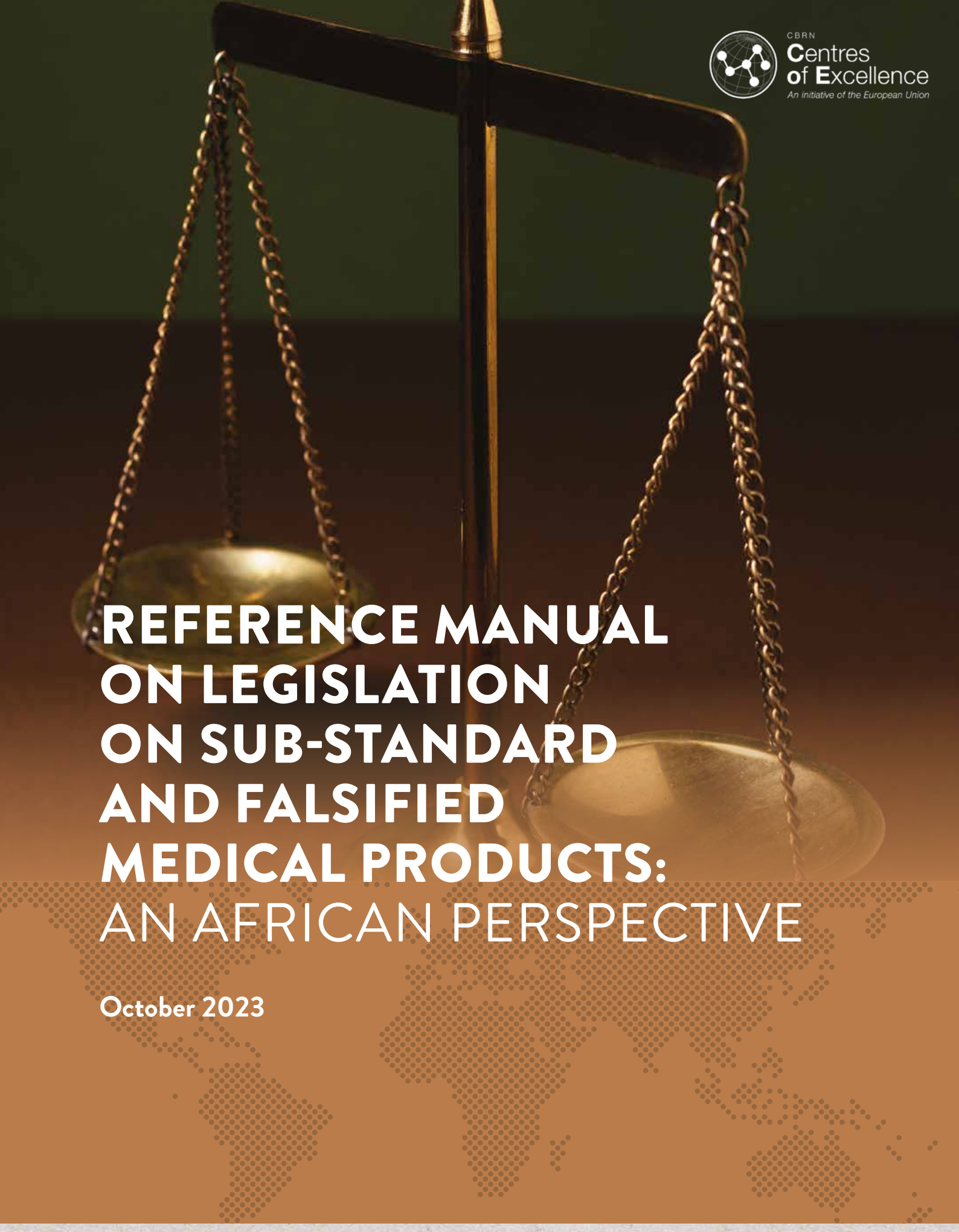

CBRN Centres of Excellence
An initiative of the European Union

REFERENCE MANUAL ON LEGISLATION ON SUB-STANDARD AND FALSIFIED MEDICAL PRODUCTS: AN AFRICAN PERSPECTIVE

October 2023

Funded by the European Union

medisafe

EXPERTISE FRANCE
GROUPE AFD

This publication was funded by the European Union. Its contents are the sole responsibility of Expertise France and do not necessarily reflect the views of the European Union.

Table of Contents

TABLE OF CASES	page

Foreword

The Reference Manual on Legislation on Substandard and Falsified Medical Products: An African Perspective, was developed under European Union Medisafe project P66 IFS/2017/390-601 implemented by Expertise France, Agence Francaise de Developpement, Ministry of Europe and Foreign Affairs*. The overall objective of MEDISAFE is to support the fight organized crime related to the manufacturing and trafficking of falsified medical products for better public health outcomes, in eleven countries in Eastern and Central Africa. It does so by strengthening partner countries' capacities in the law enforcement and pharmaceutical domains by strengthening their legal frameworks and promoting regional cooperation and harmonization in terms of approaches and procedures. The objective of the Reference Manual is to provide comprehensive guidance on the necessary legislative framework to ensure an effective national and regional response to the risks associated with Substandard and Falsified Medical Products. It aims to identify the key rules and roles necessary in national legislation and makes recommendations based on international and regional best practices.

The Reference Manual includes a general **introduction**, followed by two main sections. **The section dealing with the regulatory system** is based on the African Union Model Law on Medical Products Regulation of 2016 (hereinafter AU Model Law), which aims to "establish an effective and efficient system of medical products regulation and control and ensure that such products meet required standards of safety, efficacy and quality."[1] AUDA-NEPAD published in 2021 a Guidance Document on how to domesticate the provisions of the Model Law.[2] The Reference Manual expands on that Guidance by highlighting issues relevant to prevention, detection of and response to SFMP and providing examples from national laws, and addresses gaps, as well as foreseen amendments to the Model Law. It follows the nine regulatory functions as defined in the World Health Organization (WHO) Global Benchmarking Tool (GBT) for Evaluation of National Regulatory System of Medical Products (2021). It also refers to the role of the future African Medicines Agency, established by the Treaty for the Establishment of the African Medicines Agency (AMA) of 2019.

The section covering the criminal justice response, describes the necessary offences to be established in criminal law to effectively prevent and respond to trafficking in falsified medical products; the necessary tools for investigation and prosecution, including international cooperation in criminal matters; and measures for the protection of the rights of victims and ensuring the safety of witnesses. It relies on *the United Nations Convention against Transnational Organized Crime of 2000, and the UNODC publication Combating Falsified Medical Product related Crime: Guide to good legislative practices.*[3] *It also includes references to the the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health of 2011* (hereinafter: the MEDICRIME Convention) where appropriate. It identifies the key elements that should be included in legislation and provides examples from national laws and case law. The **Conclusions** chapter provides a summary of the key messages of the Reference Manual and a checklist for legislators.

Expertise France wishes to express its deep appreciation to the European Union, the African Union, and the African Union Development Agency-New Partnership for Africa Development, East Africa Community, the Intergovernmental Authority on Development, WHO, UNODC, and to the group of experts who have contributed to the development of this Reference Manual.

Antoine PEIGNEY
Director Health Department / Expertise France

* The project is implemented within the framework of the **European Union (EU) Chemical, Biological, Radiological, and Nuclear (CBRN) Risk Mitigation Centres of Excellence (CoE) Initiative**

https://cbrn-risk-mitigation.network.europa.eu/index_en

1. Article 3, *the African Union Model Law on Medical Products Regulation of 2016* (hereinafter: The AU Model Law).

2. AUDA-NEPAD, *Guidance Document for Domestication of the African Union Model Law on Medical Products Regulation (2021).* Available at https://www.nepad.org/publication/guidance-document-domestication-of-african-union-model-law-medical-products (Hereinafter: AUDA-NEPAD Guide).

3. UNODC. *A guide to good legislative practices on Combating Falsified Medical product- Related Crime (2019).* https://www.unodc.org/documents/treaties/publications/19-00741_Guide_Falsified_Medical_Products_ebook.pdf (Hereinafter: UNODC Guide).

EXECUTIVE SUMMARY

Substandard and Falsified Medical Products (SFMP) pose a serious threat to public security and public health in the African continent. The highest prevalence of the falsified and substandard medicines was registered in Africa. It was estimated that African states imported 70% of their medical products, making them especially vulnerable to the risks of SFMP.

An effective national response to SFMP requires:

- **A strong regulatory system to prevent, detect and respond to SFMP; and**
- **An adequate criminal justice response to offences related to manufacturing and trafficking in falsified medical products, including in the context of transnational organized crime, which includes deterring sanctions and tools for international cooperation.**

Efforts to provide an adequate regulatory response thus far included the African Union Model Law on Regulation of Medical Products from 2016, and the WHO Global Bench marking Tool for Evaluation of National Regulatory System of Medical Products from 2021, which provide the framework for the regulatory system. However, most Member States of the African Union have not adopted legislation that incorporates all the necessary elements from the Model Law, and do not meet all the indicators in the WHO Tool.

In the area of criminal justice, the gap is even wider since laws to criminalize manufacturing and trafficking in falsified medical products as a form of organized crime are missing in most Member States of the African Union, and where relevant offences exist in the law, penalties are very low and do not reflect the severity of the offence or its harmful consequences. UNODC developed in 2019 a guide to good legislative practices on Combating Falsified Medical product- Related Crime, which provides detailed guidance for drafting criminal provisions in law. The Guide is based on the UN Convention against Transnational Organized Crime of 2000 (UNTOC), which most Member States of the African Union have ratified.

One of the challenges in adopting adequate legislation on SFMP, is the usage of different terminology in different laws and international instruments. The Reference Manual therefore recommends the harmonization of definitions in Member States in the region by adopting the WHO definitions.

SUBSTANDARD MEANS **AUTHORIZED MEDICAL PRODUCTS THAT FAIL TO MEET EITHER THEIR QUALITY STANDARDS OR SPECIFICATIONS, OR BOTH.**

FALSIFIED MEANS **MEDICAL PRODUCTS THAT DELIBERATELY/FRAUDULENTLY MISREPRESENT THEIR IDENTITY, COMPOSITION, OR SOURCE.**

The Reference Manual includes a list of proposed definitions for all the relevant terms, based on the most recent and regionally applicable instruments, including the Treaty for the Establishment of the African Medicines Agency (AMA) of 2019, which entered into force in 2021.

