COVID-19 and the Increasing Risks of Substandard and Falsified Pharmaceutical products in Africa: A public health and security issue

A contribution to the 74th World Health Assembly

REPORT OF THE ONLINE HIGH-LEVEL ROUNDTABLE

25 May 2021

#BFSFMs

Brazzaville Foundation

A high-level international summit - on Saturday 18 January 2020, the Lomé Initiative was officially launched in Lomé, Togo, by H.E. Faure Gnassingbé, President of Togo; H.E. Yoweri Museveni, President of Uganda; H.E. Macky Sall, President of Senegal; and representatives of H.E. President Denis Sassou N'Guesso, H.E. President Nana Akufo-Addo and H.E. President Mahamadou Issoufou. The World Health Organization was represented by Dr. Tedros Adhanom Ghebreyesus, Director-General, and Dr. Matshidiso Rebecca Moeti, Regional Director for Africa. H.E. Omar Hilale, Vice-President of the Executive Board of UNICEF, was also present.

The Brazzaville Foundation

The Brazzaville Foundation is an independent not-for-profit organisation registered with the Charity Commission for England and Wales since 2015. Its vision is to help find African solutions to Africa's major challenges and give them lasting impact. The work programmes are designed to support the African Union's Agenda 2063 and the achievement of the United Nations Sustainable Development Goals (SDGs).

The Brazzaville Foundation contributes to design, promote and support African initiatives in the following areas:

- **Peace** – including the resolution of international and internal conflicts.
- **Environment** – including the protection of ecosystems, biodiversity and communities.
- **Health** – including maintaining and improving the health and well-being of populations.

Fighting medicines that kill

Trafficking of substandard and falsified medicines poses a severe threat to individuals, families, communities and nations, depriving them of access to high quality and affordable medications. Sensitive to this major health scourge, the Brazzaville Foundation launched an initiative in 2017 to combat fake medicines. African governments have joined forces with public and private sector actors and civil society to find the keys to fighting together against this scourge that threatens public health and to provide patients with essential medicines and quality care.

The Lomé Initiative

On Saturday 18 January 2020, the Lomé Initiative, developed by the Brazzaville Foundation, was formally launched in Lomé, Togo, by H.E. Faure Gnassingbé, President of Togo; H.E. Yoweri Museveni, President of Uganda; H.E. Macky Sall, President of Senegal, as well as representatives of H.E. President Denis Sassou-Nguesso, H.E. President Nana Akufo-Addo, and H.E. President Mahamadou Issoufou.

The states signed a political declaration which set the following objectives:

- **Put in place legislation** to criminalise the trafficking of substandard and falsified medicines and impose heavy criminal penalties.
- **Sign and ratify international agreements**, including the MEDICRIME Convention, the Palermo Convention against Transnational Organised Crime, and the treaty establishing the African Medicines Agency.

In 2021, three countries have indicated their willingness to join the Lomé Initiative: Gambia, Guinea Bissau, and the Democratic Republic of Congo. The Brazzaville Foundation provides technical support to the Ministers of Health of the signatory countries, and the various ministries that have a role to play in this fight.

The Lomé Initiative partnership

The Republic of Congo

The Republic of Ghana

The Republic of Niger

The Republic of Senegal

The Republic of Togo

in charge of the programme's political coordination

The Republic of Uganda

ALLEN & OVERY

The law firm Allen & Overy carried out the legislative audit during 2020.

Brazzaville Foundation

General introduction

A contribution to the 74th World Health Assembly

Nearly two billion people in the world lack access to needed medicines, vaccines and medical devices. This situation encourages the circulation of substandard or falsified pharmaceutical products, posing a serious threat to individuals and nations. Between 2013 and 2017, 1,500 reports of substandard or falsified products were received by WHO, most of which (42%) came from the African continent. Since the start of the COVID-19 pandemic, this figure has continued to rise, creating new challenges in the pharmaceutical supply chain, where falsified vaccines, therapeutics and diagnostics are circulating.

