



Republic v Pharmacy and Poisons Board; Association of Kenya Medical Laboratory Scientific Officers & 2 others (Exparte); Kenya Medical Laboratory Technicians and Technologists Board (Interested Party) (Judicial Review E049 of 2023) [2024] KEELRC 2017 (KLR) (24 July 2024) (Ruling)

Neutral citation: [2024] KEELRC 2017 (KLR)

**REPUBLIC OF KENYA
IN THE EMPLOYMENT AND LABOUR RELATIONS COURT AT NAIROBI
JUDICIAL REVIEW E049 OF 2023**

**AN MWAURE, J
JULY 24, 2024**

BETWEEN

REPUBLIC APPLICANT

AND

PHARMACY AND POISONS BOARD RESPONDENT

AND

ASSOCIATION OF KENYA MEDICAL LABORATORY SCIENTIFIC OFFICERS EXPARTE

ASSOCIATION OF KENYA MEDICAL LABORATORY ASSESSORS ... EXPARTE

KENYA NATIONAL UNION OF MEDICAL LABORATORY OFFICERS EXPARTE

AND

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD INTERESTED PARTY

RULING

1. The exparte applicant filed a Notice of Motion application dated 2nd January 2024 on grounds THAT:
 1. an Order of certiorari be issued
 2. to remove into the High Court and quash the entire decision of the Respondent made on 26th November 2023, inviting applications for the positions of In-Vitro Diagnostics Experts and for the positions of Blood and blood products experts.



3. an order of prohibition to restrain the Respondents employees from the implementation/ or enforcement of the entire decision of the Respondent made on 26th November 2023, inviting applications to fill the positions of In vitro Diagnostics Experts and positions of In Blood and Blood products Experts with a view to entering into contracts of employment and acting upon such applications for the aforesaid positions and/or from entering into any contract in respect thereof.
4. the costs of this application be provided for.

Ex-parte Applicants' Case

2. The ex-parte applicants aver that pursuant to Section 5(2) of the *Kenya Medical Laboratory and Technicians Act*, the Interested Party's objects and function is to exercise general supervision and control over the training, business, practice and employment and to advise the government thereto.
3. The ex-parte applicants aver that on 26/11/2023, the Respondent called for invitations from qualified members of the public to apply for positions of diagnostic experts and blood products experts.
4. The ex-parte applicants aver that diagnostics experts and blood product experts the Respondent seeks to hire intend to usurp on the Interested Party's statutory responsibilities to develop and review PPB guidelines on the quality, safety and performance of diagnostics; and to guide and develop standards used in in-vitro diagnostics.
5. It's the ex-parte applicants' case that the Respondent's decision will lead to double regulation and result to conflicting regulations over medical laboratory technicians and technologists and is unconstitutional, ultra vires and unlawful.
6. The ex-parte applicants aver that the Respondent's intended action contravenes its legitimate expectation that medical laboratory technicians shall not be subjected to double regulations and the national government shall not exercise or interfere with the same functions and powers.
7. The ex-parte applicants aver that section 25(1) of the Act requires the Interested Party in regulations to prescribe the terms and conditions of the business and practice of laboratory technicians and technologist engaged in private practice giving rise to Legal Notice no.113 of 2011.
8. The ex-parte applicants aver that the legal notice was the outcome of stakeholder meetings including the 29th World Congress of Biomedical Laboratory Science held on 6th -10th June 2010 prior to its enactment.
9. The ex-parte applicants aver that the Interested Party regulates the pre-validation certification to ensure IVD s with good quality test performance used in medical laboratories. The licensed medical laboratories must have a laboratory superintendent and quality assurance manager in accordance with ISO 15189:2012.
10. It's the ex-parte applicants' case that the Respondent has no contact with the practice of the medical laboratory professionals considering performance studies and evaluations aspects of validation takes place in laboratories.
11. The ex-parte applicants avers that all registered and licensed medical laboratories conducting validation of in-vitro diagnostics as conducted are regulated by the Interested Party.



12. The ex-parte applicants avers that all in-vitro diagnostics and blood experts at the time of enactment of Legal Notice 113 of 2011 are identified and registered through the pre-validation segment of the validation processes.