In the area of regulation, the Reference Manual recommends the establishment by law of a **National Regulatory Authority** with the necessary powers to maintain a medical products register; grant marketing authorization; conduct pre-market and post-marketing surveillance; regulate the promotion and advertising of medical products; disseminate a range of information to health professionals and the public including awareness raising of the risks associated with SFMP and how to detect them; establish a reporting system with clear reporting duties and incentivize self-reporting; establish industry market vigilance; conduct product analysis to ensure quality, safety, performance and efficacy of medical products; establish quality control laboratories for quality checks; design appropriate schemes for effective medical products traceability; order recall, detention, suspension, withdrawal, cancelation of marketing authorization and safe disposal of SFMP; investigate conducts related to the manufacture, import, export, storage, distribution, sale and use of SFMP; and collaborate with institutions at the national, regional and international levels. It discusses the challenges of informal markets, and the need to supervise destruction of medical products in a safe manner (hence using the term “safe disposal”). The Reference Manual provides examples of such laws from several African countries. It also includes a checklist for legislators with all relevant items.

In the area of criminal justice reform, the Reference Manual recommends that States adopt in their national laws relevant criminal offences including:

- Manufacturing, selling, falsifying and possessing falsified medical products;
- Obstruction of justice, failure to report, and gross negligence in handling medical products;
- Participation in an organized criminal group, corruption and money laundering;
- Conspiracy to commit any of these offences, as well as organizing, aiding and abetting.

The Reference Manual also recommends the adoption of adequate and proportionate sanctions that reflect the seriousness of the offence and allow for extradition and mutual legal assistance between states. This implies a sentence of maximum four years of imprisonment, as a minimum (**serious offence** as defined in UNTOC). The Reference Manual provides an overview of other important tools in the investigation and prosecution of the offences, including witness protection and whistle-blower protec-

tion. It addresses the special needs of victims and makes some recommendations to States on how to best respect and fulfil their rights. In particular, it highlights the importance of ensuring compensation to victims affected by the use of SFMP.

Throughout the Reference Manual there are references to the unique challenges faced by countries in the region, and to examples of legislation, case-law and practices from African countries. It aspires to provide an African perspective on this complex and complicated issue, and does so in an innovative way by discussing together regulatory and criminal law, and exploring the links between them, as well as the range of legal tools available to counter infractions of the law (from administrative, to civil and criminal law).

ACKNOWLEDGEMENTS

Expertise France wishes to acknowledge the valuable suggestions and contributions of the following experts who participated in the first Expert Group Meeting held in Seychelles on 29 January to 2 February 2023: Ms. Anita Sands (WHO), Mr. Jayeola Babatunde (WHO), Ms. Riikka Puttonen (UNODC), Ms. Jane Mashingia, (EAC-MRH) and Mr. Anthony Bakenga Kapeta, (AUDA-NEPAD), Mr. Jean Bosco Hitimana (Burundi), Mr. Samuel Ngandu (DRC), Ms. Frehiwot Mequanint (Ethiopia), Ms. Yvonne Nkrumah (Ghana), Mr. Moses Sikuta (Kenya), Ms. Kahaki Jere (Malawi), Mr. Happy Mukama (Rwanda), Ms. Lucile de Comarmond (Seychelles), Mr. Pascal Morin (Seychelles), Mr. Iskari Fute (Tanzania), Ms. Tusa Bernard Njwaba (Tanzania), Ms. Rachel Nsiyoma Lutalo (Uganda). Ms. Amelie Nourrice (Seychelles) and Mr. Victor Pool (Seychelles) also provided inputs. A first draft of the Reference Manual was circulated to participants for their written comments on 21 March 2023.

A second draft of the Reference Manual was presented and discussed during the second Expert Group Meeting on "MEDISAFE Reference Manual on Legislation on Substandard and Falsified Medical Products", held in Kenya from 15 to 19 May 2023. Expertise France wishes to acknowledge the valuable suggestions and contributions of the following experts who participated in that meeting: Mr. Babatunde Jayeola (WHO); Ms. Riikka Puttonen (UNODC), Ms. Margareth Ndomondo-Sigonda (AUDA-NEPAD); Mr. Anthony Bakenga Kapeta (AUDA/NEPAD); Mr. Jean Bosco Hitimana (Burundi); Mr. Samuel Ngandu (DRC); Ms. Frehiwot Mequanint (Ethiopia); Ms. Yvonne Nkrumah (Ghana); Mr. Moses Sikuta (Kenya); Ms. Kahaki Jere (Malawi); Mr. Happy Mukama (Rwanda); Mr. Pascal Morin (Seychelles); Mr. Iskari Fute (Tanzania); Ms. Tusa Bernard Njwaba (Tanzania); Ms. Rachel Nsiyona Lutalo (Uganda); Ms. Hope Ndhlovu-Chanda (Zambia); and Ms. Mtendere Gondwe, AU Office of Legal Counsel; Dr. Jane Mashingia, (EAC); Mr. Louis DEY (EU RCO Kenya); Mr. Harro Wittermans (UNICRI Kenya); Mr. Wilbur Gachoki (Kenya); Ms. Jeniva Jasson NEP (Tanzania); Ms. Amne Issa ZFDA (Zanzibar); Mr. Getachew Genete (Ethiopia) and Mr. Mphatso Kawaye (Malawi). Mr. Khalid Abdelrahman (IGAD) and Mr. Oscar Alarcón Jiménez (Committee of the Parties to the MEDICRIME Convention, COE) provided written comments on the Draft Reference Manual.

The Reference Manual was prepared by Ms. Miri Sharon, International Consultant. The development of the Reference Manual was overseen by Dr. Reychad Abdool, Team Leader, and Mr. Juan Cepeda, Project Coordinator (both of Medisafe Project, Expertise France).

Expertise France expresses its gratitude for the support provided by the African Union, the African Union Development Agency-New Partnership for Africa Development (AUDA/NEPAD), the East African Community, WHO (HQ and AFRO) and UNODC HQ; to the drafting and finalization of the Reference Manual.

ACRONYMS AND ABBREVIATIONS

AMA	African Medicines Authority
AU	African Union
AUDA-NEPAD	African Union Development Agency
EAC	East African Community
ECOWAS	Economic Community of West African States
EU	European Union
EU CBRN COE	European Union Chemical, Biological, Radiological, and Nuclear Risk Mitigation Centres of Excellence Initiative
FSCA	Field Safety Corrective Action
GBT	WHO Global Benchmarking Tool for Evaluation of National Regulatory System of Medical Products (2021).
GMP	good manufacturing practices
IGAD	Intergovernmental Authority on Development in Eastern Africa
LE	licensing establishments
LR	national lot release
LT	laboratory testing
MA	marketing authorization and registration
MC	market surveillance and control
MLA	mutual legal assistance
NCL	national control laboratory
NRA	national regulatory authority
SADC	South African Development Community
SFMP	Substandard and Falsified Medical Products
UN	United Nations
UNCAC	United Nations Convention against Corruption
UNODC	United Nations Office on Drugs and Crime
UNTOC	UN Convention against Transnational Organized Crime
VL	vigilance
WHA	World Health Assembly
WHO	World Health Organization

I. INTRODUCTION

A. Scope of the Reference Manual – Substandard and Falsified Medical Products

The current Reference Manual applies to substandard and falsified medical products. These are the current terms used by the international community, as defined by the World Health Assembly in 2017.[4] Previously, international and national legal sources applied different terms such as counterfeit, fake, spurious, and adulterated. The definitions adopted by WHA were welcomed by experts which commented that this was "a welcomed improvement over the previous complex and disputed "working definition" of "substandard/spurious/falsely-labelled/falsified/counterfeit medical products," as it squarely focuses on public health." [5]

The Reference Manual therefore adopts the WHA definitions.

Substandard (or "out of specification") mean **authorized medical products that fail to meet either their quality standards or specifications, or both**. According to the explanatory note *"These are authorised/registered medical products that have become substandard usually due to a genuine manufacturing error, degradation during transportation and storage or they have expired. Substandard medical products usually require a regulatory response."* [6]

Falsified mean **medical products that deliberately/ fraudulently misrepresent their identity, composition, or source**. According to the explanatory notes *"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 NRA.

"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.

Falsified medical products are those where the packaging and contents have been intentionally designed to deceive any person by visually replicating a genuine registered product or give the appearance, they are a genuine registered product or is a registered medical product that has been intentionally manufactured to a standard which is below the required specification. Falsified medical products usually require a criminal investigation and sanction, sometimes in conjunction with regulatory action." [7]

The AU Model Law of 2016 uses different terms for falsified medical products, however it refers to the WHO meanings.[8] The AUDA-NEPAD Guidance on the Model Law of 2021, recommended that "the new terminology 'Substandard and Falsified (SF) Medical Products' be used in national legislation". It was also recommended that the term 'counterfeit' should not be used.[9] The term "counterfeit" is now usually defined and associated with the protection of intellectual property rights."[10] In order to ensure a harmonized approach to SFMP, the Reference Manual applies the same definitions.

The Reference Manual does not cover intellectual property rights. Nothing in this reference manual is to be interpreted as applying to intellectual property rights or as making a distinction between originator medicines and generic medicines.

The Reference Manual's recommendation is that States adopt the same definitions in all the relevant laws, in order to ensure consistency in application of the law regulating the production of medicines and medical products and the criminal law and ensure a harmonized approach to by all national authorities.

It is noted that WHA also defined **Unregistered/unlicensed** as "medical products that have not undergone evaluation and/or approval by Regulatory Authority for the market in which they are marketed/distributed or used." According to the explanatory note, *"Unregistered/unlicensed medical products can be products that have not undergone any clinical trials or regulatory approval anywhere in the world, or products that have been licensed or registered in other countries, but do not have marketing authorizations in the country where they are being supplied (and have not received a waiver on humanitarian grounds)."* Unregistered/ unlicensed medical products are not under the purview of this Reference Manual.

4. WHO, *Report by the Director-General on the Member State mechanism on substandard/spurious/falsely-labelled/falsified/ counterfeit medical products*, document A70/23, (2017) annex, appendix 3. 2 Working Definitions (hereinafter: WHO Report on SSFFC 2017).

5. A Olliaro E, Olliaro P, Ho CWL, Ravinetto R. *Legal Uncertainty-The Gray Area around Substandard Medicines: Where Public Health Meets Law*. 102(2) Am J Trop Med Hyg. (2020) 262-267.

6. WHO Report on SSFFC (2017), supra note 4.

7. WHO Report on SSFFC (2017), supra note 4.

8. **"substandard/spurious/falsified/falsely-labelled/counterfeit medical product"** means the like-named products as defined by the World Health Organisation; AU Model Law, definitions.

9. AUDA-NEPAD Guide, supra note 2, pages 16-17.

10. Report of the informal technical working group on draft working definitions of substandard/spurious /falsely-labelled/falsified/counterfeit (SSFFC) medical products A/MSM/5/7 23 November 2016, para. 8.

