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Review Article

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The Legal and Institutional Framework of Market Surveillance and the Fight against Spurious, Falsely Labelled, Falsified or Counterfeit Product in West Africa: The Case of Togo

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Abstract

The worsening of the phenomenon of the circulation of spurious, falsely-labelled, falsified or counterfeit product (SFFC) in the world has prompted several African countries to take part in a number of international initiatives and to develop national strategies. Although often unknown to the general public, in Togo, there are institutions and bodies in charge of regulation, and a legal framework for the control and monitoring of the drug market. The law n°2009-007 of May 15, 2009 on the public health code and the law n°2015-10 of November 24, 2015 on the penal code are the main legal instruments that allow, in addition to the international conventions to which Togo is a party, to define the legal framework, the qualification of the offences and the sanctions applicable in the context of such offences. While the definitions and sanctions imposed may be diverse, the penal code remains the most specific text incriminating offenses in the context of PMQIF.

Keywords: Togo, Counterfeit, MEDICRIME, PALERME, Market Surveillance

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1. Introduction

In recent years, the world is facing an increase of the circulation of spurious, falsely-labelled, falsified or counterfeit product (SFFC), with very serious health consequences, resulting in the death of thousands of patients worldwide each year. This is especially true in countries with weak or non-existent regulatory and health surveillance systems. The African continent is one of the most affected with a proportion that can range from 30 to 70% of fake medicines circulating on the market. In 2018, a study conducted by Word Health Organisation (WHO) estimated between 3.8% and 8.9% of deaths were due to the use of substandard and falsified antimalarials in sub-Saharan Africa. (1)

Aware of these health, security and economic issues many African countries, with the support of non-governmental organizations (NGOs), are putting in place supranational and national legal, political and institutional mechanisms to reduce the scale of this phenomenon.

Among the strategies that can be used to reduce and curb the circulation of illicit drugs are: the establishment of strict regulations, an efficient legal system, a sufficiently restrictive law enforcement system, and an effective market control and surveillance system. (2)

Togo, a West African country, is firmly committed to this fight and has taken part in numerous initiatives, set up a legal system of repression and surveillance that could allow him to fight this phenomenon efficiently. It

has also adhered to several conventions, international and community agreements, which, depending on their scope and interests, influence national law to a greater or lesser extent. The fact that they have been brought to light makes it possible, on the one hand, to enlighten both the user and the industrialists on the actions carried out and the sanctions provided for; and on the other hand, to sensitize the jurisdictions and institutions to the application of the measures put in place in order to curb the propensity of PMQIF and to make it possible to secure the drug market in Togo.

2. Supranational legal instruments in the fight against PMQIF

The worldwide awareness of the phenomenon of counterfeit drugs has found a favourable resonance in Togo. It has been translated into various political commitments to which are added the adhesion to international conventions, and other legal instruments to which it is party.

2.1 The Palermo Convention: United Nations Convention against Transnational Organized Crime

The Palermo Convention was born out of an awareness of the threat and risks posed by criminal organizations. (3) This convention was adopted on November 15, 2000 following the resolution n°55/25 of the General Assembly of the United Nations (UN). It was opened for signature in December 2000 and entered into force less than three years later on September 29, 2003.

From Interpol and WHO investigations, it was shown that organized criminal groups engaged in crimé related to falsified medical products would use the same routes and techniques as those used for trafficking in other illicit goods. Therefore, at the fifth session of the conference on transnational crime held in Vienna from 18 to 22 October 2010, it was then decided to raise PMQIF-related offenses to the same level of serious crimes. According to Article 2 of the Convention, a serious crime is: "any act constituting an offence punishable by a maximum deprivation of liberty of not less than four years or a more severe penalty". (4)

To date, the convention has 190 signatory countries, of which 147 are signatories. In 2000, five French-speaking West African countries, including Togo, joined the Palermo Convention. This signature by the Togolese state was effective on December 12, 2000 and was ratified on July 2, 2004. (5)

2.2 The MEDICRIME Convention: Council of Europe Convention on counterfeiting of medical products and similar crimes threatening public health

The MEDICRIME convention is the first specific international convention criminalizing the traffic of fake medicines. Initiated by the Council of Europe, it was adopted on December 8, 2010 by the Committee of Ministers, then opened for signature on October 28, 2011 at the Moscow Conference. (6) It is open for accession to the members of the Council of Europe but also to other states on invitation of the Committee of Ministers.

