

The background of the top half of the cover is a photograph of several books standing upright on a shelf. The focus is on the spines of the books, which are slightly blurred, creating a sense of depth. The colors of the spines are muted, including shades of brown, blue, and white.

Kenya Association of Pharmaceutical Industry

Strategic Plan 2021 – 2025

Foreword

The Kenya Association of Pharmaceutical Industry (KAPI) as an industry association is keen on driving policy, regulatory and legislative agendas focused on improving access to safe, quality-assured biopharmaceutical products and technologies to the Kenyan people. This is to be realized through evidence based policy advocacy for an enabling business environment for the member companies while feeding into the national agenda for Universal Health Coverage (UHC) and National Prosperity.

Additionally, we acknowledge the critical role played by different stakeholders in the healthcare space both in health service delivery by the healthcare providers (HCPs), regulation of health products, technologies and practice and the healthcare financing mechanism among others. Anchored on this and our commitment to sustainable systems in the health space, we set forth to review our previous plan, consult with stakeholders and collate insights that will guide our operations in the subsequent years i.e., 2020/2024.

As we developed and now set out to implement this Strategic Plan 2020/2024, our commitment to excellence is never stronger, the agility is not capped and collaboration will be the fuel that helps us in the realization of these aspirations. Through mutually beneficial engagements with stakeholders, socially conscious advocacy for policy matters and strengthened internal processes, the next phase is an era to redefine healthcare business in the country.

We urge you to join us on this journey and be part of the process, acknowledging that we all have a part to play.

Thank You,

Dr Anastasia Nyalita

Immediate Past Chairperson

Kenya Association of Pharmaceutical Industry (KAPI)

Acknowledgement

Willy Soriney

Chairperson

Kenya Association of Pharmaceutical Industry

List of Abbreviations

CAS	Chief Administrative Officer
DG	Director General
HIV/AIDS	Human immune-deficiency virus infection and Acquired Immune Deficiency Syndrome
IFPMA	International Federation of Pharmaceutical Manufacturers & Associations
IGAD	Intergovernmental Authority on Development
ICT	Information and Communications Technology
KAPI	Kenya Association of the Pharmaceutical Industry
KES.	Kenya Shillings
KEPSA	Kenya Private Sector Alliance
KHF	Kenya Healthcare Federation
KHPOA	Kenya Health Professions Oversight Authority
KMA	Kenya Medical Association
KPA	Kenya Association of Pharmaceutical Technicians
KRA	Kenya Revenue Authority
KOGS	Kenya Obstetrical and Gynecological Society
M&E	Monitoring and Evaluation
NEMA	National Environment Management Authority
NNAK	National Nurses Association of Kenya
NQCL	National Quality Control Laboratory
PESTEL	Political, Economic, Socio-Cultural, Technological, Environmental, and Legal Factors analysis
PPB	Pharmacy and Poisons Board
PR	Public Relations
PSK	Pharmaceutical Society of Kenya
SGDs	Sustainable Development Goals
SWOT	Strengths Weaknesses Opportunities and Threats analysis

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Executive Summary

This Strategic Plan 2021/2025 is a continuation and build up to the previous Strategic Plan 2014 – 2018 of the Kenya Association of Pharmaceutical Industry (KAPI).

It provides key strategic directions after sixty years of building and nurturing on the foundations of the organization with the aim of representing manufacturers (or their local representatives) that through research invent and develop health products and technologies (i.e. Biopharmaceuticals, Vaccine Healthcare, Medical devices, Diagnostics) that significantly improve people’s lives. KAPI represents the industry voice and promotes efficiency in the pharmaceutical industry to ensure that health products and technologies of the highest quality can be readily available for diagnosis, health promotion, prevention and treatment of diseases.

Developed through a participatory process that included internal and significant external stakeholders of KAPI, the plan provides an elaborate route map that will steer the organization for the next five years in the new contexts of a changing public health, regulatory and policy environment. In its development, a contextual analysis of the external environmental scan using PESTEL analysis and an internal SWOT analysis, was undertaken to evaluate the strategic options and direction chosen.

The plan provides the strategic direction, emerging themes, objectives, time-frame, measures and resource requirements necessary for KAPI interventions in leadership and governance, resource mobilization and service provision, collaborations and partnerships and communications and public relations.

The mission has remained consistent with the vision changing slightly with inclusion of “technologies” so as to align with the Health Act as well as adapt and remain relevant in the changing environment. The core values were maintained and in line with the vision, and mission.

The strategic architecture of the Plan period are as follows:

- Leadership & Governance
- Resource Mobilization & Service Provision
- Collaborations & Partnerships
- Communications, ICT & Public Relations
- Corporate Social Responsibility

These will be achieved through the following core objectives:

- Ethics
- Excellence
- Integrity
- Partnerships

These core objectives will be implemented through the leadership and management structures as stipulated and mandated by the KAPI constitution comprising of the following:-;

- i. The Annual General Meeting;
- ii. The Executive Board;
- iii. The Secretariat led by the CEO and

iv. The Standing Committees

The leadership and governance will be achieved through the Executive Committee as the Board of Directors steering the strategy plan through the determination of the mission and strategy and the use of code of conduct and good governance in steering the organization, while providing oversight and support to the secretariat headed by the CEO.

In resource mobilization and services provision, the association will continuously strive to improve its service offering to members and explore more opportunities to enhance and diversify them based on new value additions obtained through an interactive feedback engagement with the members. A phased implementation to a full-fledged secretariat to be headed by a substantive CEO is considered necessary for the efficiency and effectiveness of the association and its continued sustainability.

Collaborations and partnerships with various external stakeholders on regulation, research, trade and policy, and funding will be forged with current and prospective local and international stakeholder within the pharmaceutical industry and other stakeholders with direct or indirect impacts on the industry.

In order to build the association's professional brand name and maintain relevance and visibility, communications and public relations with various contacts and the general public will be enhanced and maintained. This will be advanced by leveraging the use of Information Communication Technology (ICT) for the dissemination of information on matters relating to the industry of public interest especially on regulation, public health and trade practices. These will be guided by strong and reliable communications and PR strategy, tactics and events.