B. Overview – the problem of SFMP in the region

The threats posed by the spread of substandard and falsified medical products are globally recognized, and include adverse health, economic and socioeconomic impacts for individuals and for society at large.[12] The World Health Organisation estimated in 2017 that about 10.5% of medicines on the global market were substandard or falsified.[13] A compilation of data undertaken by WHO in 2018 concluded that "the prevalence of substandard and falsified medicines in low- and middle-income countries was 13.6% overall (19.1% for antimalarial and 12.4% for antibiotics). The highest prevalence of the falsified and substandard medicines was registered in **Africa** (18.7%).[14] It was also estimated that African states imported 70% of their medical products,[15] making them especially vulnerable to the risks of SFMP. The estimated economic impact ranged widely from $10 billion to $200 billion.[16] SFMP affected people who have limited access to health care services or who are dependent on medical treatment for longer periods of time. Patients from developing countries are mainly affected by falsified "antipyretics, analgesics, and antitussives, such as paracetamol elixir, cough syrup, or teething mixture containing diethylene glycol".[17]

The high profits that may be gained from trafficking in falsified medical products, coupled with a low risk of detection and prosecution, and the lack of adequate sanctions, make it an attractive form of crime, both for organized criminal groups and for individuals.[18] In low income countries, substandard production of medical products may be the result of limited capacity of producers; spread through informal markets which provide more affordable access to medicines; and procurement practices of donors that are not always aligned with national efforts.[19] There are many challenges that need to be addressed in order to ensure an effective national and regional response to the risks associated with SFMP, but the one most often cited is inadequate national legislation resulting in weak regulatory systems, weak penal sanctions and enforcement mechanisms.

Considering the cross-border nature of this phenomenon, regional and international coordination and collaboration are key in an effective response. Therefore, harmonization of civil and criminal legislation of countries in the region is highly desirable. The African Union has taken measures to ensure such harmonization by adopting *the African Union Model Law on Medical Products Regulation in 2016 and the Treaty for the Establishment of the African Medicines Agency* (AMA) in 2019. However, since the adoption of the Model Law in 2016, new definitions of substandard and falsified medical products were adopted by the World Health Assembly in 2017, and some gaps were identified in relation to the response to SFMP. The Model Law, while including some offences and sanctions, does not provide a comprehensive framework for the criminal justice response to offences in falsified medical products.

The current Reference Manual is intended to provide guidance for **harmonization, regulation and enforcement** of the legal response to SFMP, by creating a comprehensive legal framework. However, to achieve the intended results, legislation should be complemented by the necessary institutional, human and budgetary resources, including measures to address the demand for affordable quality medicines.[20]

11. The same approach was adopted by the UN Office on Drugs and Crime. See UNODC Guide, supra note 3, page 2.

12. WHO, *A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products*. (2017), page 21, Box 5. "**Health impact:** adverse effects (for example toxicity or lack of efficacy) from incorrect active ingredients; failure to cure or prevent future disease, increasing mortality, morbidity and the prevalence of disease; progression of antimicrobial resistance and drug-resistant infections; loss of confidence in health care professionals, health programmes and health systems. **Economic impact:** increased out-of-pocket and health system spending on health care; economic loss for patients, their families, health systems and manufacturers (and other actors in the supply chain) of quality medical products; waste of human effort and financial outlay across the health system, further straining resources, staff and infrastructure; increased burden for health care professionals, national medicine regulatory authorities, law enforcement and criminal justice systems. **Socioeconomic impact:** lost income due to prolonged illness or death; lost productivity costs to patients and households when seeking additional medical care, the effects of which are felt by businesses and the wider economy; lack of social mobility and increased poverty." For a detailed analysis see also OECD, **Trade in Counterfeit Pharmaceutical Products** (2020), Chapter 7. Impact of counterfeit medicines, at https://www.oecd-ilibrary.org/sites/ad927008-en/index.html?itemId=/content/component/ad927008-en .

13. World Health Organization, WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products. (Geneva, Switzerland 2017), pages 2-3.

14. Ozawa S, Evans DR, Bessias S, Haynie DG, Yemeke TT, Laing SK, Herrington JE., Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries: A Systematic Review and Meta-analysis. 1(4) JAMA Netw Open (2018).

15. Cartwright, R., & Baric, A, The rise of counterfeit pharmaceuticals in Africa. Policy Brief, Enact, 2(6). (2018). 1–15

16. Ozawa et al (2018), supra note 14.

17. Aminu N, Sha'aban A, Abubakar A, Gwarzo MS. Unveiling the Peril of Substandard and Falsified Medicines to Public Health and Safety in Africa: Need for All-Out War to End the Menace. Medicine Access @ Point of Care 2017; 1.

18. See for example UNODC, Trafficking in medical products in the Sahel (2023): "Investigations have revealed the involvement of a wide range of opportunistic actors in trafficking in medical products in the Sahel countries, from employees of pharmaceutical companies, public officials, law enforcement officers and health agency workers to street vendors, all motivated by potential financial gain." Ibid. Page 7.

19. Pisani E, Nistor AL, Hasnida A, Parmaksiz K, Xu J, Kok MO. Identifying market risk for substandard and falsified medicines: an analytic framework based on qualitative research in China, Indonesia, Turkey and Romania. 7 Wellcome Open Research. (2019) 70.

20. Olliaro et al., supra note 5.

C. Regional Harmonization

Regional harmonization is an important element of the response to SFMP in the region. It allows for coordination and cooperation between national regulatory authorities, as well as cooperation in criminal matters between law enforcement officers and prosecutors. The national legal framework should take into account the relevant legal provisions of all applicable regional instruments, and ensure its national authorities are empowered to cooperate and coordinate with other national authorities in the region. It is important to note that some of the regions have developed initiatives related to SFMP, and some have not. Below is information of those regions.

As there is a risk of abuse of free trade zones for transferring SFMP across national borders, national laws should also include provisions for effective policing of the zones by relevant agencies, including through market control and market surveillance of medical products.[21]

1. THE AFRICAN UNION

The African Union Agenda 2063 includes a goal to harmonize the regulatory systems in Africa (goal 3). The establishment of the African Medicines Agency (AMA) is a key step towards such harmonization. As at May 2023, 23 Member States ratified the treaty for the establishment of AMA.[22] The AMA is a result of the foundation built by the AMRH Initiative launched in 2009 as part of Pharmaceutical Manufacturing Plan for Africa (PMPA). The adoption of the Treaty provides a common framework for regulatory actions on medical products, and supports the fight against SFMP by coordinating the policies of Member States.

The main objective of the AMA is to enhance capacity of countries and regions "to regulate medical products in order to improve access to efficacious medical products on the continent" (article 4). Article 6 of the AMA defines the main functions of the Agency, including collecting, storing and sharing information on substandard and falsified medical products. It will also share information globally and cooperate with regional regulatory bodies, such as the European Medicines Agency and WHO; and provide technical assistance and resources to its Member States. Among the anticipated benefits of the AMA, once fully functional, are the growth of local manufacturing capacity, promoting regulatory cooperation and harmonization in cooperation with the 8 regional economic communities, setting priorities that are relevant to the continent, increase in the availability of information and a more robust response to falsified medical products.[23]

The African Union AUDA-NEPAD also developed in 2016 the Model Law on the regulation of Medical Products, to assist Member States in developing adequate legislation and to promote regional harmonization. It was perceived as an appropriate tool to assist legislators, which is less cumbersome than the drafting and ratification of a new treaty. The Model Law is referenced to throughout this Reference Manual.

2. REGIONAL INITIATIVES

Regional cooperation is highly important in light of the transnational nature of trafficking in falsified medical products and the export and import of substandard medical products. Regional initiatives for harmonization and cooperation in regulation of medical products have been implemented in the past 20 years by some regional economic communities in Africa. There are 8 regional communities in Africa, yet detailed information was more difficult to obtain for some. Below is a brief overview.

i. The East African Community

Article 118 of the EAC Treaty (treaty for the establishment of the East African Economic community, chapter 21 on coordination) establishes co-operation on health and specifically asks Partner States to harmonize drug registration procedures so as to achieve good control of pharmaceutical standards without impeding or obstructing the movement of pharmaceutical products, and hence facilitates access to pharmaceutical products within the Community. The EAC Technical Cooperation Framework Agreement has been domesticated by all 7 EAC National Medicines Regulatory Authorities (NRAs) since 2018. The EAC has also developed mutual recognition frameworks (MRF) for different cadres of professionals. The Common Market Protocol facilitates the movement of people, products and services, which is another key milestone after the adoption of the customs union.

The EAC Medicines Regulation Harmonization (MRH) Programme was launched in March 2012 to establish a harmonized regulatory system in the region that enables approval of medicines through various regulatory pathways. This programme covers the entire life-cycle of the medical product's clinical trials, post marketing surveillance etc. Some of the activities under the programme in collaboration with national NRAs lead to the discovery of SFMP. The partner countries are required to take action on the basis of findings of joint activities.

ii. The Intergovernmental Authority on Development (IGAD) in Eastern Africa

IGAD has developed the framework of the IGAD Medicines Regulatory Harmonization (MRH) Initiative of selected priority medicines in order to determine avenues for collaboration between IGAD Secretariat and Member States' National Medicines Regulatory Authorities (NMRAs). It is aimed

21. Philip Osarobo Odiase. *Recalibrating African health laws to combat substandard and falsified medical products: Beyond COVID-19*, 1(2) International Journal of Civil Law and Legal Research 2021; 01-09. Page 6

22. See ratification status at the following link (accessed on 24.4.2023): https://au.int/sites/default/files/treaties/36892-sl-TREATY_FOR_THE_ESTABLISHMENT_OF_THE_AFRICAN_MEDICINES_AGENCY_2.pdf

23. Chattu, V. K., Dave, V. B., Reddy, K. S., Singh, B., Sahiledengle, B., Heyi, D. Z., Nattey, C., Atlaw, D., Jackson, K., El-Khatib, Z., & Eltom, A. A. *Advancing African medicines agency through global health diplomacy for an equitable pan-African universal health coverage: A scoping review*, 18(22) International Journal of Environmental Research and Public Health (2021) 11758.

at enhancing institutional capacity in the area of medicines registration and the review an applications for marketing authorization for priority medicines. IGAD has developed a Regional approach to Medicines Quality Surveillance, with the establishment of the IGAD working group (IWG) including experts and officials in charge of pharmacovigilance and post-marketing surveillance from IGAD Member States' NMRAs with technical assistance from the 'Promoting the Quality of Medicines' (PQM) program.

iii. The Economic Community of West African States (ECOWAS)

ECOWAS adopted in April 2014 a Regional Pharmaceutical Plan (ERPP).[24] The West African Health Organization developed an operational strategic plan and a legal framework to enforce the fight against SFMP. A regional ECOWAS Medicines Anti-counterfeit Committee (EMACCOM) was constituted with members drawn from the National Medicines Regulatory Authorities of all the 15 ECOWAS Member States.[25]

iv. The Southern African Development Community (SADC)

The Southern African Development Community (SADC) Pharmaceutical Programme was created in June 2004, to respond to the need to use appropriate pharmaceuticals as central to disease treatment and prevention as well as to address the need for standardized legislation for pharmaceutical usage and avoid disparate treatments for diseases currently affect healthcare in the region. Shortly after the inception of the Pharmaceutical Programme, SADC established the Protocol on Health in August 2004, with specific provisions (Article 29) for improving access, affordability, and effectiveness of pharmaceuticals within the region. The SADC Pharmaceutical Business Plan (2007- 2013) was published in 2007 to improve sustainable availability and access to affordable, quality, safe, efficacious essential medicines. One of the strategies to achieve this is by harmonizing standard treatment guidelines and essential medicine lists and strengthening regulatory capacity; supply, and distribution of basic pharmaceutical products through ensuring a fully functional regulatory authority with an adequate enforcement infrastructure.

v. Other economic communities

Other economic communities in Africa include the Common Market for Eastern and Southern Africa (COMESA); Economic Community of Central African States (ECCAS); Community of Sahel–Saharan States (CEN–SAD); and the Arab Maghreb Union (AMU).

