

# PAULYNE WAIRIMU(DR)

Regulatory Systems Strengthening | Policy & Strategic Advisor on health Systems | International Negotiator on access to Medicines and Health Technologies | Trade, IP & Public Health | Global Health Diplomacy.

## Profile

The Covid-19 pandemic presented an opportunity for changing the policy and regulatory framework of medical products which include diagnostics previously not given much consideration by regulators.

Nairobi, Kenya

Sensing the urgent need to create a mechanism for fast-tracking the regulatory process for diagnostic enabling patient access, I implemented the use of Emergency Use Authorization mechanism for Kenya, that availed to the market diagnostics for use in the face of the pandemic.

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As a regulator, the need for adaptability, with the clear need to balance public health needs and demands has created the opportunity for development of high skills in Communication, quick thinking, decision making, and excellent organizational structure.

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Exposure and participation at the international Fora, through representation of the government to the World Health Assembly; panelist at the World Trade Organization as well as Consultancy at the World Health organization has sharpened by International business etiquette, diplomacy and knowledge of health at the global, regional and national context.

## Professional Development

### Graduate Institute of International and Development Studies, Geneva

***Executive Certificate of Advanced Studies in Global Health Diplomacy (Specialities- Global Health Diplomacy, Public health, Trade & Intellectual Property, Drug Policy, Legal Instruments (2018-2019)***

The intertwined facets between Trade Related Intellectual properties, Public Health and trade which policy makers should balance to achieve progressive and inclusive rules, have broadened by breath of knowledge in global health trends. This course had helped me gain understanding and key concepts in areas of health diplomacy and governance from within a rapidly changing environment; Gained understanding of the diplomatic processes in view of improving negotiation skills.

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**Masters of advanced studies in International strategy and adaptive Leadership-focus on Global Health Diplomacy, International negotiation and policy-making, Global Legal Instruments, Drug Policy, Intellectual Property & Public Health (2019-2020)**

To build on the skillsets gained at the advanced certificate level, I have enrolled on the international strategy and adaptive leadership Master's program, with a focus on Global health diplomacy, International negotiation and policy-making, Global Legal Instruments, Drug Policy & Intellectual Property. I endeavor to develop knowledge in key areas of development in health, and the constantly changing Global health dynamics related to health policy. Strategic leadership is a vital skill to harness in the development of health policies that respond to the current changing trends.

**International Medical Regulators Forum (IMDRF) September 2017-Ottawa Canada**

Represented Kenya at the IMDRF, policy development, guidance documents and enhancing professional and proficient adoption of documentation for purposes of Domestication. Kenya having been given the Observer position to the IMDRF, i was able to gain invaluable information through participation in the meetings exchange of ideas from the other regulatory authorities.

### Key Positions Held

#### Global Positions

**WTO- Dispute Settlement Body Panelist -Ongoing (2020-2021)**

The world trade organization (WTO) dispute settlement body is responsible for engaging member-states who bring forward a dispute settlement. I was nominated as a panelist for an ongoing dispute pharmaceutical dispute settlement which is currently taking place. This high-profile position is the first time that a public health expert from Africa has been bestowed upon and is a reflection of the trust and expertise given by this international body.

**WHO Technical Consultant- Regulatory system development and strengthening for Medical Devices& IVDs. March 2019**

Being the resource person, I organized a situational analysis of the health system for Eritrea, this involved visiting the health institutions and speaking the responsible persons. With this information, a tool for capacity building, learning and interaction was developed through teaching the team that was interviewed during the situational analysis. A final recommended policy document was developed and shared with the team.

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### **Government representation to the 68,69,70,71st world Health Assemblies (WHA), Geneva Switzerland**

As part of the government representative to the WHA, Country level policies that are drafted through resolution by the member states of the United Nations, are discussed. As a presenting delegate, i have been able to harness diplomatic negotiations for policies. Advise the health ministers on mechanism to harness follow up and implementation of policies.