Tracking will be implemented through a monitoring and evaluation matrix over the five year period, and segmented into annual plans for ease of performance review, analysis and remedial correction, where key targets are not being met.

1. Background

1.1 Introduction

This section provides an overview of the Kenya Association of Pharmaceutical Industry (KAPI), its background, guiding principles and mandate, and the methodology utilized in the development of the 2021 – 2025 strategic plan.

1.2 Kenya Association of Pharmaceutical Industry (KAPI)

Kenya Association of Pharmaceutical Industry (KAPI) is a membership organization, established in the late 1960s, representing manufacturers (or their local representatives) that through research invent and develop health products and technologies (e.g., Biopharmaceuticals, Vaccine Healthcare, Medical devices, Diagnostics) that significantly improve people's lives. KAPI represents the industry voice and promotes efficiency in the pharmaceutical industry to ensure that medical products and healthcare technologies of the highest quality can be readily available for diagnosis, health promotion, prevention and treatment of diseases.

The organization is guided by its pillars as espoused in its vision, mission and core values which are covered exhaustively in the Strategic Direction and Focus section in this document.

1.3 Rationale for 2021 – 2025 Strategic Plan

The development of this Strategic Plan has been necessitated by the changing regulatory and practice environment of the association and a need to be positioned, suited and responsive to the market trends. This is to ensure that strategies are developed to overcome the anticipated challenges and to ensure the realization of the strategic objectives through successful implementation of the key initiatives as outlined by this strategic plan.

The process entailed a review of the previous Strategic Plan 2014-2018 looking at the achievements of the organization from the previous strategy, lessons learnt, the strengths that can be capitalized on and the challenges/shortfalls to be addressed. We mainly reviewed the performance against targets, institutional strengths and weaknesses, and the financial performance.

1.4 Approach and Methodology used in Strategy Development

A participatory approach and methodology was used in the development of the strategic plan including literature review, key informant interviews with both internal and external stakeholders, a membership survey administered digitally through SurveyMonkey to collect and collate views and opinions on current and proposed enhancements to the strategic plan.

The Executive Board strategy planning team reviewed members' inputs which are incorporated in this output document, with a realignment of the vision, maintenance of the mission and mandate for improved service delivery to members.

2. Contextual Analysis

2.1 Introduction

This section covers the contextual analysis both in terms of the external and internal environments of the firm through the use of the Political, Economic, Social, Technological, Environmental, and Legal (**PESTEL**) framework analysis tool that scans the external uncontrollable factors that may impact on the organization and the Strengths, Weaknesses, Opportunities and Threats (**SWOT**) analysis. The strengths and weaknesses are internal controllable factors which the management can use to mitigate for or against the external opportunities and threats faced by the organization.

2.2 PESTEL Analysis

The PESTEL analysis of the external environment impacting on the organization are as follows;

2.2.1 Political Factors

- The political environment in Kenya has remained relatively stable though transitional due to political uncertainties heightened markedly during pre-election and election periods.
- Universal and Primary Healthcare initiatives to improve access and affordable healthcare services in line with Vision 2030 and Sustainable Development Goals (SDGs),
- The Big Four Agenda with Universal Healthcare Coverage (UHC) as a strategic pillar
- Emergence of Regional integration and Harmonization Agencies that are likely to lead to expected changes in rules and guidelines
- Government Taxation: Evolving tax regime creates unpredictability in business operations e.g. the railway levy, effects of the VAT Bill increasing taxation of healthcare commodities such as medical devices and some medicines.
- Policy changes e.g. introduction of ICT in government functions, free maternity services.
- Multiple regulations and concomitant fees from non-pharmaceutical bodies such as Nursing Council of Kenya, Kenya Medical Laboratory Technicians and Technologists Board.
- Emerging local Pharmaceutical manufacturing sector.

2.2.2 Economic Factors

- Middle class growth means that there is increased healthcare spend
- Middle class growth may also pose changes in lifestyle and increase in lifestyle diseases.
- The threat of substandard and falsified medicines subjects KAPI Member companies to commercial and patient service risks.
- There has been an increase in generic players and number of generic products accessible to the general population and this has influenced the market trends for branded medicines and products
- More out of pocket expenditure on healthcare by patients due to low penetration of health insurance schemes.
- The rising unemployment rate, especially in the youth age category, inflation, income inequality and poverty are putting pressure on living standards and reduction of consumer purchasing power which directly affects the ability of the citizenry to pay for services including healthcare.

2.2.3 Social and Cultural Factors

- Changing access to healthcare through donor funded programmes. The longevity of these programmes is under threat due to decreased funding from donors because of either global economic and political issues or increased GDP Per Capita making Kenya ineligible for funding from some programmes.
- Patients who are more aware of their rights to access to healthcare services and medicines, such as the push from the diabetes or cancer advocacy groups to increase access to medicines
- The current impact of the COVID-19 has led to inappropriate stocking of medicines.
- Urbanization currently at about 25% of whom 76% live in informal settlements
- There is an increase in self-medication driven by economic and access to service.
- Epidemiological disease pattern change from communicable diseases to non-communicable diseases

2.2.4 Technological Factors

- Technological factors and advancements impacts on healthcare provision- through telemedicine, eLearning, robotic surveying, eHealth systems and ePayment.
- Increased awareness/access to health information through sources such as internet and GSM mobile information, health columns in news media.
- Access to healthcare and Health insurance through mobile money platforms.
- Technology in the management of health issues such as the use of SMS in management of TB Patients and dial-a-doctor services.

2.2.5 Environmental Factors

- Climate change that affects food production and nutrition, incidences of disease outbreaks and water and sanitation
- Challenges on disposal of unused and expired drugs

2.2.6 Legal and Regulatory Factors

- Conformance to legal provisions and legal requirements
- Legislations e.g. Health Act 2019, Kenya Health Professions Oversight Authority (KHPOA) and the creation of regulatory bodies for the registration, licensing and inquiry of healthcare professionals of which the membership is drawn.
- Emerging regulatory provisions

2.3 SWOT Analysis

The SWOT analysis of the internal strengths and weaknesses and the external opportunities and threats impacting on the organization are as follows;

2.3.1 Strengths

- Member companies producing innovative products with a rich history of new product development.
- Members are diverse frontliners in the pharmaceutical industry with a good technical knowledge base.