D. *Applicable legal principles – legal context*

Activities related to substandard and falsified medical products may be subject to different types of law:

i) Administrative law – which applies to the establishment and functioning of administrative bodies, such as national regulatory agencies (public health law is a branch of administrative law);

ii) Civil law – which regulates private rights such as those created by contracts or in consumer laws; and

iii) Criminal law – which defines offences against the public and establishes sanctions against offenders.

In adopting national legislation on SFMP, legislators should take into account all applicable legal rules, however the focus of the Reference Manual is on the protection of public health and the prevention of manufacturing of SFMP and trafficking in falsified medical products.

Chapter II of the Reference Manual covers administrative and civil law in the context of the regulatory system, and chapter III covers criminal law. The connections between these different legal responses, and the recommended approach regarding when it is most appropriate to apply each of these bodies of law, are discussed throughout the Reference Manual.

These bodies of domestic law are all influenced by and subject to relevant rules and norms of international law, such as international human rights law (IHRL), transnational criminal law, global health law, and international trade agreements.[26] The relevant provisions of international instruments are mentioned under each of the specific topics. To frame the discussion, below is an overview of the relevant approaches.

1. SFMP IN THE CONTEXT OF THE HUMAN RIGHT TO HEALTH

International Human Rights Law establishes basic human rights that everyone is entitled to, and creates corresponding obligations for States to respect, protect and fulfil them. Article 6 of the International Covenant on Civil and Political Rights (ICCPR, 1966) recognizes and protects the inherent right to life of every human being. The use of substandard and falsified medicines may result in death,[27] therefore governments should take all necessary measures to protect individuals within their jurisdiction from that risk.

Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR, 1966) establishes the right to the "highest attainable standard of physical and mental health". This implies detailed legal obligations of States to respect, protect and fulfil the right to health.

States are under an obligation to protect the public from the risks associated with SFMP, to provide access to medical services for victims of falsified medical products and those suffering harm as a result of the use of substandard medical products, and to fulfil the right in a non-discriminatory manner that protects the most vulnerable groups within society.

24. WAHO/TECHNICAL DOCUMENT/ 04.14 available online at https://www.unido.org/sites/default/files/2016-01/ECOWAS_Regional_Pharmaceutical_Plan_0.pdf.

25. Ibid, pages 24-25.

26. Olliaro et al, supra note 5. See for example the case scenario on page 265.

27. See for example Renschler JP, Walters KM, Newton PN, Laxminarayan R., *Estimated under-five deaths associated with poor-quality antimalarials in sub-Saharan Africa*. 92(6) American Journal of Tropical Medicine and Hygiene (2015) 119-126.

This includes for example a duty "to control the marketing of medical equipment and medicines by third parties". It also implies that "states parties should refrain at all times from imposing embargoes or similar measures restricting the supply of another State with adequate medicines and medical equipment". Health facilities, services and goods must be accessible to all, both physically and economically. This includes equitable access to medicines of sufficient quality, as well as "scientifically approved and unexpired drugs". The "failure to protect consumers and workers from practices detrimental to health, e.g., by employers and manufacturers of medicines or food" is considered **a violation of the right**, and could therefore create a ground for bringing a case against the state (CESCR General Comment 14).[28]

The African Charter of Human and Peoples' rights (1981) establishes relevant rights as well: article 4 establishes the right to life and integrity of the person; and article 16 (1) states "every individual shall have the right to enjoy the best attainable state of physical and mental health". The Charter also makes it the responsibility of state parties to ensure access to adequate medicines and holds them accountable in the event of a failure to respect the right.[29]

The right to health also includes the obligation to abstain from "imposing discriminatory practices relating to women's health status and needs".[30] The Committee on Economic, Social and Cultural Rights also recommended that "[s]tates integrate a gender perspective in their health-related policies, planning, programmes and research in order to promote better health for both women and men".[31] Integrating a gender approach in health-related activities implies a gender-responsive framework for prevention and detection of SFMP. Guidance on this specific issue is limited.[32]

2. SFMP AND DEVELOPMENT (HEALTH & RULE OF LAW)

The Sustainable Development Goals (SDG) 2030,[33] provide an important framework for addressing SFMP in national policies and laws. Sustainable Development Goal 3, 'establishing Good Health and Well-Being', is most relevant. Sub-target 3.8 specifies access 'to safe, effective, quality and affordable essential medicines and vaccines for all'. SFMP disproportionately affect developing countries, yet they are still missing from the discussions on SDG 3. "The full scale of the challenge in Africa is not fully understood, but research suggests that the problem and its impact are severe. If the continent is to make headway in achieving SDG 3, the issue of counterfeit medicines must move higher up on policy agendas".[34] The SDGs also establish the principle of "leaving no one behind" focusing on ensuring that the most marginalized groups in society have access to services such as affordable health care. The African Union's Agenda 2063 also establishes under goal 3 the target of "expanding access to quality health care services, particularly for women and girls".[35]

SDG 16 on "peace, justice and strong institutions" is also relevant, as it establishes as a target to "promote the rule of law at the national and international levels and ensure equal access to justice for all". The rule of law includes important aspects for legislation (both criminal and civil). Among the goals of SDG 16 are also to "substantially reduce corruption and bribery in all their forms"; and "promote and enforce non-discriminatory laws and policies for sustainable development".

3. FALSIFIED MEDICAL PRODUCTS AND ORGANIZED CRIME

The high profits that can be obtained from illicit trafficking of falsified medical products provide an incentive for organized criminal groups to engage in this criminal activity.[36] In 2020, the Conference of the States Parties to the UNTOC Convention adopted Resolution 10/5 on *Preventing and combating the manufacturing of and trafficking in falsified medical products as forms of transnational organized crime*,[37] confirming that "the United Nations Convention against Transnational Organized Crime constitutes a useful tool for international cooperation in preventing and combating the manufacturing of and trafficking in falsified medical products in those cases falling within its scope." It also called upon States parties "to make the manufacturing of and trafficking in falsified medical products, in appropriate cases and in accordance with national legislation, a serious crime as defined in article 2, paragraph (b), of the Organized Crime Convention".[38]

28. CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) Adopted at the Twenty-second Session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000 (E/C.12/2000/4).

29. Philip Osarobo Odiase. *Recalibrating African health laws to combat substandard and falsified medical products: Beyond COVID-19*, 1(2) International Journal of Civil Law and Legal Research 2021; 01-09. Footnote 50 referring to Durojaye E. 'The Approaches of the African Commission on to the Right to Health under the African Charter' [2017] 17 Law, Democracy and Development 393 at 397. It also notes that in the case of "*Purohit and Moore v The Gambia* [52], while upholding states' responsibility to ensure access to healthcare, the African Commission on Human and Peoples' Rights held that Article 16 of the Charter imposes a positive obligation on states to ensure without discrimination, universal access to medical products and health services by all persons within the state's territory" (Communication No. 241/2001 (2003); ACHPR 49 (May 2003).

30. CESCR General Comment No. 14, para. 34.

31. CESCR General Comment No. 14, para. 20.

32. See for example the European Committee on Crime Problems (CDPC), A Gender Perspective on the Counterfeiting/Falsification of Medical Products and Similar Crimes: Concept Note (2017). I did not find any follow up document except a short presentation of Peggy Maguire Director General European Institute of Women's Health, on Sex and Gender in Medicine Friday 9th July 2021 Presentation, available online at https://rm.coe.int/na-famed-presentation-p-maguire-gender-webinar/1680a3335d. Additional research is required in order to establish

33. Resolution adopted by the General Assembly on 25 September 2015 (A/70/1) Transforming our world: the 2030 Agenda for Sustainable Development.

34. Cartwright & Baric, supra note 15, page 1 (summary). See also Mackey TK, Vian T, Kohler J. *The sustainable development goals as a framework to combat health-sector corruption*. 96(9) Bull World Health Organ (2018) 634-643

35. Available at https://au.int/agenda2063/goals.

36. UNODC, *trafficking in medical products in the Sahel* (2023), OECD/EUIPO. *Trade in Counterfeit Pharmaceutical Products* (2020).

37. See https://www.unodc.org/documents/treaties/UNTOC/COP/SESSION_10/Resolutions/Resolution_10_5_-_English.pdf

38. For guidance on domestication of UNTOC, see UNODC *Model Legislative Provisions against Organized Crime*, second edition (2021).

E. Definitions

The following definitions apply to the legal framework on SFMP. Most of them are based on WHO definitions,[39] but some are from the AU Model Law and the AMA Treaty. Consistent terms have been adopted for the regulatory and the criminal systems, unless otherwise mentioned, to ensure all national laws apply similar definitions. Harmonizing definitions is also important as a basis for cooperation between states in criminal and regulatory matters. In the area of criminal justice, this is especially important as a basis for extradition and mutual legal assistance.

MEDICAL PRODUCTS

The WHO defines medical products to include medicines, vaccines, and medical devices.[40]

The AU Model Law defines medical products to include medicines, vaccines, diagnostics and medical devices.[41]

The AMA Treaty defines medical products to include **medicines, vaccines, blood and blood products, diagnostics and medical devices**.[42]

UNODC Guide defines medical products to include medicines, excipients, active substances, medical devices, **their parts and materials, and accessories used in conjunction with medical devices**.[43]

For the purpose of this Reference Manual, the definition included in the AMA Treaty is adopted to ensure protection of public health and widest coverage of falsified medical products. It is also recommended to add **any parts or materials or accessories used in conjunction with medical devices**, as these items could also be falsified, and thus pose a threat to public health.