Respondent's Case

13. The Respondent avers that Section 45(1) of the [Health Act](#) establishes the Kenya Health Professions Oversight Authority whose functions under Section 48(1) include to arbitrate disputes between statutory regulatory bodies, including conflict or dispute resolution amongst Boards and Councils and to receive and facilitate the resolution of complaints from aggrieved parties and regulatory bodies.
14. It's the Respondent's case that the ex-parte applicants fall within the meaning of the aggrieved parties under Section 48(1) of the [Health Act](#) and as such they ought to have exhausted the dispute resolution mechanisms provided under the Act.
15. The Respondent avers that Section 63 of the [Health Act](#) makes it clear that parliament's intention is that there is only one regulatory body responsible for the regulation of health products and health technologies. Therefore, the regulation of health products and health technologies could not be an overlapping function of more than one regulatory body.
16. The Respondent avers that the Health Laws (Amendment) Act, 2019 amended the [Pharmacy and Poisons Act](#) introducing sections 3A and 3B which provided for the powers and functions of the Respondent.
17. The Respondent avers that section 3B (1) of the [Pharmacy and Poisons Act](#) provided it is responsible for the regulation of health products, technologies and the profession of pharmacy. Further section 35A provides no person can manufacture any medicinal substance unless he has been granted a manufacturing licence by the Respondent; such manufacturer must apply and obtain a licence from the Respondent; and every premises used for the manufacture of such medicinal substances must be licenced by the Respondent.
18. It's the Respondent's case that it is the only body mandated to regulate health products including human and veterinary medicines, medical products, medicinal substances, vaccines, diagnostics, medical devices, blood products, traditional and alternative medicine, therapeutic feeds and nutritional formulations, cosmetics and related products.
19. The Respondent avers that section 35 of the [Medical Laboratory Technicians and Technologists Act, 1999](#) gives the Interested Party powers to prescribe regulations providing the terms and conditions of the business and practice of laboratory technicians engaged in private practice.
20. The Respondent avers that the Interested Party's mandate is limited to licensing and regulation of laboratory facilities to ensure compliance of the law and neither the law nor practice grants the Interested Party the mandate to regulate products.
21. It's the Respondent's case that the parliament intended to mandate it to regulate health products including blood products and in-vitro diagnostics.
22. The Respondent avers that the Medical Laboratories (Equipment and Reagents Validation) Regulations, 2011 being a subsidiary legislation is ultra vires the [Medical Laboratory Technicians and Technologists Act](#) and cannot supersede the express provisions of the [Pharmacy and Poisons Act](#) which vests the authority to regulate all medical products on the Respondent including in-vitro diagnostics.



23. It's the Respondent's case that the *Pharmacy and Poisons Act* demonstrates it has the mandate of regulating blood products and regulate in-vitro diagnostics.
24. The Respondent avers that the Interested Party's role is regulation of the business and practice of laboratory technicians and technologists involving carrying out medical laboratory analysis and investigations and has nothing to do with the regulations of medicines, medicinal products and substances, medical devices or health products including blood and blood products or in-vitro diagnostics.
25. The Respondent avers that the adverts inviting applications for the positions of in-vitro diagnostics experts and blood product experts did not undermine the role of the Interested Party. The two adverts are within the mandate of the Respondent and it only seeks to regulate the specific health products (in-vitro diagnostics and blood products) and not the business and practice of laboratory technicians and technologists.
26. It's the Respondent's case that parliament did not intend the Respondent and Interested Party have jurisdiction in the regulation of health products.