On the 74th World Health Assembly, held from 24 May to 1 June 2021, and World Africa Day on 25 May, the Brazzaville Foundation brought together a panel of key players in the fight against falsified and substandard medicines on the African continent for a high-level roundtable.

This meeting, benefiting from the diversity of the sectors represented, highlighted the methods and tools available to effectively counter this traffic, which threatens the health of African populations and the stability of the States affected.

Programme

Moderator

- Mr Richard Amalvy, Chief Executive, Brazzaville Foundation

Panel 1 –
Falsified and Substandard Medicines in Africa: Lessons Learned from the COVID-19 Pandemic

Opening speeches

- Prof. Moustafa Mijiyawa, Minister of Health and Public Hygiene, Republic of Togo, Political Coordinator of the Lomé Initiative

Panelists

- Dr. Fatoumata Binta Diallo, Resident Representative, WHO Togo
- Dr. Stanislav Kniazkov, Regulatory System Officer, WHO Regional Office for Africa
- Mr Michel Sidibé, Special Envoy for the African Medicines Agency, African Union
- Mr Greg Perry, Deputy Director General, IFPMA; Vice President, Fight the Fakes Alliance
- Mr Gregory Rockson, Co-founder and Managing Director, mPharma

Panel 2 –
Trafficking in falsified medicines: Reducing Criminal Activity and Supporting the Rule of Law

Panelists

- Dr. Idi Illiassou Mainassara, Minister of Public Health, Republic of Niger
- Mr Jean-Louis Bruguière, former anti-terrorist judge; Member of the Advisory Board, Brazzaville Foundation
- Mr Adam Aspinall, President, Fight the Fakes Alliance
- Dr. Chantal Lacroix, Deputy Regional Representative, UNODC
- Mr Oscar Alarcón-Jiménez, Executive Secretary of the Committee of the Parties to the MEDICRIME Convention, Council of Europe

Conclusion of the roundtable

- Prof. Moustafa Mijiyawa, Minister of Health and Public Hygiene, Republic of Togo
- Mr Richard Amalvy, Chief Executive, Brazzaville Foundation

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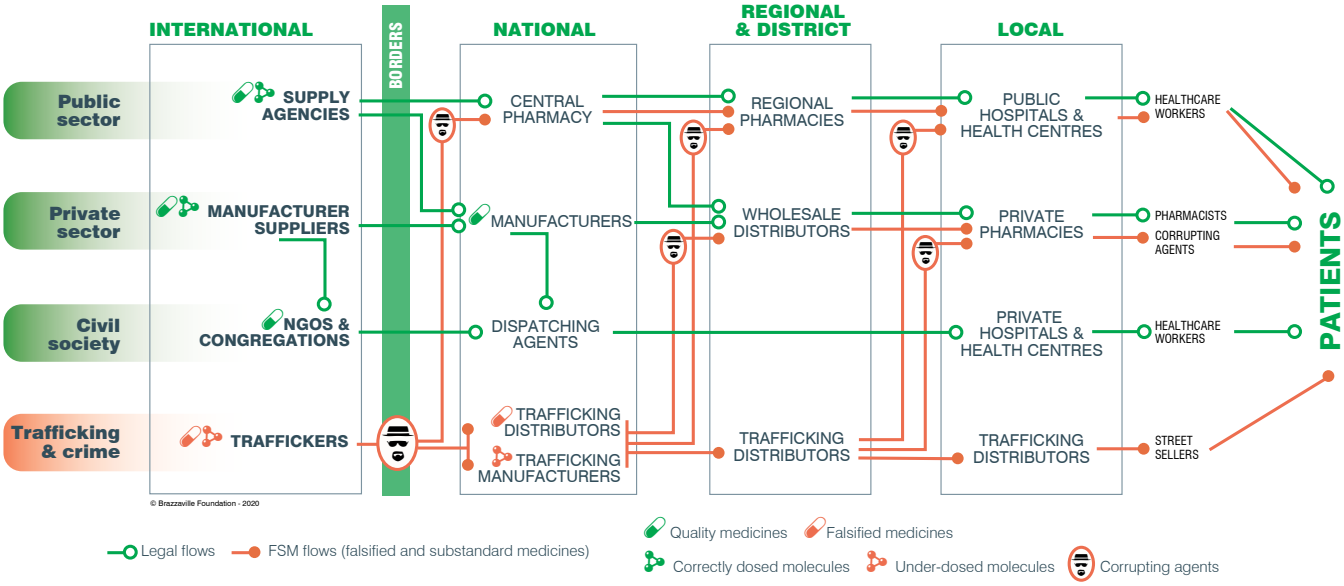
Introductory remarks