It obliges the ratifying states to criminalize everything related to:

- The manufacture of counterfeit medical products;
- supplying, offering to supply and trafficking in counterfeit medical products
- Falsification of documents;
- The unauthorized manufacture or supply of medical products and the placing on the market of medical devices that do not meet the requirements of conformity. (7)

To this date, only five French-speaking West African countries have signed it. Although Togo has repeatedly expressed its intention to join, it has not yet been signed. Table 1 below summarizes the international conventions in which Togo has participated.

Table 1. Summary table of Togo's accession and ratification of various international conventions

Pays	Palerme convention		MEDICRIME convention	
	Signature	Ratification	Signature	Ratification
Togo	12/12/2000	02/ 07/2004	No	No

2.3 WHO Regional Strategy for the Regulation of Medical Products in the African Region, 2016-2025 (8)

The Regional Committee for Africa, meeting at its sixty-sixth session in August 2016, adopted the WHO Regional Strategy on the Regulation of Medical Products in the African Region. WHO has provided support to strengthen regulatory systems through numerous collaborative initiatives, including the African Vaccine Regulatory Forum, the African Medicines Regulatory Harmonization Initiative, harmonization projects in the regional economic communities, and the African Medicines Agency. However, countries still face challenges in the governance of their regulatory systems and lack sufficient human, financial, and technical resources to ensure the proper functioning of their national drug regulatory authorities (NRAs). As a result, most NRAs do not have the capacity to complement these regional efforts, resulting in limited impact at the country level.

This regional strategy aims to ensure that national drug regulatory authorities are strengthened to effectively fulfill their mandate. The strategy prioritizes interventions that improve the governance of regulatory systems, strengthen collaboration, harmonize standards, facilitate the implementation of joint regulatory activities, and strengthen the capacity of national authorities to expand access to quality-assured medical products.

2.4 The African Union (AU) Model Law on the Regulation of Medical Products (9)

Adopted in January 2016, the model law aims to establish an effective and efficient system for the regulation and control of medical products and to ensure that these products meet the required standards of safety, efficacy, and quality. It is the result of a partnership between the AU Commission, the African Union Development Agency (ADUA/NEPAD), the Pan African Parliament (PAP), the WHO and other partners, including the Access and Delivery Partnership (ADP), to serve as a model for member states in strengthening and harmonizing the regulation of medical products and is intended to be a framework for the creation of a harmonized regulatory environment on the continent. (10)

Its scope covers all medical products (medicines, vaccines, diagnostic and medical devices), including those in veterinary medicine. It establishes the National Agency/Authority as an autonomous structure responsible for the implementation and enforcement of all regulatory functions.

2.5 Directive n°06/2020/CM/UEMOA on the status of pharmaceutical regulatory authorities in WAEMU Member States (11)

Taking into account the pharmaceutical policy documents adopted by WAEMU Member States giving the structures in charge of pharmacy and medicines the mission of ensuring the quality, efficacy and safety of use of health products; and considering the weak capacities of the pharmacy and medicines directorates in the implementation of pharmaceutical regulatory functions and the inadequacy of the financial resources allocated and mobilized, the Member States of the Union adopted Directive n°06/2020/CM/UEMOA on the status of the pharmaceutical regulatory authorities The scope of competence of the pharmaceutical regulatory authority includes:

