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India gets new guidelines for distribution practices of drugs

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Bangalore: India is being touted to play a crucial role in the domain of biologics and biosimilars, as their presence becomes more prevalent in the country. A recent development in this regard has been the release of guidelines on good distribution practices (GDP) for biologic medicines by the Central Drug Standards Control Organization (CDSCO).

The guidelines were released with an objective to assist in ensuring quality of biological products during all aspects of distribution process, including procurement, purchasing, storage and transportation. The latest document, which has been effective since October 8, 2012, replaces the previous draft version that was released by the CDSCO on September 17, 2012.

The guideline clearly mentions that "The principles of GDP shall be applicable to biological products, which are moving forward in the distribution chain from the manufacturer, to the entity responsible for dispensing or providing biological products to the patient."

The guideline also highlighted that the principles of GDP would also be applicable "to products which are moving backwards in the chain, for example, as a result of the return or recall thereof and shall be applicable for donated biological products."

The new rules also state that each entity must clearly highlight who is responsible, in order to see that the drugs are kept safe along the supply chain. One of the major requirements for this is the use of validated temperature-control system in order to ensure that the correct transportation conditions are maintained between distributor and customer.

There has been increase in the number of tainted drugs that reach the customers. To avoid such instances, the guideline presses on the point that there needs to be better cooperation among regulators, manufacturers, distributors and law enforcement authorities. It is also stated that all biological product distributors shall establish and maintain quality system. The guideline urges the documented quality policy describing the overall intentions and requirements of distributors regarding quality.

There have been a number of collaborations in the past, for instance in August this year, Dr. Reddy's won the co-commercialization rights for antibody biosimilars that Merck Serono develops for the oncology market in the US. This new guideline is expected to help boost such collaborations by further streamlining the process of distribution of biologics products and to make sure proper instructions are in place for the manufacturers till the product reaches the customers. To read the complete CDSCO guidelines in .PDF format, click here.