

## IN THE HIGH COURT OF SINDH KARACHI

### **Present:**

Mr. Justice Muhammad Ali Mazhar  
Mr. Justice Adnan Iqbal Chaudhry.

C.P. No. D-190 of 2017	A-One Laboratory, Khairpur and 46 others versus Province of Sindh and another.
C.P. No. D-340 of 2017	Global Laboratory, Khairpur and 24 others versus Province of Sindh and another.
C.P. No. D-588 of 2017	Dastagir Clinical Laboratory, Naushahro Feroze and 21 others versus Province of Sindh and another.
C.P. No. D-1910 of 2017	Rajesh Kumar and 02 others versus Province of Sindh and another.
For the Petitioners	Mr. Mukesh Kumar Khatri, Advocate for the Petitioners in all Petitions.
For the Respondents	Mr. Ghulam Shabbir Shah, Additional Advocate General Sindh, and Ms. Rakhshanda Waheed, State Counsel, alongwith Mr. Jamaluddin, Additional Secretary Health, Government of Sindh.
Date of hearing	11-09-2018

### **JUDGMENT**

**Adnan Iqbal Chaudhry J.** - These are more or less identical petitions brought to challenge acts taken by health officials to stop the medical laboratories of the Petitioners. Therefore, we proceed to decide these petitions by a common judgment.

1. The Petitioners, who hail from various Districts of Sindh, including Khairpur, Sanghar, Umerkot, Mirpurkhas, Dadu, Shaheed Benazirabad, Tharparkar, Ghotki, Sukkur and, Naushahro Feroze,

claim to be certified Laboratory Technicians, and in support of that they rely on a Laboratory Technician Certificate or a Diploma issued to them by the Sindh Medical Faculty. Per the Petitioners, they are operating medical laboratories where they provide the public with services of running prescribed clinical tests and test reports.

2. By way of background, the memo of petition states that that vide order dated 27-10-2016 passed by this Court at Hyderabad Circuit in C.P. No. D-2940/2015, this Court had directed the Director General Health that *“he shall ensure that any laboratory being operated through technician or other than qualified pathologists, shall be stopped forthwith and action shall be taken against all those laboratories”*; and that vide another order dated 10-11-2016 passed by this Court at Hyderabad Circuit in C.P. No. D-1557/2015, this Court had directed that *“regarding those laboratories which are running without authority, the Medical Superintendent, LUMHS, present in person, contends that only pathologist and Hematologist can open and run the affairs of laboratories, thus, Director General Health is directed to ensure that only those laboratories, which are organized by the competent persons, shall be allowed and all those laboratories, which are running/operated by unskilled or incompetent person, shall be sealed without any further delay”*. Apparently, the order dated 10-11-2016 passed in C.P. No. D-1557/2015 was assailed by some of the Laboratory Technicians before the Supreme Court of Pakistan in Civil Petitions No. 814-K and 819-K/2016, wherein, by an order dated 30-11-2016, the Honourable Supreme Court suspended the order dated 10-11-2016 passed in C.P. No. D-1557/2015. The grievance of the Petitioners is that they are being compelled by the official Respondents to shut-down their medical laboratories pursuant to the aforesaid orders passed in C.P. No. D-2940/2015 and C.P. No. D-1557/2015.

3. Mr. Mukesh Kumar Khatri, learned counsel for the Petitioners submitted that the law does not stipulate that only a pathologist is qualified to operate a medical laboratory, and that the same can also

operated by a certified Laboratory Technician, inasmuch as the processing of clinical tests and test reports is by automated equipment that do not require the expertise of a pathologist. Learned counsel submitted that the shutting-down of the Petitioners' laboratories has put the public at great inconvenience and expense as the public now has to travel to bigger cities to engage medical laboratories run by pathologists. Learned counsel further submitted that since the order dated 10-11-2016 passed in C.P. No. D-1557/2015 remains suspended by the Supreme Court in Civil Petitions No. 814-K and 819-K/2016, the reliance placed thereon by the official Respondents to shut-down the laboratories/business of the Petitioners, is misplaced. Therefore, the Petitioners pray for writs to restrain the official Respondents from stopping the laboratories/business of the Petitioners, and for directions to de-seal their laboratories.

