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स्वास्थ्य और परिवार कल्याण मंत्रालय
(स्वास्थ्य और परिवार कल्याण विभाग)
अधिसूचना

नई दिल्ली, 19 मार्च, 2019

सा.का.नि. 227(अ).—औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 12 की उप-धारा (1) और धारा 33 की उप-धारा (1) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, भारत के राजपत्र, असाधारण, भाग II, खंड 3, उप-खंड (i), में अधिसूचना संख्या सा.का.नि. 104 (अ), तारीख 1 फरवरी, 2018 द्वारा, औषधि तकनीकी सलाहकार बोर्ड के परामर्श के पश्चात केंद्रीय सरकार, नई औषधि और नैदानिक परीक्षण नियम, 2018 के प्रारूप को प्रकाशित किया गया था, प्रभावित होने वाले सभी व्यक्तियों से पैंतालीस दिनों की अवधि समाप्त होने से पहले आपत्तियां और सुझाव आमंत्रित किए गए है, जब उक्त अधिसूचना वाले उक्त राजपत्र की प्रतियां जनता को उपलब्ध कराई गई थी;

और, उक्त अधिसूचना वाली राजपत्र की प्रतियां 7 फरवरी, 2018 को जनता के लिए उपलब्ध करा दी गई थीं;

और, उक्त प्रारूप अधिसूचना के उत्तर में प्राप्त सभी आपत्तियों और सुझावों पर केंद्रीय सरकार द्वारा समयक रूप से विचार किया गया है;

और, माननीय उच्चतम न्यायालय ने रिट याचिका सं. 79/2012 (पीआईएल-डब्ल्यू) के साथ रिट याचिका (एस) (सिविल) नं. 33/2012 स्वास्थ्य अधिकार मंच, इंदौर और अन्य बनाम भारत संघ और अन्य के साथ-साथ पाया कि नई नैदानिक परीक्षण नियमों को तत्काल अंतिम रूप दिया जाएगा

अब, केंद्रीय सरकार, औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 12 और धारा 33 द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, ने औषधि तकनीकी सलाहकार बोर्ड के साथ परामर्श करने के पश्चात निम्नलिखित नियम बनाती है, अर्थात:–

(w) "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, except in accordance with the provisions of the Act and the rules made thereunder, as per conditions specified in the labelling thereof and has not been approved as safe and efficacious by the Central Licencing Authority with respect to its claims; or

(ii) 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; or

(iii) a fixed dose combination of two or more drugs, approved 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, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug;

Explanation.— The drugs, other than drugs referred to in sub-clauses (iv) and (v), shall continue to be new drugs for a period of four years from the date of their permission granted by the Central Licencing Authority and the drugs referred to in sub-clauses (iv) and (v) shall always be deemed to be new drugs;

(x) "orphan drug" means a drug intended to treat a condition which affects not more than five lakh persons in India;

(y) "pharmaceutical formulation" means any preparation for human or veterinary use containing one or more active pharmaceutical ingredients, with or without pharmaceutical excipients or additives, that is formulated to produce a specific physical form, such as, tablet, capsule or solution, suitable for administration to human or animals;

(z) "pharmacovigilance" means the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other drug- related problem;

(aa) "phytopharmaceutical drug" means a drug of purified and standardised fraction, assessed qualitatively and quantitatively with defined minimum four bio- active or phytochemical compounds of an extract of a medicinal plant or its part, for internal or external use on human beings or animals, for diagnosis, treatment, mitigation or prevention of any disease or disorder but does not include drug administered through parenteral route;

(bb) "placebo" means an inactive substance visually identical in appearance to a drug being tested in a clinical trial;

(cc) "post-trial access" means making a new drug or investigational new drug available to a trial subject after completion of clinical trial through which the said drug has been found beneficial to a trial subject during clinical trial, for such period as considered necessary by the investigator and the Ethics Committee;

(dd) "registered pharmacist" shall have the meaning as assigned to it in clause(i) of section 2 of the Pharmacy Act, 1948 (8 of 1948);

(ee) "Schedule" means the Schedule annexed to these rules;

(ff) "serious adverse event" means an untoward medical occurrence during clinical trial resulting in death or permanent disability, or hospitalisation of the trial subject where the trial subject is an outdoor patient or a healthy person, prolongation of hospitalisation where the trial subject is an indoor-patient, persistent or significant disability or incapacity, congenital anomaly, birth defect or life threatening event;

(gg) "similar biologic" means a biological product which is similar in terms of quality, safety and efficacy to reference biological product licenced or approved in India, or any innovator product approved in International Council of Harmonisation (ICH)member countries;

(hh) "sponsor" includes a person, a company or an institution or an organisation responsible for initiation and management of a clinical trial;

(ii) "State Licencing Authority" means Licencing Authority appointed by a State Government having qualifications specified in rule 49A of the Drugs and Cosmetics Rules, 1945;