Richard Amalvy
Chief Executive of the Brazzaville Foundation

“ To combat the trafficking of substandard and falsified medicines, it is necessary to understand how the pharmaceutical supply chain works at each of its levels. To this end, the Brazzaville Foundation has mapped out the supply chain. ”



Patients can access falsified and substandard medicines in three ways:

- Via illegal local markets (e.g., street vendors).
- Via the national official distribution channel (e.g., private/public hospitals and health centres, private pharmacies).
- Via the Internet: as crime is transnational, there is a need to coordinate legislation at the international level.

Combating trafficking in SFMs requires a systemic approach. These plans require to:

- Establish inter-ministerial mechanisms to ensure rigorous implementation of new criminal legislation at the national level and to improve cooperation between states.
- Create regulatory and supervisory processes and need qualified people with integrity to implement and maintain them.
- Imagine ways of setting up production units at the national level in conjunction with the pharmaceutical industry.
- Evaluate the programme’s success and readjust the strategy in the light of national specificities and feedback.

The national plans should be structured around three complementary areas of action:

- Public health
- Safety
- The rule of law

The partners in the development and implementation of the national plans are **public and private decision-makers representing a wide variety of professions and functions in the pharmaceutical supply chain:**

- Security forces and customs
- Professional orders in the health and legal jobs
- Representatives of the pharmaceutical industry
- Managers of hospitals, health centres and pharmacies

The priority targets are:

- Women who are both buyers and sellers of falsified medicines.
- Young people who can change purchasing behaviour.

Panel 1 –
Falsified and Substandard Medicines in Africa Lessons Learned from the COVID-19 pandemic

Opening speeches

Prof. Moustafa Mijiyawa
Minister of Health and Public Hygiene, Republic of Togo,
Political Coordinator of the Lomé Initiative

" The trafficking of falsified and substandard medicines goes beyond public health. "

Trafficking in fake medicines is a multi-sectoral problem, both in its nature and implications. This phenomenon concerns all products, including commonly used antibiotics, anti-inflammatories, and specialised products. Beyond the public health tragedy it causes, trafficking is also a security problem. With revenues estimated at 200 billion dollars, it is one of the funding sources for terrorist organisations. For the past ten years, seizures have been increasing in Africa.

There are many causes of this trafficking, both on the supply and demand sides. On the supply side, insufficient regulation of the pharmaceutical sector, weak legislation against the repression of illicit trade, and low local production capacity contribute to it. On the demand side, the low availability of essential medicines and the financial cost that these products can represent for the population are all elements that favour its development.

To this end, different entities need to federate to improve their effectiveness in action. The recent COVID-19 pandemic confirmed the importance of the action and awareness initiated in Lomé. Since 2020, fake masks, drugs and vaccines have circulated around the world. A concerted effort is needed to overcome this global scourge.

Established in 1948, the World Health Organisation (WHO) is the United Nations (UN) specialised agency for public health and has been involved in the fight against falsified and substandard medical products since the 1985 Nairobi Expert Conference on the Rational Use of Drugs.

Dr Fatoumata Binta Diallo

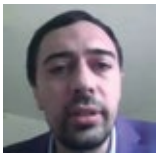
Resident Representative, World Health Organization in Togo

" COVID-19 has increased the demand for drugs, creating an opportunity for the wrong people. "

The context of the COVID-19 pandemic has caused a significant increase in demand for vaccines and other medical products, disrupting supply chains. Exploiting this sudden high demand, which supply is struggling to meet, criminal groups have seized the opportunity to develop fake medical products and infiltrate known legitimate distribution channels.

