REPUBLIC OF KENYA

IN THE HIGH COURT OF KENYA AT NAIROBI

JUDICIAL REVIEW DIVISION

MISCELLANEOUS CIVIL APPLICATION NO. 159 OF 2016.

IN THE MATTER OF AN APPLICATION FOR JUDICIAL REVIEW ORDERS OF CERTIORARI, PROHIBITION AND MANDAMUS

AND

IN THE MATTER OF THE PHARMACY AND POISONS ACT, (CAP.244), LAWS OF KENYA

AND

IN THE MATTER OF ARTICLE 43 OF THE CONSTITUTION OF KENYA

AND

IN THE MATTER OF: THE DECISION ON 10TH MARCH, 2016 BY THE 3RD RESPONDENT TO STOP NATIONAL QUALITY CONTROL LABORATORY FROM PERFORMING ITS STATUTORY FUNCTION

BETWEEN

REPUBLIC.....APPLICANT

-VERSUS-

MINISTRY OF HEALTH…….....1ST RESPONDENT

DR. CLEOPA MAILU, CABINET SECRETARY, .

MINISTRY OF HEALTH……...…..…....……2ND RESPONDENT

DR. NICHOLAS MURAGURI, PRINCIPAL

SECRETARY, MINISTRY OF HEALTH.....3RD RESPONDENT

PHARMACY & POISONS BOARD.……...….....4TH RESPONDENT

NATIONAL QUALITYCONTROL LABORATORY…....5TH RESPONDENT

THE HON. THE ATTORNEY GENERAL…….....…..6TH RESPONDENT

AND

FEDERATION OF KENYA PHARMACEUTICAL

MANUFACTURERS.....INTERESTED PARTY

-AND-

PHARMACEUTICAL SOCIETY OF KENYA.....AMICUS CURIAE

***EXPARTE*: DR. PIUS WANJALA**

JUDGEMENT

Introduction

1. By a Notice of Motion dated 6th April, 2016, the ex parte applicant herein, **Dr. Pius Wanjala**, sought the following orders:

> **1. AN ORDER OF CERTIORARI to have the decision of the 3rd Respondent, the Principal Secretary of Ministry of Health vide circular Ref: MOH/ADM/1/2/17/VOL.I of 10th March, 2016, which was copied to 2nd Respondent, stopping the National Quality Control Laboratory from performing the functions conferred by Section 35A(5) and 35I(b) of the *Pharmacy and Poisons Act*, CAP 244 Laws of Kenya, removed into the High Court for purposes of its being quashed;**
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> **2. An order of certiorari that to have the Gazette Notices 147 of 1981, 142 of 1991 and any other Gazette Notice that Gazetted, as regards and relates to, Rule 10 of the Pharmacy and Poisons (Registration of Drugs) Rules, removed into the High Court for purposes of its being quashed;**
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> **3. An order of prohibition to prohibit and restrain the 4th Respondent (Pharmacy and Poisons Board) from acting upon the 3rd Respondent's circular of 10th March, 2016 by usurping the functions of the National quality Control Laboratory of; inspecting premises and issuing certificates of compliance to Good manufacturing practices (GMP); by sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of manufacture is being followed, as provided for in sections 35 A (5) and 35 I (b) of the *Pharmacy and Poisons Act*, CAP 244 Laws of Kenya; as well as those under section 35D of analytical testing of medicinal samples;**
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> **4. An order of mandamus to compel the 5th Respondent (National Quality Control Laboratory) to perform its functions as conferred in Sections 35 A (5) and 35 I (b) of the Pharmacy and Poisons Act, CAP 244 of inspecting premises and issuing certificates of compliance to Good manufacturing practices (GMP); by sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of manufacture is being followed;**
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> **5. Costs**

Applicant's Case

2. According to the applicant, he is qualified and registered pharmacists employed by the Public Service

Commission and is currently stationed at the 5th Respondent herein, the National Quality Control Laboratory (hereinafter referred to as "the Laboratory") as Senior Deputy Director.

3. The applicant averred that from his knowledge as a specialist of pharmaceutical regulations, any Regulatory Authority of whichever nature, world over, is characterized by any or all of the functions of licensing/registration/authorization; certification; and/or inspection. The applicant further averred that the ***Pharmacies and Poisons Act*** (hereinafter referred to as "the Act") provides for two independent Medicines Regulatory Authorities, the Pharmacy and Poisons Board and the National Quality Control Laboratory, each with distinct and complementary mandates of medicines Control. He disclosed that prior to 1992 Kenya had a single medicines regulatory body - the Pharmacy and Poisons Board (hereinafter referred to as "the Board"), under the Act, which lacked provisions for inherent quality control laboratory system to perform two essential regulatory functions of analysis of all medicinal samples on behalf of government on one hand and inspection of premises and issuance of certificates of compliance to Good Manufacturing Practices (GMP) by sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of manufacture is being followed on the other hand.

4. It was the applicant's averment that an attempt to address above gap was by gazettement of Rule 10 of the ***Pharmacy and Poisons (Registration of Drugs) Rules*** (hereinafter referred to as "the Rules") through Gazette Notices of 147 of 1981 and 142 of 1991.

5. In the applicant's view, since Rule 10 above did not properly address the need for the laboratory sample analysis, the Government through Parliament, in line with global practices, amended (through creation of eleven (11) new sections as 35A to 35K in the Act to establish a second independent and complimentary regulatory body - the Laboratory - in 1992, to deal with the above mandate, which is to analyze all medicinal samples on behalf of government (section 35D of the Act) and inspect premises and issue certificates of compliance to Good Manufacturing Practices (GMP) by sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of manufacture is being followed (sections 35A(5) & 35I(b).

6. It was therefore the applicant's case that effectively, the 1992 establishment of the Laboratory through amendment of the Act rendered nugatory Rule 10 of the Rules and the Ministry of Health ought to have degazetted the Gazette Notices 147 of 1981 and 142 of 1991 as regards and relates to Rule 10 of the Rules.

7. According to the applicant the Regulation of manufacture of medicines, as provided for under Part III A of the Act, sections 35A, 35B and 35I(b), is by three sequential regulatory functions as follows:

> a. Prescription of manufacturing method for medicines manufacturers: This is the mandate of the Board as provided for in section 35B of the Act which provides that: *"Every person who is granted a manufacturing license under section 35A shall comply with the good manufacturing practices prescribed by the Board"*. The Board has since prescribed the World Health Organisation (WHO) Good manufacturing Practices (GMP), as the standard method for manufacturers of medicines;
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> b. Certification of manufacturers' compliance to the above prescribed method by way of inspecting premises and issuing certificates of compliance to Good manufacturing practices (GMP); through sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of manufacture is being followed: This is the mandate of the Laboratory as provided for in sections 35A (5) and 35 I (b).
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> c. Licensing of the Manufacturers of medicines (on the basis of above compliance certification) which is the mandate of the Board as provided for in section 35A (1 - 4).

8. It was the applicant's belief that the rationale behind Parliament's creation of two independent but complementary medicines regulatory bodies is to address the aspect of conflict of interest between the Pharmacy and Poisons Board (the Board) and the Laboratory which are the two sole institutions that

regulate medicines in this country hence the performance and/or non-performance of their regulatory mandate is a matter of extreme public interest and an indispensable aspect of National security: So important are these two institutions as theirs is not just a statutory mandate but is now a recognized Constitutional mandate under Article 43 of the Constitution of Kenya, 2010 which gives every Kenyan the right to the highest attainable standard of health which is largely realized through these institutions.

9. The applicant averred that on 10th March, 2016, the 3rd Respondent herein, the Principal Secretary of Health (hereinafter referred to as "the PS") issued a Circular Ref: MOH/ADM/1/217/VOL.1 directing the Director of the Laboratory to stop implementation of the above functions of sections 35A(5) & 35I(b) of the Act, of Inspecting premises and issuing certificates of compliance to Good Manufacturing Practices (GMP); by sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of manufacture is being followed; ostensibly because, according to him:

(a) Rule 10 of the Rules, empowers the Board to perform the said functions. However the applicant contended that the said rule cannot supersede sections 35A(5) and 35I(b) of the Act, Cap 244 which mandate the Laboratory to perform the stated functions;

(b) That Kenya has only one single medicines regulatory body- the Board, which should be the one to perform the functions of Inspecting premises and issuing certificates of compliance to Good manufacturing practices (GMP); by sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of manufacture is being followed: in line with global practices and the harmonization of East Africa as provided for in section 35 A (1) of the Act.

10. To the applicant, even if Rule 10 was to apply, it should not have been implemented because of the existing court order issued in the High Court Miscellaneous Application No. 402 of 2015 on 18th November, 2015 that barred all the activities by the Secretariat, which require the endorsement of the Board that is currently not yet constituted. In the applicant's view, the above purported unilateral amendment of sections 35A(5) and 35I(b) of the Act or selective application of Rule 10 of the Rules follows an earlier unilateral appointment of the 6th Board of the Laboratory by the Registrar of the Board and the PS and which action was challenged through Judicial Review Proceedings in High Court Miscellaneous Civil Cause No. 214 of 2011 in which, vide the Court's judgment delivered on 19th May, 2014, quashed the appointment and further found that, *inter alia*, *the motivation behind that unilateral appointment, was to establish a Board that would implement devious designs of the officials at the Ministry of Health for importation of substandard medicines to the Kenyan Market and that the Registrar of Board was also practicing nepotism in posting officers to the Board thus ensuring that dangerous medicines easily enter the country through patronage*.

11. The applicant averred that consequent to the above Judgement, an independent current 7th Board of Management the Laboratory was competitively appointed, which is quite firm against manipulation, a scenario that explains why the PS had to resort to Rule 10 of the Rules to defeat the functions of the 5th Respondent which, the previous unlawful 6th Board of management did not implement to serve the interest of Ministry officials and despite having been enacted to detect and seal the fate of manufacturers of substandard and counterfeit medicines. To the applicant this was the reason why the PS selectively favoured Rule 10 of the Rules over express statutory provisions of sections 35A(5) and 35I(b) of the Act. It was further contended that the above circular and Rule 10 of the Rules notwithstanding, the Board does not have any laboratory nor laboratory experts to effectively carry out the said functions as set out in the Act.

12. The applicant disclosed that the above directive by PS was in response to a letter by the Chairman of the Board of Management of the Laboratory dated 7th March, 2016, which had requested the 2nd Respondent herein, Cabinet Secretary (hereinafter referred to as "the CS") to support the Director of the Laboratory in carrying out the above specific function of inspecting several premises and issuing certificates of Compliance to Good Manufacturing Practices (GMP); by sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of

manufacture is being followed; after it was reported that the Board was interfering with the said mandate.

13. According to the applicant, on receipt of the above circular, the Director marked it to him for advice and in his view, the circular was clearly whimsical, unconstitutional and illegal as it purported to amend specific statutory provisions without going through Parliament and he thus advised the Director to report the matter to the Cabinet Secretary in line with section 25 of the ***Public Officer and Ethics Act***, but the Director declined, electing to obey the order, obviously, for fear of victimization.