MEDICINE

WHO definition 1. Any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient; and

2. Any substance or combination of substances marketed or manufactured to be marketed for treating or preventing disease in human beings, or with the view of making a medical diagnosis in human beings, or to restoring, correcting, or modifying physiological function in human beings. **Medicine and pharmaceutical product** are often used interchangeably. (WHO Quality Assurance of Medicines Terminology Database).

Pharmaceutical product - Any product intended for human use or veterinary product intended for administration to food-producing animals, presented in its finished dosage form, which is subject to control by pharmaceutical legislation in either the exporting or the importing state, and include product for which a prescription is required, products that may be sold to patients without prescriptions, biologicals, vaccines. It does not however include medical devices.[44]

The AU Model Law and the AMA treaty define medicine as: any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in: -

a) The diagnosis, treatment, mitigation, modification, or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or

b) Restoring, correcting, or modifying any somatic or psychic or organic function in humans, and includes any veterinary medicine (AU Model Law, article 4; AMA Treaty, article 2).

For the purpose of this Reference Manual, the definition included in the AMA Treaty is adopted as it seems to include the elements from the WHO definition, and this is in line with regional harmonization.

BLOOD PRODUCTS

The WHO defines blood products as - Any therapeutic substances derived from human blood, including whole blood, blood components and plasma-derived medicinal products. (WHO Quality Assurance of Medicines Terminology Database).

The AMA defines blood products as - Any therapeutic substances derived from human blood for the use in the treatment of diseases or other medical conditions (AMA Treaty, article 2).

MEDICAL DEVICE

WHO defines Medical device as - Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury;
- investigation, replacement, modification, or support of the anatomy, or of a physiological process;
- supporting or sustaining life;

39. WHO, Quality Assurance of Medicines Terminology Database – list of terms and related guidance (March 22, 2022) available at https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/mqa-terminology-sept-2020.pdf?sfvrsn=48461cfc_10&download=true

40. Quality Assurance of Medicines Terminology Database – list of terms and related guidance.

41. AU Model Law, article 4.

42. AMA Treaty, article 2. Available at https://au.int/sites/default/files/treaties/36892-treaty-0069_-_ama_treaty_e.pdf

43. UNODC Guide, supra note 3, pages 10-11

44. World Health Organization. WHO Technical Report Series, No. 929, 2005 Annex 4 WHO guidelines for sampling of pharmaceutical products and related materials. Available at https://www.who.int/publications/m/item/annex-4-trs-929

- control of conception;
- cleaning, disinfection, or sterilization of medical devices;
- providing information by means of in vitro examination of specimens derived from the human body; and

does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means. (WHO Quality Assurance of Medicines Terminology Database).

The AU Model Law and the AMA treaty define "medical device" as any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article: -

a) intended by the manufacturer to be used, alone or in combination, for humans or animals for:-

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process;

(iv) supporting or sustaining life;

(v) control of conception;

(vi) disinfection of medical devices; or

(vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and

b) which does not achieve its primary intended action in or on the human or animal body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means. (AU Model Law, article 4; AMA Treaty, article 2).

For the purpose of this Reference Manual, the definition included in the AMA Treaty is adopted, as it is wider.

Vaccine - A biological preparation that improves immunity to a particular disease (WHO Quality Assurance of Medicines Terminology Database).

DEFINITIONS RELATED TO THE REGULATION OF MEDICAL PRODUCTS

Compassionate use means access to unregistered medical products in special or emergency situations. In general, either the patient has a severe or life-threatening illness and existing therapy has failed, or the disease is a rare one for which specialist medicines do not have a local marketing authorization. The medical products are still experimental, or at any rate unproven, and the government is not obliged to fund their supply (AU Model Law, article 4).

Inspection means an officially conducted examination (i.e. review of the conduct of the trial, including quality assurance, personnel involved, any delegation of authority and audit) by relevant authorities at the site of investigation and/or at the site of the sponsor in order to verify adherence to Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) as set out in this document (AU Model Law, article 4).

Inspector means a person authorized to perform inspection activities by the [National] Medical Products Regulatory Agency, pursuant to this Law (AU Model Law, article 4).

Market includes a variety of systems, institutions, procedures, social relations and infrastructures for medical products sale, and barter or exchange or supply or dispose of to a person (AU Model Law, article 4).

Informal market of medical products - A sector of national or local economy where: – the manufacture, import or export, distribution, sale, supply, or purchase of medical products takes place outside of the legal, regulatory or administrative oversight of relevant public health or regulatory authorities; – The medical products have or have not been assessed for safety, efficacy or quality by public health and regulatory authorities;* and – The aforementioned activities may be conducted by persons or entities with or without appropriate qualifications and may take place in a physical, virtual or hybrid environment. Authorized products found on the informal market are not considered substandard and falsified products per se. (WHO Quality Assurance of Medicines Terminology Database).

Marketing authorization (MA) means a legal document issued by the competent Agency/Authority for the purpose of marketing or free distribution of a product which has been approved after evaluation for safety, efficacy and quality (AU Model Law, article 4).

Marketing authorization holder (MAH) refers to any person or entity that holds the legal responsibility for the product on the market by submission of the required documentation on a product that has been listed after evaluation as registered or approved. It also refers to a person or legal entity allowed to apply for a change to the MA or license. Also referred to as the "manufacturer" or "applicant" (WHO Glossary).[45]

Mutual recognition means the acceptance of one National Medical Products Regulatory Agency's certification of standards and procedures for medical product regulation by another National Medical Products Regulatory Agency (AU Model Law, article 4).

Manufacture means all operations of purchase of materials and starting materials, preparation of the active pharmaceutical ingredient (API) and of the pharmaceutical product, including packaging and repackaging, labelling and re-labelling, quality control, release, storage and distribution and the related controls (AU Model Law, article 4).

Sell means to sell by wholesale or retail, and includes to import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorise, direct or allow a sale, or prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to a person, whether for a consideration or otherwise, and also includes offering

45. WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control), available at https://extranet.who.int/pqweb/content/glossary .

or attempting to sell, or receiving for sale, or having in possession for sale, or exposing for sale, or sending or delivering for sale, or causing or allowing to be sold, offered or exposed for sale, and “sale” and “sold” have a corresponding meaning; (AU Model Law, article 4).

- **Storage** means storing of medical products up to their point of use (AU Model Law, article 4).
- **Supply** means having in possession for the purpose of supply (AU Model Law, article 4).
- **Wholesaler** means sale of goods in large quantities, as for resale by a retailer (AU Model Law, article 4).

CRIMINAL JUSTICE-RELATED DEFINITIONS

- **Organized criminal group** shall mean a structured group of three or more persons, existing for a period of time and acting in concert with the aim of committing one or more serious crimes or offences established in accordance with this Convention, in order to obtain, directly or indirectly, a financial or other material benefit. (UNTOC, article 2).
- **Predicate offence** shall mean any offence as a result of which proceeds have been generated that may become the subject of an offence as defined in article 6 of this Convention; (UNTOC, article 2).
- **Proceeds of crime** shall mean any property derived from or obtained, directly or indirectly, through the commission of an offence. (UNTOC, article 2).
- **Serious crime** shall mean conduct constituting an offence punishable by a maximum deprivation of liberty **of at least four years** or a more serious penalty; (UNTOC, article 2).
- **“Freezing” or “seizure”** shall mean temporarily prohibiting the transfer, conversion, disposition or movement of property or temporarily assuming custody or control of property on the basis of an order issued by a court or other competent authority; (UNTOC, article 2).
- **“Confiscation”**, which includes forfeiture where applicable, shall mean the permanent deprivation of property by order of a court or other competent authority; (UNTOC, article 2).
- **“Controlled delivery”** shall mean the technique of allowing illicit or suspect consignments to pass out of, through or into the territory of one or more States, with the knowledge and under the supervision of their competent authorities, with a view to the investigation of an offence and the identification of persons involved in the commission of the offence (UNTOC, article 2).

II. THE LEGAL FRAMEWORK FOR REGULATORY RESPONSE

A. *Introduction*

One of the key challenges in addressing SFMP is a weak regulatory system. A strong regulatory system ensures adequate access to quality medicines, while preventing the manufacturing of substandard medicines, and controlling the market to detect any falsified medicines that may have entered it.[46] This implies continuous strengthening of the NRA, including identifying areas for improvement, strict quality control (either by the NRA or another agency working closely with it), functional enforcement unit and strong working relationships with other agencies. Other challenges include systemic corruption and security risks, which may increase the risk of SFMP entering the country.

The World Health Organization recommends a three-pronged approach to SFMP: prevent, detect, and respond. Member States should "PREVENT the manufacture, sale and consumption of substandard and falsified medical products; implement systems to DETECT any substandard or falsified products that are already in the supply chain; and RESPOND quickly and proportionately to any incidents that are detected, in ways that safeguard patients and the supply chain, take appropriate action against those responsible, whilst not causing unnecessary shortages".[47] It also recommends that States "adopt **transparent and comprehensive legal provisions, regulations and guidelines** to provide the legal powers for national authorities to fulfil essential regulatory functions; as well as a documented strategy and guidelines relating to the prevention, detection and response to substandard and falsified medical products".[48]

1. APPLICABLE LEGAL NORMS/STANDARDS

The **African Union Model Law on Medical Products Regulation** (2016) provides a template for countries for legislation to establish the regulatory system. It is a "soft law" instrument that provides benchmarks for legislators,[49] but does not provide guidance on enforcement of the law. The Model Law is expected to be amended in 2024, to address some gaps, and in particular to provide a clear definition of "Sub-standard and Falsified Medical Products",[50] and to amend the provisions related to offences and sanctions. The Model Law is referenced throughout the chapter where relevant.

2. THE REGULATORY FRAMEWORK FOR MEDICAL PRODUCTS

The goal of regulation should be to ensure access to essential and life-saving medications, and at the same time provide diligent supervision and control to prevent errors in production and storage. Unless otherwise mentioned, the regulatory section covers both substandard and falsified medical products. From a public health perspective, both have the same negative impacts on patients who are entitled to the same constitutional rights of public health.

