GOVERNMENT OF INDIA
MINISTRY OF SCIENCE AND TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

LOK SABHA
ADMITTED UNSTARRED QUESTION NO. 1705
TO BE ANSWERED ON 30.07.2025

Status of Adoption of Alternatives to Animal Testing

1705. Shri Tangella Uday Srinivas:

Will the Minister of SCIENCE AND TECHNOLOGY

be pleased to state:

(a) whether the Department of Biotechnology (DBT) has developed or funded protocols for validation of non-animal alternatives such as organ-on-chip, 3D tissue models, or in vitro systems for use in regulatory or toxicological testing, if so, the details thereof;

(b) whether DBT has engaged with regulatory authorities like CDSCO or CPCSEA to facilitate the recognition and adoption of these alternatives; if so, the details thereof;

(c) whether the Government has created or is planning to create a national repository or publicly accessible database of validated non-animal testing methods, if so, the details thereof;

(d) whether DBT's funding guidelines for research projects and biotech startups include provisions that mandate or incentivise the use of non-animal methods wherever scientifically feasible, if so, the details thereof;

(e) the details of the number of startups or private research institutions supported by DBT or BIRAC during the last five years for developing or commercialising cruelty-free testing technologies, and

(f) whether any international collaborations exist in this area, if so, the details thereof?

ANSWER

MINISTER OF STATE (INDEPENDENT CHARGE) FOR THE MINISTRY OF SCIENCE AND TECHNOLOGY & EARTH SCIENCES
(Dr. Jitendra singh)

(a) Department of Biotechnology has undertaken initiatives to nurture and develop 3D tissue models like organoid models or in-vitro systems - 3D printed models for potential applications in cell therapy, pre-clinical models for drug discovery, *in-vitro* cell based

models for understanding disease pathophysiology. One of DBT autonomous institutes-BRIC-inStem is developing 3D tissue and organoid models to test and quantify the developmental toxicology of new chemical entities that could enable drug discovery programs by eliminating the use of animal models for studying the developmental toxicity. However, the Department has not yet developed protocols for validation of non-animal alternatives.

(b) Preliminary consultative discussion have been initiated by BIRAC to discuss the regulatory challenges in this regard, however the Department has not yet engaged with the regulatory authorities to facilitate the recognition and adoption of these alternatives.

(c) Sir, no such national repository or any public accessible database of validated non-animal testing methods has yet been established.

(d) Department is fostering and catering 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 etc, and in-vitro based models for disease biology. However, as of now DBT's funding guidelines for research projects and biotech start-ups has not mandated or incentivized the use of non-animal methods wherever scientifically feasible.

(e) BIRAC has supported projects to Pandorum Technologies, Reagene Biosciences, ISMO Bio-Photonics Pvt. Ltd., Strand Life Sciences and Sri Ramachandra Institute for Higher Education and Research for developing 3D tissue models, organ-on-chip, in-vitro model systems and platforms for non-animal methods. One of DBT's autonomous institute-BRIC-inStem has a spin-off company dedicated to developing alternate and affordable lab reagents and toxicology models for Indian academia and industry.

(f) Department of Biotechnology has not undertaken any international collaboration in this area.

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