- Medicines, including magistral, hospital and officinal preparations;
- Raw materials for pharmaceutical use;
- Medical devices, reagents and other laboratory products;
- Cosmetic products;
- Nutritional supplements: and any other product considered as a health product by the legislation in force.
- According to the directive, the pharmaceutical regulatory authority is a public entity with legal personality and management autonomy. It is placed under the technical supervision of the Minister of Health and the financial supervision of the Minister of Finance. The operational departments must include the following structures for the implementation of the main regulatory functions devolved to the authority:
- Examination of applications for authorization to set up pharmaceutical establishments and other health structures falling within its area of competence;
- Study of applications for authorisation to practise for health professionals within its field of competence;
- Quality control of medicines;
- Pharmaceutical inspection, including monitoring sites for clinical trials and other health products;
- Control of clinical trials;
- Control of information and advertising on health products;
- Health product approval;
- Vigilances;
- Issuance of visas for the import and export of health products

3. National legal provisions and institutions in Togo

The implementation of these manifest political commitments, adherence to international conventions and various supranational initiatives is demonstrated in Togo by the step-by-step construction of a national institutional and legal framework that starts from the existing while being inspired by international legal recommendations and obligations.

3.1 The institutional framework of the regulation of the fight against PMQIF in TOGO

Medicines are a product whose importance for health and particularity are such that their regulation and market control are entrusted to specialized institutions and bodies. In Togo, different institutions are in charge.

The Ministry of Health TOGO

The Ministry of Health in Togo is responsible for defining the main orientations of the country's health policy, taking into account the government's main socio-economic development axes and priority public health problems. Through its health policy, it aims to ensure the highest possible level of health for the entire population by doing everything possible to develop a system based on public and private, individual and collective initiatives, which is accessible and equitable, and which is capable of satisfying the right to health of all, particularly the most vulnerable. (12) This is an objective in which medicines have a special place, especially in terms of improving the availability and quality of medicines and other health products. Also from an operational and organizational point of view, coordination has been entrusted to the Directorate of Pharmacy, Medicines and Laboratories (DPML), which articulates its objectives around a national strategic pharmaceutical plan (PSPN).

The Directorate of Pharmacy, Medicine and Laboratories (DPML)

The Directorate of Pharmacy, Medicines and Laboratories has several missions defined by ministerial order. It participates in the fight against abuse, illicit drug trafficking, counterfeiting and falsification of medical products in collaboration with national and international organizations. It has four divisions and an inspection cell. (13) The Division of Medicines and Other Health Products of the DPML, includes the section

of registration and market control of health products, which among its missions is also responsible for:

- The control of the import and export and distribution of pharmaceutical products, including those intended for promotion and donations in collaboration with the competent customs services.
- To organize the activities of quality controls of the pharmaceutical products put on the market in collaboration with the national laboratory of quality control of medicines and the cell of inspection.
- To set up and maintain a database concerning the import and export of pharmaceutical products.
- The registration of medicines.

The DPML has an inspection unit that works in close collaboration with its divisions. It ensures the application and compliance with the legislation and regulations relating to drugs and pharmacy, to ensure the inspection of establishments, but also to propose legislative and regulatory reforms in collaboration with other departments concerned.

Created since 2019, by ministerial decree, Togo's national quality control laboratory is not yet operational, which prevents a systematic analysis of products submitted for approval, but also of drug samples upon their entry into the territory or during inspection rounds to check their quality against the required specifications. (14)

Law enforcement agencies

In this fight against PMQIF, the DPML is assisted by law enforcement agencies working closely with it :

- The Customs and Indirect Taxation Office :

This is a department within the Togolese revenue office that manages the entire flow of products and commodities transiting through Togo's land, port and border borders. Its mission is to enforce the Customs Code and the tariff legislation in force in Togo. It works in collaboration with the DPML to confirm the nature of medical products entering the territory as well as the authenticity of the authorizations granted for import and export (15).

- The Central Office for the Repression of Illicit Drug Trafficking and Money Laundering (OCRTIDB)

This is a repressive body for all offenses related to the use, possession, abuse and illegal trafficking of drugs, narcotics, psychotropic or doping substances and precursors, as well as the laundering of the proceeds of criminal activity. Created in January 2004 by Decree N°2004/053 on the creation and attribution of the Central Office for the Repression of Illicit Drug Trafficking and Money Laundering, it acts as an interface with police, gendarmerie, customs and other services involved in the fight against illicit drug trafficking and money laundering.(16) The central office can take on any case requiring technicality and specialization in its field of action. In this respect, it has a right of inspection and evocation for each case and with respect to the service referred to. It may also refer to any department cases relating to drugs and money laundering.