4. On the other hand, Mr. Ghulam Shabbir Shah, learned AAG Sindh, accompanied by the Additional Secretary Health, Government of Sindh, submitted that the purpose and function of a Laboratory Technician is to act in aid of a pathologist, whereas, in operating medical laboratories themselves, the Petitioners hold out to the public that they are pathologists. He submitted that the qualification of the Petitioners as Laboratory Technicians does not make them competent to operate medical laboratories, which act, not only does it put the public health at risk, but is also in contravention of the Sindh Healthcare Commission Act, 2013.

5. From the record it appears that the order dated 10-11-2016 passed in C.P. No. D-1557/2015 was essentially a reiteration of the order dated 27-10-2016 passed in C.P. No. D-2940/2015, and that the latter order (in C.P. No.D-1557/2015) was suspended by the Honourable Supreme Court in Civil Petitions No.814-K and 819-K/2016 while granting leave to appeal. It appears that the petitioners before the Supreme Court were not parties before the

High Court and filed the said petitions for leave to appeal on the principle laid down in the case of *H.M. Saya*<sup>1</sup>. However, the Petitioners before us, who too claim to be Laboratory Technicians aggrieved of the order dated 10-11-2016 passed in C.P. No.D-1557/2015, have not approached the Supreme Court of Pakistan either by way of similar petitions for leave to appeal, or by way of joining the pending appeals. Instead, it is their case that till the order dated 10-11-2016 passed in C.P. No. D-1557/2015 remains suspended in appeal before the Supreme Court of Pakistan, the official Respondents cannot rely on the same to close-down the medical laboratories of the Petitioners. With that we entirely agree; and since the question whether a medical laboratory can only be run by a qualified pathologist, is presently *sub-judice* before the Honourable Supreme Court of Pakistan (Civil Petitions No.814-K and 819-K/2016), we do not express any opinion on that aspect of the matter. However, there is another aspect of the matter, one not contemplated nor controverted by the Petitioners. Even assuming that the Petitioners, as certified Laboratory Technicians, are 'qualified' to run/operate a medical laboratory, they are still confronted by the Sindh Healthcare Commission Act, 2013.

6. **The Sindh Healthcare Commission Act, 2013 [the SHCC Act]**, which came into effect on 20-03-2014, was enacted "*to make provision for the improvement, access, equity, and quality of healthcare service, to ban quackery in all its forms and manifestations and to provide for ancillary matters.*" Section 3 of the SHCC Act provided for the establishment of the Sindh Healthcare Commission [SHCC]. Vide notification published in the Sindh Gazette on 09-11-2017, the Commission framed '**The Commission Regulations, 2017 of the Sindh Healthcare Commission**' [SHCC Regulations].

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<sup>1</sup> PLD 1969 SC 65

7. The following provisions of the SHCC Act and SHCC Regulations highlight the purpose and functions of the SHCC, and are relevant to the matter at hand.

“4.(1) The Commission shall perform such functions and exercise such powers as may be required to improve the quality of healthcare services and clinical governance and to ban quackery.

(2) Without prejudice to the generality of the provisions of subsection (1), the Commission shall –

- (a) maintain register of all healthcare service providers;
- (b) grant, revoke and renew licenses to persons involved in the provision of the healthcare services and to vary terms and conditions and purposes of the licenses;
- (d) operate accreditation programs in respect of the healthcare services and to grant accreditation to such healthcare service providers who meet the prescribed criteria and standards;
- (e) enquire and investigate into maladministration, malpractice and failures in the provision of healthcare services and issue consequential advice and orders;
- (o) issue regulations, guidelines, instructions and directives to persons involved in the provision of healthcare services;
- (q) take necessary steps to put ban on quackery;

(5) The Commission shall conduct third party evaluation through independent performance/ clinical audit of healthcare establishments in the private sector.”