14. However, conscious of the import of the circular and being part of the public consumer of medicines, the applicant decided, in his personal citizenry capacity, to draw the attention of the Cabinet Secretary to the above unlawful order with the view to have it withdrawn so as to allow the Laboratory perform its statutory function of ensuring quality control of medicines. However, in consideration that the Cabinet Secretary signed a performance contract to have the Director perform the same functions, he refused or declined to withdraw the said illegal and in-subordinating circular for, obviously, fear of being viewed as fighting with his Principal Secretary, yet, the Public is being exposed to dangerous medicines as a consequence.

15. It was averred that the Board of Management of the Laboratory, discussed the above circular in its meeting of 16th March, 2016 and resolved that it was not only an illegal directive but it also contravened the performance contract between the Board and the Cabinet Secretary and thus directed the Chairman to write to the Cabinet Secretary to inform him of the same, and directed the Director to continue with the function of Sampling medicinal substances under production in any manufacturing premises for laboratory testing through Inspection of Pharmaceutical Manufacturing Premises for purposes of compliance certification of Good Manufacturing Practices (GMP). It was the applicant's position that the above contradictory directives by the Principal Secretary and the Board of Management of the Laboratory to the Director created a stalemate that required the intervention of the Cabinet Secretary, but the stalemate persisted hence this honourable Court ought to issue direction in the matter.

16. The applicant averred that the fee charged for the said services would be a major source of revenue for the Laboratory, and that therefore, by stopping the Laboratory from performing the above function, it is a sure way of strangling the Laboratory since more often than not, it's unable to meet its financial obligations. To him, so bad is its financial situation that in 2009, for instance, the then Permanent Secretary directed the Board, by virtue of being the appointing authority of the Board of management of the Laboratory, to advance Ksh.40 million to the Laboratory but there was no response. A recent follow up on the same was met with harsh response from the Board and on 1st March 2010, the former (then) Permanent Secretary of Ministry of Medical Services, **Prof. J.O Kiyiapi** invited the Efficiency Monitoring Unit (EMU) to look into allegations of malpractices and suspected acts of corruption, including importation of substandard and counterfeit medicines at the Board (the Board).

17. The applicant averred that having distinguished himself in sealing the loopholes that previously existed in the Trade Department at the Board by streamlining the department through putting effective systems in place while he was at the helm of the said Department, in April, 2010, the Efficient Monitoring Unit identified him as a whistle blower who would be key to assisting it fulfill the mandate that had been placed upon it by the said Permanent Secretary when he invited it to investigate the goings on at the Board. It was averred that the EMU submitted its Audit report on the above in March 2011, which confirmed corruption of dealings in substandard and counterfeit medicines, including registering of medicines that had failed analytical tests by the Laboratory and authorizing importation of medicines from manufacturing companies that had failed purported inspection compliance certification by Pharmacy and Poison Board itself. The report further observed that among the contributory factors of substandard and counterfeit medicines was the fact that the Laboratory did not perform its function of inspecting manufacturing premises as mandated by section 35A(5) of the Act; and recommended that the Minister should ensure that Laboratory performed all its functions as outlined under section 35A(5) of the said Act. As a result, the Cabinet Secretary and the Board of Management, signed a performance contract on 27th November, 2015, that required the Director to inspect several premises and issue certificates of compliance to Good Manufacturing Practices (GMP); by sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of manufacture is being

followed as per sections 35A(5) & 35I(b) of the Act, by end of 2015/16 Financial year.

18. The applicant disclosed that he faced a series of various aspects of victimization for having been a whistle blower to corruption at the Board, which resulted into his interdiction by the then Permanent Secretary in May, 2011. Consequently, he lodged Judicial Review Proceedings in High Court Miscellaneous Civil Cause No. 131 of 2011 in which, vide the Court's judgment delivered on 14th October, 2011, the Court quashed the interdiction and further, held *inter alia*, that the said interdiction had been actuated by malice directly as a result of his firm stand against endemic corruption at the Board and which corruption was confirmed by the Court which judicial findings of graft had been confirmed by the Efficiency Monitoring Unit Report of March, 2011 and whose recommendations, including requiring the Minister of Health to deploy out the majority of the staff of Pharmacy and Poisons Board, has to date, not been implemented.

19. The applicant therefore averred that the Ministry, due to corruption, , has been resisting the application of sections 35A(5) and 35I(b) of the Act in order to:

a. Protect the manufacturers of substandard medicines from being detected and thus ensure continued manufacturing of substandard medicines by disabling the legal system-National Quality Control Laboratory from inspecting premises and issuing certificates of compliance to Good Manufacturing Practices (GMP); by sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of manufacture is being followed: thus exposing the general public to dangerous medicines and which continued exposure of the public to the said dangerous medicines directly undermine the Constitutional mandate under Article 43 of the Constitution of Kenya, for personal gain;

b. With the above objective, to financially strangle the Laboratory thus paralyse it from performing its Medicines Quality Control mandate, by disabling it from revenue collection of fees from Pharmaceutical manufacturers;

c. Ensure that the Laboratory does not deliver its performance contract parameter of inspecting several manufacturers by end of June 2016, for it to be cited for sanctions that may include demotions or even dismissals of the key officials by Public Service Commission.

20. It was disclosed that prior thereto, on 21st July 2014, the then Principal Secretary of the Ministry of Health, **Prof. Fred Sergor**, vide letter of 30th July 2014, directed the Registrar of the Board to allow the Laboratory to perform its statutory functions including inspection of Pharmaceutical manufacturing premises in the following terms but the Registrar responded vide a letter dated 11th August 2014 informing the Principal Secretary that the said directive cannot be implemented because inspection of Pharmaceutical Manufacturing Premises (GMP) is a function of the Board. The applicant also averred that he was aware that the Laboratory sought the opinion of the Attorney General on the matter and vide letter of 7th November, 2014 the Attorney General requested the Principal Secretary to convene a meeting between the Laboratory and the Board for him to deliver his legal advice but, aware that the Attorney General would obviously advise as per express sections 35A(5) and 35I(b) of the Act, the Ministry of Health reprimanded the Director of the Laboratory for having requested the Attorney General's legal opinion, and the Ministry never invited the Attorney General to render his legal opinion on the matter.

21. The applicant further contended that in view of the above and in the interest of harmonious working relationship between the two complementary regulatory bodies under the same Ministry, the Board of Management the Laboratory met the Registrar of the Board, on 2nd September, 2015 to discuss the matter but he declined and as a result the Board of management of the Laboratory directed, on the 30th November 2015, the Director to implement the provisions of sections 35A(5) and 35I(b) of the Act, from January 2016. Accordingly, on or around 18th February 2016, the Director started to implement the same by first inviting the association of Pharmaceutical manufacturers for a meeting but the association, on 3th March, 2016 stated that the Board had dissuaded them from cooperating with the Laboratory.

22. It was the applicant's case that the overriding interest in the discharge of public duties which falls on the shoulders of the CS and the PS is that the administrative decisions should be lawful and made in the public interest and not arbitrarily for personal interests and that public interest would, in this case, dictate that the CS, PS & the Ministry support the Laboratory to sample medicinal substances under production for laboratory testing, through inspection of Pharmaceutical Manufacturing Premises for compliance certification to Good Manufacturing Practices (GMP) for promotion of quality medicines.

23. It was therefore the applicant's case that the purported Circular Ref: MOH/ADM/1/217/VOL.1 of 10th March, 2016 by the Principal Secretary herein was based on personal interests aimed at perpetuating corrupt practices at the Board and getting rid of National quality Control Laboratory. To him, under the Constitution, Public interest demands that the exercise of public duties be undertaken reasonably, rationally and not capriciously and/or maliciously, and that, therefore, purported suspension and or amendment of sections 35A(5) and 35I(b) herein is a clear example where a public duty is being performed with a collateral intent of personal gain rather than seeking to achieve what is in the public interest. He disclosed that the Report on Management Systems Audit of Pharmacy and Poisons Board by Efficiency and Monitoring Unit compiled in March, 2011 confirmed the existence of rampant corruption at the Board including issuing official import permits for counterfeit medicines and condoning the retailing of counterfeit drugs on the market on the basis of which it made several recommendations to the Respondents.

24. The applicant asserted that in view of the foregoing, the existence of Rule 10 of the Rules is unlawful as it expressly contravenes section 35A(5) and 35I(b) of the Act, and therefore is a nugatory and whose existence is being exploited to deny the public their right to the highest attainable standard of health under article 43 of the Constitution which is largely realized through quality medicines which are sampled during production in any manufacturing premises and certified that the method of manufacture approved by the Board is being followed and therefore this Honourable court ought to have it removed into the High Court for purposes of its being quashed.

25. It was submitted by the applicant that scrutiny of both Gazette Notices-Legal No. 142 of 1991 and 147 of 1981 confirm that Rule 10 of the Rules was not gazetted under the said gazette Notices and that the 4th Respondent, or any other Respondent, has not demonstrated that the said Rule 10 was gazetted under any other Gazette Notice to warrant its preliminary objection on the basis of limitation of time under Order 53 Rule 2 ***Civil Procedure Rules***. In the premises, the origin and authenticity of the said Rule 10 is in question and thus impossible to quantify the months or years that have elapsed.

26. With respect to Order 53 rule 2, the applicant relied on **Republic vs. Institute of Certified Public Secretaries of Kenya Ex-Parte Mundia Njeru Geteria [2010] eKLR, Rep vs. The Judicial Commissioner of Inquiry Into the Goldenberg Affair and Others Ex Parte Jackson Mwalulu Misc. App.1279/04** and **Kenya Commercial Bank Ltd vs. Kenya National Commission on Human Rights [2008] eKLR**.

27. The applicant submitted that Rule 10 of the Rules is nullity '*ab initio*' by virtue of section 24(2) of the ***Statutory Instruments Act*** and section 31(b) of the ***Interpretation and General Provisions Act*** for being ultra-vires section 35A(5) & 35I(b) of the main Act-***Pharmacy and Poisons Act.*** The applicant further, submitted that section 44 of the ***Pharmacy and Poisons Act***, which empowers the CS in consultation with the Board to make rules with respect to stipulated matters does not include the registration of drugs. Thus, the entire ***Pharmacy and Poisons (Registration of Drugs) Rules***, including Rule 10, are *ultra-vires* the powers of the 2nd and 4th Respondents to make Rules as further, the same Registration of Drugs Rules are hanging without foundation in the Act since registration of drugs should be regulated by substantive Act. In this respect the applicant relied on **Kenya Commercial Bank Ltd vs. Kenya National Commission on Human Rights [2008] eKLR**.

5th Respondent's Case

28. The application was supported by the 5th Respondent herein, the National Quality Control Laboratory

(the Laboratory).

