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CDSCO drafts guidelines on recall and rapid alert system for drugs

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The guidelines are biologics and vaccines as well and the targets would be enforced in the next three to four months

Usha Sharma - *Mumbai*

The Central Drugs Standard Control Organization (CDSCO) has released a draft version of guidelines on recall and rapid alert system for drugs including biologics and vaccines. It has called for suggestions or objections from the industry stakeholders to submit responses before November 7, 2012.

***Dr GN Singh**, Drug Controller General of India (DCGI) said,* "Our mission and vision is to safeguard and enhance public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical device. To comply with this, we will address these aspects before enforcing into an act. We have published draft guidelines on October 22, 2012 and asked the stakeholders to revert back before November 7, 2012. Once we will get responses, we will review them accordingly. The suggestions or objections, if found to be in public interest will be forwarded to the Ministry of Health."

"The review process will take 45 days and then will be sent to the Health Ministry and then to the Law Ministry. Overall, we are expecting that it will take three to four months to become an act," Singh added.

A rapid alert system is to transmit only those alerts whose urgency and seriousness cannot permit any delay in transmission. Assessment must be made of the seriousness of the defect, its potential for causing harm to the patient or (in case of veterinary product) harm to animals, consumers, operators and the environment.

In the Drugs & Cosmetics Act & Rules, there is a reference for product recalls, complaint and adverse reactions in Para 27 & 28 of Schedule M and also conditions of license for defective product recall in Rule 74 (j) and Rule 78 (i), but effective and uniform recall procedure, with time lines at every level of supply chain is required and at present auditing and accountability is not in place. This has been observed in instances where drugs declared as not of standard quality by Government analyst, incidents where serious adverse effects or death have been reported, in case of banned drugs under Section 26 A, defects where involuntarily the manufacturer withdraws drugs from the market etc. These guidelines are applicable to all quality defective product reports and reported incidents of safety and efficacy received for all drugs including vaccines and biologics.

These guidelines are expected to be followed by licensees (manufacturers, importers, stockists, distributors, retailers) and the recall could be voluntary or statutory. The procedure may also be used by drugs control authorities of central or state when urgent action is required to protect public or animal health.

These guidelines shall help in adopting stepwise procedures to be followed in recall strategy and also help in recall evaluation at every level and achieve compliance within the time frame. Based on the category of risks involved, a time line of within 24 hours up to a maximum of 72 hours for class I recall, for class II recall up to a maximum of 10 days and for class III recall up to a maximum of 30 days is allowed.

The time line for initiation of recall procedure would commence from the receipt of information as notified by the concerned State/Central Drugs Control Department under statutory recall or voluntary recall by the manufacturer on its own. The recall has to be initiated immediately without any prejudice of the outcome of Section 25(3) and Section 25(4) of the Drugs & Cosmetics Act 1940 for adducing the evidence.

The time line for stopping sale/ distribution of defective product under class I shall be ensured within 24 hours and the physical recall being completed within 72 hours. The class II and class III recalls shall be ensured upto 10 and upto 30 days respectively.