FAQs on New Drugs and Clinical Trials

1. Whether the New Drugs and Clinical Trial Rules, 2019 (NDs & CTs Rules, 2019) is applicable only for New Drugs and Investigational New drugs for human use?

Yes. Regulation for New drugs for veterinary use will continue to be as per Part XA of the Drugs and Cosmetics Rules, 1945.

2. What is a “new drug”?

A new drug means;

i. a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent has not been approved as safe and efficacious by Central Licencing Authority (CLA) i.e. DCG(I) with respect to its claims; or

ii. a drug approved by the CLA for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or

iii. a fixed dose combination of two or more drugs, approved by CLA separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or

iv. a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central Licencing Authority; or

v. a vaccine, r-DNA derived product, living modified organism, monoclonal antibody, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug;

3. What is an “investigational new drug ( IND)”

An “investigational new drug (IND)” means a new chemical or biological entity or substance that has not been approved for marketing as a drug in any country.

4. What is a “subsequent new drug”?

A subsequent new drug means a drug approved by the Central Licencing Authority for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form. A subsequent new drug also includes a new drug already approved in the country.