29. According to the Laboratory, the World Health Organization (WHO) International Conference on Primary Health Care declaration in Alma-Ata in 1978, the WHO Conference of Experts on the Rational Use of Drugs held in Nairobi in 1985, and the WHO Revised Drug Strategy, adopted by the World Health Assembly in May 1986, identified effective functioning National drug regulation and control systems as the only means to assure safety and quality of medicines, which is a prerequisite for delivery of health care. In accordance with the WHO Guidelines for Good Manufacturing Practice (GMP) and inspections, which is the prescribed method-GMP inspection standard-by the Pharmacy and Poisons Board, an effective GMP inspection should contain an aspect of collecting samples under production for Laboratory analytical testing.

30. It was averred that in 1992 Parliament amended ***Pharmacy and Poisons Act***, by inserting sections 35A to 35K which created National Quality Control Laboratory, it corrected the problem which had been caused by the omission in the Act of the mandate of analyzing medicinal samples on behalf of government and compliance certification to Good manufacturing practices (GMP) of medicinal substances: and which mandate was bestowed upon the Laboratory for avoidance of conflict of interest within the Board, for complementarity and checks and balances. Consequently, both the Laboratory and the Board are complementary National medicines regulatory and control bodies under the Ministry of Health by virtue of both being body corporates under the same and only medicines regulatory statute in Kenya (the ***Pharmacy and Poisons Act***, CAP 244 Laws of Kenya) and having complementary statutory powers: one with regulatory role of licensing and registration and the other one charged with the role of quality assurance by ensuring compliance certifications respectively; but each with clear and distinct functions and mandate.

31. It was averred that though the copies of Gazette Notices 147 of 1981 and 142 of 1991 exhibited in the affidavit of the ex parte Applicant it is indicted at the footnotes under page 110 of the Act that Rule 10 of the Rules was gazetted under Gazette Notices 147 of 1981 and 142 of 1991, the said Gazette Notices do not contain Rule 10 of the Rules. It was therefore contended that there is a legality question over Rule 10 of the Rules in the absence of evidence of its enactment and thus it may well be said to have come into being by the decree of the 3rd Respondent's circular Ref: MOH/ADM/1/2/17/Vol.1 of 10th March 2016. It was therefore averred that if the Board wishes to object on lack of jurisdiction of this court to deal with prayer no.2 on the premises of Order 53 of the ***Civil Procedure Rules'*** requirement of less than six months period, then, the onus is on the shoulders of the Board to demonstrate that Rule 10 of the Rules was enacted earlier than the 10th March, 2016 circular.

32. The Laboratory further averred that even if it is assumed that Rule 10 was enacted in 1981/91, the same was voided and nullified by Parliament in 1992 on enactment of section 35A(5) and 35I(b) of the ***Pharmacy and Poisons Act***, by virtue of sections 24 and 31 of ***Statutory Instruments Act*** and ***Interpretation and General Provisions Act*** respectively, and was thus only revived by the 10th March, 2016 Circular. It was however deposed that Rule 10 of the Rules does not confer any power on the Registrar of the Board to issue compliance certificates of Good Manufacturing Practices as he has been doing, which is blatant usurpation of the powers of the Laboratory. It was the Laboratory's position that sections 35A(5) and 35I(b) of the Act, deliberately set aside the inspection and issuance of GMP Compliance certificate to Pharmaceutical Manufacturers as one of the powers of the Director of the Laboratory. Conversely, there was no power given to the Registrar of the Board to inspect and issue GMP compliance certificates to Pharmaceutical Manufacturers. The only powers which the Board could exercise were the powers to License the Premises and Drug Registration certificates and prescription of the method of manufacture under section 35B of the Act and which the Board has adopted the World Health Organization (WHO) Good manufacturing Practice and Inspection guidelines, as confirmed in its Replying affidavit.

33. The Laboratory deposed that whereas it has always been its desire to start GMP inspections, as for instance captured in the Board of Management's strategic Plans since 2005, the reason why sections 35A (5) and 35I(b) of the Act had never been implemented since its inception in 1992 is that some of the former occupants of the offices of the CS and PS had been verbally directing the Laboratory against

implementation of the GMP compliance certification under the Act, just as the 10th March, 2016 circular, and went further to make deployments that ensured the Board continued with implementation of the said Rule 10 over and above the parent Act, among other activities.

34. The Laboratory concurred with the ex parte applicant's position and averred that the PS's circular Ref: MOH/ADM/1/2/17/Vol.1 of 10th March, 2016 merely stated what had been happening, with regard to GMP compliant certification, for many years, as summarized below:

> **(i) THAT** with the support and knowledge of the 1st Respondent, the Board had usurped the statutory mandate of the Laboratory;
>
> **(ii) THAT** the Laboratory had been subtly barred by the Board and 1st Respondents from performing its statutory mandate of GMP compliant certification;
>
> **(iii) THAT** contrary to the averments of the Board, the 10th March, 2016 circular clearly stopped the Laboratory from performing its statutory mandate by referring to presentation paper of 13th January, 2016 and numerous correspondence to the Pharmaceutical Industry;

35. The Laboratory disclosed that on 6th July, 2016, it received another circular Ref: MOH/ADM/BOARDS//13/1/12/VOL.III/36 dated 29th June, 2016 from the Board titled withdrawal of letter Ref: MOH/ADM/1/2/17/Vol.1 but which circular was never addressed nor copied to any other party in these proceedings and which circular stated thus:

> *Reference is made to the above letter Ref: MOH/ADM/1/2/17/Vol.1 of 10th March, 2016 (Copy attached). This is therefore to inform you that the above letter is officially withdrawn. Be advised accordingly.*

36. To the Laboratory being too far short of the above content, withdrawal circular Ref: MOH/ADM/BOARDS//13/1/12/VOL.III/36 dated 29th June, 2016 does not effectively withdraw circular Ref: MOH/ADM/1/2/17/Vol.1 of 10th March, 2016, which is still alive and effective. Nevertheless, subsequent to the purported withdrawal circular and even after this honorable court's stay orders , the Board, in blatant defiance of the said orders, had since August, 2016 continued to collect GMP fees and proceeded to carry out GMP inspections-compliance certification in India and other sites that supply medicines to Kenya, including Europa Healthcare Ltd, Sunpar Pharmaceuticals Ltd, Healthcare formulations, Win Medicare, Zen Pharma PVT Ltd and Unichem Pharmaceuticals among others.

37. It was however the Laboratory's case that the above withdrawal circular amounts to admission of the issues in this matter. It was however its view that the cause of resignations of the Pharmacists who on the Board of Management is the Board after this honorable Court dismissed on 5th June, 2015 the 3rd and 4th Respondent's application to set aside the Exparte Applicant's stay orders of 5th April, 2016. The Laboratory disclosed that it received information that from one of the three Pharmacists that resigned that the Board had instructed some of the Board members to defer, during the 24th June, 2016 meeting of the Board, the implementation of the orders in these proceedings. However, after the plan to defer failed to succeed, the Board ordered them to resign from the Board of Management of the Laboratory or face possible consequences of dismissals by their respective employers by virtue of the Board being the regulator of the employers. It was further disclosed that one of the Board member who resigned is a member of training Committee of the Board and another one has been a member of the Board for three consecutive terms and was only awaiting for the 4th consecutive appointment. To buttress this the Laboratory averred that the true position is as contained in the letter written by the Chairperson of the Laboratory's Board of Management to the CS on the matter: and that the Board is on record for interfering with the independence of the Laboratory's Board of Management as was witnessed in 2011 resignations of the Chairperson and member of the said Board of Management.

38. The Laboratory denied that there is any pending case of misappropriation of Ksh.60 million at the

Laboratory and contended that in fact, the Public Investment Committee of National Assembly, vide its letter of 18th November, 2016, directed the Board to make submission on its audited accounts and liaise with the office of the Auditor General for concurrence and guidance before submission of its report on 29th November, 2016 and that the Laboratory finalized the report after concurrence with the Auditor General that the alleged Kshs. 60 million can only be accounted for by the 1st, 2nd, & 3rd Respondents.

39. The Laboratory averred that following the orders of this honorable court in these proceedings, the Laboratory had since carried out Good Manufacturing Practice Audits in several Pharmaceutical manufacturing sites for purposes of compliance certifications and 40% of the sites, which had been certified by the Board as compliant, were found to be non-Compliant to GMP and should not continue with production of medicines until quality assurance systems are installed. It was contended that the Board has and continues to frustrate the Laboratory from implementing her statutory functions under sections 35A(5) and 35I(b) of ensuring that only medicines from GMP certified sites are supplied to Kenya through subtle manoeuvres as demonstrated through correspondence with Kenya Network Trade Agency (KENTRADE) and others. The Laboratory therefore asserted that it was necessary that in order to guarantee implementation of sections 35A(5) and 35I(b) of the Act by the 5th Respondent, this honourable court should consider grant of both prohibitory and mandamus orders to the Exparte Applicant as sought.

40. Based on legal advice, it was contended by the Laboratory that in other jurisdictions which have single medicine's regulatory Authority such as Tanzania and Uganda, the Laboratory is an integral part of the Authority, which provides quality Control and assurance functions and that in Kenya, the ***Pharmacy and Poisons Act*** provides that the Control of quality of medicines is through analytical tests of medicinal samples for issuance of certificate of analysis and GMP inspections for issuance of GMP compliance certification respectfully and which complementary functions are the prerogative of the Laboratory.

41. On behalf of the Laboratory, it was submitted that it is only sections 35(A)5 and 35I(b) in the entire ***Pharmacy and Poisons Act***, Cap 244 of the Laws of Kenya that mandates the Director of the Laboratory, and not any other authority, to inspect premises and issue certificates of compliance to Good Manufacturing practices. Rule 10 of ***Pharmacy & Poisons (Registration of drugs) Rules***, which does not appear in any Gazette Notice (Gazette Notices Legal No. 142 of 1991 & 147 of 1981), it was submitted expressly conflicts with the provisions of the parent Act-Sections 35 A (5) and 35 I (b) of the ***Pharmacy and Poisons Act*** and does not confer power to issue certificates of compliance to Good Manufacturing practices.

42. In support of its submissions, the Laboratory relied **U.S vs. Butler, 297 U.S. 1[1936]**, **Kenya Country Bus Owners' Association (Through Paul G. Muthumbi – Chairman, Samuel Njuguna – Secretary, Joseph Kimiri – Treasurer) & 8 Others vs. Cabinet Secretary for Transport & Infrastructure & 5 Others [2014] eKLR** and **Republic vs. Council of Legal Education & Another Ex-Parte Mount Kenya University [2016] eKLR.**

1st, 2nd & 6th Respondent's Case

43. In opposition to the application, 1st, 2nd and 6th Respondents filed the following grounds of opposition:

a) The application is frivolous vexatious and an abuse of court process.

b) There is no decision to be quashed as the alleged impugned decision (one dated 10th March, 2016) was withdrawn on 29th June, 2016.

c) The application is based on contradictory allegations which borders on mere belief, suspicion and speculations and hence incapable of any judicial review determination.

d) There are no clear reliefs sought as the application is neither here nor there.

e) There are no orders sought against the 6th Respondent.