In the course of 2021, just over 8 tons of various drugs were seized through his intermediary. These include cannabis (4.7 tons), synthetic drugs (3.3 tons) and cocaine (56 kg). (17) Also on June 5, 2022, the OCTRIB announced the seizure of nearly one ton of psychotropic products, tramadol and counterfeit drugs, as well as adulterated beverages and fuel in Lomé.

- The Mixed Container Control Unit (UMCC)

This is a control team composed of gendarmes, police officers, foresters, customs officers, port officials, etc. They are frequently solicited, and their main function is the control of containers. They generally carry out routine checks on containers entering the autonomous port of Lomé according to a sampling based on their own criteria and on information received. For example, in the case of drug containers, the UMCC verifies that the import authorization has been granted by the DPML and carries out an inspection of the container.

- The National Anti-Drug Commission (CNAD),

As part of the fight against drugs, a National Anti-Drug Committee was created in April 1996 by decree.(18) It is in charge of all problems related to the fight against drugs. It is the government's advisory body in the field of the fight against drug trafficking and abuse. It is the government's advisory body in the fight against drug trafficking and abuse. It has created a commission for legislation, repression and destruction of drugs which, as its name indicates, is responsible for proposing legislation, repressing trafficking and controlling the destruction of products that have been the object of illicit trafficking. (19)

3.2 The legal framework of the struggle:

Many African countries, including Togo, after independence have based their present legislation on the legacy left by colonization. Several other laws have been added to this legacy. Law 98/008 of March 15, 1998, on drug control, already penalizes all trafficking in products that fall within its scope of activity. (20) Penalties range from 5 to 10 years' imprisonment and a fine of 100,000 to 50,000,000 CFA francs, or from one of these two penalties only to 10 to 20 years' imprisonment and a fine of 250,000 to 125,000. 000 CFA francs or one of these two penalties only, those who have contravened the legislative and regulatory provisions concerning the export, import, international transport, offer, sale, distribution, brokerage, sale, delivery of high-risk drugs. Although the drug code does not extend to all drugs, it serves as the basis for the first efforts to combat counterfeit drugs, most of which are subject to strict controls because they are trafficked, misused, and because of their health hazards.

The framework law of 2000 is specifically devoted to pharmacy and medicines, and the one that first specifically sets out the framework for regulation and monitoring of the market. (21) The majority of the

articles constituting it will be revised and transposed into Book IV of the Public Health Code instituted by law n°2009-007 of 15 May 2009.(22) The definition of medicines and other related products is included. However, no mention is made of the definition of counterfeit or falsified medicines, nor of counterfeiting. It sets out the legal framework for the supply and trade of medicines in Togo, as well as the pharmaceutical monopoly.

Indeed, article n° 279 of the CSP of Togo stipulates that pharmacists benefit from a monopoly of competence with regard to the purchase, preparation, holding, wholesale, retail sale and any dispensing of medicines intended for human medicine. It also defines the rules for the practice of the pharmaceutical profession and the sanctions that apply to it. Penalties are attributed in article n° 317 of the health code for: "any person who has contributed, favored, participated, directly or indirectly in the introduction on the national territory of medicines or products subject to the pharmaceutical monopoly which would not be registered and authorized for importation. The penalty is a fine of five hundred thousand to 500,000 CFA francs (762 euros) and a prison sentence of three to six months or one of these two penalties only. In case of recidivism, these penalties may be doubled. In addition, the goods fraudulently introduced into the national territory are seized as well as any vehicle or equipment involved in the commission of the offence. Articles 420 and 421 of the same code provide for sanctions for pharmacists who have delivered or participated in the introduction of unregistered counterfeit and falsified products into the territory. In addition to the above sanctions, they may be issued a temporary or permanent ban on practicing the profession.

