

Commission approves modern animal-free testing for drugs

New guidelines for pharma makers will come into effect from July 1

In a step that would spare animals from suffering due to drug experiments, the Indian Pharmacopoeia Commission has approved modern, animal-free tests for drug manufacturers. In the 2018 edition of Indian Pharmacopoeia, that provides guidelines on tests for drugs manufactured and marketed in India, the IPC has replaced the pyrogen test carried out on rabbits and the abnormal toxicity test carried out on guinea pigs and mice with tests that can be done in test tubes.

The guidelines in the edition will come into effect from July 1.

Dr. G.N. Singh, Secretary-cum-Scientific Director of the IPC confirmed the development.

“We have been focussing on various issues concerning human safety as well as animal safety when it comes to drug manufacturing. If alternative methods are available through which animals don’t have to suffer, they should be applied effectively”, Dr. Singh told *The Hindu* adding that alternative tests are equally effective.

The pyrogen test is carried out to check impurity or substance that can cause adverse side-effects. For the test, the drug is injected into a rabbit and the animal is closely observed for feverish symptoms.

The abnormal toxicity test is carried out to check potential hazardous biological contamination in vaccine formulations.

This batch test is done before the product is approved for marketing. In this,

mice or guinea pigs are injected with the vaccine. The scientists observe if there is death of any animal.

New mandate

With the Indian Pharmacopoeia Commission's new mandate, the pyrogen test will be replaced by a bacterial endotoxin test or a monocyte activation test which can be carried out in test tubes. Vaccine manufacturers can apply for waiver for the abnormal toxicity test by getting a compliance certificate from the National Control Laboratory instead.

People for the Ethical Treatment of Animals (PETA) India has been pushing for doing away with the cruel methods of testing on animals for the past several years.

“We had written to the IPC in 2015 with several suggestions. Our suggestions were discussed in a meeting of the expert committee on vaccine standards that was held in 2016 and a few of them have finally been approved”, said PETA India's science policy adviser Dr. Dipti Kapoor who termed IPC's mandate as a progressive step.

She said tests like the one for abnormal toxicity have been removed by the U.S. and European pharmacopoeia as they are not an efficient marker.