Under Section 2 of the SHCC Act:

“(xv) “healthcare establishment” means a hospital, diagnostic center, medical clinics, nursing home, maternity home, dental clinic, homeopathic clinic, Tibb clinic, acupuncture, physiotherapy clinic, pharmacy or any system of the treatment

- (a) wholly or partly used for providing healthcare services; and
- (b) declared by Government, by order published in the official Gazette, as a healthcare establishment;

(xvi) “healthcare services” means services provided for diagnosis, treatment or care of persons suffering from any physical or mental disease, injury or disability including procedures that are similar to forms of medical, dental or surgical care but are not provided in connection with a medical condition and includes any other service notified by Government;

(xvii) “healthcare service provider” means an owner, manager or incharge of a healthcare establishment and includes a person

registered by the Pakistan Medical Dental Council, National Council for Tibb and Homeopathy or Nursing Council, pharmacy service provider;

(xxix) “quack” means a pretender providing health services without having registration of Pakistan Medical Dental Council, Council for Tibb and Homeopathy and Nursing Council;”

The SHCC Act also introduced a registration and licensing regime as follows and to the following effect:

“13.(1) A healthcare service provider shall not provide healthcare services without being registered under this Act.

(2) An existing healthcare service provider shall, within a period of ninety days of the coming into force of this Act, apply for registration in accordance with this Act.

(3) A person seeking to be registered as a healthcare service provider shall make an application to the Commission in the prescribed form and accompanied by such particulars, documents as the Commission may prescribe.

(4) If a person fulfills the requirements of this section, the Commission shall issue a certificate of registration to the person within thirty days otherwise the applicant shall be considered as having provisionally registered for ninety days.

(5) The Commission may impose a fine which may extend to five hundred thousand rupees upon a healthcare service provider or any other person who practices without registration.

14. (1) A healthcare establishment shall not be used except in accordance with the terms and conditions of a license issued under this Act.

(2) If a healthcare establishment is not licensed under this Act or is used otherwise, the Commission may impose a fine, which may extend to five hundred thousand rupees upon the healthcare service provider.

15. (1) Within thirty days of the issuance of the certificate of registration, or such other time as may be fixed by Government, the healthcare service provider shall make an application for a license to the Commission in the prescribed form which shall be accompanied by such particulars, documents and fees as the Commission shall prescribe schedule.

17. (1) Every license of a healthcare establishment shall specify the kind of healthcare establishment for which it is issued and the purposes thereof.

(2) A licensed healthcare establishment shall not be used for any purpose other than the purpose in respect of which the license is issued and purposes incidental thereto.

(3) The Commission shall maintain a register of all licensed healthcare establishments and may enter in the register any necessary details or other particulars of the healthcare establishment.

21. (1) The Commission shall develop framework and procedures for the accreditation of the healthcare establishments and issue necessary guidelines and instructions in this behalf in phased manner.

(2) The Commission shall review best national and international practices in accreditation and build supportive links and enter into collaborations and agreements with national and international organizations in relation to accreditation of the healthcare establishments.

35. All executive authorities and law enforcement agencies of Government shall act in aid of the Commission.

#### Regulation 13. Unregistered Healthcare Service Provider

(1) The Commission shall issue a notice to the unregistered Healthcare Service Provider directing him to get himself registered within thirty days, failing which coercive measures including imposition of fine and closing down/sealing the Healthcare establishment shall be taken.

(2) In case of no response within 30 days of the communication, the Commission may impose a fine which may extend to five hundred thousand rupees upon a healthcare service provider or any other person who practices without registration U/S 13(5) and the Commission may close down/seal the healthcare establishment till the defaulter fulfils all the requirements for registration and may refer the case to the competent forum for further proceedings.

#### Regulation 35. Determination of "Quack"

In pursuance to Section 2 (xxix) of Sindh Health Care Commission Act 2013, a Healthcare Service Provider shall be deemed as "quack" if he/she is;

- (i) Duly qualified but not validly registered with Pakistan Medical & Dental Council, Council for Tibb and Homeopathy and Nursing Council;
- (ii) Neither qualified nor registered with the relevant council;
- (iii) Duly qualified and validly registered but providing services beyond the provisions of his registration;
- (iv) Neither duly qualified nor validly registered but practicing under the name of a qualified and validly registered medical practitioner.