- Good local, regional and international reputation. e.g. KHF/ IFPMA affiliation with a strong global goodwill
- Commitment to ethics and common stance on issues due to good internal cohesion among members.
- Good financial base through member subscription.
- Strong Corporate Governance
- Professional membership.

2.3.2 Weaknesses

- Historical inconsistency due to lack of strong institutional framework.
- Lack of a permanent operational base and secretariat and therefore burdening the membership.
- Competition of member's time and resources between company time and KAPI.
- Absentia in meetings and low participation of members in KAPI initiatives.
- Limited diversity of representation in the sector with need to diversify and expand membership categories through the constitutional amendments
- Holding of elections annually affects strategy implementation continuity

The organization will adopt intervention measures to mitigate upon these weaknesses so as to limit the negative impacts on organization strategic objectives.

2.3.3 Opportunities

- Expansion of membership
- Constitutional review
- Broader scope of work and influence
- Regional economic blocs broadens influence and access to a larger market and provides opportunity for single point of influence through harmonized regulatory platforms. KAPI resources base provides opportunity to influence the larger market
- Recognition by international government and partners offers opportunity for greater influence
- Institutionalization of KAPI provides opportunity to be more influential and draw more members
- Networking with other stakeholders increases opportunity to influence the industry
- Health is among the Governments' Big Four Agenda

2.3.4 Threats

- Regulatory inefficiencies such as delayed registration, lack of implementation of existing guidelines and many guidelines still in draft stage hence leading to delayed access to medicines.
- Outdated regulatory framework, e.g. CAP 244, Laws of Kenya.
- Corruption leading to increased cost of doing business.
- Proliferation of substandard and falsified products and illegal imports due to corruption and lack of proper regulatory controls.
- Duplicity of processes and regulatory bodies trying to regulate and hence making it difficult and costly to do business e.g. PPB, Nursing council, KMLTTB, KEBS, NQCL etc.
- Due to weak visibility of KAPI in various forums and authorities, critical input of KAPI as a stakeholder is disregarded and KAPI is not included in some stakeholder discussions.
- Numerous taxes being imposed on Pharmaceuticals and Medical devices e.g. Railway levy, VAT Bill.
- Unfavorable economic performance impacted by COVID-19 that may affect the ability of insurance in the health sector and affordability of medicines

- Lack of consistent synchronized short and long term legislation and policy direction in healthcare (Vision 2030 Vs. Big Four Agenda).
- High level corruption which diverts resources from investments in healthcare

3. Strategic Direction

3.1 Introduction

This segment provides Vision, Mission and Core Values which will provide the impetus for KAPI strategy into the future. In tandem with this, our strategic pillars provide the route map aligning our Strategic Direction to the Vision, Mission and Core Values.

3.2 KAPI Vision, Mission and Values

3.2.1 Vision Statement



To lead in the provision of innovative world class quality healthcare solutions, products, technologies and services.

3.2.2 Mission Statement



To promote an ethical, innovative and responsible healthcare industry.

3.2.3 Core Values

Our vision and mission will be guided by and achieved through our fundamental core values which are:



- Ethics
- Integrity
- Excellence
- Partnerships

3.3 Strategic Pillars

The five strategic pillars of KAPI that the plan will be based on are;

1. Leadership & Governance
2. Resource Mobilization & Service Provision
3. Collaborations & Partnerships
4. Communications, ICT & Public Relations
5. Corporate Social Responsibility

3.3.1 Leadership & Governance

Leadership and Governance are the apex pillars that will anchor the success and sustainability of KAPI in providing guidance and implementation of our strategic plan and thus a key priority focus based on our Vision, Mission and supported by our Core Values that permeates through the

organizational matrix including the Executive Committee, Management Staff and the membership. This pillar is spelt out in the Constitution of our organization which establishes and elaborates the various roles, functions, responsibilities and accountabilities required at all levels. Based on the evolving and changing needs and circumstances of KAPI, amendments may be suggested and passed through the established channels to mirror on the new demands placed on the organization.

The Constitution of KAPI, provides an elaborate accountability of roles, responsibilities and duties to be undertaken by the following:

- i. Membership through the Annual General Meeting
- ii. The Executive Board
- iii. The Secretariat led by the CEO and
- iv. The Standing Committees

Using good governance principles of accountability and transparency together with the code of conduct, the Executive Committee is to provide leadership and guidance to the KAPI membership towards the realization of KAPI's mandate as articulated in the KAPI Constitution, KAPI's Vision and Mission Statements and ensure that through collaboration with the secretariat in the implementation and monitoring and evaluation of the strategic plan, the sustainability and viability of the organization is maintained and attained, and the desired levels stated.

The Executive Committee comprises of nine (9) members, namely;

- i. Chairperson
- ii. Vice Chairperson
- iii. Immediate Past Chairperson
- iv. Executive Secretary
- v. Honorary Treasurer
- vi. Four (4) Executive Board members

And a provision to co-opt subject matter experts by the board on a short term basis as shall be required.

The standing committees will include;

3.3.1.1 Trade, Policy and Regulation Committee

This committee is responsible for engagements with the relevant stakeholders on policy and trade matters in a timely and responsive manner and enables the association keep abreast with the dynamic changes on policy and trade as they occur. They are guided by the Committee Terms of Reference (TORs) as spelled out in accordance with the constitution.

3.3.1.2 The Compliance, Legal and Governance Committee

This committee is mandated to enable KAPI drive the promotion and embedding of ethical principles and practices in the pharmaceutical industry in Kenya in accordance with the KAPI CODE OF PRACTICE and the IFPMA guidance on good business practices. They are guided by the Committee Terms of Reference (TORs) as spelled out in accordance with the constitution.

3.3.1.3 Communications and Public Relations Committee

This committee is mandated to enable KAPI to engage with the relevant healthcare stakeholders in a coherent and responsive manner presenting accurate information and

building sound relationships between KAPI, its collaborators and stakeholders. It's also responsible in shaping public discourse in line with the mandate of the association. The committee is guided by the Committee Terms of Reference (TORs) as spelled out in accordance with the constitution.