Applicants' Submissions

27. The Applicants submitted that they are not statutory bodies and could not refer the dispute herein to the Authority as contemplated under Section 48 of the *Health Act*. The only avenue they had was to file the judicial review application in court. It relied on the case of *Republic v Independent Electoral and Boundaries Commission (I.E.B.C.) Ex parte National Super Alliance (NASA) Kenya & 6 others* [2017] eKLR.
28. The Applicants submitted that the Respondent's mandate and functions are set out under the *Pharmacy and Poisons Act*, it does not include the development and review of PPB guidelines on the quality, safety and performance of Diagnostics. The diagnostics experts and blood and blood products experts that the Respondent seeks to hire intend to usurp on the statutory responsibilities of the Interested Party to guide and develop standards to be used in the regulation of In-Vitro Diagnostics.
29. It is the Applicants' submission that the Interested Party has faced various challenges on its regulatory mandate such as whether the power to register license and regulate the business and practice of private Medical Laboratories vests in the Interested Party or the Medical practitioners and Dentists Board which was settled in the case of *Republic Versus Kenya Medical Laboratory Technicians and Technologists Board & Anor Ex parte Anil Tailor & 4 others* (2013) eKLR where following a detailed analysis, the Honourable Court held that the regulatory mandate of the Interested Party is not limited to public institutions but extends to private Medical laboratories and the Interested Party has a regulatory mandate over medical laboratories situated within private health facilities.
30. The Applicants submitted that the Interested Party has well laid down structures and processes to execute this mandate of validating invitro diagnostics in tandem with Section 40 of the *Medical Laboratory Technicians and Technologists Act*, regional and global trends through ISO 15189 and ISO 13485 for the manufacture of quality invitro diagnostics.
31. The Applicants submitted that the purpose of validation of invitro diagnostics by the Interested party is to minimize poor quality laboratory test results which may lead to misdiagnosis using reagents, test kits and equipment, inappropriate treatment with potentially life-threatening consequences to patients.



32. It's the Applicants' submission that section 5 of the [Medical Laboratory Technicians and Technologists Act](#) provided that the business of medical laboratory technicians and technologists is hinged on their hands-on analysis of human specimens using diagnostic test kits, equipment, reagents and accessories (also known as in-vitro diagnostics-IVDs) an area where pharmacists and their related pharmaceutical technologists lack technical skills and competencies.
33. The Applicants submitted that both the Respondent and Interested Party are respective regulatory bodies and the Respondent should not treat the Interested Party as subservient and should be stopped from encroaching on the mandate of the Interested Party or otherwise interfering with the delivery of its functions. Section 5 of the [Medical Laboratory Technicians and Technologists Act](#) establishes the Interested Party as a State Corporation and not as a department of the Respondent.
34. The Applicants submitted that the guidance and development of standards to be used in the regulation of In-Vitro Diagnostics is a preserve of the Interested Party board as provided for under the [Medical Laboratory Technicians and Technologists Act](#). The Respondent's decision will lead to double regulation and will result in conflicting regulations over Medical Laboratory Technicians and Technologists and is unconstitutional, unlawful, ultra vires and contravenes statute.

Respondent's Submissions

35. The Respondent submitted that Section 45(1) of the [Health Act](#) establishes the Kenya Health Professions Oversight Authority whose function is to arbitrate disputes between statutory regulatory bodies including conflict or dispute resolution amongst boards and councils. Although the application has been filed by the Applicants, there is an apparent conflict between the Respondent and Interested Party.
36. The Respondent submitted that the Applicants fall within the category of aggrieved parties therefore ought to exhaust the dispute resolution mechanisms provided under the Section 48 of the [Health Act](#) by referring the dispute to the Kenya Health Professions Oversight Authority before filling the instant application.
37. The Respondent submitted that where [the constitution](#) and the law give a different body or institution power to deal with disputes or complaints, the court's jurisdiction is residuary and not primary. Conditions precedent must be fulfilled before one invokes the jurisdiction of the court; the Applicants have not fulfilled these conditions herein.
38. The Respondent submitted that the [Medical Laboratory Technicians and Technologists Act](#) does not have the technical definition of business and practice of laboratory technicians and technologists though it may be inferred that it involves carrying out medical laboratory analysis and investigations. Therefore, the Interested Party's mandate is limited to licencing and regulation of laboratory facilities and has no role in regulation of medical products.
39. The Respondent submitted that the intention of Section 62 of the [Health Act](#) was to establish a single regulatory body for the regulation of health products and technologies. This was cemented by sections 3A and 3B introduced by the amendment of the Pharmacy and Poisons Board Act that vested the regulation of all health products including blood and blood products as the Respondent's sole preserve.
40. It's the Respondent's submission that in execution of this mandate led to it putting out the advert inviting members of the public to apply for the positions of diagnostics experts and blood and blood products experts.



41. The Respondent submitted that in furtherance to its mandate, it has developed and adopted a guidance document presented in court that describes the processes and general requirements to applicants for the submission of medical devices and in-vitro diagnostics registration. Therefore, it has in no way acted against or undermined the Interested Party's role.