44. It was submitted on behalf of the said Respondents that on 29th June, 2016, the PS withdrew the impugned decision of 10th March, 2016 stopping the Laboratory from performing the functions conferred by section 35A(5) and section 35I(a) of the ***Pharmacy and Poisons Act*** which is the substance of these proceedings. It was therefore submitted that the application before this Court has been spent as there is nolonger in existence such decision.

45. With respect to the prayer seeking to quash Gazette Notices 147 of 1981 and 142 of 1991 it was submitted that the applicant has not provided grounds upon which the same should be quashed. As regards the order for mandamus it was submitted that the same cannot issue as the applicant had not demonstrated what the 1st and 2nd Respondents failed to do to warrant the issuance of the same.

46. The said Respondents therefore urged the Court, based on several authorities cited to dismiss the application.

4th Respondent's Case

47. It was The 4th Respondent Board's case that Court lacks jurisdiction and mandate to determine this case on the following four (4) grounds:-

a) Lack of a decision to quash due to the fact that on 29th June 2016 the Principal Secretary, Ministry of Health (the 3rd Respondent herein), the author of the contentious circular, within his mandate, competence and authority, wrote a letter addressed to the Director of the Laboratory withdrawing the circular of 10th March 2016. Additionally, on 3rd August 2016 the Advocates of the 4th Respondent filed an affidavit before this Honorable Court drawing the attention of the court to the said letter of withdrawal from the 3rd Respondent and in essence pointing out that the substantive notice of Motion filed by Applicant particularly Prayer (a), (c) and (d) hereinabove have been overtaken by events, as according to the tenets of Order 53 of the ***Civil Procedure Rules, 2010*** and the ***Law Reform Act Cap 26*** there exists no decision to be heard and determined by this Honorable Court as the matter has become moot and if at all the court is inclined to adjudicate on this matter, then the orders issued will be in vain. It was however by the Board that despite the said letter dated ***10th March 2016*** having been since withdrawn, the same was an attempt by the Principal Secretary to clarify the confusion which had been created by the Applicant and was not based on any erroneous interpretation of the law as suggested by the Applicant.

b) Action barred by statutory limitation and therefore prayer (b) sought by the applicant has no legal basis. In this case the decision the Applicant is seeking to quash is the ***Gazette Notices 147 of 1981*** and ***142 of 1991*** as regards and relates to Rule 10 of the ***Pharmacy and Poisons (Registration of Drugs) Rules*** yet the Applicant has failed to annex these legal notices to cause the court make a reliable findings on them. Further, these notices were legislated over thirty (30) years ago thus, they are barred by statutory doctrine of laches. Furthermore, the issues as pertains to the legality of a subsidiary legislation can only be canvassed and determined through a Constitutional Petition and not a Judicial Review which strictly deals with administrative actions as under Article 47 of the Constitution of Kenya, 2010, which is clearly not the case here. The Board therefore contended that this Court lacks the jurisdiction to deal with the issue and relied on **Owners Motor Vessel "Lillian S" Vessel vs. Caltex Oil (K) Ltd" (1989) KLR 1**

48. According to the Board, by it's legal mandate as the main regulator to inspect, issue license and inspect on pharmaceutical manufacturing industries as provided for under the Act, it is not usurping the powers of the Laboratory or any other body.

49. It was averred that the Laboratory is established under section 35D of the Act not as a complementary body to the Board but as a facility to support the Board. On the other hand, in law Part III A which

covers sections 35A and 35B of the Act and titled "***Manufacture of Medicinal Substances"*** speaks to licensing of manufacturers of medicinal substances located within Kenya by the Board and therefore should not be extended to licensing of manufacturers of medicinal substances by National Medicines Regulatory Authorities of countries where the companies are located. According to the Board, the said Part IIIA which covers sections *35A* and *35B* of the Act and titled "*Manufacture of Medicinal Substances*" only covers manufacturers based in Kenya as they are the only manufacturers licensed by the Board. However, the Act does not have international jurisdiction therefore the Board does not and cannot license foreign manufacturers but can only recognize valid licenses issued by their respective NMRAs equivalent to the Board in addition to the current Good manufacturing Practices (GMP) certification that is carried out by the Board.

50. According to the Board, one has resisted the application of Sections 35 A(5) and 35 I of the Act as claimed by the Applicant which mandates the Laboratory, the technical arm of the Board, to undertake its mandate as outlined under section 35D of the Act hence the Board has not usurped the powers or mandate of the Laboratory as alleged. To the Board, the creation of the Laboratory under Part IIIB of the Act was to support the Board as a testing facility as outlined under section 35D of the Act and not to complement it as erroneously suggested by the Applicant. The Board therefore denied that the gazettement of the ***Pharmacy and Poisons (Registration of Drugs) Rules*** was due to a gap on laboratory analysis. On the contrary, it asserted that the said rules were mainly to regulate the importation, manufacture for sale and or sell of any drug within Kenya.

51. The Board contended that the powers granted to the Laboratory's Director under section 35A (5) and 35I are not applied in isolation but is to enable the said Director to effectively undertake its mandate as outlined under section 35D of the Act. The Board averred that neither the Laboratory's Director nor any of its members of staff has been stopped from entering any manufacturing premise within Kenya for purposes of certifying that that the method of manufacture approved by the Board is being followed in fulfillment of its mandate as outlined under Section 35D of the Act. It however averred that the role of the Laboratory in "manufacturing premises", has been categorically spelt out under section 35A(5) and is limited to inspection with a view to "sample and certify that the method of manufacture approved by the Board is being followed" as opposed to a comprehensive inspection to confirm compliance with Good Manufacturing Practices (GMP) of entire sections of manufacturing premise, which is carried out by the Board.

52. It was therefore reiterated that in totality of the foregoing background, there is no conflict as suggested by the Applicant, between the provisions of section 35A and 35B regarding the functions of the Laboratory in fulfilling its mandate of sampling and testing pursuant to section 35D of the Act against the provisions of Rule 10 of the ***Pharmacy and Poisons (Registration of Drugs) Rules*** which speaks to GMP inspections as a prerequisite to registration of a drug in the Kenyan market.

53. The Board averred that in Kenya the Board is the only National Medicines Regulatory Authority (NMRA) recognized globally, and further that the Laboratory is recognized globally as a laboratory. According to the World Health Organization (WHO), the role of the Laboratory is specific to ensuring standards and checking quality of drugs & medicinal substances by performing physical, chemical, biological and other pharmaceutical evaluation of drugs and medicinal substances, which it then informs the Government through the Board of the results of such tests so that appropriate action can be taken if products do not comply with set specifications for safety and effectiveness.

54. It was the Board's position that pursuant to the provisions of rule 10 of the drug registration rules, it conducts an inspection of any manufacturing plant before issuing a certificate of drug registration to a manufacturer of drugs within Kenyan market which inspection, is done purely as a prerequisite for registration of drugs and medicinal substances.

55. According to the Board there is no conflict created by Rule 10 as the Rule is applied for purposes of registration of drugs whereas section 35 (5) and 35 I (b) of the Act speaks to the powers of the Laboratory's Director which are intended at enabling him fulfill his mandate specific outlined under section 35D of the Act. The Board averred that GMP Inspection is a process in drug registration in which

a report generated therefrom informs the Board as to whether to allow a drug to be imported, manufactured for sale or to be sold within Kenya and has nothing to do with the provisions of sections 35A (5) and 35 I (b) of the Act which are the powers of the Laboratory's Director intended to enable him fulfill its mandate granted under section 35D of the Act. Flowing from the above, it was averred that the said GMP inspection is part of the registration process for drugs as a practice to verify that Module 3 (Quality) of the documentation that the Chemistry, Manufacturing and Controls (CMC) are in place and maintained to ensure that products are consistently manufactured and controlled to meet quality standards that does not pose danger to the members of the public.

56. With respect to the applicant's conduct it was averred that the Applicant's decision to challenge the circular was part of his scheme targeted at ensuring that Laboratory conducts GMP Inspections after he was posted to the facility. Ironically, the Applicant whilst working at the Board he had actively participated in GMP Inspections as a Lead Inspector and had not at any given instance doubted the mandate of conducting GMP Inspections by the Board.

57. The Board therefore argued that the Notice of Motion Application dated 6th April 2016 by the Applicant has not established a case to warrant the granting of the orders sought hence it should be dismissed with cost to the Board.

Interested Party's Case

58. On behalf of the interested party, after setting out the relevant legal provisions, this Court was urged that as a result of the legal battle between the Board and Laboratory, to make a determination as to which of the two bodies ought to conduct the inspections. The interested party averred that its intention was to give a guide as to the current market practices and offer its opinion on how the exercise should be conducted, so as to ensure fairness, sobriety and predictability in the market, and further ensure that drugs manufactured and distributed within the country are safe and of high standards.

59. According to the interested party, inspection of pharmaceuticals manufacturing premises and sampling of medicinal products has always been conducted by the Board which has all along been in-charge of the inspection mandate, and has issued various licenses and Certificates as provided for in the Act which licenses and certificates are current (issued in the year 2016), and the Certificates of Good Manufacturing Practices are actually valid for Two (2) years.

60. The interested party therefore contended that purely of the grounds of customs and the history of inspections of manufacturing premises, the Board should be allowed to continue with its mandate since in its view, allocating the mandate to the Laboratory would, in essence, lead to confusion in the industry, and in effect invalidate the licenses and certificate of good manufacturing practices already issued, and call for a fresh process of inspections. This would lead to levying of double charges to the manufacturing entities, which would be arbitrary and unfair.

61. The interested parties further contended that it had held many consultative meetings with both the Laboratory and the Board concerning the issue of inspection of manufacturing premises from which it was established that the Laboratory currently lacks both financial and human resource capacity to carry out the mandate of inspections and sampling of drugs, a fact that is well admitted by it.

62. It was therefore contended that it would be foolhardy to increase the mandate of a body that is already straddled with capacity issues.

63. According to the interested party, it has long been determined that where there are two conflicting positions between a statute and subsidiary legislation, the provisions of the statute take precedence over those of the subsidiary legislation. However, where a court is called upon to make a determination as to conflicting provisions within the same statute, it ought to be guided by the rules of statutory interpretation. It referred to Blackstone for the proposition that, "***The fairest and most rational method to interpret the will of the legislator, is by exploring his intentions at the time when the law was made***." In order to determine the intention of the legislator in drafting and passing of the Act, the interested party

urged the Court to consider the words, the context, the subject matter, the effects and consequence, or the spirit and reason of the law. The interested party also relied on the decision by the Australian High Court in **Cooper Brookes (Wollongong) PTY Ltd. vs. Federal Commissioner of Taxation (1981) 147 CLR 297.**

64. According to the interested party's reading and interpretation of the provisions of the Act, the establishment of the Laboratory was for it to act as a technical or enforcement arm of the Board, and not necessarily as a competing or completely independent body. In the interested party's understanding of the relevant legal provisions, the Laboratory was created as a body operating under the Board, with the mandate of acting as a facility for carrying out sampling of drugs and facilitating inspection of manufacturing premises which mandate is, however, to be undertaken at the behest and guidance of the Board, and not as an independent venture.

