



SENATE OF PAKISTAN

Report No.2 of 2020

REPORT OF THE
STANDING COMMITTEE ON NATIONAL HEALTH SERVICES,
REGULATIONS AND COORDINATION

**“The Drug Regulatory Authority of Pakistan (Amendment) Bill, 2020”
introduced by Senator Muhammad Javed Abbasi on 13th July, 2020.**

PRESENTED BY
SENATOR KHUSHBAKHT SHUJAT
Chairperson SSC on National Health Services, Regulations and Coordination

SENATE SECRETARIAT

REPORT OF THE SENATE STANDING COMMITTEE ON NATIONAL HEALTH SERVICES, REGULATIONS AND COORDINATION

I, Chairperson of the Senate Standing Committee on National Health Services, Regulations and Coordination have the honor to present the report, on behalf of the Committee on "The Drug Regulatory Authority of Pakistan (Amendment) Bill, 2020" introduced by Senator Muhammad Javed Abbasi on 13th July, 2020 and referred by the House to the Standing Committee on National Health Services, Regulations and Coordination.

2. The matter was referred to the Senate Standing Committee on National Health Services, Regulations and Coordination for consideration and report to the House.

3. The composition of the Committee is as under:-

1. Senator Khushbakht Shujat	Chairperson
2. Senator Ayesha Raza Farooq	Member
3. Senator Bahramand Khan Tangi	Member
4. Senator Dilawar Khan	Member
5. Senator Dr. Asad Ashraf	Member
6. Senator Dr. Ashok Kumar	Member
7. Senator Sikandar Mandhro	Member
8. Senator Dr. Ghous Muhammad Khan Niazi	Member
9. Senator Liaqat Khan Tarakai	Member
10. Senator Prof. Dr. Mehr Taj Roghani	Member
11. Senator Sana Jamali	Member
12. Senator Sardar Muhammad Shafiq Tareen	Member
13. Senator Syed Muhammad Ali Shah Jamot	Member
14. Minister for National Health Services, Regulations & Coordination	Ex-Officio Member

4. The Standing Committee considered the issue in its meeting held on 6th August, 2020. The Committee disposed of the Bill and decided to submit the report to the House. The meeting was attended by the following members, namely:-

1. Senator Khushbakht Shujat	Chairperson
2. Senator Dr. Asad Ashraf	Member
3. Senator Dr. Ghous Muhammad Khan Niazi	Member
4. Senator Sana Jamali	Member
5. Senator Sardar Muhammad Shafiq Tareen	Member
6. Senator Muhammad Javed Abbasi	Mover



SUMMARY

The Mover, Senator Muhammad Javed Abbasi gave a detailed briefing on objects and reasons of the Bill. While explaining the purpose of the Bill, the Mover stated that the word "non-drug" causes confusion and thus excludes many of the medicines from the definition of "drug" given under schedule No.I of the Drug Regulatory Authority of Pakistan Act, 2012. So deletion of the word "non-drugs" will bring clarity. Also that the scope of enactment will become wider in terms of providing safety to the public at large. In view of the Mover, the present Act excludes many of the drugs from definition and their sale, price and authenticity cannot be ensured by the Drug Regularity Authority. Defining the word "drug", the Mover described that all the supplements fall under the definition of "drug" all over the world. It is a lacuna in our legislation. For comprehensive enactment and implementation it is deemed necessary to provide a sound health cover to the public.

The proposed amendments in the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) are as follows:

Amendment of section 2, Act XXI of 2012.- In the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), hereinafter to referred to as the said Act, in section 2, in clause (xv), the brackets and the word "(non-drugs)", shall be omitted.

Amendment of section 4, Act XXI of 2012.- In the said Act, in section 4, in sub-section (1), in clause (h) the brackets and the word "(non-drugs)", occurring twice, shall be omitted.

The Drug Regulatory Authority of Pakistan (DRAP) agreed with the proposed amendments in the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012).

The Committee after detailed deliberation unanimously endorsed the amendment proposed by Senator Muhammad Javed Abbasi. In light of discussion, the Committee recommended that the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) as reported by the Standing Committee may be passed by the House. The Bill as reported by the Standing Committee is annexed as "A" and the Bill introduced in the Senate is annexed as "B."


(Mavald Iqbal)
Secretary Committee


(Senator Khushbakht Shujat)
Chairperson Committee

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, 2020.
(2) It shall come into force at once.
2. **Amendment of section 2, Act XXI of 2012.**- In the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), hereinafter to referred to as the said Act, in section 2, in clause (xv), the brackets and the word "(non-drugs)", shall be omitted.
3. **Amendment of section 4, Act XXI of 2012.**- In the said Act, in section 4, in sub-section (1), in clause (h) the brackets and the word "(non-drugs)", occurring twice, shall be omitted.

STATEMENT OF OBJECTS AND REASONS

The word "non-drug" after the words Health and OTC Products are inconsistent to the definition of the term 'DRUG' given under SCHEDULE-1 of the Drug Regulatory Authority of Pakistan Act, 2012 and also misused in case of assurance of safeness, effectiveness and reasonable pricing of drugs and therapeutic goods.

SENATOR MUHAMMAD JAVED ABBASI
Member-In-Charge

ANNEX B

As
[TO BE INTRODUCED IN THE SENATE]

A

BILL

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SENATOR MUHAMMAD JAVED ABBASI
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