Analysis and Determination

42. The first issue for the court's determination is whether this court lacks jurisdiction to hear and determine the judicial review application owing to the doctrine of exhaustion.
43. The doctrine of exhaustion is aptly dealt with in *Robert Khamala Situma & 8 others v Acting Clerk of the Nairobi City County Assembly* [2022] eKLR as follows: -

“The Doctrine of Exhaustion is defined in Blacks Law Dictionary 10th Edition as follows –

“exhaustion of remedies. The doctrine that, if an administrative remedy is provided by statute, a claimant must seek relief first from the administrative body before judicial relief is available. The Doctrine's purpose is to maintain comity between the courts and administrative agencies and to ensure that courts will not be burdened by cases in which juridical relief is unnecessary.

Section 90 of the *Fair Administrative Action Act* provides for the Doctrine of Exhaustion thus –

Procedure for judicial review

Subject to subsection (2), a person who is aggrieved by an administrative action may, without unreasonable delay, apply for judicial review of any administrative action to the High Court or to a subordinate court upon which original jurisdiction is conferred pursuant to Article 22(3) of *the Constitution*.

The High Court or a subordinate court under subsection (1) shall not review an administrative action or decision under this Act unless the mechanisms including internal mechanisms for appeal or review and all remedies available under any other written law are first exhausted.

- (3) The High Court or a subordinate Court shall, if it is not satisfied that the remedies referred to in subsection (2) have been exhausted, direct that applicant shall first exhaust such remedy before instituting proceedings under sub-section (1).
- (4) Notwithstanding subsection (3), the High Court or a subordinate Court may, in exceptional circumstances and on application by the applicant, exempt such person from the obligation to exhaust any remedy if the court considers such exemption to be in the interest of justice.
- (5) A person aggrieved by an order made in the exercise of the judicial review jurisdiction of the High Court may appeal to the Court of Appeal.



44. The doctrine was aptly captured by the Court of Appeal in *Republic v National Environment Management Authority Ex parte Sound Equipment Ltd*, (supra), where the Court of Appeal observed:

“... Where there was an alternative remedy and especially where Parliament had provided a statutory appeal procedure, it is only in exceptional circumstances that an order for judicial review would be granted and that in determining whether an exception should be made and judicial review granted, it is necessary for the court to look carefully at the suitability of the statutory appeal in the context of the particular case and ask itself what, in the context of the statutory powers, was the real issue to be determined and whether the statutory appeal procedure was suitable to determine it ...”

45. In *William Odhiambo Ramogi & 3 others v Attorney General & 4 others; Muslims for Human Rights & 2 others (Interested Parties)* [2020] eKLR the Court held as follows;

“The question of exhaustion of administrative remedies arises when a litigant, aggrieved by an agency’s action, seeks redress from a Court of law on an action without pursuing available remedies before the agency itself. The exhaustion doctrine serves the purpose of ensuring that there is a postponement of judicial consideration of matters to ensure that a party is, first of all, diligent in the protection of his own interest within the mechanisms in place for resolution outside the Courts.”

46. Section 48(1)(f) of the [Health Act](#) provides that one of the functions of the Kenya Health Professions Oversight Authority is to arbitrate disputes between statutory regulatory bodies, including conflict or dispute resolution amongst Boards and Councils.

47. The Respondent has failed to show that the ex-parte applicant are bound by the [Health Act](#) as these bodies and Interested Party are guided by the the [Medical Laboratory Technicians and Technologists Act, 1999](#).

48. Therefore, this court has jurisdiction to determine the application as judicial review was the only avenue for the applicants to institute the suit.

49. The second issue for determination is whether the ex-parte applicants are entitled to the judicial review orders sought.