With regard to the supply of medicines, the manufacture or import of any medicine, their sale and free circulation are only authorized after their registration in the national nomenclature of specialties and generic essential medicines (Art. 284 of Law No. 2009-007). Also: "No one may import medicines for use in the national territory unless he has been expressly authorized by the national commission for the registration of medicines and other pharmaceutical products for this purpose" (Art. n° 301). We can distinguish two types of importers in Togo:

- Wholesale establishments (Art. n° 303 of Law n°2009-007);
- Occasional importers (Art. n° 308 of Law n°2009-007).

The revision of the penal code in 2015 marks a major step forward in the criminalization of offenses related to the PMQIF trade. Indeed, Togo, relying on its various international commitments and relying on the WHO recommendations for the implementation of stronger measures to discourage smuggling, has increased the penalties for such offenses. This text reinforces and fills some legal gaps by introducing a definition of counterfeit medicines, by defining the offences that can be incriminated and by raising the level of the penalties that apply to them.(23) Article 848 states: "Any person who contributes to, promotes or participates, directly or indirectly, in the introduction or sale of counterfeit medicines on national territory is punished by a sentence of five (5) to twenty (20) years' imprisonment and a fine of five million (5,000,000) to fifty million (50,000,000) CFA francs, without prejudice to the other penalties provided for in this code. The court also pronounces the total confiscation of the drugs and objects of the offence. It retained the term "counterfeit products" for PMQIF. Thus, a medicine is said to be counterfeit: "when there is a false representation of its identity and/or source. This applies to the product, its packaging, or any other packaging or labeling information. Counterfeiting can apply tò specialty or generic products. Counterfeit products can be products containing the correct ingredients or components or wrong ingredients or components, containing no active ingredient or containing an active ingredient in an insufficient amounts or products whose packaging has been falsified. This definition differs somewhat from that of the MEDICRIME convention, which defines a counterfeit product as "the misrepresentation of identitý and/or source".

Table 2. Summary of national criminal legal mechanisms to fight against PMQIF in Togo

PAYS	DEFINITION AND TERM	Pharmaceutical Act / Health Code	Penal Code	Drug Code	Customs Code
TOGO	LAW No. 2015-10 of November 24, 2015 on the new penal code: Article 848: Definition of counterfeit medicine.	- Framework law revised by law N°2009-07 on the health code: illegal practice of pharmacy, infractions of the pharmaceutical monopoly, market surveillance. (22) - The penalties for such offenses are one month to one year of imprisonment and a fine of 500,000	LAW NO. 2015-10 of November 24, 2015 Portant nouveau code pénal : -Article 848: Penalty of five (05) to twenty (20) years of imprisonment and a fine of five million (7622€) to fifty million (76220€) CFA francs, without prejudice to other penalties provided for by this code. - Articles 849 to 852 of the Penal Code: These articles increase the penalties provided for in the Health	Law No. 2009/008: Penalties for drug-related offenses can range from 5 to 20 years in prison with a fine of between 100,000 and 250,000 CFA francs. Article 99 and 100	Law N°2018-07 on the national customs code: The customs code mentions the seizure of fraudulent goods, suspected of being false or goods prohibited by the customs code. (24)

		(763€) to 500,000,000 (7622€) CFA francs.	Code with regard to market surveillance of imports and the illegal practice of pharmacy.		

Also, in Togo, are not assimilated to the counterfeiting of medical products:

- Patent infringements or patent litigation subject to the provisions of Chapter VI of Title III of this Code ;
- Medical products, generics or specialties, provided that they have obtained a marketing authorizatioń in another State.
- Batches that do not meet the standards, quality defectś or failure to comply with good manufacturing or distribution practices for medical products.

In addition to this, the judge has at his disposal Article No. 849 of the Penal Code, which increases the penalties against those who have allegedly practiced pharmacy illegally to criminalize offenses that may fall outside the scope defined above.