3.3.1.4 Pharmacovigilance and Medical Affairs Committee

The committee is mandated to enable KAPI engage with relevant stakeholders in championing for quality care and patient safety. This is focused on the establishment of responsive pharmacovigilance systems and quality control measures to uphold the quality of medicines, healthcare products and technologies for the realization of positive treatment outcomes for all. The committee is guided by the Committee Terms of Reference (TORs) as spelled out in accordance with the constitution.

3.3.1.5 Medical Devices and Technologies Committee

The committee was recently instituted to guide the strategic direction and work of the association in streamlining business practices within the medical devices and healthcare technologies to ensure regulatory provisions are pro-business while factoring public health needs in the overall discourse. The committee is guided by the Committee Terms of Reference (TORs) as spelled out in accordance with the constitution.

To equip this important role, the organization, Executive Board, Senior Management, management and committee members will be trained and exposed to both internal and external Leadership and Governance Programs to enhance their skills and competencies to better execute their mandates, as stipulated in the Constitution.

The establishment of a fully-fledged and functional secretariat has been identified in previous plans as a key cog that is necessary in the running of the organization affairs. Several steps have been pursued towards achieving this objective, albeit with shortcomings due to limited financial and material resources, the secretariat as currently configured has not encompassed the ideal level envisaged in effectively and efficiently running the affairs of KAPI. This situation has necessitated some of the Executive Board members undertaking dual roles in management and oversight, which is not recommended in international good governance practice.

In the next five years, and using a phased approach, the organization is determined to have in place through competitive selection, a fully-fledged permanent secretariat headed by a substantive CEO and competent and capable management team, as detailed under the organizational structure section, in this plan. By doing this, the management and oversight will be divorced and in conformity with recommended Good Governance Practices. The Executive Board will provide overall guidance in setting the milestones and oversight on the strategic plan.

The secretariat will be equipped and tasked with the service delivery of the operational execution for strategy achievement, and with the support of the Executive Board Team, we are confident to the successful implementation of this plan. Other duties of the secretariat will be to ensure compliance to statutory internal and external obligations as stipulated by the constitution internally and the National Laws of Kenya.

3.3.2 Resource Mobilization and Service Provision

KAPI exists primarily as a platform to create an enabling environment for its members to offer and provide innovative world class quality healthcare solutions, products, technologies and services. In order to achieve this vision, it is of imperative importance for the association to mobilize resources and offer services to its membership. This will be achieved through:

- i. Maintaining and consciously expanding the products and services range,
- ii. Expanding membership eligibility,
- iii. Reviewing subscriptions that reflect fair value on products and services offered,
- iv. Focusing on value added projects and services for revenue stream diversification and
- v. Exploring other investment avenues available for the association.

The goal of this strategy pillar is to ensure sustainability of the association to perpetuity.

Continuous member's satisfaction surveys will be conducted to engage the members and offer an opportunity to receive feedback on the current products and services, and suggestions of what other areas in the value propositions can be expanded.

3.3.3 Collaborations & Partnerships

The old adage that a man is not an island aptly capture the need for the strategic pillar on collaborations and partnerships that the organization will forge with other actors including government and nongovernmental organizations, associations and societies both locally and globally. These will include and not be limited to regulatory agencies, trade associations, media, and the international umbrella association International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). KAPI will continuously scan the environment to develop collaborations with new partners during the strategy term period by leveraging on its links and networks.

KAPI will pro-actively seek to positively influence policy development through advocacy and earning a seat on forums anchored on its brand identity as a specialist authoritative reference point for pharmaceutical issues. This will enable engagement as an opinion leader earned and gained through the reputation of the association and its members.

3.3.4 Communications, ICT and Public Relations

To develop visibility of the association, KAPI will develop positive networks with the media and use this to communicate the organization's activities and contributions to the larger public. The use of internal ICT resources will also be used to effectively communicate and give opportunities through access to digital platforms such as social media and our website for training.

3.3.5 Corporate Social Responsibility

The organization will engage in innovative corporate social responsibility programs as a contribution in giving back to the society for providing the association with the license to work and mutually co-exist in enhancing human and social development. The CSR program will continuously evaluate causes that the association can engage in that have high positive impact on the target communities.

4. Strategic Implementation Matrix

4.1 Introduction

This segment provides a detailed Monitoring and Evaluation matrix including strategic pillars, objectives, outcomes, key activities and the indicators that will be evaluated to measure the success and variance levels of the strategies.

4.2 Monitoring and Evaluation Matrix

Strategic Pillars/ Objectives	Outcomes	Strategies and Key Activities	Key Performance Indicators
1. Leadership and Governance			
Strategic Objective: Develop an agile organizational structure and operating system that is highly anticipatory, responsive and flexible.	1.1 To review and revise the constitution so as to guarantee Leadership and Governance continuity	<ul style="list-style-type: none"> - To propose amendment at the AGM for the extension of Board of Directors tenure from the current 1 year to 3 years - To propose amendment in the retiring and rotation of Board members to guarantee that at least 50+1 members are retained to ensure continuity of strategic programs - To propose amendment that the Chairperson and the Vice Chairperson cannot be retired to the same period 	<ul style="list-style-type: none"> - Proposals presentation to the AGM - Ratification of proposals at the AGM - Proposals presentation to the AGM - Ratification of proposals at the AGM - Proposals presentation to the AGM - Ratification of proposals at the AGM
	1.2 Develop/Review the KAPI CODE OF PRACTICE to KAPI Board, members and staff	<ul style="list-style-type: none"> - Review and update the current KAPI CODE OF PRACTICE - Disseminate and communicate the revised KAPI CODE OF PRACTICE to KAPI Board, members & Staff 	<ul style="list-style-type: none"> - Reviewed KAPI CODE OF PRACTICE document - % of document receipt signed, read and internalized by Executive Board members and staff on the CODE OF PRACTICE

