Government of Pakistan
Drug Regulatory Authority of Pakistan
Ministry of National Health Services, Regulations and Coordination
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Islamabad, the 22nd April, 2022.

NOTIFICATION

S.R.O. 540(I)/2022.– In exercise of the powers conferred by section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), the Drug Regulatory Authority of Pakistan, with the approval of the Federal Government, is pleased to make the following rules, namely: -

1. Short title, commencement and application.– (1) These rules shall be called the Pharmacovigilance Rules, 2022.

(2) They shall come into force at once.

(3) These rules shall be applicable to perform pharmacovigilance activities during passive surveillance, active surveillance and post-authorization studies.

2. Definitions.– In these rules, unless there is anything repugnant in the subject or context, -

(i) "abuse of a therapeutic good" means persistent or sporadic, intentional excessive use of therapeutic good which is accompanied by harmful physical or psychological effects;

(ii) "active surveillance" is a process that involves, enhanced or targeted monitoring for certain events or therapeutic goods and seeks to ascertain completely the number of adverse events or adverse drug reactions through a continuous pre-planned process;

(iii) "administrative territory" means such states and territories as mentioned in Article I of the Constitution;

(iv) "adverse drug reaction" or "ADR" means response to drug or therapeutic goods which is noxious and unintended that occurs at doses normally used for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function. A response in this context means that a causal relationship between a therapeutic good and an adverse event is at least a reasonable possibility. An adverse reaction, in contrast to an adverse event, is characterised by the fact that a causal relationship between a therapeutic good and an occurrence is suspected;

(v) "adverse event" or "AE" means any untoward medical occurrence in a patient or clinical investigation subject administered a drug or therapeutic good and which does not necessarily have a causal relationship with this treatment;

(vi) "adverse event following immunizations" or "AEFI" means any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine;

(vii) "causality assessment" means the evaluation of the likelihood that medicine or therapeutic good was the causative agent of an observed adverse reaction;

(viii) "concerned board or committee" means a Board or Committee notified under the Drugs Act, 1976 (XXXI of 1976) and the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) for the purpose of licensing, registration, enlistment or any other function to which therapeutic good safety related regulatory actions or recommendations may be referred;

(ix) "data lock point" or " DLP" means the cut-off date appointed for data to be included in periodic benefits-risk evaluation report based on their international birth date;

(x) "individual case safety report" or "ICSR" means a report describing a suspected adverse drug reaction related to the administration of one or more drugs or therapeutic good to an individual patient;

(xi) "international birth date" or "IBD" means the date of the first marketing approval or registration for any product containing the active substance granted to any company in any country in the world;

(xii) "medication error" means any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient or consumer;

(xiii) "misuse of a therapeutic good" means situations where the therapeutic good or drug is intentionally and inappropriately used not in accordance with the registered therapeutic good information;

(xiv) "national pharmacovigilance centre" or "NPC" means the national pharmacovigilance centre established under rule 3;

(xv) "occupational exposure to a therapeutic good" means an exposure to a therapeutic good as a result of one's professional or non-professional occupation;

(xvi) "off-label use" refers to the use of an approved medicine under the direction or supervision of a healthcare professional for an unapproved indication, age group, dosage, route or form of administration;

(xvii) "overdose of therapeutic good" means administration of a quantity of a therapeutic good given per administration or cumulatively which is above the maximum recommended dose according to the registered therapeutic good information;

(xviii) "passive surveillance" a process where healthcare professionals or patients send spontaneous reports describing an adverse drug reaction or event after one or more therapeutic goods are administered to the registration holders or regulatory authority;

(xix) "periodic benefit-risk evaluation report" or "PBRER" is a document intended to present a periodic, comprehensive, concise and critical analysis of new or emerging information on the risks of the therapeutic good on its benefits in