65. It was therefore the interested party's case that the provisions of the Act are not ambiguous with respect to the mandates of the 4th and 5th Respondents, but merely provide for a duplicity and intertwining of duties by these two bodies. To it, the current unfortunate scenario where the Laboratory is attempting to flex its muscles and compete with the Board is as a result of an erroneous interpretation of the Act, whereby the Laboratory seems to believe that it is independent from the Board. This, it was contended, is obviously to the detriment of members of the Interested Party and possible health risks to the general citizenry and was not the spirit and intent of the Act.

66. It was the interested party's view that the mandate of the Laboratory is meant to be undertaken under the supervision and direction of the 4th Respondent, and results thereof should be applied by the latter in the issuing of GMP certificates and Licenses for manufacture of drugs for sale. The roles of these two bodies are therefore meant to be applied together, and not distinct from each other. However, from the analysis above and documentation relied by the *Ex-parte* Applicant, it is evident that the Laboratory has not been undertaking these duties, due to its financial and human resource incapacities. It was therefore the interested party's position that pending the addressing of the Laboratory's incapacity issues, the mandate of carrying out inspection of manufacturing premises and sampling of drugs should continue to be carried out by the Board, which is the fairest, legal and most logical option in the circumstances as this would ensure stability and sobriety in the drugs industry, eliminate confusion, ensure quality of drugs meant for human consumption is best regulated and cushion the affected entities from multiplicity of inspections and charges.

67. It was further contended that in the event that this court rules in favour of the Laboratory conducting the inspection, then the court should qualify such ruling to only apply to manufacturing entities that have not been subjected to the inspections, so as to avoid subjecting members of the Interested Party to double inspections and charging of inspections costs. However, in the long run, there shall be need for amendment of the ***Pharmacy & Poisons Act*** by parliament, for purposes of ensuring that creation and operationalization of the Laboratory is outlined in the clearest of terms, to avoid the current competition between the two bodies. Pending such legislative action, the *status quo* with respect to the licensing, inspection of premises and sampling of drugs, should be maintained.

68. To the interested party, the *Ex-Parte* Applicant's motion should fail.

Amicus Curiae's Case

69. According to the amicus curiae, the ***Pharmacy and Poisons Act***, Cap 244 provides for two independent Medicines Regulatory Authorities, the Pharmacy and Poisons Board and the National Quality Control Laboratory, each with distinct and complementary mandates of medicines Control. In its view, the common functions of the above medicines Regulatory Bodies are:

(a) Licensing of Pharmaceutical dealers and manufacturers under strict rules, including inspection of medicines' distribution channels;

(b) Registration of all medicines in the local market vide strict requirements, and subsequent

import/export authorizations;

(c) Surveillance sampling of medicines in the market and subsequent submission to quality control Laboratory for analysis;

(d) Recalling/mobbing up of suspected substandard and counterfeit medicines from the market;

(e) Through Quality Control Laboratory, analysis and subsequent certification of medicinal samples for enforcement of (b, c & d) above;

(f) Through Quality Control and Assurance Laboratory system, sampling medicinal substances under production through inspections for compliance certification to set methods of controlled manufacture of Pharmaceuticals, for enforcement of (a) above.

70. It was contended that sections 35(A) 5 and 35I(b) of the ***Pharmacy and Poisons Act***, Cap 244 of the Laws of Kenya [hereinafter, "the Act"], exclusively mandates the Director of the Laboratory to inspect premises and issue certificates of compliance to Good Manufacturing Practices (GMP). It was contended that while the Pharmacy and Poisons Board is maintaining to issue GMP certificates, indeed Rule 10 of ***Pharmacy & Poisons (Registration of drugs) Rules***, does not confer power to issue certificates of compliance to Good Manufacturing practices. According to the amicus, the Rules, expressly conflicts with the provisions of the parent Act-Sections 35 A (5) and 35 I (b) of the Act.

71. In view of the above, it was contended the circular Ref: MOH/ADM/1/2/17/VOL.1 of 10th March, 2016 sought to proscribe the Laboratory from performing its functions of inspecting premises and issuing certificates of compliance to Good Manufacturing Practices and transferred the same to the Board was merely a communication of what had been happening for a long time as it had already been directed by the Board, vide letter Ref: MOH/BOARDS/13/1/12/Vol.2/32 of 11th August, 2014. Later the CS sought to withdraw circular Ref: MOH/ADM/1/2/17/VOL.1 of 10th March, 2016 in 29th June, 2016, but this did not obliterate the whole subject matter as there was a loophole that needed to be sealed once and for all.

72. It was submitted that under the Constitution of Kenya, the supreme law, Article 43(1)(e) [Economic and social rights] provides that every person has the right to the highest attainable standard of health, which includes the right to health care services, a right that is directly impinged on a proper institutional framework that is specially operationalized to ensure that the system works efficiently. In the present circumstances, the right to health depends on a capable institution to ensure that the manufacture of medicines and poisons is done within the required guidelines, *to wit*, Good Manufacturing Processes. The amicus lamented that this right to Health is now compromised, when two bodies are tussling over the mandate to inspect medicines and poisons. It is thus imperative for this Court to strike a balance so that GMP is done efficiently, so as to protect, promote and respect the citizens' right to the highest attainable standard of health.

73. To the amicus, the existence of a National Quality and Control Laboratory is not just a caricature of the same, but rather it is a crucial component in ensuring that the citizens' right to the highest attainable standard of health is protected, promoted, respected and fulfilled. This is owing to the special functions that this institution is exclusively mandated to undertake, by law, which the Constitution purposes persons to adhere to. To it, if there is no order in the inspection of the quality of medicines and drugs, then these functions are left derelict, and they jeopardize the health of the nation.

74. According to the amicus, Rule 10 of ***Pharmacy & Poisons (Registration of Drugs) Rules*** seems to proffer jurisdiction to the Board, which jurisdiction is not in the parent statute. In fact, this jurisdiction is given to another institution, the Laboratory, and the Rules are seeking to take the jurisdiction away and hand it over to Board.

75. It was submitted that under the hierarchical order of statutes, the Rules should be deemed as subsidiary legislation while subsidiary Legislations should be consistent with the parent statute hence the ***Interpretation and General Provisions Act*** is therefore well placed to give definitions and the application

of written law in Kenya. This is to say that Rules are made pursuant to a power that has been defined by an Act and are therefore inferior to the Acts and are made for purposes of explaining or causing the acts to be easily applicable. However, the ***Pharmacy & Poisons (Registration of Drugs) Rules***, are expressly inconsistent with the provisions of sections 35 A (5) and 35 I (b) of the ***Pharmacy and Poisons Act*** contrary to section 24 (2) of the statutory instruments Act. In support of its submissions the amicus relied on **Kenya Country Bus Owners' Association & 8 others -vs- Cabinet Secretary For Transport & Infrastructure & 5 others [2014] eKLR** and **Republic- vs- Institute of Certified Public Accountants of Kenya Ex Parte Vipichandra Bhatt T/A J V Bhatt & Company Nairobi HCMA No. 285 of 2006.**

76. It was the position of the amicus that the mandate of inspecting premises for purposes of issuing compliance certificate for Good Manufacturing Practices (GMP) is conferred to the Director of the Laboratory, as per sections 35 (A) 5 and 35 I (b) of ***Pharmacy and Poisons Act***. It was the amicus case that as opposed to the Tanzania scenario, i**f the desire of the 3rd and 2nd Respondents is to have one single medicines regulatory body that contains the Laboratory within it like in Tanzania, then, it is only Parliament that can do so through amendment and or repeal of the law, but not through the 10th March, 2016 circular by the 3rd Respondent. But for Kenya, as per sections 35A, 35 I and others of the *Pharmacy and Poisons Act*,** the 4th and 5th Respondents have statutory mandates of medicines control which complement each other, which requires them to work hand in hand to ensure proper regulation of medicines control, but with distinctive roles with the 4th Respondent having the regulatory role whiles the 5th Respondent ensuring quality compliance.

77. The amicus concluded that Rule 10 of ***Pharmacy & Poisons (Registration of Drugs) Rules*** expressly contravenes the provisions of sections 35 A (5) and 35 I (b) of the ***Pharmacy and Poisons Act***, and should be declared unlawful and *ultra vires*. The body that is thus legally mandated to inspect premises and issuing certificates of compliance to Good Manufacturing Practices is the Laboratory, in its opinion.

78. It was further averred by the ex parte applicant that based on the aforesaid grounds, the application is fatally defective. It was further contended that the instant application is incurably defective as there is completely no nexus between the grounds of the application and the substantive prayer sought in that whereas the prayer sought is for variation of stay order granted, the grounds are geared towards alleged misinterpretation of the stay order granted.

79. To the ex parte applicant, if the Applicant's only issue is the alleged misinterpretation of the Court order of 5th April, 2016, then the logical prayer to this Honorable Court is for the Court to clarify the said Order as opposed to variation. To him, the aforesaid Court Order of 5th April, 2016 has not been misinterpreted as alleged by the 5thRespondent and himself as the 3rd Respondent has not even bothered to provide what he holds to be a true interpretation and has not cared to provide an alternative or "correct" interpretation of the same to this Honorable Court.

80. While appreciating that both the 4th Respondent and the 5th Respondent are complimentary National Medicines/drugs Regulators, by inference of their respective statutory functions, the ex parte applicant contended that the term Regulator or any of its derivatives is not in any way used in the entire ***Pharmacy and Poisons Act***, CAP 244, as reference to any of the two said National regulatory bodies. The ex parte applicant disclosed that currently, there is a phenomenal upsurge of extreme cases of substandard and or counterfeit medicines that cake or mold in government facilities, some after having been dispensed to innocent Kenyans, after supplies by Kenya Medical Supplies Authority (KEMSA), which is in turn supplied by foreign and local manufacturers.

81. It was the ex parte applicant's contention that assuming that the 3rd Respondent is indeed the said applicant, he is content with the vacuum created by the 19th April, 2016 court order that refrained all parties from taking any action as opposed to 5th April, 2016 court Order that allows 5th Respondent to discharge the functions under sections 35 A (5) and 35 I (b) of the ***Pharmacy and Poisons Act***, of inspecting and issuing certificate of compliance or otherwise of some of the above manufacturers. In the ex parte applicant's view, there is special relationship between some of the manufacturers, the 4th

Respondent and 3rd Respondent's office to the extent that the 3rd Respondent would rather have a vacuum such as the one created by the 19th April, 2016 court order that refrained all parties from taking any action than the 5th April, 2016 court order that allows the 5th respondent to discharge the functions under sections 35 A (5) and 35 1 (b) of the ***Pharmacy and Poisons Act***, of inspecting and issuing certificate of compliance or otherwise of some of the above manufactures, obviously, for fear of making more discoveries that are similar to the above, for public good.

