

**[AS INTRODUCED IN THE SENATE]**

**A**

**BILL**

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

WHEREAS it is expedient 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, 2013.

(2) It shall come into force at once.

**2. Amendment of Section 2 of Act XXI of 2012.**- In the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), hereinafter referred to as the said Act, in Section 2, in paragraph (xv), -

- “(i) before the word “health”, the word “Natural” shall be inserted;
- (ii) after the word “probiotics”, the words and commas “Vitamins, minerals, antiseptic” shall be inserted; and
- (iii) after the word “shampoos”, the words “and other products as defined by WHO” shall be inserted.”.

**3. Amendment of Section 4 of Act XXI of 2012.**- In the said Act, in Section 4, in sub-section (1), -

- “(i) in paragraph (b), in the heading, for the word “Drug”, the word “Pharma” shall be substituted;
- (ii) in paragraph (c), in the heading, for the words “Laboratory testing”, the words “Quality Control” shall be substituted and in body after the words “related to”, the words “CGMP compliance and” shall be inserted; and
- (iii) in paragraph (h), in the heading, after the word “Director”, and in body after the words “Division of”, the word “Natural” shall be inserted;”.

**4. Amendment of Section 5 of Act XXI of 2012.-** In the said Act, in Section 5,-

- (i) in sub-section (1),-
  - “(a) for paragraph (a), the following shall be substituted, namely: -
    - (a) has M Phil or PhD degree in any discipline of Pharmacy or post graduate degree in any discipline of medicine with a minimum of twenty years experience in the field of health care either from public or private sector;
    - (b) in paragraph (b), occurring at the end, the word “and” shall be omitted; and
    - (c) in paragraph (c), at the end, the word “and” shall be added and after paragraph (c) amended as aforesaid, the following new paragraph shall be added, namely: -
      - (d) the retiring age shall be 65 years.”.
- (ii) in sub-section (6), after the word “earlier”, occurring at the end, the words “on the recommendation of the Policy Board” shall be added.

**5. Amendment of Section 7 of Act XXI of 2012.-** In the said Act, in Section 7,-

- “(i) in paragraph (c), at the beginning before the word “issue”, the words “subject to the approval of the Policy Board” shall be inserted;
- (ii) in paragraph (x), occurring at the at the end, the word “and” shall be omitted; and
- (iii) in paragraph (y), for the full stop occurring at the end a semicolon and the word “; and” shall be substituted and after paragraph (y) amended as aforesaid, the following new paragraph shall be added, namely: -
  - (z) establish an effective system of Post Marketing Surveillance to ensure protection of the interest of the people through availability of the safe, effective and efficacious quality drugs and curb the availability and sale of fake substandard and non-registered therapeutic goods.”.

**6. Amendment of Section 9 of Act XXI of 2012.-** In the said Act, in Section 9, in sub-section (1), for the word "fifteen", the word "twenty-one" shall be substituted and for paragraph (j), the following paragraphs shall be substituted, namely: -

- (j) Four technical experts who are not owners/MDs of Pharma industry, to be nominated by their respective Associations. One technical expert of manufacturing and one technical expert of Quality Control from Pakistan Pharmaceutical Manufacturers' Association (PPMA) and similarly one technical expert of manufacturing and one technical expert of Quality Control from Pharma Bureau (PB); *Member*
- (k) Three experts who are Professors doctor of medicine (one each from Private, Public and Army) and three experts of Toxicology, Infectious Diseases and Epidemic Control. Five of the above to be nominated by College of Physicians and Surgeons of Pakistan (CPSP) and one Professor from Army to be nominated by Army General Head Quarter (GHQ) Military Secretary Branch; and *Member*
- (l) One expert from Clinical Pharmacy Services to be nominated by Pakistan Pharmacist Association (PPA) and one expert from Community Pharmacy Services to be nominated from Pakistan Chemists and Druggist Association (PCDA).". *Member*

**STATEMENT OF OBJECTS AND REASONS**

The amendments proposed in this Bill are very essential. The Drug Regulatory Authority was supposed to work independently as an autonomous body but the position is otherwise. Besides, the amendments proposed in this bill are of great public importance. These are necessary to improve the working of the authority and to achieve the goals for which it was established. These amendments were agreed upon by the Ex-Minister in writing as well as on the floor of the House. Without these amendments the Authority is a replica of the Ministry of Health.

SENATOR ABDUL HASEEB KHAN  
Member-in-Charge