Regulation 36. Anti-Quackery Directorate

The Commission shall establish Anti-Quackery Directorate which shall be responsible to perform all such functions and take such necessary steps as are required to put ban on quackery in the Province of Sindh in all its forms and manifestations.”

Regulation 39 of the SHCC Regulations provides for the powers / functions of Anti-Quackery team, which includes the power to inspect any healthcare establishment and to make seizures and to seal/close down the premises where Quackery is being practiced in any form, and to initiate legal action including lodgment of case against the defaulters.

The SHCC Act also provides remedies to persons aggrieved by acts taken under the SHCC Act as follows:

“30. Save as provided in this Act, no court other than the Court of the District and Sessions Judge shall have jurisdiction –

- (a) to question the validity of any action taken or intended to be taken, or order made, or anything done or purporting to have been taken, made or done under this Act; or
- (b) to grant an injunction or stay or to make any interim order in relation to any proceeding before, or anything done or intended to be done or purporting to have been done by, or under the orders or at the instance of the Commission.

31. (1) A person who is aggrieved by the –

- (a) refusal of the Commission to issue or renew a license;
  - (c) order of closing down of a healthcare establishment or making improvements in the healthcare establishment;
  - (e) imposition of fine by the Commission,
- may, within thirty days from the date of communication of the order of the Commission, prefer an appeal in writing to the District and Sessions Judge.”

Regulation 40 provides a healthcare service provider a remedy against any action of the Anti-Quackery team by way of a representation to the Chairperson Board of Commissioners SHCC who will refer the same to the Complaint Management Committee of the Board under Section 9 (n) of the Act.

8. The medical laboratories being run by the Petitioners squarely fall within the meaning of a ‘diagnostic center’ and hence a “healthcare establishment” as defined in Section 2(xv) of the SHCC Act, and the Petitioners as a “healthcare service provider” as defined

in Section 2(xvii) of the SHCC Act. The service that the Petitioners provide at their medical laboratories are of 'diagnosis' within the meaning of "healthcare services" defined in Section 2(xvi) of the SHCC Act. In other words, before the Petitioners can claim any right to operate a medical laboratory in Sindh, they have to demonstrate that notwithstanding their qualification under any other law, they are also in compliance of the SHCC Act. Section 13(1) of the SHCC Act prohibits a healthcare service provider from providing any healthcare service without being registered under the Act; and Section 14(1) prohibits the use of a healthcare establishment except in accordance with a license granted under the SHCC Act after an inspection. The contravention of the said provisions entails both penal and coercive consequences, including the closing down/sealing of the healthcare establishment (Regulation 13 of the SHCC Regulations).

Section 13 of the SHCC Act further requires that a person seeking to be registered as a healthcare service provider shall make an application to the SHCC, and if such person fulfills the requirements of the SHCC Act, the SHCC shall issue a certificate of registration, and thereafter the healthcare service provider can make an application under Section 14 of the SHCC Act for a license to use a healthcare establishment. A remedy of an appeal is then provided under Section 31 of the SHCC Act against certain orders passed by the SHCC. However, none of the Petitioners have so far even applied to the SHCC for the requisite registration. Per the learned AAG that is so because the Petitioners are 'quacks' within the meaning of the SHCC Act. But we are not inclined to make any such observation in these proceedings inasmuch as, in our view, that is a determination which in the first instance has to be made by the SHCC, and nothing stops the Petitioners from making an application to the SHCC under Section 13 of the SHCC Act.

9. The effect of the SHCC Act is that even if the Petitioners are assumed to be qualified (as distinct from 'authorized') to operate

medical laboratories, they cannot continue to do so until their laboratories (healthcare establishments) are licensed under Section 14 of the SHCC Act, and consequently no writ can issue at this stage to enable the Petitioners to operate medical laboratories. Consequently, these petitions are dismissed along with pending applications.

**JUDGE**

**JUDGE**

Karachi

Dated: \_\_\_\_-02-2019