82. It was the ex parte applicant's case that the 3rd Respondent shouldn't be bothered with who between the 4th and 5th Respondents carries out the functions under sections 35A (5) and 35 I (b) of the ***Pharmacy and Poisons Act***, of inspecting and issuing certificate of compliance or otherwise of some of the above manufacturers, but with whether the same is effectively accompanied as he has the supervisory role over the two institutions that belong to the same Ministry of Health. It was the ex parte applicant's view that the 4th Respondent (Pharmacy and Poisons Board) should have alerted the general public on said dangerous substandard medicines since part of them had already been dispensed to the public. According to him, the above are serious and dangerous scenarios that this honorable Court should seriously consider, on urgency basis, to allow the 5th Respondent (National Quality Control Laboratory) to at least carry out "Special" inspections of Dawa Pharmaceuticals Ltd, Lab & Allied Pharmaceutical, Sphinx Pharmaceuticals Ltd and Others manufacturing that include thorough investigations through sampling the said medicinal substances and others under production to ensure the approved method of manufacture is being followed for purposes of issuing a report and certificates of compliance to Good manufacturing practices (GMP) as provided for in sections 35 A(5) and 35 1 (b) of the ***Pharmacy and Poisons Act***.

Determinations

83. I have considered the application, the affidavit both for and against the grant of the prayers sought in the application, the submissions filed on behalf of the parties herein and the authorities relied on in support of the respective cases.

84. In my view, the issues for determination in this case are firstly whether the decision of the PS made vide its circular Ref: MOH/ADM/1/2/17/VOL.I of 10th March, 2016 was lawful; secondly, whether rule 10 of the ***Pharmacy and Poisons (Registration of Drugs) Rules*** is lawful; and thirdly whether the said Regulations have legal backing in the Act.

85. What provoked these proceedings was the circular by the Principal Secretary of Ministry of Health, **Dr Nicholas Muraguri,** Ref: MOH/ADM/1/2/17/VOL.I dated 10th March, 2016 in which the said Permanent Secretary stated *inter alia* as follows:

> ***Rule 10 of the Pharmacy and Poisons (Registration of Drugs) Rules, empowers the Board to inspect premises in which manufacturing of a drug is proposed to be conducted. The totality of the foregoing mandate is what constitutes GMP and its subsequent certification. This is also in line with the East African Community harmonisation of medicines regulation. In view of the above, it has been decided that the Pharmacy and Poisons Board shall continue conducting the above duties until further advised.***

86. In order to determine the said issues it is important to understand the import and impact of section 35 of the Act as amended in 1992 and the said Regulation 10 of the Regulations. It is not in doubt that the said Regulation came into effect before the amendments to section 35 of the Act. The said Regulation provides as hereunder:

> ***The Board may, before issuing a certificate of registration under these Rules, cause the premises in which the manufacturing of the drug is proposed to be conducted to be inspected by inspectors appointed for that purpose, and the inspectors shall have powers to enter the premises and inspect the plant and the process of manufacture intended to be employed in the manufacturing of the drug and make a report to the Board..***

87. By the 1992 amendment to the Act the National Quality Control Laboratory was established and the Act was amended by the introduction of *inter alia* section 35A to K. Section 35A(1) provides that:

> ***No person shall manufacture any medicinal substance unless he has been granted a manufacturing licence by the Board.***

88. In my understanding, the power to licence the manufacture of medicinal substances rests with the Board. Section 35A(2) empowers the Board to renew the manufacturing licences which expire on the 31st December of each year which renewal is subject to the conditions prescribed by the Board. Under section 35A(4) a person who intends to manufacture such substances is required to apply for the licensing of the premises in a prescribed form and pay the fees prescribed for the same.

89. Section 35A(5) however provides as follows:

> ***The Director of the National Drug Quality Control Laboratory or any member of the Laboratory staff authorized by him shall have power to enter and sample any medicinal substance under production in any manufacturing premises and certify that the method of manufacture approved by the Board is being followed.***

90. It is therefore clear that whereas the power to licence premises for the manufacture of medicinal substances rests with the Board, the Laboratory is empowered to enter such premises and sample any medicinal substances under production in such premises to certify that the method of manufacture approved by the Board is being followed. In my understanding the mandate of the Board is to prescribe the methods of manufacture of medicinal substances while it is the mandate of the Laboratory to ensure compliance with that methodology. In other words the Board deals with setting standards while the Laboratory ensures that the said standards are adhered to as set by the Pharmacy and Poisons Board. This position seems to find favour with the Board itself which contends that whereas in Kenya the Board is the only National Medicines Regulatory Authority (NMRA) recognized globally, the National Quality Control Laboratory is recognized globally as a laboratory and that the World Health Organization (WHO) recognises the role of the Laboratory as that of ensuring standards and checking quality of drugs & medicinal substances by performing physical, chemical, biological and other pharmaceutical evaluation of drugs and medicinal substances, which it then informs the Government through the Board of the results of such tests so that appropriate action can be taken if products do not comply with set specifications for safety and effectiveness.

91. I therefore agree that the two bodies play complementary but distinct roles in ensuring that the medicinal substances being manufactured are up to the standards prescribed. It is in this light that I understand the provisions of section 35B which states that:

> ***Every person who is granted a manufacturing licence under section 35A shall comply with the good manufacturing practices prescribed by the Board.***

92. In other words it is the mandate of the Board to prescribe the Good Manufacturing Practices and having done so, it falls upon the Laboratory to ensure that these Good Manufacturing Practices prescribed by the Board are being adhered to in terms of the manufacturing licence for each substance. Accordingly I agree with the applicant that it is the mandate of the Laboratory to issue certificates as regards compliance with the manufacturing methods prescribed by the Board.

93. Section 35D(1) of the Act therefore details what the Laboratory is required to do in undertaking its obligations and provides the same as follows:

> ***(a) the examination and testing of drugs and any material or substance from or with which and the manner in which drugs may be manufactured, processed or treated and ensuring the quality control of drugs and medicinal substances;***
>
> ***(b) performing chemical, biological, biochemical, physiological and pharmacological analysis***

and other pharmaceutical evaluation; and

(c) testing, at the request of the Board and on behalf of the Government, of locally manufactured and imported drugs or medicinal substances with a view to determining whether such drugs or medicinal substances comply with this Act or rules made thereunder.

94. My understanding of section 35D(1)(c) is that apart from the Laboratory's general mandate, it may specifically undertake the testing if so requested by the Government or the Board. In other words the Laboratory's mandate under section 35D(1)(c) is over and above its general mandate and therefore ought not to be construed to mean that the Laboratory only undertakes its mandate as and when directed by the Board or the Government.

95. Section 35I empowers the Laboratory to:

(a) to develop and administer a data bank on quality assurance on behalf of the Board of management;

(b) to inspect premises and issue certificates of compliance; and

(c) to advise and obtain advice from the Board of management in regard to any matter within his purview under this Act.

96. Certificate of compliance with the prescriptions of the Board are therefore to be issued by the Laboratory after the inspection carried out pursuant to the Laboratory's mandate under the Act. Upon such inspection, the Laboratory is under section 35I(c) empowered to advice the Board accordingly. That the Laboratory is also entitled to obtain advice from the Board emphasises the complimentary nature of the relationship between the two entities.

97. It is my view that the mere fact that the National Quality Control Laboratory is for some reasons starved of the financial and human resource capacity to carry out the mandate of inspections and sampling of drugs does not justify, the Principal Secretary rendering the Laboratory in-operational. It is for Parliament, if it does not deem the services of the Laboratory tenable to amend the law accordingly and not for the Principal Secretary to ignore a statutory mandate and bypass the entity entrusted by the Legislature to carry out the same.

98. The question that arises is therefore the impact of these provisions to rule 10 of the ***Pharmacy and Poisons (Registration of Drugs) Rules.*** As already stated above that rule enjoins the Board before issuing a certificate of registration under the Rules to cause the premises in which the manufacturing of the drug is proposed to be conducted to be inspected by inspectors appointed for that purpose, who have powers to enter the premises and inspect the plant and the process of manufacture intended to be employed in the manufacturing of the drug and make a report to the Board.

99. Section 31(b) of the ***Interpretation and General Provisions Act***, provides that:

No subsidiary legislation shall be inconsistent with the provisions of an Act.

100. Similarly section 24 (2) of the ***Statutory Instruments Act*** provides:

A statutory instrument shall not be inconsistent with the provisions of the enabling legislation, or of any Act, and the statutory instrument shall be void to the extent of the inconsistency.

101. In my view, it does not matter whether the particular statutory instrument or subsidiary legislation was made before or after the provision of the Act in issue was enacted. Once there is an inconsistency between the provision(s) of the Act and the subsidiary legislation or the instrument made pursuant to the Act, that instrument or subsidiary legislation must give way. To that extent I agree with the position adopted in **U.S vs. Butler, 297 U.S. 1[1936],** that:

"When an Act of Congress is appropriately challenged in the courts as not conforming to the constitutional mandate, the judicial branch of the government has only one duty; to lay the article of the Constitution which is invoked beside the statute which is challenged and to decide whether the latter squares with the former. All the court does, or can do, is to announce its considered judgment upon the question. The only power it has, if such it may be called, is the power of judgment. This court neither approves nor condemns any legislative policy. Its delicate and difficult office is to ascertain and declare whether the legislation is in accordance with, or in contravention of, the provisions of the Constitution..."

102. This was the view adopted by this Court in **Republic vs. Council of Legal Education & Another Ex-Parte Mount Kenya University [2016] eKLR**, where it held that:

"The confusion however seems to have been introduced by Regulation 16(1)(d) which suggests that the Council is empowered to order an education institution to discontinue providing legal education or training where the institution is not accredited by the Council. However as rightly pointed out the *Council of Legal Education (Accreditation of Legal Education Institutions) Regulations, 2009*, being subsidiary legislation cannot override the express provisions of the *Universities Act* by dint of section 31 of the *Interpretation and General Provisions Act* which provides that, "*no subsidiary legislation ought to be inconsistent with an Act of Parliament.*"…This principle was adopted by the Uganda Court of Appeal in David Sejjaka Nalima vs. Rebecca Musoke Civil Appeal No. 12 of 1985 where it was held that: "According to principles of construction if the provisions of a later Act are so inconsistent with or repugnant to those of an earlier Act that the two cannot stand together, the earlier Act stands impliedly repealed by the latter Act. It is immaterial whether both Acts are Penal Acts or both refer to Civil Rights. The former must be taken to be repealed by implication. Another branch of the proposition is that if the provisions are not wholly inconsistent in their application to particular cases, then to that extent the provisions of the former Act are exempted or their operation is excluded with respect to cases falling within the provisions of the Act."

