine makers were affected with WHO's decision as new products were not considered for WHO and UNICEF supplies due to inadequacies in the operational systems of the drug regulator since January 2008. The WHO approval is necessary for all international purchases and as UNICEF and WHO do not have their own testing facilities, they entrust the local governments to have a certified lab to meet the requirements.

Unfortunately as the government laboratories on which the Indian regulator, the Drug Controller General of India (DCGI), relied were shut down over quality issues. The three undertakings that were shut down are Central Research Institute, Kasauli; Pasteur Institute of India, Coonoor; and BCG Laboratory (King's Institute), Chennai.

The National Regulatory Agency (NRA--the combination of the Drug Controller General of India, Ministry of Health, and the three government units where drug tests are done) was being questioned by the WHO and other health agencies on several issues like modernization, the functioning of the NRA, surveillance methods, and the general licensing policy.

This led to a dangerous situation where approvals to a dozen new vaccines made by Indian companies, known for their quality and reliability, were put on hold in the last 12-18 months. The situation was getting out of control as it was posing a major threat to the very existence of Indian companies due to the slow progress being made on addressing the issues raised by the WHO and other health agencies.

The vaccines manufacturers were calling for speedy action to save the industry. Major leaders from the industry got together to find solutions and save the nation's vaccine industry. BioSpectrum organized a special meeting in Mumbai on August 28 to discuss the issues and highlight the measures that need to be taken on a priority basis.

The Indian government agencies agreed to an inspection by a Canadian team to guide them and lay down the rules which they must follow. It was agreed that if WHO was satisfied after this, it will temporarily lift the ban on Indian agencies.

The regulator has recommended to the Ministry of Health to set up new GMP (Good Manufacturing Practices) compliant, global standards manufacturing plants urgently to resume production of vaccines in the government sector in the country.

During a media interaction the Drug Controller General of India, Dr Surinder Singh, in Mumbai in mid-September, said that they have submitted a report to the Ministry of Health on this issue and it has concluded that the three facilities--Central Research Institute, Kasauli; Pasteur Institute if India, Coonoor; and BCG Laboratory (King's Institute), Chennai--did not follow GMP and they cannot be modernized and made GMP compliant because they are very old institutions. Some of these institutions were set up over 100 years ago.

The regulatory agency was working on improving the regulatory system by collaborating with the WHO for training activities and with the USFDA and Health Canada for other aspects. Vaccine manufacturers can now submit their revamp plans electronically. It was also introducing various e-Governance measures to bring reliability, accountability and adherence to timelines.

The vaccine industry getting a breather for another five months is a good news and the industry should now use this interim period to get together and work closely with the government and all concerned to speedily address the concerns raised by the UNICEF and WHO and raise the credibility bar.