CDSCO releases draft GDP guidelines for pharmaceutical products

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Saturday, April 13, 2024, 08:00 Hrs [IST]

The Central Drugs Standard Control Organisation (CDSCO) has released the draft guidance document on Good Distribution Practices (GDP) for pharmaceutical products, in line with the WHO Technical Report Series (TRS) on Good Storage and Distribution Practices for pharma products to avoid the introduction of spurious, adulterated, misbranded and Not of Standard Quality (NSQ) products into the market.

The guideline elaborates the procedures to be followed in transportation, shipping, labelling, dispatch and receipt of the pharma products and documentation related to distribution. It also details the methods to file complaints, for recalls and returns, and the handling of spurious, misbranded, adulterated and NSQ pharma products, among others.

The regulator also advises the stakeholders to include self-inspections in the quality system by a designated, competent person, and maintaining records of such self-inspection results along with all observations made during the inspection and if required proposal for corrective measures. There shall be an effective follow-up programme and evaluation of inspection report and corrective action taken by the management. Self-inspections should be conducted periodically, according to an annual schedule, it added.

The document, released by the Organisation earlier this month, elaborates responsibilities by various stakeholders in different stages within the supply chain, in storage and distribution of medical products. NSQ and spurious products are a significant threat to public health and safety, said the regulator.

"This guideline is intended to be applicable to all entities involved in any aspect of the storage and distribution of medical products, from the premises of the manufacturer of the medical product to his or her agent, or the person dispensing or providing medical products directly to a patient," says the document.

This includes all parties involved in trade and distribution of pharmaceutical, including the manufacturers of bulk, finished products, wholesalers, as well as others such as suppliers, distributors, Government institutions, international procurement organizations, donor agencies and certifying bodies, logistics providers, traders, transport companies and forwarding agents and their employees as well as health workers. It also covers biological products in general. However, for specific purposes, CDSCO has advised that the guidelines on Good Distribution Practices for Biological Products shall be referred to.

According to Drugs & Cosmetics Act 1940 and Drugs & Cosmetic Rules 1945, Rules 64 and 65 specify the conditions to be fulfilled to sell, stock, exhibit or offer for sale or distribute the drugs. The principles of GDP shall be applicable both to pharmaceutical products moving forward in the distribution chain from the manufacturer to the entity responsible for dispensing or providing pharmaceutical products to the patient and to products which are moving backwards in the chain, for, as a result of the return or recall thereof and shall be applicable for donated pharmaceutical products.

The document advises that all stakeholders should collaborate and an agreement shall be in place with all the individual agencies involved in the storage, transportation and distribution.

"The activities of persons or entities involved in the distribution of products shall be regulated by Drugs and Cosmetics Act 1940 and rules 1945," it adds.

All pharmaceutical product distributors shall establish and maintain quality system and there shall be documented quality policy describing the overall intentions and requirements of distributors regarding quality, authorized by the management. A responsible person shall be appointed by the management for each distribution site, who shall have defined authority and responsibility for ensuring that a quality system is implemented and maintained, says the guidelines.

The distributor, importer or exporter, and others should get appropriate authorisation to perform their functions and the distributor shall supply pharmaceutical products only to persons or entities which are themselves authorised to acquire such products either in terms of an authorisation to act as distributor or to sell or supply products directly to a patient or to his or her agent. If the activity is subcontracted, they shall also be appropriately authorised to perform the activity and shall uphold the same standards as the distributor.

Entities involved in the storage and distribution of pharmaceutical products should shall have a comprehensively designed, documented and correctly implemented quality system that incorporates GSP, GDP, principles of quality risk management and management review. Storage areas shall be maintained or designed to ensure Good storage practices (GSP).

The guideline advises that the storage conditions should be as per the national regulations and records on this shall be maintained if they are critical for the maintenance of the characteristics of the pharmaceutical products. The records shall be available for review and storage areas shall be temperature mapped under representative conditions.

The quality system shall ensure that GSP and GDP are adopted and implemented to ensure that the quality of pharmaceutical products is maintained throughout their shelf life in the supply chain; and pharmaceutical products are appropriately procured, stored, distributed and delivered to the appropriate recipients; operations are clearly specified in written procedures; responsibilities are clearly specified in

job descriptions; all risks are identified and necessary, effective controls are implemented; processes are in place to assure the management of outsourced activities; there is a procedure for self-inspection and quality audits; there is a system for quality risk management; there are systems for managing returns, complaints and recalls; and there are systems to manage changes, deviations and corrective an preventive actions (CAPAs).

There shall be authorised written quality policy and appropriate organisational structure and the quality system shall include appropriate procedures, processes and resources, it added.

"There shall be a system to assess, control, communicate and review risks identified at all stages in the supply chain. The evaluation of risk shall be based on scientific knowledge and experience and ultimately be linked to the protection of the patient. Appropriate controls shall be developed and implemented to address all risks. The effectiveness of the controls implemented shall be evaluated at periodic intervals," said the guidelines.

Pharmaceutical products shall be transported in accordance with the storage conditions indicated on the packaging information and on the label and a written agreement between the manufacturer, government institution, agent and transport company shall be in place to ensure that the transportation is as per the standards.

The storage conditions should be maintained including the temperature and humidity and if a deviation has occurred during transportation, this shall be reported to the distributor and the recipient of the product and there should be written procedures in place to investigate and deal with any failure to comply with storage requirements, such as temperature deviations.

"It is the responsibility of the distributor to ensure that vehicles and equipment used to distribute, store or handle pharmaceutical products are suitable for their use and appropriately equipped to prevent exposure of the products to conditions that shall affect their quality and packaging integrity, and to prevent contamination of any kind," says the guidance document.

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