GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 2430
TO BE ANSWERED ON THE 3rd December, 2019

Nano Pharmaceuticals

2430. SHRIMATI RAKSHA NIKHIL KHADSE:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Government is formulating a new policy & guidelines for evaluation of nano pharmaceuticals which have higher efficacy and lower toxicity than the conventional drugs; and
(b) if so, the details thereof?

ANSWER

MINISTER IN THE MINISTRY OF CHEMICALS AND FERTILIZERS
(SHRI D. V. SADANANDA GOWDA)

(a): Yes, Sir. 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 have jointly developed "Guidelines for Evaluation of Nanopharmaceuticals in India". These guidelines are an outcome of concerted Inter-Ministerial efforts coordinated by DBT. Dr.Harsh Vardhan, Honorable Minister, Science & Technology released these Guidelines on 24th October 2019

(b): Nanocarrier based targeted drug delivery is an emerging field with a lot of market potential. There are no uniform internationally accepted guidelines for evalation of nanopharmaceuticals. These "Guidelines for Evaluation of Nanopharmaceuticals in India" is one of the most important steps for delineating quality, safety and efficacy assessment of novel nanoformulations which can be commercialized. These guidelines are also intended to provide transparent, consistent and predictable regulatory pathways for nanopharmaceuticals in India.

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.

In these guidelines, the nanopharmaceuticals (nanomedicines) have been classified according to their degradability, organicity, function and status of approval. Hence, the safety and efficacy data requirements have been described for different categories of nanopharmaceuticals.

Specific scientific evidence required for approval of any nanopharmaceutical and the strategies for pharmacovigilance of such products have been incorporated in these guidelines. Each application should be considered on its own merit based on data submitted, using scientific judgment and logical argument.

These guidelines would facilitate Indian researchers and industries to optimise their research on developing the product based on the regulatory requirements which will make our country a global leader in this area.

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