In order to provide technical assistance and guidance to Member States on regulating medical products, the WHO has developed tools for the evaluation of national regulatory systems, based on nine regulatory functions. The WHO Global Benchmarking Tool [51] provides a comprehensive list of indicators under each of these functions that assess the maturity level of the regulatory system. For each of these functions, there are specific indicators on legislation.[52]

The nine functions are: Regulatory system (RS); Registration and Marketing Authorization (MA); Vigilance (VI); Market Surveillance and Control (MC); Licensing Establishments (LI); Regulatory Inspection (RI); Laboratory Testing (LT); Clinical Trials Oversight (CT); NRA Lot Release (LR).

The advice provided below on the legal framework corresponds to these nine functions, and highlights the functions that are necessary to address SFMP.[53] This should assist countries that are working towards maturity level 3 or 4, as defined by WHO. While the indicators in the GBT also assess the existence of regulations and guidelines, the Reference Manual refers mostly to primary legislation, unless it was deemed necessary to include other types of legal standards.

46. This approach was suggested by experts already in 2008. See 't Hoen E, Pascual F. *Viewpoint: Counterfeit medicines and substandard medicines: Different problems requiring different solutions*. 36(4) J Public Health Policy (2015) 384-9.

47. WHO GSMS, supra note 13, pages 46 – 60.

48. Ibid. page 58.

49. In 2021, the AUDA-NEPAD published a *Guidance Document for Domestication of the African Union Model Law on Medical Products Regulation*. It provides a chapter-by-chapter analysis of the Model Law and proposes legislative text for each of its provisions.

50. Article 22 prohibits "substandard/spurious/falsified/falsely-labelled/counterfeit medical product (SSFFC)" while Article 4 refers simply to SSFFC the definition provided by the World Health Organisation. There is a need to integrate the 2017 definition in the Model Law and align with the current designation which is "Sub-standard and Falsified Medical products". Guidance document pages 16-17.

51. World Health Organisation (WHO), *Global Benchmarking Tool (GBT) for Evaluation of National Regulatory System of Medical Products* (2021), page 2. (Hereinafter: WHO GBT).

52. There are four levels of maturity established by the WHO GBT. Level 1 – some elements of regulatory system exist. Level 2 - evolving national regulatory system that partially performs essential regulatory function. Level 3 – Stable, well-functioning and integrated regulatory system. Level 4 – regulatory system operating at advanced level of performance and continuous improvement.

53. See a list of these functions in AUDA-NEPAD Guide, supra note 2, pages 11-12. In addition to establishing its functions by law, the NRA should establish its vision, mission and strategic priorities. GBT, RS03.02.

B. The Regulatory Framework

1. THE REGULATORY SYSTEM

A National Regulatory Authority (NRA) should be established by law to fulfil all the regulatory functions related to medical products, such as assuring their quality, safety and efficacy. It should be independent and well-resourced in order to provide competent oversight of the market, including information provided to the public.[54] Ideally, this agency is responsible for all regulatory functions, however, in some countries different bodies may be legally responsible for the regulation of certain products, or perform some regulatory functions. If there is no such national agency, it would be necessary to identify in law which other agencies fulfil its functions. In some countries the regulatory function may be housed within a larger government department, nevertheless, its independence should be safeguarded.[56]

Relevant provisions of the AU Model Law

Part II of the AU Model Law covers Administration and Governance. Article 5 recommends the establishment of a national regulatory agency or authority (NRA) and Articles 6 and 7 describe its powers and functions. Articles 8-12 cover other aspects of its work, including funding. Articles 30-31 maintain that the Authority shall have the power to make regulations and guidelines necessary for its functioning under the law. Article 29 creates a monitoring and evaluation system charged with reviewing and assessing the performance of the Agency/Authority. Article 27 establishes the basis for international cooperation with other NRAs and with global mechanisms such as the WHO Member State Mechanism and Global Surveillance and Monitoring System (GSMS).

Legislation to establish the functions of the NRA should include:

1) **A clear authorization** of the institutions involved, their mandates, functions, roles, responsibilities and enforcement powers.

> **Example:** The Health Act, 2017, and the Pharmacy and Poisons Act Kenya, provide for the functions of different institutions and functionaries in the health sector.[57] The Pharmacy and Poisons Board, the National Quality Control Laboratory and the Kenya Medical Supplies Authority (KEMSA) all have relevant responsibilities to deal with SFMP.

2) **Administrative arrangements and channels of communication and coordination** when several institutions or authorities are involved in regulation and oversight (such as law enforcement, customs/border control, professional institutions, and research institutions).[58] This includes taskforces or interagency committees on SFMP.

> **Example: Ghana's Food and Drugs Authority Terms of Reference for Inter-Agency Committee for Collaboration on Substandard/Falsified (Sf) Medical Products** establish the rules for its work.
>
> The objectives of this Committee are as follows;
> - To share information and intelligence on SFMP;
> - To formulate policies for prevention, detection, and seizure of SFMP in Ghana;
> - To facilitate prosecution of cases involving offences related to trade/dealing in SFMP and their outcomes;
> - To provide strategies and recommendations on combating the menace of SFMP.
>
> **Example: Malawi's draft MOU between the NRA and Customs**[59] establishes working arrangements for the few agencies on the border, and identifies areas for cooperation such as sharing of information, joint training, etc.

2. REGISTRATION AND MARKETING AUTHORIZATION

The NRA is responsible for the evaluation of medical products in terms of safety, efficacy and quality and their approval for marketing and distribution. Once it is satisfied, it would issue a marketing authorization (MA) and register the product on a list of registered products. This is a crucial area for regulation, and where weak supervision results in opportunities for the infiltration of SFMP into the market.

Articles 13-14-15 of the AU Model Law cover Consideration of Applications for Marketing Authorizations and Licensing of Manufacturers, Importers, Exporters, Wholesalers and Distributors.

Issuing market authorizations prevents SFMP from entering the regulated supply chain. The processing leading to MA includes steps that allow a strong NRA to detect substandard and falsified products. However, a product that is issued MA could subsequently become substandard if not kept in adequate conditions, hence the need for strong and robust market surveillance by the NRA after MA is granted for a product. For falsified medical products, if a data integrity issue is detected (falsified documents that misrepresent identity, source or composition of the medical product), the NRA may request resubmission of documentation and/or verify them with a genuine manufacturer.

The process of evaluation of the medical product includes review of data on quality, safety, efficacy, and effectiveness, submitted by the applicant. The applicant is a marketing authorization holder who may be delegated by the

54. WHO GBT, supra note 51, page 2.

55. For example, auditing organizations that perform some functions related to medical devices. WHO, Manual for benchmarking of the national regulatory system of medical products and formulation of institutional development plans. (2021) page 13.

56. AUDA-NEPAD Guide, supra note 2, pages 11-12.

57. See the Pharmacy and Poisons Act and the Kenya Medical Supplies Authority Act, both available at www.kenyalaw.org .

58. WHO GBT, supra note 51, RS 01.03, page 2.

59. The draft MOU was shared with Expertise France in May 2023.

manufacturer for imported medical products or the manufacturers themselves in locally manufactured medical products.[60] A foreign manufacturer might also be an applicant, provided that it has a local representative in the country. The manufacturer is the owner of the product, and is responsible to appoint a person to be the MA holder.

Generally speaking, in order to ensure strict supervision, the rules should be very detailed and describe the documentation needed for licensing, as well as conditions for granting the MA and sanctions for infarctions. The process for granting licenses should be clear and transparent to all actors and the list of licensed manufacturers, importers, exporters, wholesalers, and distributors should be provided on an official database. Due to the complexity of the procedure to authorize new medical products, countries with limited resources may wish to prioritize well established products.

The relevant legislation should therefore include:

1) A regulatory framework of registration and for marketing authorization.

Examples: Zambia Medicines and Allied Substances Act, 2013, Part V

Article 39 (2) A person who intends to place on the market, advertise, market, manufacture, sell, import, supply, administer or deal in any manner with any medicine or allied substance shall apply to the Authority for a marketing authorisation in the prescribed manner and form.

Ghana Public Health Act, 2012, Part 7

Section 118 (1) a person shall not manufacture, prepare, import, export, distribute, sell, supply or exhibit for sale a drug, herbal medicinal product, cosmetic, medical device or household chemical substance unless the article has been registered by the Authority.

An important measure for the prevention of SFMP is the marking/**labelling** of medicines and medical products including over-the-counter medicines. This will ensure that all medicines are registered and if there is any doubt then a simple scanning can work. The regulator could develop an application that will ensure that it authenticates any registered medicine.

Example: Zambia Medicines and Allied Substances Act, 2013, Part V

Article 43. "Medicines shall be labelled in such manner as the Minister may, on the recommendation of the Authority, provide by statutory instrument."

2) A clear definition in a list that may be updated from time to time, of the regulated medical products.

Example: Zambia Medicines and Allied Substances Act No. 3 of 2013

Section 41 – Medicines List "The Minister may, on the recommendation of the Authority, by statutory instrument, provide for a list of substances to be considered as medicines."

The list is set out in a statutory instrument signed by the minister, this allows for flexibility. When there are changes on what qualifies as a medicine, the Minister and the authorities can agree more easily and make the changes in the list.

Example: Ethiopia Proclamation No.1112/2019 A Proclamation to Provide For Food and Medicine Administration

Article 4. "The executive organ shall have the power and duties to: 8/ prepare and, as necessary, revise list of essential medicines, notify registered foods and medicines to the public; issue national medicine formulary, classify medicines into different categories, revise the classification whenever necessary."

Article 20. Registration and marketing authorization of medicine and medical devices "1/Any medicine and medical device shall not be manufactured, imported, exported, stored, distributed, transported, sold, hold, used, or transfer to any other person without registration and marketing authorization. 2/The executive organ shall register and grant marketing authorization in accordance with sub-article (1) of this article after it assesses the quality, safety and efficacy of the medicine, or quality, safety, and effectiveness of the medical device".

According to the WHO Global Benchmarking Tool, information on all MAs that have been authorized, suspended, rejected, or completed should be available for users to check if medical product in their possession has MA in their jurisdiction. Information should be published in a manner that promotes transparency, but does not create panic within the public and only after conducting a thorough investigation and issuing notifications to the MA holder.

3) A requirement for the receipt of a registration or marketing authorization (MA) before placing the product on the market.

Example: Ghana Public Health Act, 2012, Part 7

Section 118 (1) a person shall not manufacture, prepare, import, export, distribute, sell, supply or exhibit for sale a drug, herbal medicinal product, cosmetic, medical device or household chemical substance unless the article has been registered by the Authority.