In response to this alarming situation, the WHO provides technical support to countries and high-level advocacy to help them address challenges of a similar nature:

- **Organisational**: weaknesses in national and international multidisciplinary coordination; porous supply systems and lack of transparency in distribution chains; price regulation mechanisms and reimbursement etc.
- **Legal**: Weak legislation for the repression of illicit trade; slow accession to international conventions.
- **Institutional**: Low local production capacity for essential medicines; inadequate regulation of the pharmaceutical and drug sector.



Dr Stanislav Kniazkov

Regulatory System Technical Officer,
World Health Organization Regional Office for Africa.

" The framework and institutions that underpin this critical area of work depend on partnerships and interdisciplinary collaboration. "

Partnerships and interdisciplinary collaboration are essential elements in the fight against falsified and substandard medicines. Two-thirds of the Member States in the WHO African Region have incorporated criminal or administrative liability provisions into their legislation. Unfortunately, only 36% have incorporated the WHO-recommended prevention, detection, and response approach into their policies. 66% of Member States have national action plans to combat falsified and substandard medical products. The lack of updating of these plans, the lack of available funding, and the lack of infrastructure to destroy falsified medicines slow down their success.

One of the areas of WHO's work in countries is strengthening the capacity of national regulatory authorities and building bridges between regulators of public health programmes. Multidisciplinary collaboration at the government level is essential. It must be accompanied by cooperation within the health sector to be fully effective.

The voice of advocates must be heard at all levels: political, community, individual patients.

In the process of being established since the adoption of its treaty by the 32nd Session of the Assembly of Heads of State and Government of the African Union in February 2019, the African Medicines Agency is the second health agency at the continental level, after the African Centres for Disease Control and Prevention, which will be tasked with building the capacity of State Parties and Regional Economic Communities (RECs) in the regulation of medicinal products to facilitate access to quality, safe, and effective medicinal products on the continent.

Michel Sidibé

Special Envoy for the African Medicines Agency, African Union

" The rapid implementation of this long-awaited, innovative instrument is essential for the establishment of actual universal health coverage and, above all, for meeting the health needs of the poorest. "

The current health situation demonstrates that the issues of medicines, vaccines and accessibility of health services are major concerns for the survival of people in Africa. Although representing 17% of the world's population, the African continent accounts for 25% of the world's morbidity rate, with one out of every four sick people being in Africa. Despite this, only 3% of the medicines consumed in Africa are produced there.

The continent faces several emergencies: a production emergency for medical products, a regulatory emergency, and an access emergency for quality products. The multiplicity of intermediaries in pharmaceutical supply chains contributes to the distribution of fake medicines, but more importantly, to legitimate medicines' high cost.

It is essential that the African Union and its member states are able to invest rapidly in common, effective and efficient regulation of medicines, medical products and technologies. Political diplomacy on health in Africa also needs to be strengthened.

The African Medicines Agency is the first part of the solution. Its role will include building national research and development capacity and harmonising drug registration regulations, and helping countries comply with best practices and international standards. These advances are prerequisites for creating an enabling environment for the continental production of medicines and vaccines, as well as for the establishment of universal social health coverage.

The International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) is a non-profit, non-governmental organisation representing pharmaceutical industry associations and companies worldwide. IFPMA promotes policies that encourage innovation, resilient regulatory systems, quality standards and sustainable health policies.

Greg Perry

Deputy Director General, IFPMA; Vice President, "Fight the Fakes" Alliance

" Poor quality care is now the main barrier to reducing mortality, ahead of lack of access to care. "

The pharmaceutical industry considers the fight against falsified medical products a fundamental part of patient safety, an area of healthcare that involves preventing and reducing the risks, errors and harm caused to patients in the healthcare setting. IFPMA has made this an integral part of its strategy in Africa and welcomes the adoption of a Global Plan of Action for Patient Safety for the period 2021-2030 by the World Health Organization.

