

British drug regulator lays guidance for move towards lesser animal testing

The draft guidance from the UK's Medicines and Healthcare products Regulatory Agency aims to reduce reliance on animal studies and aligns with a broader global push to limit such testing in drug development.



Bengaluru: Britain's medicines regulator said on Wednesday it will introduce a framework by the end of 2026, which would allow drugmakers to ask a review of the data for drugs being

developed without animal testing before applying for approval.

The draft guidance from the UK's Medicines and Healthcare products Regulatory Agency aims to reduce reliance on animal studies and aligns with a broader global push to limit such testing in drug development.

The MHRA will support efforts to move away from animal testing where scientifically appropriate, while continuing to accept applications that include animal testing based data in line with international standards, citing patients' best interests.

Developers may submit data from non-animal testing methods alongside any traditional studies, it said, adding that decisions will be taken on a case-by-case basis.

A new review mechanism will allow companies developing animal-free products to submit preclinical safety data for early assessment, the regulator said, adding that companies must report at least one human clinical trial to qualify for receiving a view on whether the data is sufficient for a full application.

The MHRA said it does not support animal testing for generic and biosimilar medicines, for drug substances that do not work in animals, and for products whose medicinal profile is well-known.

However, the regulator said it expects to see relevant animal studies for new types of drugs being studied and developed, adding that animal data for vaccines will also be accepted.

The U.S. FDA last week issued draft guidance encouraging companies to reduce animal testing and adopt alternatives such as computer simulations and organ-mimicking devices.

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