4) A requirement of demonstration of the product quality, safety and efficacy prior to registration or MA. In any case, the product should not physically be on market yet, and so it may not cause harm to population/citizens. The NRA may rely on evaluation reports prepared by other national authorities. In addition to review of data, there may be good manufacturing practices inspection (GMP) that apply to the facility where the product is being manufactured as well as quality analysis of samples of the manufactured products. The requirements for MA should be detailed and clear (could be for example: quality inspection and Laboratory testing). These requi-

60. WHO GBT, supra note 51, page 2.

rements could be detailed in an operational manual or guidelines, and usually not in primary legislation.

5) Limits on the duration of the validity of the MA and requiring periodic reviews of MAs (i.e. renewals). Any post-approval changes/variations to a product with an existing MA, should obtain a new MA from the NRA. In the absence of such MA, there is a risk for substandard or falsified medical products entering the market, since the impact of the change on the quality of the product was not assessed. Some countries do renewals every 3-5 years. Variations are post-approval changes. Renewal only applies to the original product as approved. Therefore, there should be requirements for variations.

6) Require the NRA to **withhold, suspend, withdraw, or cancel an MA** if there are concerns regarding quality, safety, or efficacy issues. If the NRA assessor detects substandard or falsified medical product, there should be a legal provision that regulatory action can be taken.

Example: Zambia Medicines and Allied Substances Act, 2013, Part V

Article 46. (1) The Authority may, where it determines that it is not in the public interest that any medicine or allied substance should be made available to the public, by notice, in writing, served on any person or in the Gazette, direct that person to return the medicine or allied substance which the person has in that person's possession to— (a) the manufacturer of the medicine or allied substance; (b) in the case of any imported medicine or allied substance, to the importer concerned; (c) deliver it or send it to the Authority or such other person as the Authority may designate.

(2) The Authority may, by notice, in writing, direct the manufacturer or importer of the medicine or allied substance referred to in subsection (1) or the person referred to in paragraph (c) of subsection (1), who has in their possession any quantity of the medicine or allied substance, including the returned quantity to deal with or dispose of that quantity in such manner as the Authority may determine

7) Legal provisions to cover circumstances under which the routine MA procedures may not be followed (e.g., for public health interest), including rules to approve donation of medical products.[61] There are some circumstances in which usual procedures for MA are exempt – such as for **compassionate use**,[62] **donations**, **emergencies** (such as COVID-19, Ebola, etc.). These products may pose a greater threat as constrained access and high demand are drivers of SFMP. However, access to safe, quality, and efficacious medical products should be upheld. Emergencies are dealt with through expedited approvals of MAs for reasons of public health concerns.

Example: Malawi Act No. 9 of 2019 Pharmacy and Medicines Regulatory Authority

Article 62.—(1) A person who intends to place on the market, advertise, market, manufacture, sell, import, supply, administer or deal in any manner with any medicine or allied substance shall apply to the Authority for a marketing authorization in the prescribed manner…

(4) This section shall not apply to— … (e) medicine imported or exported in response to **a declared health emergency;**

Example: Ghana, Guidelines for Emergency Use Authorization of Medical Products, Document No. FDA/GEN/GL-EUA/2021/04

Donations

Donations of medicines pose a particular risk, as donors might provide medicines that are close to expiry and thus might be substandard. The WHO Guidelines for medicines donations are based on four core principles that form the basis of good medicine donation practice, namely:

1. Donations of medicines should benefit the recipient to the maximum extent possible. All donations should be based on an expressed need. Unsolicited medicine donations are to be discouraged.
2. Donations should be given with due respect for the wishes and authority of the recipient, and in conformity with the government policies and administrative arrangements of the recipient country.
3. There should be effective coordination and collaboration between the donor and the recipient, with all donations made according to a plan formulated by both parties.
4. There should be no double standard in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.

If a donated product is coming from outside the country, it might not have MA and an exemption may need to be given. If the donated product is already on the market (and therefore has MA), and the donor purchases it and donates/gives to community, there is no problem with the donation. Also, the donors themselves may adopt regulations for donations– the national legislation could therefore require that donors adopt a quality assurance system.[64]

Example: Act to Establish the Liberia Medicines and Health Products Regulatory Authority (LMHRA) of 2010

Section 7. Donations of Medicines and Health Products

1) Donated medicines and health products must respond to national needs identified or established by the Ministry of Health and Social Welfare.

2) Donated Medicines and health products are subject to the provisions of Part V, as applicable.

3) In the case of emergency or disaster, the Authority may expedite or, as necessary, waive the registration of donated medicines or health products

Example: Guidelines for Drug Donations for Malawi, issued by the Ministry of Health in 2008,

61. WHO GBT, supra note 51, MA01.06, MA01.07.

62. As defined in the AU Model Law, article 4. See full text under definitions.

63. WHO Guidelines for Medicines Donations (2011) https://www.who.int/publications/i/item/9789241501989.

64. 't Hoen & Pascual, supra note 46.

"aim to improve the quality of drug donations and not hinder them. The guidelines cover all scenarios for drug donations though special arrangements may be necessary in acute emergency situations. The guidelines are to be used by both the public and private sector institutions in Malawi".

8) **The powers to recognize** and/or rely on MA-relevant decisions, reports or information from other NRAs or regional and international bodies.[65] **Reliance/recognition** is an important regulatory mechanism that can be applied for many regulatory functions in relation to SFMP, and in particular the sharing of laboratory testing reports, NRA lot release reports, and regulatory inspections. Need to be able to access report (subject to confidentiality, may agree to redact certain sections). Particularly for substandard medical products, NRAs should be able to rely on reports from other NRAs (subject to confidentiality), in order to take regulatory actions to seize and destroy, recall and destroy, etc. Article 27 of the AU Model Law includes provisions for such cooperation with other NRAs including sharing of information. Article 28 of the AU Model Law establishes that the NRA shall take such measures to ensure effective co-operation with their counterparts in other countries to "provide for mutual recognition of marketing authorization decisions".

Example: Section 123 of the **Pharmacy and Medicines Regulatory Authority Act 09/2019** of **Malawi** provides for international cooperation, including recognition of laboratory test results.

The law may also empower the NRA to recognize international standards when a national standard is not issued or adopted.

Example: Ethiopia Proclamation No.1112/2019 A Proclamation to Provide For Food and Medicine Administration

22/3 Notwithstanding to the provision of sub-articles (1) and (2) of this article, where national standard is not issued or adopted, the executive organ may regulate medicine and medical device in accordance with requirements prescribed by international organizations, other countries, and requirements or guidelines issued by manufacturing companies acceptable to the executive organ.

3. VIGILANCE

Vigilance means the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other problems related to medicines and vaccines. It guarantees the quality and safety of medical products by conducting analysis to determine the root causes of problems. It includes a **reporting system** and databases to monitor the safety of medicines and vaccines. When they are identified as SFMP, reporting is required also to the WHO Member State Mechanism and Global Surveillance and Monitoring System (GSMS), in order to share information and cooperate with other regulators in preventing the spread of SFMP. The relevant AU Model Law provision is article 16(1): Post-Marketing Surveillance and Safety Monitoring.[66]

Legislation to establish vigilance should:

1) Establish the national medical products vigilance system (e.g., defining the responsible entities as well as the roles, responsibilities, accountability, and obligations of these entities).[67]

Examples of legal provisions establishing vigilance systems: Uganda

(a) Parts III – VII of the National Drugs Policy and Authority Act Cap 206 Sections 30A & 30B, 60 & 61

(b) The Pharmacy & Drugs Act Cap 280 section 11

(c) The Narcotics Drugs and Psychotropic Substances (Control) Act, 2016 Parts 1 to part IV

(d) Penal Code Act sections 174 & 175, 187, 227 & 228

Kenya: sections 2, 3A and 3B of the Pharmacy and Poisons Act, sections 4(1)(i), 13, 14 and 14B of the Standards Act and section 24 of the National Police Service Act, section 26 of the office of director of public prosecutions Act.

Ghana: Public Health Act, 2012 (Act 851)

Section 125 (1) A local representative for a regulated product shall be appointed by the relevant body.

(2) The local representative (a) shall monitor the safety of the product granted marketing approval, and (b) shall report an adverse effect or event to the Authority during the period under which the product is registered.

(3) The Authority shall continually monitor the safety of the products regulated under this Act by analysis of the adverse effect or event reports and by any other means and take appropriate regulatory action when necessary.

2) Ensure that distributors, importers, exporters, healthcare institutions, consumers and other stakeholders are encouraged to report adverse drug reactions (ADRs) and adverse effects (AEs) to the MAH and/or NRA.[68]

3) Allow the NRA to require manufacturers and/or MAHs to conduct specific studies on safety and effectiveness under specific conditions.[69]

4) Require the manufacturer to review vigilance data to determine if their labelling (summary product characteristics, or instructions for use) requires updating to inform users of new or increased (safety) risk related to use of the medical product.

If the manufacturer becomes aware of a safety issue and does not report to the NRA or make variation/ change to reduce the risk, he or she may be subject

65. WHO GBT, supra note 51, MA01.08.

66. Note that the definition of Pharmacovigilance in Article 4 of the AU Model Law only applies to medicines, but here we apply it to other medical products as defined in the Reference Manual, including medical devices.

67. WHO GBT, supra note 51, VL01.01.

68. WHO GBT, supra note 51, VL01.03.

69. WHO GBT, supra note 51, VL01.04.

to a regulatory action. The NRA should "issue guidelines to provide for mandatory reporting and submission of periodic safety updates by the manufacturers and distributors, and voluntary reporting by health care professionals and the public" (AU Model Law article 16(3)(c)). Failure to report may also be a cause for criminal prosecution, when the manufacturer had knowledge that the medical product was of substandard quality.

Vigilance measures should also apply to **medical devices**. Manufacturers collect data on safety, quality and performance of medical devices for post-market surveillance which includes malfunction or deterioration. Any incident should be reported by healthcare professionals or citizens to the manufacturer, usually via the local authorized representative; they should also report to the NRA. This includes both adverse events to the patient, user or other person as well as any incident of deterioration or malfunction of a medical device. The manufacturer then reports certain incidents to the NRA. Healthcare professionals may also report to the NRA, but risk of duplication of reports should be mitigated. There is much less reporting on medical devices and in-vitro devices. The NRA should develop guidelines on reporting for medical devices and how to process these reports.

Example: South African Medicines and Medical Devices Regulatory Authority Act no. 132 of 1998 as amended

5. The primary object of the South African Medicines and Medical Devices Regulatory Authority is, subject to the provisions of this Act, to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, complementary medicines, veterinary medicines, clinical trials and medical devices and related matters in the public interest, and for that purpose it must-
(d) ensure that evidence of existing and new adverse events, interactions, information about pharmacovigilance is being monitored globally, analysed and acted upon.