The Fight the Fakes campaign, of which IFPMA is a founding member, aims to raise awareness and influence change in the face of the proliferation of falsified and substandard medicines. In this perspective, developing partnerships with various sectors such as universities, health professionals, and industries is essential.

The current COVID-19 context sees a proliferation of medical products in circulation, such as vaccines, tests and gloves. There are several vital points to consider to combat these falsified products effectively. First, it is essential to ensure that communities use public channels to obtain vaccines and treatments. The second element is investing in tracking and tracing technologies to alert to falsified products. Finally, reporting and information sharing are essential to enable improved supply chains.

With advanced regulatory structures, combined with a resilient and robust supply chain, the penetration of falsified medicines can be significantly reduced. In this regard, the establishment of the African Medicines Agency (AMA) is a significant step in combating falsified medicines in Africa.

Industrial companies, invested in the fight against the infiltration of fake medical products, also have their role to play and are implementing preventive measures at their level: cooperation with regulatory authorities, monitoring their supply system, and identifying their weaknesses.

Founded in 2013 in Ghana, mPharma is a healthcare start-up. It provides prescription drug inventory management for pharmacies and their suppliers. With operations in Ghana, Kenya, Nigeria, Rwanda and Zambia, it aims to improve access to affordable, quality medicines.

Gregory Rockson
Co-founder and Managing Director, mPharma.

" The supply chain is not only a logistics problem but also a data problem. "

Operating in seven African countries, the start-up mPharma has made several observations about access to quality medicines. In addition to logistical problems, lack of data is a major barrier to an efficient and resilient supply chain. It is currently not possible to obtain real-time data on drug use. Without this, community pharmacies, as the first port of call for patients and consumers, play a central role in improving access to medicines.

Based on these observations, mPharma is offering a digital structure to community pharmacies to fill this data gap. Unlike the majority system, where medicines are sourced from multiple undefined sources, this digital storefront ensures consistent product tracking. Allowing for the data collection, ensures that all medicines come from a reliable source. Consumers also benefit from a customer identifier, providing immediate contact in the event of a drug recall.

mPharma's ambition is to continue to strengthen this digital framework to become a rich and reliable source of drug use to support governments and regulators in their efforts to improve access to quality medicines for people.

Panel 2 –
Trafficking in Falsified Medicines Reducing Criminal Activity and Supporting the Rule of Law

Dr Idi Illiassou Mainassara
Minister of Public Health, Republic of Niger

" Falsified medical products are smuggled onto the market using the same channels and techniques as drugs, weapons and human trafficking. "

Falsified and substandard medical products are distributed illegally by unauthorised persons such as street vendors and unqualified stockists and by legally established structures such as private pharmacies, central pharmacies, and civil society organisations. The lack of reliable statistics complicates the fight against this scourge. In addition to the human cost, the involvement of transnational organised crime in this lucrative traffic, and particular terrorist organisations, creates a serious threat to public security in some African countries.

Niger has developed a vast strategy to combat the problem, notably through communication, repression, and intersectoral cooperation to respond to this problem. The country is committed to putting an adequate legislative and regulatory framework with the revision of the national pharmaceutical policy adopted by the Council of Ministers in April 2021. It provides for the strengthening of border controls, training and involvement of the defence and security forces. This framework observes good governance, accountability, transparency, and patient satisfaction criteria.

Formerly known as the Fight the Fakes campaign, the Fight the Fakes Alliance is a non-profit, multi-stakeholder organisation. It represents various stakeholders with a common interest in tackling the problem of falsified and substandard medicines.

Adam Aspinall
President, "Fight the Fakes" Alliance

" Patients should be able to report the existence of such pharmaceuticals to a regulator. "

Falsified and substandard medicines are a massive problem, requiring a coordinated response and the development of partnerships. Launched in 2013, the Fight the Fakes campaign represents a range of organisations, including manufacturers, wholesalers, and researchers. It aims to raise awareness of the problem of falsified and substandard medicines and to work towards solutions. In 2020, to expand its opportunities for action, it became a non-profit organisation, the "Fight the Fakes" Alliance.