50. In the case of [Republic v Director of Immigration Services & 2 others Ex parte Olamilekan Gbenga Fasuyi & 2 others](#) (2018) eKLR it was held that:

“...It is common ground that the prayers sought are Judicial Review remedies and the rules governing grant of judicial review orders do apply. Judicial Review is about the decision-making process, not the decision itself. The role of the court in judicial review is supervisory. It is not an appeal and the court should not attempt to adopt the forbidden appellate approach. Judicial Review is the review by a judge of the High court of a decision; or refusal to exercise a power of decision to determine whether that decision or action is unauthorized or invalid. It is referred to as supervisory jurisdiction- reflecting the role of the courts to supervise the exercise of power by those who hold it to ensure that it has been lawfully exercised. Judicial Review is a means to hold those who exercise public power accountable for the manner of its exercise. The primary role of the courts is to uphold the fundamental and enduring values that constitute the rule of Law. Judicial Review is more concerned with the manner in which a decision is made than the merits or otherwise of the ultimate decision.



As long as the process followed by the decision-maker are proper, and the decision is within the confines of the Law, a Court will not interfere.”

51. According to *Halsbury Law of England 4th EDN.Vol. 1* (1) para 12 page 270:

“The remedies of quashing orders (formerly known as orders of Certiorari) prohibiting orders formerly known as orders of prohibition (mandatory orders formerly known as orders of mandamus) ...are all discretionary. The court has a wide discretion whether to grant relief at all and if so, what form of relief to grant. In deciding whether to grant relief the court will take into account the conduct of the party applying and consider whether it has not been such as to disentitle him to relief. Undue delay, unreasonable or unmeritorious conduct, acquiescence in the irregularity complained of or waiver to the right to object may also result in the court declining to grant relief.”

52. Further, in Chief Constable of the *North Wales Police VS Evans* (1982)1 WLR 1155 e Lord Brightman noted:

“Judicial Review is concerned, not with the decision, but with the decision-making process. Unless that restriction on the power of the court is observed, the court will in my view, under the guise of preventing the abuse of power, be itself guilty of usurping power...Judicial Review, as words imply, is not an appeal from a decision but a review of the manner in which the decision was made.”

53. It is the ex-parte applicant’s case that by intending to hire diagnostics experts and blood and blood product experts the Respondent seeks to usurp on the Interested Party’s statutory responsibilities to develop and review PPB guidelines on the quality, safety and performance of diagnostics; and to guide and develop standards used in in-vitro diagnostics.

54. Further, the Respondent’s decision will lead to double regulation and result to conflicting regulations over medical laboratory technicians and technologists and is unconstitutional, ultra vires and unlawful. And the same contravenes its legitimate expectation that medical laboratory technicians shall not be subjected to double regulations and the national government shall not exercise or interfere with the same functions and powers.

55. On the other hand, the Respondent’s submission that Section 62 of the *Health Act* was intended to establish a single regulatory body for the regulation of health products and technologies. This was cemented by sections 3A and 3B introduced by the amendment of the Pharmacy and Poisons Board Act that vested the regulation of all health products including blood and blood products as the Respondent’s sole preserve.

56. The *Medical Laboratory Technicians and Technologists Act* establishes the Kenya Medical Laboratory Technicians and Technologists Board whose objects and functions are laid down in section 5 of the Act as follows:

“(1) The object and purpose for which the Board is established shall be to exercise general supervision and control over the training, business, practice and employment of laboratory technicians and technologists in Kenya and to advise the Government in relation to all aspects thereof.

(2) Without prejudice to the generality of the foregoing, the Board shall—



- (a) prescribe, in consultation with the College and such approved training institutions as the Board may deem appropriate, the courses of instruction for laboratory technicians and technologists;
- (b) consider and approve the qualifications of laboratory technicians and technologists for the purposes of registration under this Act;
- (c) approve institutions for the training of laboratory technicians and technologists;
- (d) licence and regulate the business and practice of registered laboratory technicians and technologists; and
- (e) regulate the professional conduct of registered laboratory technicians and technologists and take such disciplinary measures as may be appropriate to maintain proper professional standards.”

57. On the other hand, Section 62 of the [Health Act](#) provided that:-

“there shall be established by an Act of Parliament, a single regulatory body for regulation of health products and health technologies.”

