

PARLIAMENT QUESTION: Status of Adoption of Alternatives to Animal Testing

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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.

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. No such national repository or any public accessible database of validated non-animal testing methods has yet been established.

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.

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

This information was given by Dr. Jitendra Singh, Union Minister of State (Independent Charge) for Science & Technology, Minister of State (Independent Charge) for Earth Sciences, MoS PMO, Department of Atomic Energy and Department of Space, MoS Personnel, Public Grievances and Pensions, in a written reply in the Lok Sabha today.

NKR/PSM/AV

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