NATIONAL ASSEMBLY SECRETARIAT

Subject:- **REPORT OF THE STANDING COMMITTEE ON NATIONAL HEALTH SERVICES, REGULATIONS AND COORDINATION ON THE DRUG REGULATORY AUTHORITY (AMENDMENT) BILL, 2021**

I, Chairman of the Standing Committee on National Health Services, Regulations and Coordination have the honor to present this report on the Bill further to amend the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), [The Drug Regulatory Authority of Pakistan (Amendment) Bill, 2021] (moved by Ms. Uzma Riaz, MNA) (Private Member's Bill) referred to the Committee on 10th August, 2021.

2. The Standing Committee comprises the following:-

(1)	**Mr. Khalid Hussain Magsi**	**Chairman**
(2)	Dr. Haider Ali Khan	Member
(3)	Mr. Nasir Khan Musazai	Member
(4)	Mr. Jai Parkash	Member
(5)	Raja Khurram Shahzad Nawaz	Member
(6)	Dr. Muhammad Afzal Khan Dhandla	Member
(7)	Dr. Nausheen Hamid	Member
(8)	Ms. Zille Huma	Member
(9)	Ms. Fouzia Behram	Member
(10)	Ms. Aliya Hamza Malik	Member
(11)	Dr. Seemi Bokhari	Member
(12)	Mr. Nisar Ahmad Cheema	Member
(13)	Mr. Mukhtar Ahmad Malik	Member
(14)	Dr. Samina Matloob	Member
(15)	Dr. Darshan	Member
(16)	Mr. Mahesh Kumar Malani	Member
(17)	Dr. Shazia Sobia Aslam Soomro	Member
(18)	Mr. James Iqbal	Member
(19)	Mr. Ramesh Lal	Member
(20)	Ms. Sams-un-Nisa	Member
(21)	Minister In-Charge *National Health Services, Regulations and Coordination*	Ex-officio Member

3. The Committee considered the Bill as introduced in the National Assembly placed at Annexure-A, in its meetings held on 3rd November, 2021 and 01st December, 2021. The Committee recommends that the said Bill may not be passed by the National Assembly.

-Sd/-
(MR. KHALID HUSSAIN MAGSI)
Chairman

-Sd/-
(TAHIR HUSSAIN)
Secretary
Islamabad, the 15th June, 2022

Annexure-A

[AS INTRODUCED IN THE NATIONAL ASSEMBLY]

A
BILL

further to amend the Drug Regulatory Authority of Pakistan Act, 2012

WHEREAS it is expedient further to amend the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), for the purposes hereinafter appearing;

It is hereby enacted as follows:-

1. **Short title and commencement.**-(1) This Act may be called the Drug Regulatory Authority of Pakistan (Amendment) Act, 2021.

(2) It shall come into force at once.

2. **Amendment of section 4, Act XXI of 2012.**- In the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012),in section 4, in sub-section (1), for the word "thirteen" the word " fourteen" shall be substituted and after paragraph (m) the following new paragraph shall be added, namely:-

"(n) **Director Research and Product specialization.**-He shall be incharge of the Division for Research and Product specialization that includes pharmacogenomics, pharmacoepidemiology, biostatistics and specialized pharmacology, and experimental neuropsychopharmacology, which shall be responsible for conducting research for clinical trials as well as on aspects other than clinical trials and other matters connected therewith and ancillary there to;

STATEMENT OF OBJECTS AND REASONS

The drug system encompasses four main stages—research and development; regulatory review; medication manufacturing, distribution, and marketing; and medication use—that each contain multiple critical control points at which quality, safety, and efficacy can be addressed, and at which breakdowns can occur.

The R&D process involves more than the development of new products; it encompasses the overall generation and disclosure of high-quality data that can be used with confidence by providers and patients in medical care, by providers and technology vendors to populate knowledge bases and clinical decision-support systems, by regulators in assessing benefit/risk balances for protection of the

public health, and by researchers for continued innovation and advancement of science and medicine. Issues related to study design, data quality, and disclosure can have direct bearing on the development of the medication knowledge base needed to support clinicians and pharmacists in clinical decision making and prescribing; preparation and administration of appropriate dosages; and monitoring of patient response (positive and negative) to a medication, particularly the ability to discern symptoms of disease from effects of the drug. Public availability of information from trials also is necessary to support consumers in their self-care, disease management, and medication self-management. Data quality can be compromised by poor clinical study designs, less-than-optimal methods of data analysis, and/or conflicts of interest that affect the objectivity of investigators. The failure to disclose negative study results (e.g., serious adverse side effects) can have fatal effects on patients.

Research must be an integral part of the DRAP tasks; it supports the scientific expertise of the institute both internally and externally. A key objective is the combination of regulatory work and research to take advantage of synergistic effects. Research work also opens new perspectives for scientific staff of the institute. Scientific projects to be initiated at the DRAP should be focused on certain defined research areas; they are internationally competitive and meet high quality standards supporting the DRAP's role as one of the leading drug regulatory authorities in Asia.

Research at the DRAP should be concentrated on important and contemporary research focal points with regard to the marketing authorization of medicinal products and improving the safety thereof as well as concerning the recording and assessment of risks in connection with medical devices. These focal points should be represented by different interdisciplinary research groups that co-operate closely in the development of research issues with leading national and international research facilities both on university and non-university levels. As a major licensing authority the DRAP's research should also promote the regulatory expertise of its scientific staff on an on-going basis. Research and product specialization must be important components of DRAP's structural design. Separate departments need to work on identifying and tracking falsified medicines, medicine shortages, as well as parallel imports.

Research Division in the DRAP would focuss on following areas of research:

a. The research areas pharmacogenomics and individualised pharmacotherapy are concerned with the variability of patients' drug responses that is caused by inborn genetic differences. Research in this area concentrates on expanding the knowledge of molecular, preclinical, and clinical principles in order to arrive at a personalised pharmacotherapy. The aim is to identify the exact causes for individual differences and the variability of desired drug