58. Section 2 of the Act defines health products, health technology and human blood products as follows: -

“health” refers to a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity;

“health technology” refers to the application of organized knowledge and skills in the form of devices, medicine, vaccines, procedures and systems developed to solve a health problem and improve the quality of life;

“human blood products” means any product derived or produced from blood, including plasma, sera, circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells;”

59. The functions of this regulatory body are provided under Section 63 of the [Health Act](#) that it shall: -

- a. licence health products and health technologies;
- b. licence manufacturers and distributors of health products;
- c. conduct laboratory testing and inspection of manufacturing, storage and distribution facilities of health products and technologies;
- d. control of clinical trials;
- e. conduct advertising and promotion, post marketing surveillance for quality, safety and disposal of health products and health technologies;
- f. regulate contractors for medical devices and physical security for products including radioactive material and biological products.”



60. Pursuant to Section 62 of the *Health Act*, the *Pharmacy and Poisons Act* is amended by introducing section 3A and 3B in which the Pharmacy and Poisons Board is granted powers and functions as follows:

“ 3A Powers of the Board

The Board may—

- a. formulate guidelines for regulating the manufacture, import and export, distribution, sale and use of medical products;
- b. grant or withdraw authorization for conducting clinical trials of medical products;
- c. grant or withdraw marketing authorization for medical products subject to appropriate conditions and revise such conditions for marketing authorization as necessary;
- d. recall medical products from the market;
- e. grant or withdraw licenses to manufacturers, wholesalers, retailers, importers, exporters and distributors;
- f. investigate conduct related to the manufacture, import, export storage, distribution, sale and use of medical products;
- g. levy, collect and utilize fees for services rendered;
- h. prescribe the standards appropriate for new medical products; new uses, dosages, and formulations of existing medical products; and such other categories as may be appropriate;
- i. constitute technical and expert advisory committees;
- j. institute administrative, civil and criminal proceedings;
- k. exercise such other powers as necessary for the performance of its functions.

3B. Functions of the Board

- (1) The Board shall be responsible for the regulation of health products, technologies and the profession of pharmacy.
- (2) The Board shall perform the following functions in relation to regulation of health products and technologies—
 - a. advise the national and county governments in all matters relating to the safety, packaging and distribution of medicines;
 - b. ensure that all medicinal products manufactured in, imported into or exported from the country conform to prescribed standards of quality safety and efficacy;
 - c. ensure that the personnel, premises and practices employed in the manufacture, storage, marketing, distribution and sale of medicinal substances comply with the defined codes of practice and other prescribed requirements;



- d. enforce the prescribed standards of quality, safety and efficacy of all medicinal substances manufactured, imported into or exported out of the country;
 - e. grant or revoke licenses for the manufacture, importation, exportation, distribution and sale of medicinal substances;
 - f. maintain a register of all authorized medicinal substances;
 - g. publish, at least once in every three months, lists of authorized or registered medicinal substances and of products with marketing authorizations;
 - h. regulate licit use of narcotic, psychotropic substances and precursor chemical substances in accordance with either the Single Convention on Narcotic Drugs of 1961, the Convention on Psychotropic Substances 1971, and the UN Convention against Illicit Traffic Drug and Psychotropic Substances, 1988;
 - i. consider applications for approval and alterations of dossiers intended for use in marketing authorization of medicinal substances;
 - j. inspect and license all manufacturing premises, importing and exporting agents, wholesalers, distributors, pharmacies, including those in hospitals and clinics, and other retail outlets;
 - k. prescribe a system for sampling, analysis and other testing procedures of finished medicinal products released into the market to ensure compliance with the labeled specifications;
 - l. conduct post-market surveillance of safety and quality of medical products;
 - m. monitor the market for the presence of illegal or counterfeit medicinal substances;
 - n. regulate the promotion, advertising and marketing of medicinal substances in accordance with approved product information;
 - o. approve the use of any unregistered medicinal substance for purposes of clinical trials and compassionate use;
 - p. approve and regulate clinical trials on medicinal substances;
 - q. disseminate information on medical products to health professionals and to the public in order to promote their rational use;
 - r. collaborate with other national, regional and international institutions on medicinal substances regulation;
 - s. advise the Cabinet Secretary on matters relating to control, authorization and registration of medicinal substances; and
 - t. perform any other function relating to regulation of medicinal substances.
- (3) The Board shall perform the following functions in relation to regulation of the profession of pharmacy—
- a. promote the practice of pharmacy that complies with universally accepted norms and values;