Strategic Pillars/ Objectives	Outcomes	Strategies and Key Activities	Key Performance Indicators
	<p>1.3 To develop, strengthen and enhance oversight and management roles in KAPI</p>	<ul style="list-style-type: none"> - Provide training on the KAPI CODE OF PRACTICE to KAPI Board, members and staff - Ascertain that KAPI Board, members and staff sign to adhere to the code of conduct - To measure compliance to the CODE OF PRACTICE by developing feedback measures. - Align and benchmark CODE OF PRACTICE with International Federation Pharmaceutical Manufacturers and Associations (IFPMA) Code of Practice. - To gradually separate the functions of the Board of Directors from management to oversight - To develop an effective secretariat headed by the CEO/management team tasked with the daily operational affairs of KAPI 	<ul style="list-style-type: none"> - Training program attendance record - Signed documentation by Executive Board, members and staff - % of adherence and conformity by Executive Board, members and Staff - % of reported, investigated and remedial measures undertaken for nonconformance on the code of practice issues - Audit report to mirror conformance - Establishment of secretariat Board and Management role separation - Establishment of secretariat

Strategic Pillars/ Objectives	Outcomes	Strategies and Key Activities	Key Performance Indicators
		<ul style="list-style-type: none"> - and answerable to the Board of Directors - To competitively recruit and retain a substantive management team for managerial and operational affairs of KAPI. - Use of well-defined Key Performance Indicators (KPI's) for performance appraisal and evaluation - Fair and competitive compensation - Training and development opportunities for career growth - Succession planning of key positions 	<ul style="list-style-type: none"> - Recruitment Procedures and processes followed - JD's for all staff positions - Periodical Performance measurement and variance scores of each staff - Statutory compensation policy guidelines - Number of personnel trained - Number of relevant courses attended - Documented Delegation of tasks and Succession Plans
	<p>1.4 To ensure conformity to statutory legal requirements and KAPI standard operating processes and procedures</p>	<ul style="list-style-type: none"> - Develop/ Review and update the current standard operating processes and procedures - Timely release of Annual Financial Reporting - Returns to the Registrar of Societies - Payment of statutory tax obligations - Holding Annual General Meetings on time 	<ul style="list-style-type: none"> - Qualified reports on compliance certification and clearance by authorities e.g. KRA - Financial and Auditors Reports - Annual returns to the Registrar of Societies - Payment of Tax obligations – KRA - AGM meeting minutes and members attendance list

Strategic Pillars/ Objectives	Outcomes	Strategies and Key Activities	Key Performance Indicators
	1.5 Building a rich repository of KAPI heritage	<ul style="list-style-type: none"> - Researching and tapping into the wealth and experience of the founding members on the rich historical developments and milestones of KAPI - Documenting the historical journey and milestones of KAPI - Disseminating and continuously updating the KAPI journey 	<ul style="list-style-type: none"> - Documented research process - Publication of KAPI journey - Members receipt of publication (via email, etc.)
<p>2. Resource Mobilization & Service Provision</p> <p>Strategic Objective: Develop a resource mobilization strategy in order to tap, expand & diversify revenue stream generation & recruit, retain and expand membership through value add products & services with increased membership categories within the wider industry players</p>	2.1 To maintain and enhance the current products and services offered through the secretariat and standing committees	<ul style="list-style-type: none"> - To ensure value for members through proactive, timely and efficient execution and service delivery of the trade, policy & regulation, compliance & communications & public relations committees - To develop, enhance and entrench the Pharmacovigilance & Medical Affairs & medical devices & technologies committees - Proactively engage members to obtain 	<ul style="list-style-type: none"> - Number of Products and Services offered - Number of expanded products and services offered - Advocacy and Policy papers engaged in and submitted - Issues resolved - Establishment of the two committees - Evaluation of services offered - Quarterly members survey results

Strategic Pillars/ Objectives	Outcomes	Strategies and Key Activities	Key Performance Indicators
		<ul style="list-style-type: none"> feedback regarding new product & services required through periodical members surveys 	<ul style="list-style-type: none"> - Number of implemented initiatives suggested
	2.2 To expand KAPI membership eligibility criteria through redefined constitutional amendments	<ul style="list-style-type: none"> - Diversify membership categories to attract new members from various categories relevant to KAPI 	<ul style="list-style-type: none"> - Amended constitutional mandate and membership scope
	2.3 To continuously review membership subscriptions to maintain membership revenues	<ul style="list-style-type: none"> - To maintain competitive subscription pricing in line with product and service value to members - To adjust membership fees in line with inflationary trends in the economy 	<ul style="list-style-type: none"> - Financial subscription reviews - Pricing reviews
	2.4 Focus on special projects and services	<ul style="list-style-type: none"> - To pursue pay-for service opportunities. - Consulting services, Research and test studies opportunities – Thematic funded research - Online training & Interactive pay-to-access services 	<ul style="list-style-type: none"> - Number of services initiated - Revenue generated - Number of projects undertaken - Number of trainings conducted - Number of graduates certified
	2.5 Expanded sources of revenues	<ul style="list-style-type: none"> - Investments (e.g. Bonds, in real estate for rentals and others) 	<ul style="list-style-type: none"> - % increase in revenues generated

Strategic Pillars/ Objectives	Outcomes	Strategies and Key Activities	Key Performance Indicators
<p>3. Collaborations & Partnerships</p> <p>Strategic Objective: Develop and implement annual plans for engagement with key local and international stakeholders in the areas of regulation, trade, funding, and partnership.</p>	<p>3.1 To continuously and proactively engage the following key stakeholders through our established standing committees</p> <ul style="list-style-type: none"> • Regulatory – PPB, CS, PS, DG, KEBS • Trade – KRA, ACA, Customs, KEBS • Funding- Industry and others • Partnerships- KEPSA, KHF • Public Relations - communication, branding, CSR, advocacy and awareness creation. • Internal stakeholder engagement • External academic collaborations and shaping of industry perspective 	<ul style="list-style-type: none"> - Maintaining current collaborations and partnerships e.g. KMA, NNAK, KHF, PSK, etc. - Identification of other new suitable partners - Structured engagements with partners - Engagement with all media channels-Print/ Electronic and digital channels - Training of new members on leadership - Retraining of existing members in leadership - Engagement with training institutions to co-design and execute training programs to shape industry perspectives. 	<ul style="list-style-type: none"> - Number of old partners retained - Number of new partners engaged - Meetings and outcomes on agreed engagement issues - Dialogue meetings attended - Number of successful campaigns initiated and undertaken - Level of communication awareness achieved - Leadership forum participants register - No. of forums hosted; - Revenue gained from such activities.

