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CDSCO extends WHOâ??s GMP certificate

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The certificate has been extended to 3 years from its previous time limit of 2 years in order to encourage more product registration for exports



In a move to improve ease of doing business, India is increasing the validity of the World Health Organization's (WHO) Good Manufacturing Practices (GMP) certificate to three years. The measure, taken up by the Central Drugs Standard Control Organization, would also result in more product registration for exports. The protocol for clinical trial approvals has also been changed by setting the timeline of approval at 45 days. Once approval does not come within this timeline, the protocol would deemed to be approved.

According to the drug controller general of India, Eshwara Reddy the certificate was earlier valid for only two years.

With this extension, the government is hoping to promote pharmaceutical exports to untapped markets, including China, which has agreed for a high level bilateral round table to pave way for Indian pharma to get market access and penetration in their market. They are also placing emphasis on the need for reaching out to newer markets in Africa, where affordability is a key issue that can be addressed by Indian exporters