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ISCR welcomes new drugs and clinical trial rules 2019

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Focused on patient rights, safety and well-being

Welcoming the New Drugs and Clinical Trial Rules, 2019 which were notified by the Ministry of Health & Family Welfare and made public on March 25th, the Indian Society for Clinical Research (ISCR) said that the new Clinical Trial Rules are well balanced and will further the conduct of ethical and quality clinical trials in the country which, in turn, will benefit patients.

“We thank the Ministry of Health & Family Welfare and CDSCO for notifying the Rules which were long coming and will go a long way in reassuring local and global stakeholders about India’s commitment to building a robust regulatory and clinical research ecosystem. The new Rules protect the rights, safety and well-being of patients, while ensuring a strong scientific base for the conduct of clinical trials,” said Dr Chirag Trivedi, President, ISCR. “We hope this will lead to more stability and growth in clinical research being done in India which will ultimately ensure that our patients have access to faster and more effective treatment.” India has the second largest population in the world and the highest disease burden but does less than 1.2% of global clinical trials.

According to ISCR, some of the salient features of the Clinical Trial Rules are:

- Deemed approval for clinical trials in 30 working days, if no communication is otherwise received from the Central Licensing Authority, for drugs discovered in India or for drugs whose R&D is done in India and proposed to be manufactured and marketed in India. This is a huge push towards encouraging local drug development.

- 90 working days approval timelines for global clinical trials. This will support India’s participation in global drug development as these timelines are globally competitive and in line with timelines in developed countries.
- Pre and post submission meetings have been introduced. This is a welcome step as it will provide clarity to various applicants and help smoothen the application process.
- Conditions for providing post-trial access of drugs to patients who require it have been defined for the first time.
- The validity of Clinical Trial approval has been determined as two years to initiate a study which is extendable by one year. This step is important in ensuring initiation of approved studies and quicker access to new treatment for patients.
- For the first time, Orphan Drugs have been defined as a drug intended to treat conditions which affects not more than five lakh persons in India. In addition, fee waivers for orphan drug trials will encourage more trials for rare diseases in India.

- Requirements and the conditions to be met for conducting Bioavailability and Bioequivalence studies have been included in the Rules, including the specifications for centres conducting such studies. This provides clarity for planning, conduct and reporting such studies.
- The rules specify the conditions under which data from a local clinical trial may not be required to be submitted along with the application for permission to import a new drug for sale or distribution. This rule also specifies the conditions for conducting a Phase IV clinical trial in India for such new drugs for establishing its safety and effectiveness. This will help in providing early access to Indian patients to drugs already approved in the specified countries.
- Finally, there is no changes in the rules for safety reporting process and timelines and in the process and requirement for compensation payout which is an acknowledgement that the current system is working well.

“We are grateful to the regulatory authorities for ensuring a collaborative and consultative process, involving all stakeholders, in developing the new rules. As we all know, clinical trials in India went through a very challenging few years and we are still in the process of rebuilding the trust and confidence of sponsors in placing trials in India. It is incumbent on all those involved in clinical research to publicise the new rules so that we can have more clinical trials in India. Our patients are waiting,” added Dr Trivedi.