### **African Medical Devices Forum (Formerly, Pan-African Harmonization Working Party)**

As the Vice Chair for the AMDF, I have contributed in shaping the regulatory landscape of Africa. Developing health systems for least developed economies and advising on infrastructure for existing yet weak system has been one key pillars.

### **Global Harmonization Working Party (GHWP)**

As Kenya's representative to the GHWP, my primary responsibility included championing for Kenya to become a member of the GHWP. GHWP Provides a platform for development of key guidelines and expert information sharing. This in turn has facilitated the development of the regulatory framework for medical devices and In Vitro Diagnostics.

### **East African Community (EAC)**

As the regional expert for the EAC region, I coordinate and participate in the development of policy guide, regulatory framework and decisions for medical devices and In-Vitro Diagnostics.

### **Assistant Director Pharmaceutical Services/Pharmaceutical Specialist Ministry of Health**

**Nov 2017-Date**

Charged with the duties of advising on best pharmaceutical practices to the ministerial team and keeping abreast with scientific new developments. This role has guided in the development of guidance documents for the registration of medical devices for Kenya part of the technical working group for the development of a national policy document for medical devices.

### **Head of Medical Devices, Pharmacy and Poisons Boards, Ministry of Health 2012-2017**

Continental Position

Regional Position

National Position

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Tasked with the regulation of Medical Devices at the National Medicines regulatory authority, a regulatory framework set up was required to help develop key guiding documents. Responsible for the development of guiding principles under the International medical devices forum.

### **Product Evaluation and Registration Directorate, Pharmacy and Poisons Board, Ministry of Health – 2011-2013**

Understanding of the pharmaceutical sector in Kenya is a vital aspect of health products and technologies. Skillsets in good manufacturing practices, medicines pricing and access were developed during this time.

#### Professional Development

### **Regulatory Affairs Professional Association (RAPS)**

Member-Emerging Markets 4/25/2018 - 4/24/2020

### **Health Products and Food branch (HPFB) International Regulators Forum -Health Canada- October 19th-21st 2016.**

### **East Africa Community Harmonization**

Training on Advanced Good Manufacturing Practices under EAC regulation Harmonization Project (13-24th April 2015).

Good Manufacturing Practices- GMP Training in GMP Inspection of Pharmaceutical products based on WHO requirements (10-21st February 2014).

### **African Society for Laboratory Medicines, WHO-**

Clinical Performance of In-Vitro Diagnostics Medical Devices 20-24th October 2014.

### **-Center for Pharmaceutical Advancement and Training (CEPAT)**

Dossier Evaluation and Medicines registration, GMP Best practices -July 8-19th 2013, March 10-21st 2014

### **-United States Food and Drugs Administration (USFDA)**

Reviewing Generic Drug application and PEPFAR reviews 24-28th September 2012.

**Royal Brompton and Harefield Hospital, Knightsbridge, London United Kingdom**

## PAULYNE WAIRIMU(DR)

Preregistration Pharmacist- 2009-2010

### Education

#### **Graduate Institute of International and Development Studies, Geneva**

-Executive Certificate of Advanced Studies in Global Health Diplomacy (Specialities- Global Health Diplomacy, Public health, Trade &Intellectual Property, Drug Policy, Legal Instruments (2018-2019)

-Masters of advanced studies in International strategy and adaptive Leadership Focus on Global Health Diplomacy, International negotiation and policy-making, Global Legal Instruments, Drug Policy & Intellectual Property (2019-2020)

#### **World Trade Organization (WTO) 2017**

**6-10th November**

(Intellectual Property, Government Procurement and competition Division, Institute for Training and Technical Co-operation) Workshop on Trade and Public Health.

#### **INSEAD, Business School of the World. Leadership Communication with Impact**

**June-July 2018**

Effective communication as a leader is a skill gained through proactive listening and participation. To communicate effectively, personality and developed strengths are key in how effective a message can be delivered. Leaders need to communicate effectively for impactful message delivery.

#### **Welsh School of Pharmacy, Cardiff University, Wales UK — MPHARM,2005-2009**

Master of Pharmacy Degree

#### **References**

Available on request.