- b. prescribe the minimum requirements and consider and approve the qualifications of persons wishing to be registered as pharmacists under this Act;
- c. prescribe the minimum requirements and consider and approve the qualifications of persons wishing to be enrolled as pharmaceutical technologists under this Act;
- d. maintain a register of all persons registered or enrolled under this Act;
- e. prescribe and conduct examinations for purposes of recognition, registration or enrolment under this Act;
- f. establish or prescribe the different categories of pharmacy business and the scope of practice of persons registered or enrolled in terms of this Act, or the services or acts which shall for purposes of this Act be deemed to be services or acts specially pertaining to pharmacists or pharmaceutical technologists, and the conditions under which those services may be provided or the acts which may be performed;
- g. approve institutions to be established or accredited under the *Universities Act* (Cap. 210) training pharmacists, and mid-level institutions training pharmaceutical technologists;
- h. license the practice of pharmacists and pharmaceutical technologists under this Act;
- i. approve and license the premises for the practice by pharmacists and pharmaceutical technologists under this Act;
- j. regulate the professional conduct of pharmacists and pharmaceutical technologists and take such disciplinary measures as may be appropriate to maintain proper professional standards and ethics;
- k. establish, approve and accredit continuing professional educational programs for pharmacists and pharmaceutical technologists;
- l. establish and maintain a professional code of conduct for pharmacists and pharmaceutical technologists; and
- m. perform any other function relating to regulation of the profession of pharmacy.”

61. In view of the foregoing, it is evident that the Interested Party’s mandate is to licence and regulate the business and practice of registered laboratory technicians and technologists; and regulate the professional conduct of registered laboratory technicians and technologists and take such disciplinary measures.

63. As submitted by the Respondent, the long title of the *Pharmacy and Poisons Act* defines the Act as “an Act of Parliament to make provision for the control of the profession of pharmacy and trade in drugs and poisons.”



64. Further, the *Pharmacy and Poisons Act*'s definition of health products above and medical devices as:

“medical device” means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article—

- (a) intended by the manufacturer to be used, alone or in combination, for humans or animals for—
 - (i) diagnosis, prevention, monitoring, treatment or alleviation of disease;
 - (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
 - (iii) investigation, replacement, modification or support of the anatomy or of a physiological process;
 - (iv) supporting or sustaining life;
 - (v) control of conception;
 - (vi) disinfection of medical devices; or
 - (vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and
- (b) which does not achieve its primary intended action in or on the human or animal body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means”

65. The Respondent has proved that it indeed it is regulatory body established under section 62 of the *Health Act* to regulate health products and health technologies and therefore it was within its mandate to invite applications for the positions of In-Vitro Diagnostics Experts and for the positions of Blood and blood products experts.

66. The act is clear the roles of the interested party is distinct from the role of the respondent the Pharmacy Poisons Board as per the various legislation regulating the two respective bodies.

67. In conclusion, the Court is satisfied the applicant failed to establish sufficient grounds to grant the prayers sought being 1, and 2 of the notice of motion dated 2nd January 2024. The same is not meritorious and is not granted.

68. Each party to meet the costs of this application.

DATED, SIGNED AND DELIVERED VIRTUALLY IN NAIROBI THIS 24TH DAY OF JULY, 2024.

ANNA NGIBUINI MWAURE

JUDGE

Order

In view of the declaration of measures restricting Court operations due to the Covid-19 pandemic and in light of the directions issued by His Lordship, the Chief Justice on 15th March 2020 and subsequent directions of 21st April 2020 that judgments and rulings shall be delivered through video conferencing or via email. They



have waived compliance with Order 21 Rule 1 of the Civil Procedure Rules, which requires that all judgments and rulings be pronounced in open Court. In permitting this course, this Court has been guided by Article 159(2)(d) of *the Constitution* which requires the Court to eschew undue technicalities in delivering justice, the right of access to justice guaranteed to every person under Article 48 of *the Constitution* and the provisions of Section 1B of the Procedure Act (Chapter 21 of the Laws of Kenya) which impose on this Court the duty of the Court, inter alia, to use suitable technology to enhance the overriding objective which is to facilitate just, expeditious, proportionate and affordable resolution of civil disputes.

A signed copy will be availed to each party upon payment of Court fees.

ANNA NGIBUINI MWAURE

JUDGE

