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BILL

to develop mechanisms for making Tuberculosis (TB) Case Notification mandatory in the Islamabad Capital Territory and restricting over-the-counter sale of anti-Tuberculosis medication

WHEREAS Tuberculosis (TB) is an infectious disease endemic in Pakistan causing great human suffering making it imperative to reduce its morbidity and mortality in the country, in the national interest and also to fulfill our international commitments and obligations in this regard; and

WHEREAS it is necessary to ensure that TB patients receive only quality assured (QA) TB medicines; and to provide for matters ancillary thereto;

It is hereby enacted as follows:-

1. **Short title and commencement.**- (1) This Act shall be called The ICT Tuberculosis (Notification) Act, 2021.
(2) It shall extend to the Islamabad Capital Territory.
(3) It shall come into force at once.
2. **Definitions.**- (1) In this Act, unless there is anything repugnant in the Subject or Context,
 - (i) "Anti-tuberculosis drugs" means first line and second line drugs used for the treatment of Tuberculosis including but not restricted to the drugs mentioned in schedule to be notified by the Government from time to time given individually or in fixed dose combinations;
 - (ii) "Combined Management Unit, Tuberculosis Section" means the Tuberculosis Section of the Combined Management Unit for controlling AIDS, TB and Malaria;
 - (iii) "District Health Officer" means the District Health Officer of Islamabad district / Islamabad Capital Territory;
 - (iv) "Form" means the Tuberculosis Notification Form provided in the Schedule;
 - (v) "Government" means the Government of Pakistan;
 - (vi) "Laboratory" means a pathological laboratory conducting tests for human diseases;

- (vii) "Laboratory In-charge" means the owner of laboratory and includes the person who performs the tests on a specimen in the Laboratory;
- (viii) "Licensing authority" means authority for issuing licenses for retail and wholesale of drugs and medicines including anti-tuberculosis drugs;
- (ix) "License holder" means a person in whose favor licensing authority has issued a license enabling for the retail sale or wholesale of drugs and medicines including anti-tuberculosis drugs.
- (x) "Local public health facility" means and includes: all public sector Hospitals, Medical Centers, Rural Health Centers; Basic Health Units, and Dispensaries involved in TB Care in the Islamabad Capital Territory;
- (xi) "Medical Practitioner" means a person who is registered with the Pakistan Medical Commission;
- (xii) "Ministry" means the Federal Ministry of National Health Services, Regulation and Coordination, Government of Pakistan;
- (xiii) "Notify" means a notification to the relevant officer in the District Health Office or local public health facility, of a diagnosed TB patient, in accordance with the procedures set forth under this Act;
- (xiv) "Patient" means a person confirmed to be suffering from Tuberculosis on the basis of any diagnostic test prescribed in the National TB guidelines for pulmonary or extra-pulmonary TB patients;
- (xv) "Prescription" means medicines or drugs prescribed by a registered medical practitioner or registered traditional medicine practitioner;
- (xvi) "Prescribed protocols" means tuberculosis treatment regime;
- (xvii) "Prescription holder" means a person in possession of a valid prescription;
- (xviii) "Presumptive patient" means a person suspected to be suffering from TB having symptoms of cough and fever for more than two weeks duration without any known cause or explanation;

- (xix) "Privacy and confidentiality" means that any information relating to patients, their families and contacts, will not be disclosed to any party except the appropriate medical professionals providing care and support to the patient;
- (xx) Quality assured medicines means medicines recommended for use by the WHO End-TB Strategy and WHO's relevant medicines prequalification program and authorized for use in Pakistan by the Drug Regulatory Authority of Pakistan;
- (xxi) "Registered traditional medicine practitioner" means a person who is registered under section 24 of the Unani, Ayurvedic and Homeopathic Practitioners Act (II of 1965) as amended from time to time;
- (xxii) "Valid prescription" means a prescription issued by a registered medical practitioner that has not lapsed or been superseded, and has not already been used for dispensing drugs;

PART-II-A

TUBERCULOSIS CASE NOTIFICATION, RECORD KEEPING AND EDUCATIONAL OUTREACH

3. Development and Distribution of Notification Forms.- The office of the District Health Officer Islamabad shall distribute and deliver copies of the TB case Notification Form-A given at annex-I in the Schedule-II to every medical practitioner, private clinic, private hospital, registered traditional medicine practitioners, community leaders, TB civil society organizations and heads of hospitals and health facilities operating within the Islamabad Capital Territory, as may be necessary.

4. Duties of registered Traditional Healthcare provider. (1)A registered traditional healthcare provider shall notify the patient by sending a complete Form as provided in Form B Schedule, to the District Health Officer or a local public health facility.

(2) They shall also be obliged to,

- (a) Inform their patients about the availability of free diagnostic and treatment services through public health facilities;
- (b) The strategies for preventing the spread of tuberculosis;
- (c) display a poster describing the notification requirement, symptoms of tuberculosis and measures that prevent its spread at a conspicuous location, which may be visible to the patients;
- (d) advise the patients to access social protection systems as support during the course of their treatment;
- (e) refer patients to appropriate counseling in the instance of side effects, and;

(f) inform the patient of the obligation for TB diagnosis, treatment and reporting to adhere to principles of privacy, confidentiality and freedom from stigma and discrimination.

5. Notification of Tuberculosis patients by private pathological laboratories and hospitals. (1) When a Laboratory identifies a positive Tuberculosis test result in a specimen of an individual, the Laboratory In charge shall send a complete Form as provided in Form-C Schedule, to the District Health Officer or a local public health facility.

(2) The head of a private hospital or clinic with more than one medical practitioners shall submit a complete form as provided in Form-D given in Schedule, to the District Health Officer or a local public health facility.

PART-II-B

RESTRICTING THE SALE OF ANTI-TUBERCULOSIS DRUGS

6. Prohibition on over-the-counter sale of anti-tuberculosis drugs.-

(1) A license holder including a pharmacy or a chemist/druggist store may not sell anti-tuberculosis drugs except to a valid prescription holder.

(2) If a license holder doubts the validity of a prescription, a license holder shall verify the contents of a prescription by contacting the issuing registered medical practitioner. If the authenticity of a prescription cannot be confirmed, a license holder shall refuse to sell anti-tuberculosis drugs to the customer.

7. Prohibition on prescribing anti-tuberculosis drugs.- A person may not prescribe anti-tuberculosis drugs unless he/she is a registered medical practitioner.

8. Maintenance of record of sales of anti-tuberculosis drugs by the license holder.- (1) A license holder shall maintain a record of sales of anti-tuberculosis drugs, as prescribed.

(2) A license holder shall share and transmit the record of sales of the prescribed anti-tuberculosis drugs.

9. Quality Assurance measures.- It will be incumbent upon the District Health Officer, private sector health professionals and pharmacies to ensure that only quality assured (QA) TB medicines; are provided to the patients.

PART III

IMPLEMENTATION PROVISIONS

10. Process of Notification.- A person responsible for notifying the patient under the provisions of this Act, shall fill in the prescribed form and send it by registered post or deliver it by hand to the District Health Officer or local public health facility within a week of diagnosing the case