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New version of Schedule M to ensure compliance with standards of drugs and promote exports: Dr Eswara Reddy

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Larger companies with a turnover of over Rs 250 crore have been asked to implement the changes within 6 months



"With gene and stem cell therapy among others coming up as new frontiers in healthcare today, personalised medicine, biotechnology and advanced therapies are driving the need for revision of Schedule M", said Dr Eswara Reddy, Joint Drugs Controller, Central Drugs Standard Control Organisation (CDSCO) while speaking on the sidelines of a workshop on “Revision of Schedule M” in Mumbai recently.

The workshop was organised by the CDSCO in association with the Indian Drug Manufacturers’ Association (IDMA).

He further described the need for revision of Schedule M, Good Manufacturing Practice (GMP) requirements keeping in mind current changes in the concept of quality of drugs, convergence of Indian standards with global standards, and technological advancements in manufacturing and testing of drugs.

The Union health ministry had, on August 2, 2023, notified a 6 to 12 months deadline for the pharma industry to implement revised Schedule M. It had given six months time for small manufacturers and 12 months time to large units, to get their World Health Organisation-Good Manufacturing Practices (WHO-GMP) certification.

Larger companies with a turnover of over Rs 250 crore have been asked to implement the changes within 6 months, while medium and small-scale enterprises with a turnover of less than Rs 250 crore have been asked to do so within one year.

Dr Reddy further explained, “The revised Schedule M has mandatorily stipulated product quality review on an annual basis for quality risk management. This majorly includes reviewing all batches that had failed, review of non-conformance related investigations, corrective and preventive action (CAPA) taken, review of complaints and recalls, and qualification status of equipment such as heating, ventilation, air conditioning, water and compressed gases.”

Dr Reddy reiterated that the new version of Schedule M is designed to ensure compliance to the standards of drugs, promote exports, promote innovation and also to build trust and confidence in the quality of drugs manufactured and sold.

Schedule M prescribes requirements to the manufacturing plants of pharmaceutical companies for maintenance, manufacturing, control and safety testing, storage and transport of material, written procedures and records, traceability etc. The revised GMP guidelines have come at a relevant time when India is reinforcing itself as the global pharmaceutical manufacturing hub.

IDMA has organised a series of events in the last two years to advance the cause of the nation and the Indian pharmaceutical industry, especially the MSME sector. “IDMA will continue to organise more such value-additive events in future,” said IDMA President Dr Viranchi Shah.

Observation from ongoing risk-based inspections necessitated the government to take a relook at the current GMP regulations and Quality Management Systems (QMS) being followed by pharmaceutical manufacturers. It was revealed that some pharmaceutical firms have come under the scanner due to unethical practices like poor documentation, lack of process and analytical validations, absence of self-assessment and quality failure investigation among others.

GMP comprises mandatory standards that build and bring quality to products by way of control on materials, methods, machines, processes, personnel, facility or environment, etc. The GMP system was first incorporated in 1988 in Schedule M of the Drugs and Cosmetics Rules, 1945, and the last amendment was made in June 2005. WHO-GMP standards are now part of the revised Schedule M.

Schedule M prescribes requirements of facilities and their maintenance, personnel, manufacture, control and safety testing, storage and transport of material, written procedures and records, and traceability among others.

Some of the major changes which will happen with the introduction of the revised Schedule M are the introduction of a pharmaceutical quality system (PQS), quality risk management (QRM), product quality review (PQR), qualification and validation of equipment, change control management, self-inspection, quality audit team, suppliers audit and approval, stability studies as per recommended climate condition, validation of GMP-related computerised system and specific requirements for manufacturing of hazardous products among others.

A draft notification was issued on October 5, 2018, to upgrade and synchronise the Schedule M of the Drugs and Cosmetics (D&C) Rules, 1945 in compliance with WHO-GMP standards.

In 2001, the Second Amendment to the GMP was made based on 1992 WHO GMP guidelines. These guidelines were effective from December 11, 2001, for new units and January 1, 2004, for existing units which were further extended for one year.

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