GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

RAJYA SABHA
UNSTARRED QUESTION NO. 2843
TO BE ANSWERED ON 17TH MARCH, 2026

PROMOTION OF ANIMAL-FREE DRUG TESTING METHODS IN THE COUNTRY

2843. SHRI S NIRANJAN REDDY:

Will the **Minister of HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether Government has examined the need to promote animal-free drug testing methods, including non-animal methods (NAMs) such as organ-on-chip, AI-based models and human-cell-based assays;

(b) whether India proposes to align its regulatory framework with global developments in phasing out animal testing for drug development;

(c) the steps taken to strengthen infrastructure, validation mechanisms and funding support for adoption of NAMs in the country; and

(d) whether any dedicated centres of excellence or national platforms are being established to promote research, industry collaboration and faster adoption of human-relevant testing technologies?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a) to (d): Central Drugs Standard Control Organization (CDSCO) regulates safety, efficacy and quality of the drugs for Human and Animals use under the provisions of Drugs & Cosmetics Act, 1940 & Rules, 1945 made there under.

A provision has been incorporated in Indian Pharmacopoeia (IP) - General Monograph, Addendum 2024 (to IP 2022) under General requirement of Veterinary Vaccine wherein the batch safety test using target animals may be omitted if conditions prescribed therein are complied.

Ministry of Health and Family Welfare has published G.S.R. No. 175 (E) dated 09.03.2023, wherein non-clinical testing methods has included cell-based assay, organ chips and micro physiological systems, sophisticated computer modelling and other human biology -based test methods under the New Drugs and Clinical Trials (NDCT) Rules, 2019.

NDCT Rules, 2019 contains provisions that the animal toxicology studies may be planned, designed and conducted as per the International Council for Harmonization (ICH)

guidelines to promote safe, ethical development and availability of new drugs with reduced use of animals in accordance with 3R (Reduce/Refine/Replace) principles.

Department of Biotechnology under Ministry of Science & Technology has informed about its support to research & innovation for developing processes or technologies for application of non-animal methods in areas of cell therapy, pre-clinical models for drug discovery for screening drugs/lead molecules/ new chemical entities/ vaccines, and in-vitro based models for disease biology.

Biotechnology Research and Innovation Council-inStem (Institute for Stem Cell Science and Regenerative Medicine (BRIC-inStem) under Department of Biotechnology is involved in 3D tissue and organoid models to test and quantify the developmental toxicology of new chemical entities for drug discovery programs by eliminating the use of animal models.

Through Biotechnology Industry Research Assistance Council (BIRAC), several projects have been supported for developing 3D organoid models, organ-on-chip, in-vitro model systems and platforms for non- animal methods.

Under the Precision Biotherapeutics-monoclonal antibodies vertical, of the Biomanufacturing initiative recently, the Department of Biotechnology has supported a project on "Validation of a Human-Relevant Lung-on-Chip Platform" as an alternative to Animal Models for Preclinical Toxicity Assessment of Monoclonal Antibodies" at Institute of Chemical Technology, Mumbai.

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