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Govt releases guidelines for evaluation of nanopharmaceuticals

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The guidelines would facilitate translational research in line with the regulatory requirements



The Union Minister for Science & Technology, Earth Sciences and Health & Family Welfare, Dr. Harsh Vardhan has released "Guidelines for Evaluation of Nanopharmaceuticals in India", at an event in New Delhi recently.

Dr. Harsh Vardhan informed that these "Guidelines for Evaluation of Nanopharmaceuticals in India" is one of the most important steps for delineating quality, safety and efficacy assessment of the novel nanoformulations. He further added that these guidelines are intended to provide transparent, consistent and predictable regulatory pathways for nanopharmaceuticals in India.

Nanocarrier based targeted drug delivery is an emerging field with introduction of nanopharmaceuticals in the market. These nanoformulations have higher efficacy, lower toxicity and are safer than the conventional drugs. Indian researchers would be facilitated to undertake research in line with the regulatory guidelines and is expected that Industry would be keen to participate from the beginning of the research pipeline towards product development and commercialisation. Further, private investments would also be attracted since these guidelines would strengthen the regulatory system.

The guidelines apply to the nanopharmaceuticals in the form of finished formulation as well as Active Pharmaceutical Ingredient (API) of a new molecule or an already approved molecule with altered nanoscale dimensions, properties or phenomenon associated with the application of nanotechnology intended to be used for treatment, in vivo diagnosis, mitigation, cure or prevention of diseases and disorders in humans

The guidelines would facilitate translational research in line with the regulatory requirements. Guidelines will also facilitate the decision making by regulator during clearances to newer products based on nanotechnology and similarly to researchers to get clearance for their products to launch in market. End users will also be benefited by the quality assured anticipated products in the market in accordance to the guidelines.

This document will give impetus to initiate activities for developing safety guidelines for other domains like agri-inputs and agri-products, cosmetics, implantable devices, through interventions of nanotechnology.

The guidelines will pave the way for significant benefits through such cutting edge technology and contribute to the mission on "Affordable Health Care for All".

The Guidelines are developed by Department of Biotechnology (DBT), Ministry of Science and Technology, Indian Council of Medical Research (ICMR) and Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare and is an outcome of all concerned Inter-Ministerial efforts coordinated by DBT.