The COVID-19 pandemic highlighted the phenomenon and the responsiveness and ingenuity of traffickers in seizing new market opportunities and replicating packaging and detection methods. Also, the period showed a correlation between the media coverage and its counterfeiting: the more significant the media attention, thereby inflating demand, the greater the opportunity for criminals. In addition to the severe consequences that these pharmaceuticals can have on consumers' health, their circulation generates distrust in the effectiveness of medical products. This phenomenon fuels the scepticism of some people towards vaccination.

In addition to its health consequences, trafficking impacts the economic development of many countries. Indeed, some developing countries spend more than 30 billion US dollars on falsified and substandard medicines each year. These figures do not consider the socio-economic costs that affect populations and societies.

Brazzaville Foundation

A former French judge internationally known for his work in the fight against terrorism, Jean-Louis Bruguière has played a leading role in the investigation of major terrorist cases. Among other commitments, he is a member of the advisory board of the Chertoff Group and assists the Brazzaville Foundation in its work on falsified and substandard medicines.

Jean-Louis Bruguière

Former anti-terrorist judge;
Member of the Advisory Board, Brazzaville Foundation

" The adaptation and harmonisation of the legislation of African countries is essential to criminalise trafficking. "

Trafficking in fake medicines, like trafficking in arms, drugs, tobacco, and human beings, continues to fuel and finance terrorist organisations across Africa. This phenomenon has been intensified by the end of the Islamic State's caliphate in the Syrian-Iraqi area, depriving its organisations of financial resources and pushing them to diversify.

In addition to its health aspect, the trafficking of fake medicines poses a major security problem. The Lomé Initiative, initiated by the Brazzaville Foundation and launched by six States in January 2020, aims to enact legislative measures to criminalise trafficking. An audit of existing legislation in the signatory countries has been undertaken within this framework. It will be used to create, complete and above all harmonise texts criminalising trafficking in these countries. It was found that the penalties are not dissuasive and are sometimes evaded. Therefore, it is necessary to set up extradition processes to severe and dissuasive repression. Finally, the signature and ratification of the MEDICRIME Convention by the Lomé Initiative countries is essential to fight against fake medicines in Africa.

Established in 1997, the United Nations Office on Drugs and Crime is the UN body for combating international crime, drugs and terrorism. The organisation has 54 regional offices, covering over 150 countries. The UNODC published in 2019 a Good Legislative Practice Guide to Combat Crime Involving Falsified Medical Products to assist countries in adopting or strengthening their legislation in this area and protecting public health.

Dr Chantal Lacroix

Deputy Regional Representative,
United Nations Office on Drugs and Crime

" A holistic approach, addressing prevention, law enforcement and integrated at national, regional and international levels, is needed to combat trafficking. "

Within the Palermo Convention and the Merida Convention framework, UNODC supports States in combating pharmaceutical trafficking, facilitating partnerships, and building capacity. The organisation promotes an integrated approach at national, regional, and international levels and encourages collaboration, information exchange, joint investigations and seizures between countries.

Chantal Lacroix highlighted the interconnectedness of the issues related to the trafficking of falsified medicines, justifying the development of integrated programmes to combat trafficking-related crime effectively. The areas of action include cybercrime, corruption, securing supply chains, money laundering, maritime security, and border management. This holistic approach has the threefold objective of preventing the manufacture, sale, and consumption of falsified medical products, detecting falsified medical products, and suppressing trafficking to protect patients and the supply chain.

In West and Central Africa, the core of the work of the UNODC regional office lies in mobilising partnerships and building capacity in five pillars:

- Raising public awareness through communication campaigns
- Strengthening legal frameworks and information exchange
- Innovation
- Forensic science and the analysis of evidence and trends
- The strengthening of police and judicial cooperation and the digitalisation of the judicial system

The Council of Europe, founded in 1949, is an international organisation with 47 member states working to strengthen human rights, democracy and the rule of law. The MEDICRIME Convention, which entered into force in 2016, is the first and only international legal instrument addressing falsified and substandard medical products from a criminal perspective.