103. However before the Court finds that a particular instrument or subsidiary legislation is inconsistent with the Act, it must be satisfied that the two provisions cannot stand together. What the Court is required to do is to construe the instrument with the necessary alterations, adaptations, qualifications and exceptions necessary to bring it into conformity with the Act. It is only when the instrument cannot, despite such construction, conform to the Act that the Court would be entitled to nullify the instrument. In other words the Court ought to, as was held in **David Sejjaka Nalima vs. Rebecca Musoke Civil Appeal No. 12 of 1985** ask itself whether t**he two instruments can stand together, so that if the provisions are not wholly inconsistent in their application to particular cases, then to that extent the provisions of the former Act are exempted or their operation is excluded with respect to cases falling within the provisions of the Act. In my view, it is in these circumstances that the Court is empowered to "read in" certain stipulations in a statute in order to give meaning to it rather than opt for the drastic remedy of nullifying an otherwise useful provision. This, in my view is the position of Cooper Brookes (Wollongong) PTY Ltd. vs. Federal Commissioner of Taxation (1981) 147 CLR 297** where it was held that:

"**If the choice is between two strongly competing interpretations…the advantage may lie with that which produces the fairer and more convenient operation so long as it conforms to the legislative intention.**"

104. In this case rule 10 does not specify who is to carry out the inspection but simply enjoins the Board to ensure that inspection is carried out by the relevant agencies. In this case the relevant agency is the National Quality Control Laboratory. It is therefore my view that rule 10 ought to be read in a manner that enjoins the Board to ensure that the inspection and certification of the relevant premises are inspected by the Laboratory before licences are issued or registrations effected. To that extent I find that Rule 10 of the ***Pharmacy and Poisons (Registration of Drugs) Rules*** is not inconsistent with the provisions of sections 35A(5) and 35I(b) of the ***Pharmacy and Poisons Act.***

105. It was contended that since impugned the decision (one dated 10th March, 2016) was withdrawn on 29th June, 2016, there is no decision to be quashed. It is not in doubt that by a circular Ref: MOH/ADM/BOARDS//13/1/12/VOL.III/36 dated 29th June, 2016 the Board withdrew the letter Ref: MOH/ADM/1/2/17/Vol.1. However, Section 11 of the ***Fair Administrative Action Act, 2015*** provides as follows:

> ***(1) In proceedings for judicial review under section 8 (1), the court may grant any order that is just and equitable, including an order***
>
> ***(a) declaring the rights of the parties in respect of any matter to which the administrative action relates;***
>
> ***(b) restraining the administrator from acting or continuing to act in breach of duty imposed upon the administrator under any written law or from acting or continuing to act in any manner that is prejudicial to the legal rights of an applicant;***
>
> ***(c) directing the administrator to give reasons for the administrative action or decision taken by the administrator;***
>
> ***(d) prohibiting the administrator from acting in a particular manner;***
>
> ***(e) setting aside the administrative action or decision and remitting the matter for reconsideration by the administrator, with or without directions;***
>
> ***(f) compelling the performance by an administrator of a public duty owed in law and in respect of which the applicant has a legally enforceable right;***
>
> ***(g) prohibiting the administrator from acting in a particular manner;***
>
> ***(h) setting aside the administrative action and remitting the matter for reconsideration by the administrator, with or without directions;***
>
> ***(i) granting a temporary interdict or other temporary relief; or***
>
> ***(j) for the award of costs or other pecuniary compensation in appropriate cases.***

106. This provision is similar in terms to Article 23 of the Constitution provides that a court "may grant appropriate relief, including a declaration of rights". “Appropriate relief” in my view must mean an effective remedy. This must necessarily be so, for without effective remedies for breach, the values underlying and the rights entrenched in the Constitution cannot properly be upheld or enhanced. This Court is therefore empowered to fashion appropriate remedies. One must therefore recall the words of **Lord Denning** in **O’Reilly vs. Mackman [1982] 3 WLR 604, 623** that:

> **“Just as the pick and shovel is nolonger suitable for the winning of coal, so also the procedure of mandamus, certiorari, and actions on the case are not suitable for the winning of freedom in the new age. They must be replaced by new up-to-date machinery, by declarations, injunctions, and actions for negligence...We have in our time to deal with changes which are of equal constitutional significance to those which took place 300 years ago. Let us prove ourselves equal to the challenge. Now, over 30 years after, we do have the new and up-to-date machinery...To revert to the technical restrictions...that were current 30 years or more ago would be to reverse that progress towards a comprehensive system of administrative law that I regard as having been the greatest achievement of the English courts in my judicial lifetime. So we have proved ourselves equal to the challenge. Let us buttress our achievement by interpreting section 31 in a wide and liberal spirit. By so doing we shall have done much to prevent the abuse or misuse of power by any public authority or public officer or other person acting in the exercise of a public duty.”**

107. Mercifully for us the law now empowers the Court in judicial review proceedings to make declaratory orders.

108. It was contended that section 44 of the ***Pharmacy and Poisons Act***, which empowers the Cabinet Secretary in consultation with the Board to make rules with respect to stipulated matters does not include the registration of drugs. Thus, the entire ***Pharmacy and Poisons (Registration of Drugs) Rules***, including Rule 10, are ultra-vires the powers of the 2nd and 4th Respondents. Accordingly, the said Rules are hanging without foundation in the Act since registration of drugs should be regulated by substantive Act.

109. It is true that where an authority is empowered to make subsidiary legislation, that mandate must strictly be in accordance with the provisions of the enacting statute. In other words an authority must only act pursuant to the enabling legal provision. This was the position in **Republic vs. County Council of Murang'a Ex Parte Makuyu Transporters Self Help Group & Others Nyeri HCMCA No. 40 of 2009** where **Sergon, J** expressed himself as follows:

> **"The main argument of the applicant is that the Respondent had no discretion to increase fees under section 18 of the Local Government Act. It is also stated that the Respondent did not consult the applicants as required under rules 8 and 9 of the Local Government (Single Business Permit) Rules, 2008. This submission is correct since the Respondent purported to exercise discretion under the wrong provisions of the law. The Respondent had no jurisdiction to do so under section 18 of the Local Government Act and therefore acted outside the law. The best thing the respondent could have done was to withdraw the gazette notice but it opted to soldier on. Consequently on this account alone the motion is found to be with merit."**

110. As has been held time without a number, where a statute donates powers to an authority, the authority ought to ensure that the powers that it exercises are within the four corners of the statute and ought not to extend its powers outside the statute under which it purports to exercise its authority. In **Republic vs. Kenya Revenue Authority Ex Parte Aberdare Freight Services Ltd & 2 Others [2004] 2 KLR 530** it was held that the general principle remains however, that a public authority may not vary the scope of its statutory powers and duties as a result of its own errors or the conduct of others.

111. I therefore associate myself with the position in **Kenya Commercial Bank Ltd vs. Kenya National Commission on Human Rights [2008] eKLR** where it was held at page 15, *inter alia* that:

> **"We are also of the view that Regulation 27 is ultra vires the Act because it has no underpinning in the Act…Regulations which should basically provide for procedure cannot be made to displace the substantive law under the Act. Regulation 27 is hanging with no foundation in the Act and we find that it is ultra vires the Act."**

112. Section 44 of the ***Pharmacy and Poisons Act*** provides that:

> ***(1) The Minister may, after consultation with the Board, make rules with respect to any of the following matters or for any of the following purposes—***
>
> ***(a) Prohibiting the sale by retail of a specified Part I poison except on a prescription duly given by a duly qualified medical practitioner, dentist or veterinary surgeon and for prescribing the form and regulating the use of those prescriptions;***
>
> ***(b) prohibiting, regulating or restricting the sale of Part II poisons or of any specified Part II poisons by any of the persons licensed under section 28 or section 32 or by any class of those persons;***
>
> ***(c) exempting from any of the provisions of this Act relating to the sale of poisons any article or substance containing poison or any class of those articles or substances or for dispensing with or***

relaxing with respect to poisons any of the provisions contained in Part III;

(d) Prohibiting, regulating or restricting the manufacture, sale or advertising of drugs, pharmaceutical preparations and therapeutic substances;

(e) The safe custody and storage of poisons;

(f) The importation, exportation, transport and labeling of poisons;

(f) the importation and exportation of drugs;

(g) The containers in which poisons may be supplied;

(h) The addition to poisons of specified ingredients for the purpose of rendering them readily distinguishable as poisons;

(i) The compounding and dispensing of poisons;

(j) The period for which books or registers required to be kept for the purposes of this Act is to be preserved;

(k) The fees to be paid for anything to be done under this Act;

(l) The procedure to be observed by the Board;

(m) The conduct of inquiries by the Board under section 12 and the attendance of witnesses and the production of evidence thereat;

(mm) prescribing the qualifications for registration of pharmaceutical analysts;

(n) Anything which is by this Act required or authorized to be prescribed.

(2) The power to make rules under this section with respect to poisons or drugs includes the power to make rules with respect to any class of poisons or drugs or any particular poison or drug.

113. It is clear that the ***Pharmacy and Poisons (Registration of Drugs) Rules*** do not disclose under which provision of the law they were made. That omission however does not necessarily render the rules unlawful if a basis therefor can be found within the parent Act. Section 44(1)(n) of the Act empowers the Cabinet Secretary to make rules with respect to *"anything which is by this Act required or authorized to be prescribed"*. It has not been contended that the said rules are not required or necessary for the proper implementation of the Act. Accordingly, I do not agree that they ought to be nullified on that basis alone.

114. I must however disabuse the Board of the notion that this Court in the exercise of its judicial review jurisdiction has no power to declare an instrument as being inconsistent with the parent legislation. In **Re Bivac International SA (Bureau Veritas) [2005] 2 EA 43** the Court appreciated that:

> **"…judicial review…has become the most powerful enforcer of constitutionalism, one of the greatest promoters of the rule of law and perhaps one of the most powerful tools against abuse of power and arbitrariness."**

115. Whereas the Board's position may have carried weight under the retired Constitution, that is nolonger the position under the current transformative Constitution under which Article 23(3) provides that:

> ***In any proceedings brought under Article 22, a court may grant appropriate relief, including—***

i. a declaration of rights;

ii. an injunction;

iii. a conservatory order;

iv. a declaration of invalidity of any law that denies, violates, infringes, or threatens a right or fundamental freedom in the Bill of Rights and is not justified under Article 24;

v. an order for compensation; and

vi. an order of judicial review.