Strategic Pillars/ Objectives	Outcomes	Strategies and Key Activities	Key Performance Indicators
	<p>3.2 Maintain positive collaboration with the umbrella International Federation Pharmaceutical Manufacturers and Associations (IFPMA)</p> <ul style="list-style-type: none"> • Ensure timely subscription to IFPMA • Pursue areas of common interests in terms of best practices-Projects • Pursue training, research, ethics and business integrity support to KAPI code of practice, organized regulatory workshops, etc. • UHC, Access Accelerated, IP, ethics, promoting an innovation ecosystem 	<ul style="list-style-type: none"> - Maintain collaboration with international membership partner - Joint ventures in projects-research projects - Collaboration with other partners in offering training - Development of updated curriculum - Training workshops on leadership - Talks by external expert resource consultants - Developing platform for dissemination of information and ramping up advocacy 	<ul style="list-style-type: none"> - Maintained of good standing order - Number of trainings held - Participants attendance register - Number of modules developed - Number of training conducted - No of participants trained - Number of activities/projects driven collaboratively
<p>4. Communications & Public Relations</p> <p>Strategic Objective: Develop a proactive, adaptive and anticipatory information research and dissemination strategy.</p>	<p>4.1.Setting up and operationalizing an information research and dissemination system responding to emerging diseases, trade and relevant health policy issues</p>	<ul style="list-style-type: none"> - To develop a digital platform for information research and dissemination for identified issues in the KAPI website/social media platforms 	<ul style="list-style-type: none"> - Established functional IT platform

Strategic Pillars/ Objectives	Outcomes	Strategies and Key Activities	Key Performance Indicators
	<ul style="list-style-type: none"> • Setting up of an information & communication committee comprising of 5 members • Setting up an IT platform that stores data and shares the information leveraging on KAPI website • Developing an access-to-pay researched documents 	<ul style="list-style-type: none"> - Committee set up - Data storage on KAPI website - Develop library for research documentation - Payment system in place 	<ul style="list-style-type: none"> - Committee set up that is functional and operational - Maintained database - Number of access and revenues received
<p>5. Sustainable Development and Shared Value Investing Strategic Objective: Coordinate robust, strategic and beneficial CSR initiatives for the association and its membership.</p>	<p>5.1. Establishing engagements with and working with strategic organizations and partners in the country on CSR initiatives including schools, hospitals, patient advocacy & support groups, civil society organizations, public health initiatives etc.</p>	<ul style="list-style-type: none"> - Mapping of strategic partners and stakeholders for CSR work - Signing of MOUs and engagement contracts on CSR initiatives to be executed together - Mobilization of member companies to adopt different CSR projects and initiatives mapped by the association - Execution of health related and community empowering initiatives 	<ul style="list-style-type: none"> - Register/Log of probable partners for the execution of the associations strategic CSR agenda - Number of MOUs and contracts signed - Number of member companies involved in industry led CSR activities - Number of CSR activities executed and reports/media coverage for the same

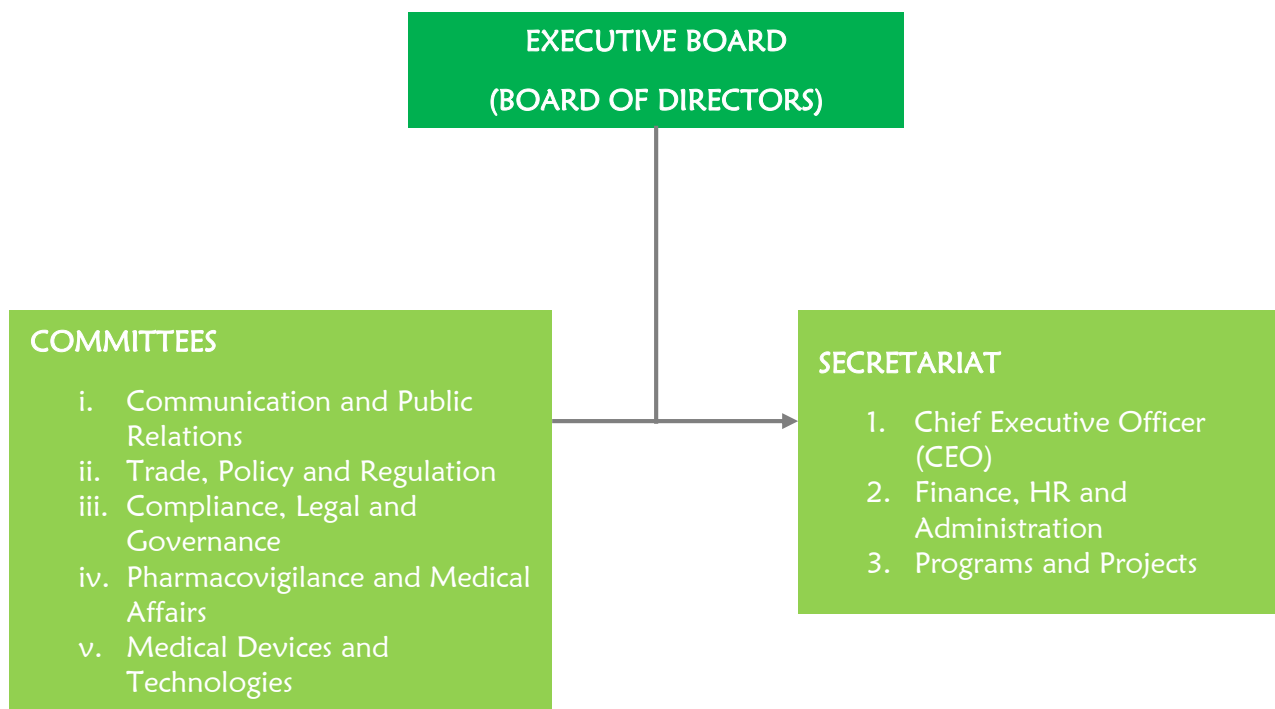
5. Strategic Capabilities

5.1 Introduction

A strong, vibrant and well-coordinated organizational structure is a requisite for the implementation of any strategic plan. KAPI has a well-defined Board Management structure that has been undertaking both oversight and operational management of the affairs of the organization. This structure has been identified as a weak link and hence the need for the establishment of a substantive secretariat led by a CEO and team prioritized in this strategic plan. Taking cognizance of the constrained financial and material resources currently available, it has been proposed that the establishment be staggered and phased through the five year period.

