CENTRAL DRUGS STANDARD CONTROL ORGANIZATION | MGRM | K.V.R. MURTHY | SURINDER SINGH | E-GOVERNANCE

Rs250 cr to make drugs regulatory process completely paperless

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People-friendly step: Drugs controller general of India Surinder Singh says the World Health Organization has shown interest in the project. Manoj Kapparath / Mint

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New Delhi: The ministry of health and family welfare will invest close to $50 million (Rs250 crore) in the Central Drugs Standard Control Organization's (CDSCO) e-governance initiative. The initiative, the first of its kind in the world, will be developed by New York-based technology solutions provider **MGRM**. The application aims to enable transparency and efficiency in the working of the CDSCO.

"Details of licensing, regulation, monitoring and even inspection audits will seamlessly be available through the software," says K.V.R. Murthy, group chairman of MGRM.

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This will work not only for companies, who will be able to submit all applications and data online, but will also smoothen the interface between various officials of the drug controller's office. Companies will even be able to file, track and review their patent applications online.

"Once an application is submitted online," explained drugs controller general of India (DCGI) Surinder Singh, "the information or protocol will be split according to work category and will then go to the official assigned for that job. This means that no one person will have access to complete information except a few senior officials."

This model of work distribution will ensure privacy and data protection since officials in the ministry or in a company will not have permission to change or download any data from the site.

In fact, according to the proposed plan, unauthorized attempt to access information will immediately send off an alert making it difficult to break into the system. The first phase of the project is expected to be completed in a year, following which CDSCO, along with MGRM, will float a national tender inviting developers to bid for the project. The project itself is expected to be up and running by 2013.

"The e-governance project will most of all benefit the general public. The way we intend to develop it, public will have access to list of medicines that are banned, approved and that can cause allergic reactions," said Murthy.

That apart, the project will also aid companies in tracking the movement of their applications and would then be able to base their development targets based in this.

The DCGI's e-governance initiative has received interest from the World Health Organization and Health Canada—the Canadian health regulator.

"They have approached us and have shown a lot of interest in signing an MoU (memorandum of understanding) on the same," said Singh. What is even more comforting is that adverse drug reactions in volunteers who enrol for multiple clinical trials in quick succession at the prospect of high remuneration will not be able to do so. Finger printing software, part of the project, will interlink clinical trial softwares, allowing companies to enrol only first time volunteers.

In most developed countries, though the pharma companies can submit applications online, the processing is done through physical transactions. The e-governance initiative will make India's regulatory process completely paperless.

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