The main legal instruments criminalizing PMQIF trafficking is summarized in Table 2:

3.3 Analysis of the legal framework of the repression of the PMQIF phenomenon in Togo

A drug authorized for marketing must meet sufficient standards of quality, safety and efficacy to be placed on the market. When its quality is at stake or its origin is feared, several terms are used: counterfeit drugs, fake drugs, substandard drugs, street drugs. The WHO has shown through resolution WHA 41.16 of 1988 its interest in helping to "institute programs to prevent and detect the export and import of contraband pharmaceuticals". (25) Aware of the need for States to agree on a single term to describe fake medicines, it has initiated several working groups on this issue. Thus, after a first attempt to retain a common definition of fake medicines in 1992 by the term counterfeit, the WHO adopts in 2010 the term SSFFC (substandard/spurious/falsely-labelled/falsified/ counterfeit medical products). (26) In November 2015, at the fourth meeting of the Member States' mechanism that replaced the impact group, a working group was created to clarify the definition of SSFFC products, with the aim of ending the lack of consensus on this definition. It will lead to the adoption at the 70th session of the WHO on 29 May 2017 of the term " spurious, falsely-labelled, falsified or counterfeit (SFFC)". Under this term refers 3 definitions: “

- Substandard medical products: Also called “out of specification”, these are authorized medical products that fail to meet either their quality standards or their specifications, or both.
- Unregistered/unlicensed medical products: Medical products that have not undergone evaluation and/or approval by the NRRA for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.
  These medical products may or may not have obtained the relevant authorization from the national/regional regulatory authority of its geographical origin.
- Falsified medical products: Medical products that deliberately/fraudulently misrepresent their identity, composition or source. Any consideration related to intellectual property rights does not fall within this definition. Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product.

“Identity” shall refer to the name, labelling or packaging or to documents that support the authenticity of an authorized medical product.
“Composition” shall refer to any ingredient or component of the medical product in accordance with applicable specifications authorized/recognized by NRRA.
“Source” shall refer to the identification, including name and address, of the marketing authorization holder, manufacturer, importer, exporter, distributor or retailer, as applicable.
Medical products should not be considered as falsified solely on the grounds that they are unauthorized for marketing in any given country.” (27)

In Togo, the term used for SFFCs is "counterfeit", whose definition is closer to the one given by the MEDICRIME convention and a little less to the one currently used by the WHO. However, the use of different terms can lead to confusion for the judge when it comes to deciding certain disputes and allow certain criminals to escape the jurisdiction. Although the definition currently used by the WHO seems to be broader than the one used in Togo, the fact remains that offences related to unregistered products can be punished in the context of the illegal practice of pharmacy.

Moreover, an examination of the sanctions that can be applied by the judge in the context of such offences might seem contradictory in view of the coexistence of several legal texts with the same value according to the Kelsen pyramid. According to Nicolas Molfessis, "the survival of the old law and the immediate application of the new law favor the coexistence within the same legal order of several positive laws, applicable to identical situations [...]. The same situation is placed under the empire of various special rules which add up to determine, by agglutination as it were, the applicable law".(28) The coexistence of various texts could thus be in favour of stronger and more effective applicable legislation. Although the principle of subsidiarity in criminal law could be raised, which would require that

the least severe penalty be applied when judging a crime, this could strictly speaking only apply here in the context of the illegal practice of pharmacy. It is important to emphasize that despite the diversity of texts, in Togo the most specific text for PMQIF-related offences remains the penal code. It is thus the specific and applicable text.

4. Conclusion

Togo is one of the West African countries whose political commitment to the fight against PMQIF has been reflected in the establishment of a strict and binding institutional and legal framework. Today, legal instruments allow judges to sentence offenders to up to twenty years' imprisonment, which is one of the highest penalties in the subregion for such offenses. Togo is thus one of the examples in the subregion, although it has neither signed nor ratified the MEDICRIME convention.

However, much remains to be done in the operationalization of the different bodies and institutions, and in the application of the texts for an effective fight against the trade of fake medicines.

However, the fight against the illicit market and trafficking in fake medicines cannot be the business of a single State or group of States, but rather requires regional and even international cooperation. Following the example of the WAEMU initiative carried out by WAHO for the harmonization of texts on the regulation of medicines in West Africa, one could imagine in the coming years the establishment of a model law will be harmonized.

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Conflict of Interest

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