5.2 Proposed Organization Structure

The proposed overall organizational long term organizational structure of KAPI is as detailed below;



The governance and management of KAPI is derived from the AGM and is vested upon the Executive Board in outlined in its constitution.

5.2.1 Executive Board

The Executive Board comprises of nine (9) members, namely;

- i. Chairperson
- ii. Vice Chairperson
- iii. Immediate Past Chairperson
- iv. Executive Secretary
- v. Honorary Treasurer

- vi. Four (4) Executive Directors
And a provision to co-opt subject matter experts by the board on a short term basis as shall be required.

The mandate of the board is to provide leadership and guidance to the KAPI membership towards the realization of KAPI's mandate as articulated in the KAPI Constitution, KAPI's Vision and Mission Statements. The executive board plays oversight roles and offers guidance in the day to day running of the association affairs through a Chief Executive Officer (CEO).

In the organizational structure, the Board of Directors functions will include;

- **Determine mission and strategy**
This responsibility includes creating and reviewing the mission and vision statements and strategy that articulates the organization's goals, and means of achieving those goals and setting strategy and providing oversight of programmatic work.
- **Select, support and evaluate the CEO.**
Reaching consensus on the CEO's responsibilities and undertaking a careful and competitive search to find the right and qualified individual for the position. It will also develop and maintain a succession plan for replacing an executive in case of exit. Provision of support to the CEO once appointed through financial and material resourcing will be a crucial requirement of the Board.
- **Ensure effective planning.**
The Board will actively participate in an overall planning process in regards to longer-term strategic planning and annual work planning. The Board should assist in monitoring the organization's performance against planned goals, and adaptively managing the plan.
- **Provide oversight of programs and services.**
The board's will determine which programs are consistent with the organization's mission and monitor their effectiveness, calling for performance evaluations and improvements as policy.
- **Oversee financial management and protection of assets.**
The board will assist in developing and approving an annual budget that supports the association's work plans and ensures that proper financial controls are in place to protect the assets of the organization and to select an auditor and review and respond to the results of an audit on an annual or bi-annual basis.

5.2.2 Committees

The standing committees which are established from the staff from member organizations, serving on a voluntary basis, will ensure that the roles and responsibilities of the committees are fully carried out (in line with the TOR's) and proper reporting done from time to time. This will include the 5 established committees and any other that may be determined by the board.

The Committees are as follows:

- a. Communication and Public Relations
- b. Trade, Policy and Regulation
- c. Compliance, Legal and Governance
- d. Pharmacovigilance and Medical Affairs

- e. Medical Devices and Technologies

5.2.3 Organization Structure of the Secretariat

KAPI will put in place a structured secretariat headed by Chief Executive Officer, and with the following functional mandates/responsibilities:

- a. Finance, Human Resource and Administration
- b. Programs and Projects

5.2.4 Chief Executive Officer

The Chief Executive Officer is responsible to the Board for the management of KAPI including but not limited to:

- i. Providing effective leadership for the realisation of the vision and mission.
- ii. Implementing the strategic plans.
- iii. Implementing the Boards policies.
- iv. Effective governance and management of the operations.
- v. Legal and Compliance matters
- vi. Prudent management of resources.
- vii. Public Relations and Corporate communications.

5.2.4.1 Finance

The responsibility of this department includes:

- i. Financial management and accounting.
- ii. Budgeting and budgetary control.
- iii. Investments.

5.2.4.2 Human Resource and Administration

The responsibility of this department includes:

- i. Human Capital Management and Development.
- ii. Staff welfare.
- iii. Administration.
- iv. Property and Asset Management.

5.2.4.3 Programs and Projects

The responsibility of this department will include:

- i. Business Development.
- ii. Projects Implementation.
- iii. Coordination of Association Programs and Projects.

The structure will continually be evaluated and if need arises, other functional departments will be expanded.

6. Monitoring and Evaluation

6.1 Introduction

In order to ensure that our strategic plan is on course, and well implemented, a monitoring and evaluation framework is necessary as it increases understanding of goals and objectives and the relationships between resources, capabilities and competencies, factors and processes that will be used to measure performance implementation.

6.2 Annual Plans

In order to increase the success of our strategic plan, detailed annual implementation plans for each year will be used for monitoring and evaluation of the efficiency and effectiveness of the plan. The performance successes and shortfalls, in each year, will be well documented forming the basis for the development of subsequent year plans which will be developed through consultative forums involving inputs by all stakeholders.