Oscar Alarcón-Jiménez
Executive Secretary, Committee of the Parties to the MEDICRIME Convention, Council of Europe

" The falsification of medical products is a global problem. It violates basic human rights and poses a major threat to public health; it is therefore an international crime. "

The MEDICRIME Convention is the first and only international legal instrument addressing falsified and substandard medical products from a criminal perspective. Its purpose is threefold: to prosecute certain acts, to protect the rights of victims and to promote national and international cooperation. There are several reasons for having an international instrument on the subject. Firstly, it is essential that the same legal definition of a falsified medical product is used and understood worldwide. Secondly, to stop trafficking, falsification activities need to be sanctioned and legislation harmonised.

Four criminal offences form the core of the MEDICRIME Convention:

- Counterfeit manufacturing
- Making available and trafficking in counterfeits
- Falsification of documents such as notices, packaging, and administrative records
- Similar offences involving threats to public health referring to products that are not adulterated but do not have legal or administrative authorisation

States' accession to the MEDICRIME Convention, particularly in Africa, is essential for several reasons. It offers harmonisation of legislation, links a multiplicity of actors in the fight against counterfeiting, offers tools for national and international cooperation, and prevents the risks and protects the victims of falsified and substandard medical products.

Today, 18 states have ratified the Convention, and 16 states have signed it. Benin, Burkina Faso, Côte d'Ivoire, Guinea, Morocco, and Niger have signed on the African continent. The Republic of Congo, Mali and Tunisia have been invited to join the Convention by the Committee of Ministers.

Conclusions of the roundtable

The COVID-19 pandemic has seen the risk of falsified and substandard pharmaceutical products increase significantly in Africa. The infiltration of falsified vaccines, therapeutics and diagnostics threatens the health of populations, weakens supply chains and strengthens trafficking networks.

This health crisis reminded us of the importance of a concerted response to trafficking and revealed the capacity of governments to deploy interministerial actions in an emergency.

The roundtable, composed of experts from different fields, demonstrated that all actors in the fight against trafficking agree on the need for an approach based on:

- **Coordination**: the regulatory framework must be strengthened in a coordinated manner at all levels - national, continental, and international
- **Awareness-raising**: concerted advocacy, but also information and awareness-raising, must be carried out
- **Integrity of the supply chain**: It is essential to strengthening the supply chain by identifying its weaknesses and implementing the necessary means to prevent intrusion by poor quality medicines

Proposals from the roundtable

At the end of the roundtable, several measures to combat the trafficking of falsified and substandard medicines emerged from the discussions. These proposals can be divided into five themes:

Legislative
- Promoting the signature and ratification of the African Medicines Agency Treaty by African countries
- The accession of African countries to the MEDICRIME Convention and other conventions related to the fight against trafficking in falsified and substandard medicines
- The creation of regional minimum standards to strengthen legislative frameworks
- Strengthening the normative framework of the fight in a coordinated manner and at all levels

Governance
- The development and implementation of a national action plan
- Implementing an inter-ministerial response within governments
- Strengthening political diplomacy on health in Africa
- Harmonisation of approaches between the African Union, its technical partners, and the Lomé Initiative

Technical, logistical, IT and security
- Establishing relationships with local pharmacies to collect data on consumption and supply chains
- Building a reliable database on pharmacies and medicines
- Strengthening border control with the training and involvement of law enforcement, customs, and justice
- The development of a reliable detection system as a risk prevention tool
- The development of prevention and awareness-raising tools
- The development of technologies to effectively combat cybercrime and strengthen product tracking in the supply chain

Economic and financial
- The development of a universal health coverage system to counter the argument of financial inaccessibility

International
- Strengthening cooperation between national, continental, and international actors

Brazzaville Foundation

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