116. Judicial review is therefore nolonger just a statutory or common law remedy but is a constitutional remedy hence the distinction between judicial review remedies and constitutional remedies have become more blurred than ever. In jurisdictions with similar constitutions as ours, this position has been held to ring true. This was the position of **Chaskalson, P** in the Constitutional Court of South African case of **Pharmaceutical Manufacturers Association of South Africa & Another vs. Minister of Health Case CCT 31/99** where he held that:

> **"Powers that were previously regulated by the common law under the prerogative and the principles developed by the courts to control the exercise of public power are now regulated by the Constitution…Whilst there is no bright line between public and private law, administrative law, which forms the core of public law, occupies a special place in our jurisprudence. It is an incident of the separation of powers under which courts regulate and control the exercise of public power by the other branches of government. It is built on constitutional principles which define the authority of each branch of government, their inter-relationship and the boundaries between them. Prior to the coming into force of the interim Constitution, the common law was "the main crucible" for the development of these principles of constitutional law. The interim Constitution which came into force in April 1994 was a legal watershed. It shifted constitutionalism, and with it all aspects of public law, from the realm of common law to the prescripts of a written constitution which is the supreme law. That is not to say that the principles of common law have ceased to be material to the development of public law. These well-established principles will continue to inform the content of administrative law and other aspects of public law, and will contribute to their future development. But there has been a fundamental change. Courts no longer have to claim space and push boundaries to find means of controlling public power. That control is vested in them under the Constitution which defines the role of the courts, their powers in relation to other arms of government, and the constraints subject to which public power has to be exercised. Whereas previously constitutional law formed part of and was developed consistently with the common law, the roles have been reversed. The written Constitution articulates and gives effect to the governing principles of constitutional law. Even if the common law constitutional principles continue to have application in matters not expressly dealt with by the Constitution, (and that need not be decided in this case) the Constitution is the supreme law and the common law, in so far as it has any application, must be developed consistently with it, and subject to constitutional control."**

117. I therefore do not see any bar to the Court exercising its judicial review jurisdiction declaring an instrument unlawful or even that the same is unconstitutional as long as the Court is so satisfied.

118. However, to the extent therefore that the Principal Secretary issued the circular Ref: MOH/ADM/1/2/17/VOL.I of 10th March, 2016, stopping the National Quality Control Laboratory from performing the functions conferred by section 35A(5) and 35I(b) of the ***Pharmacy and Poisons Act***, CAP 244 Laws of Kenya, the Principal Secretary acted illegally and in excess of his powers. By his actions, the Principal Secretary purported to render an Act of Parliament in-operational. I daresay that by a stroke of the pen in form of a circular, the Principal Secretary rendered a provision of an Act of Parliament a dead

letter of the law. This, in my view, is the highest form of impunity by a member of the executive. When a member of the executive takes it upon himself to render an enactment by Parliament superfluous by issuing directives which are clearly unlawful, it can only be a manifestation of what **Warsame, J** (as he then was) decried in **Mohamed Aktar Kana vs. Attorney General Nairobi HCCP No. 544 of 2010.** To paraphrase the learned judge, the new Constitutional dispensation has introduced a system of governance under the Constitution. These principles enjoin state officers to adhere to the national values and principles of governance under Article 10 of the Constitution which include the rule of law. Public offices, it must be remembered are held in trust for the people of Kenya and therefore Public Officers must carry out their duties for the benefit of the people of the Republic of Kenya. They must remember that under Article 129 of the Constitution executive authority derives from the people of Kenya and is to be exercised in accordance with the Constitution in a manner compatible with the principle of service to the people of Kenya, and for their well-being and benefit. To operate outside the law in my view amounts to perpetuation of a fundamental breach of the Constitution and to legalise impunity at this very young age of our Constitution. Those who accept to serve in public offices must be guided by the provisions of the Constitution and cannot be permitted to breach the Constitution with remarkable arrogance or ignorance and that is my view of an action taken with a view to undermine the legislative mandate. In this case it was contended which contention was no seriously disputed that the Laboratory sought the opinion of the Attorney General on the matter and vide letter of 7th November, 2014 the Attorney General requested the Principal Secretary to convene a meeting between the Laboratory and the Board for him to deliver his legal advice but the Ministry of Health instead reprimanded the Director of the Laboratory for having requested the Attorney General's legal opinion, and the Ministry never invited the Attorney General to render his legal opinion thereon.

119. The importance of the Attorney General's view on the interpretation of the law was emphasised by **Nyamu, J** (as he then was) in **Midland Finance & Securities Globetel Inc vs. Attorney General and Another [2008] KLR 650** in which the Learned Judge cited with approval the decision **Bank of Uganda vs. Banco Arabe Espanol [2007] EA 333** that:

> **"The opinion of the Attorney General as authenticated by his own hand and signature regarding the laws…and their effect or binding nature or any agreement contract or other legal transaction should be accorded the highest respect by government and public institutions and their agents…It is improper and untenable for the Government…or any other public institution or body in which the Government…has an interest to question the correctness or validity of that opinion in so far as it affects the rights and interest of 3rd parties. As a country we must have and maintain an acceptable measure or standard of public morality and the Attorney General should be held to his bargain, both on the ground of public morality and on the principle of good faith (*pacta sunt servanda*)."**

120. It is therefore highly advisable for public servants, the government and its institutions to seek the legal opinion of the Attorney General in areas where they are not sure of how to proceed with their proposed action and abide by the same in order to avoid rushing in decision which may well turn out to be reckless and unlawful hence subject the tax payer to unnecessary costs.

121. It was contended that since Rule 10 was made more than six months before these proceedings were instituted this Court cannot quash the same. This contention was based on Order 53 rule 2 of the ***Civil Procedure Rules*** which provides that:

> ***"Leave shall not be granted to apply for an order of certiorari to remove any judgment. Order, decree, conviction or other proceedings for the purposes of its being quashed unless the application for leave is made not later than six months after the date of the proceeding or such shorter period as may be prescribed by any Act, and when the proceeding is subject to appeal and time is limited by law for the bringing of the appeal, the judge may adjourn the application for leave until the appeal is determined or the time for appealing has expired."***

122. This provision was the subject of the decision in **Rep vs. The Judicial Commissioner of Inquiry Into the Goldenberg Affair and Others Ex Parte Jackson Mwalulu Misc. App.1279/04** where,

Nyamu, **Ibrahim** and **Makhandia** held that:

> **"The 6 months limitation only applies to formal judgments, orders, decrees, convictions or other proceedings from an inferior court or Tribunal but not any other decision by a tribunal or other body and does not apply to decisions that are nullities. The court observed that Order 53 rule 2 Civil Procedure Rules did not include anything covered by the principle of ultra vires or nullities or decisions made without jurisdiction and I am inclined to agree with the latter decision. Order 53 Rule 2 Civil Procedure Rules must apply to the matters listed hereunder but a decision which is a nullity 'ab initio' is no decision at all and an order of certiorari can lie at any time. In the circumstances, the Bylaws/Regulations cannot be said to be challenged outside the time allowed but it is upon the Applicant to demonstrate that they are nullities or made without jurisdiction. This court would have jurisdiction to hear and determine the matter."**

123. A similar conclusion was arrived at in **Kenya Commercial Bank Ltd vs. Kenya National Commission on Human Rights [2008] eKLR,** where **Nyamu**, **Wendo** and **Dulu, JJA** in granting the leave held that:

> **"What is sought to be quashed is the Regulations which are said to have been gazetted on 16/9/05 vide Gazette Supplement 67 of 2005 and yet this application was filed on 16/11/06, over a year after the gazettement. We do agree with the submission by Mr. Ojiambo and which submission we subscribe to, that Order 53 Rule 2 only relates to the challenge of formal orders set out under that rule that is judgments, decrees, orders etc. It does not apply to other decisions like this situation. This has been so held in Rep. Vs. National Hospital Insurance Fund Ex Parte Cotu. Misc. 1747/04 And Republic Vs. Judicial Commission Of Enquiry Into The Golden Berg Affair ex parte Mwalulu HCCC 1279/04. In the latter case, the three Judge bench also held that the 6 month's limitation only applies to formal orders mentioned in Rule 2 and nothing else and that it does not apply to decisions which are null *ab initio*."**

124. It is therefore my view that whereas speed is key to the exercise of discretion in granting judicial review relief, the six months period does not apply to these proceedings.

125. Having considered the issues raised herein I do make the following findings:

> **1. That these proceedings are not time barred.**
>
> **2. The Pharmacy and Poisons Board and the National Quality Control Laboratory play complementary but distinct roles in ensuring that the medicinal substances being manufactured are up to the standards prescribed.**
>
> **3. Whereas the power to licence premises for the manufacture of medicinal substances rests with the Pharmacy and Poisons Board, the National Quality Control Laboratory is the entity empowered to enter such premises and sample any medicinal substances under production in such premises and to certify that the method of manufacture approved by the Board is being followed. In other words the Board deals with setting standards while the Laboratory ensures that the said standards are adhered to as set by the Board and to advice the Board accordingly.**
>
> **4. That the *Pharmacy and Poisons (Registration of Drugs) Rules*, are not ultra-vires the powers of the 2nd and 4th Respondents.**
>
> **5. That Rule 10 of the *Pharmacy and Poisons (Registration of Drugs) Rules* is not inconsistent with with the provisions of sections 35A(5) and 35I(b) of the *Pharmacy and Poisons Act.***
>
> **6. That to the extent therefore that the Principal Secretary issued the circular Ref:**

MOH/ADM/1/2/17/VOL.I of 10th March, 2016, stopping the National Quality Control Laboratory from performing the functions conferred by section 35A(5) and 35I(b) of the *Pharmacy and Poisons Act*, CAP 244 Laws of Kenya, the Principal Secretary acted illegally and in excess of his powers.

Orders

126. In the premises I hereby issue the following orders:

1. Declaration that the decision of the 3rd Respondent, the Principal Secretary of Ministry of Health vide circular Ref: MOH/ADM/1/2/17/VOL.I of 10th March, 2016, stopping the National Quality Control Laboratory from performing the functions conferred by Section 35A(5) and 35I(b) of the *Pharmacy and Poisons Act*, CAP 244 Laws of Kenya, unlawful.

2. An order of prohibition to prohibiting and restraining the 4th Respondent (Pharmacy and Poisons Board) from by usurping the functions of the National Quality Control Laboratory of inspecting premises and issuing certificates of compliance to Good Manufacturing Practices (GMP); by sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of manufacture is being followed, as provided for in sections 35 A (5) and 35 I (b) of the *Pharmacy and Poisons Act*, CAP 244 Laws of Kenya; as well as those under section 35D of analytical testing of medicinal samples.

3. An order of mandamus to compel the 5th Respondent (National Quality Control Laboratory) to perform its functions as conferred in Sections 35 A (5) and 35 I (b) of the Pharmacy and Poisons Act, CAP 244 of inspecting premises and issuing certificates of compliance to Good manufacturing Practices (GMP); by sampling any medicinal substance under production in any manufacturing premises to certify that the approved method of manufacture is being followed.

4. Costs of these proceedings are awarded to the applicant to be borne by the 1st, 2nd and 3rd Respondents.

127. Orders accordingly.

Dated at Nairobi this 16th day of March, 2017

G V ODUNGA

JUDGE

Delivered in the presence of:

Mr Naikuni with Mr Larabi for the 4th Respondent

Miss Chimau for Mr Munene for the 1st, 2nd and 5th Respondents and holding brief for Mr Masika for the applicant

CA Mwangi