The annual plans will include the following;

- i. Strategic Initiatives or Activities conducted
- ii. Outputs
- iii. Time Frame
- iv. Key Performance indicators
- v. Responsibility
- vi. Resource requirements- budgets
- vii. Risks, assumptions and mitigations

7. Strategic Plan Budget

BUDGET ITEM	Unit Cost (Ksh.)	Frequency	2021	2022	2023	2024	2025	TOTAL
STRATEGIC PILLAR 1: LEADERSHIP AND GOVERNANCE								
Strategic Objective 1: Develop an agile organizational structure and operating system that is highly anticipatory, responsive and flexible.								
1.1 To review and revise the constitution so as to guarantee Leadership and Governance continuity								
Proposals of constitutional amendments	400,000	Once	400,000	-	-	-	-	400,000
1.2 Develop/Review the KAPI Code of Practice to all KAPI Board members and staff								
Development/Review of Code of Practice	30,000	Once	30,000	-	-	-	-	30,000
Dissemination of Code of Practice	500,000	Annual	500,000	500,000	500,000	500,000	500,000	2,500,000
Code of Practice Training	150,000	Annual	150,000	150,000	150,000	150,000	150,000	750,000
Monitoring and Evaluation of dissemination of CoP	50,000	Annual	50,000	50,000	50,000	50,000	50,000	250,000
To measure conformance to the Code of Practice	100,000	Annual	100,000	100,000	100,000	100,000	100,000	500,000
Benchmark IFPMA Code of Practice	300,000	Annual	300,000	300,000	300,000	300,000	300,000	1,500,000
1.3 To develop, strengthen and enhance oversight and management roles in KAPI								
Recruitment of CEO & Management Team	300,000	Once	300,000	-	-	-	-	300,000
Compensation Salaries for CEO & Team	3,000,000	Annual	3,000,000	3,000,000	3,000,000	3,000,000	3,000,000	15,000,000
Training and Development Budget for Employees	100,000	Annual	100,000	100,000	100,000	100,000	100,000	500,000
Training and Development of Board on Governance	5,000,000	Once	5,000,000	-	-	1,000,000	-	6,000,000
1.4 To ensure conformity to statutory legal requirements and KAPI standard operating processes and procedures								
Develop/ Review and update the current standard operating processes and procedures	-	-	-	-	-	-	-	-
Annual Financial Reporting & Audit Costs	125,000	Annual	125,000	125,000	125,000	125,000	125,000	625,000
Returns to the Registrar of Societies	Nil	-	-	-	-	-	-	-
Statutory Taxes	1,800,000	Annual	1,800,000	1,800,000	1,800,000	1,800,000	1,800,000	9,000,000
Annual General Meeting Costs	200,000	Annual	200,000	200,000	200,000	200,000	200,000	1,000,000

BUDGET ITEM	Unit Cost (Ksh.)	Frequency	2021	2022	2023	2024	2025	TOTAL
1.5 Building a rich repository of KAPI Heritage								
Research and Development, Dissemination, Records and Archiving Costs	1,000,000	Annual	1,000,000	500,000	250,000	500,000	500,000	2,750,000
SUB-TOTAL COSTS S01								41,105,000
STRATEGIC PILLAR 2: RESOURCE MOBILIZATION & SERVICE PROVISION								
Strategic Objective 2: Develop a resource mobilization strategy in order to tap, expand & diversify revenue stream generation & recruit, retain and expand membership through value add products & services with increased membership categories within the wider industry players.								
2.1 To maintain and enhance the current products and services offered through the secretariat and standing committees								
Committee operations – i. Communication and Public Relations ii. Trade, Policy and Regulation iii. Compliance, Legal and Governance iv. Pharmacovigilance and Medical Affairs								
Establishment and operational budget – i. Medical Devices and Technologies								
Member feedback surveys	10,000	Annual	10,000	10,000	10,000	10,000	10,000	50,000
2.2 To expand KAPI membership eligibility criteria through redefined constitutional amendments								
New member mobilization costs	200,000	Annual	200,000	200,000	200,000	200,000	200,000	1,000,000
2.3 To continuously review membership subscriptions to maintain membership revenues								
Membership subscriptions	Nil	-	-	-	-	-	-	-
2.4 Focus on special projects and services								
Consulting services, Research and test studies opportunities – Thematic funded research	5,000,000	Bi-annual	5,000,000	-	5,000,000	-	5,000,000	1,500,000
Development of Curriculum & Training Program	500,000	Annual	500,000	500,000	500,000	500,000	500,000	1,500,000
Online Training & Interactive pay-to-access Services	100,000	Annual	100,000	100,000	100,000	100,000	100,000	500,000
CME Accreditation Fees	100,000	Annual	100,000	100,000	100,000	100,000	100,000	500,000
2.5 Expanded sources of revenues								

BUDGET ITEM	Unit Cost (Ksh.)	Frequency	2021	2022	2023	2024	2025	TOTAL
Investments in real estate for rentals and others	Nil	-	-	-	-	-	-	-
SUB-TOTAL COSTS S02								5,050,000
STRATEGIC PILLAR 3: COLLABORATIONS AND PARTNERSHIPS								
Strategic Objective 2: Develop and implement annual plans for engagement with key local and international stakeholders in the areas of regulation, trade, funding, and partnership.								
3.1 To continuously and proactively engage the following key stakeholders through our established standing committees								
Cost of current collaborations and partnerships	250,000	Annual	250,000	250,000	250,000	250,000	250,000	1,250,000
Cost of new partnerships	250,000	Annual	250,000	250,000	250,000	250,000	250,000	1,250,000
Media engagement costs	1,800,000	Annual	1,800,000	1,800,000	1,800,000	1,800,000	1,800,000	9,000,000
3.2 Maintain positive collaboration with the umbrella International Federation Pharmaceutical Manufacturers and Associations (IFPMA)								
Membership subscription with IFPMA	500,000	Annual	500,000	500,000	500,000	500,000	500,000	2,500,000
SUB-TOTAL COSTS S03								14,000,000
STRATEGIC PILLAR 4: COMMUNICATIONS AND PR								
Strategic Objective 4: Setting up and operationalizing an information research and dissemination system responding to emerging diseases, trade and relevant health policy issues								
4.1. Focus on special projects and services								
Digital platform establishment & operation costs	500,000	Annual	500,000	500,000	500,000	500,000	500,000	2,500,000
SUB-TOTAL COSTS S04								2,500,000
STRATEGIC PILLAR 5: SUSTAINABLE DEVELOPMENT AND SHARED VALUE INVESTING								
5.1. To coordinate robust, strategic and beneficial CSR initiatives for the association and its membership								
Stakeholder Engagement	250,000	Annual	250,000	250,000	250,000	250,000	250,000	1,250,000
Project Execution	1,000,000	Annual	1,000,000	1,000,000	1,000,000	1,000,000	1,000,000	5,000,000
SUB-TOTAL COSTS S05								6,250,000
TOTAL BUDGETED COSTS								68,905,000