5) Establish a national reporting system

Article 28 of the AU Model Law recommends the creation a national information management system which allows for sharing information at regional and continental levels in accordance with national laws, bilateral and multilateral agreements

National reporting systems should be put in place to allow voluntary reporting of suspected cases of both substandard and falsified medical products by health workers, and consumers. It should include guidelines to provide for mandatory reporting and submission of periodic safety updates by the manufacturers and distributors. The different mechanisms for consumers should allow for anonymous reporting in order to encourage reporting. Usually, the NRA will be responsible for receiving the reports and assessing them.

Other bodies may receive reports of suspected SFMP such as the police, or the Ministry of Health.[70] These bodies should report to the NRA, as safe disposal of SFMP can only be done under the supervision of the NRA. The NRA's core functions need to be clearly established by law to ensure that other agencies are aware of the need to inform the NRA.

There should also be authorization in the law/regulations to allow for reporting to regional and international bodies, such as the future African Medicines Authority, and the WHO Global Surveillance and Monitoring System (GSMS). The GSMS was established in resolution WHA 65.19 of 26 May 2012 as a mechanism for international collaboration among Member States, from a public health perspective, excluding trade and intellectual property considerations. The goal of the GSMS is "to protect public health and promote access to affordable, safe, efficacious, and quality medical products, and to promote through effective collaboration among Member States and the Secretariat, the prevention and control of substandard and falsified medical products and associated activities."

Example for reporting on contaminated cough syrup in the Gambia:

Paediatricians reported to the National Ministry of Health a steadily increasing cases of young children with acute kidney injury mostly manifesting as anuria >>WHO was notified >>> Investigation revealed connection with consumption of Substandard/ Falsified paediatric medical products >> Suspect medicines were quarantined >> suspect medical products samples were collected and analysed at international QC labs >> Consumption of SF medical products was confirmed >> WHO global alert was issued.[71]

The NRA should also report back to the public, subject to a general rule of non-disclosure of information on the business or affairs of any person, obtained in the course of work with the Authority, unless is falls into one of the three exceptions listed in article 34 of the Model Law (in the performance of its functions, under a court order, or if it is in the public interest). Raising awareness of the public and encouraging them to report is an important aspect of detecting SFMP.

Reporting duties

The law could establish specific reporting duties for professionals that are expected to inform of any reasonable suspicion such as healthcare professionals, manufacturers, or pharmacists. National experts could identify those professionals who should be subject to mandatory duty.

They could be established as positive duties. For example, according to the law in Ethiopia, reporting by manufacturers is mandatory when there are suspicions that medical products are substandard, including their own. They are even responsible for the costs of such post marketing sur-

70. WHO GBT, supra note 51, MA01.06, MA01.07.

71. As defined in the AU Model Law, article 4. See full text under definitions.

veillance (request provision). The NRA also has responsibility to monitor a product once it was approved, this is why market surveillance is so important.

When it comes to **falsified medical products**, there could be sanctions on failure to report, including criminal sanctions.[72] It may be necessary in some cases to protect those providing information, for example through whistle-blower protection (see below in the criminal justice section). Genuine manufacturer's opinion should be sufficient to prove the product is falsified e.g. testing of suspect product, attestation, certificate of analysis, method of analysis, export permit from country of origin (if not domestically manufactured).

Other institutions that conduct market surveillance (e.g. research/academic institutions, professional associations, private sector etc.) should include reporting mechanisms in their policies and guidelines.

Example: Proclamation No.1112/2019 Food and Medicine Administration Proclamation----- Ethiopia

38. Post marketing surveillance

1/Every manufacturer and importer, as appropriate, shall perform periodic monitoring of the quality, safety, and efficacy or effectiveness of its manufactured or imported medicine and medical device.

2/Every manufacturer, importer, or wholesaler of a medicine or medical device shall, when required by the executive organ or on its own will, perform a post marketing surveillance that would enable it to continuously monitor its medicine or medical device; establish a vigilance system, and furnish adverse event information and other required information.

The reporting should lead to regulatory action in the case of identified SFMP. For imported medical products, the MA holder will be required by legal provisions to destroy and dispose of substandard or falsified medical products. If donated or emergency use medical products are found to be substandard, national authorities (NRA or Ministry of Health) may decide to recall and dispose of suspect products or conduct an FSCA (for medical device).[73]

Cases related to falsified medicines reported to the police would still be shared with the NRA for administrative actions. The NRA should conduct inspections of establishments and seize the suspect product, collect evidence, and collaborate with law enforcement officials to initiate criminal investigation and prosecution. Inspectors should be able to take regulatory action to close the premises/establishments (licensed or unlicensed), etc. (see below under 6. Regulatory Inspection).

6) Allow **recognition and/or reliance on vigilance-related decisions**, reports, or information from other countries or regional or international bodies.[74] This is usually done in the framework of bilateral or multilateral agreements. One of the goals of the AMA is to promote mutual recognition of regulatory decisions. Article 28(2) of the AU Model Law establishes that "the appointing authority and/or the Agency/Authority, as the case may be, shall take such measures to ensure effective co-operation with their counterparts in other countries to: - c) provide for the recognition of regional, continental and other international technical guidelines e) provide for mutual recognition of marketing authorization decisions; "

Example: regional cooperation & mutual recognition (EAC)

The treaty establishing the EAC in chapter 21 article 118, establishes a basis for cooperation to strengthen health systems, and harmonize medical regulation and labs. It allows to share information by conducting scientific evaluation of products and assessment of products. It also provides for cooperation with other agencies including AMA in the future. AMRH is the first regional harmonization initiative in the health sector, applying common market protocol to allow for mutual recognition. Specific tools include:

a. East African Community Mutual Recognition Procedures (EAC-MRP)[75]

b. Cooperation Framework Agreement for EAC Partner States National Medicines Regulatory Authorities, Final Draft, April 2018

Article 6: Responsibilities of NMRAs 6.1 The Partner States hereby agree to implement Article 4 and that each NMRA shall undertake to…e) Conduct Post marketing surveillance of products on the market and share information, including updating the reports where necessary, used as basis for making a decision to support granting of **recognition/approval** by other NMRAs;

4. MARKET SURVEILLANCE AND CONTROL

Market surveillance and control is an essential function of national regulatory authorities, which ensures the quality, safety, and efficacy of medical products on the market and is achieved through:[76] control of import activities; **effective prevention, detection, and response to substandard and falsified medical products**; market surveillance programme for monitoring the quality of medical products; control of promotional materials, marketing and advertising.

It also includes controlling the circulation of products through 'Track and Trace' technology solutions. An efficient track-and-trace system can help pharmaceutical manufacturers, Importers, NRAs and other actors manage their supply chain and mitigate the risks associated with SF pro-

72. UNODC Guide, supra note 3, pages 27-28.

73. **A Field Safety Corrective Action** (FSCA) is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of an IVD that is already placed on the market. It is triggered by information about any problem with an already distributed IVD that poses an unacceptable increased risk when that IVD is used. https://extranet.who.int/pqweb/vitro-diagnostics/field-safety-corrective-action.

74. WHO GBT, supra note 51, VL01.07.

75. Mentioned in Ndomondo-Sigonda M, Miot J, Naidoo S, Masota NE, Ng'andu B, Ngum N, Kaale E. Harmonization of medical products regulation: a key factor for improving regulatory capacity in the East African Community. 21(1) BMC Public Health 187. 2021. The cooperation agreement is available online at https://www.tmda.go.tz/uploads/publications/en1594215479-Cooperation%20Framework%20Agreement%20for%20EAC%20Partner%20States%20National%20Medicines%20Regulatory%20Authorities..pdf .

76. WHO GBT, supra note 51, page 151.

ducts. Such control may be established by law. For example, in the United States, the Drug Supply Chain Security Act, passed in 2013, "outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs that are distributed in the United States", and thus protect consumers from falsified or substandard medical medicines.[77]

There should be legal provisions in place enabling the national medicines regulatory authority (NMRA) to seize, quarantine, sample, analyze, recall, and destroy substandard and falsified medical products (destruction should be done safely hence the term used below is "safe disposal"). There should also be legal provisions in place for the inspection, investigation, enforcement, and proportionate sanctioning of those engaged in the manufacturing, importing, exporting, selling and distributing of SFMP. There should also be a documented strategy and guidelines in place and implemented relating to the prevention, detection, and response to substandard and falsified medical products.[78]

Relevant provisions of the AU Model Law include articles 6(1) & 7(1), (2) – regulating import and export; and articles 7(7) & 19 - control of promotion and advertisement of medical products.

The legislation adopted by member States should therefore:

1) Regulate **import activities** including

- Permanent regulatory intervention at designated entry and exit ports where medical products are being moved.
- Allow for product inspection at ports of entry. In Kenyan ports, for example, there are joint teams to inspect products (such as customs, police, pharmacy and poisons board, counterfeit authority).
- There should be clear regulations on the processes for transport of medicines and medical products through customs and at borders.
- Additional Import permits may be required to import medical products (e.g. in Malawi).
- Ensuring that the incoming batch matches the import documents.

2) Authorize market surveillance and control activities which **include product sampling** from different points of the supply chain. This allows tracking which products comes into the country. When there is a strong NRA presence in the port of entry, including the ability to take samples, this is sufficient. Otherwise, you may apply stricter limits on import and apply a risk based approach (applied to import from specific countries). In some cases, the customs authorities are controlling the ports.

Example: Kenya Health Laws Amendment Act 2020, gives the Pharmacy and Poisons Board Kenya (PPB) powers to *"monitor the market for the presence of illegal or counterfeit medicinal substances"*.

3) Control of promotion, marketing, and advertising of medical products to avoid communication of false or misleading information.

Ghana: Public Health Act, 2012 (Act 851)

Section 114 (1) A person shall not advertise a drug, a herbal medicinal product, cosmetic, medical device or household chemical substance to the general public as a treatment, preventive or cure for a disease, disorder or an abnormal physical state, unless the advertisement has been approved by the Authority.

4) **Define the role of NRA in dealing with SFMP, and allow for regulatory action.**[79] **The NRA should have administrative powers to take action on recall, suspension, withdrawal and/or safe disposal** of substandard and falsified (SF) medical products (article 6 of the AU Model Law). Possible actions may also include the **issuance of a separate warning set** to a list of institutions and key persons dealing with handling medical products.

a. **Recall of certain batches.** The NRA has responsibility to supervise the recall and make sure the batches were recalled. The NRA could help the manufacturers conduct the **recall** in a manner that does not harm their business, and give them the option to retain the batches to the office of the NRA. The costs of the recall are usually borne by the owner of the product, usually either the manufacturer or the MA holder. The role of the regulators in recalls – at times the regulator will initiate the recall. The NRA is responsible for verifying the effectiveness of the recall (including verifying the quantity of the batch).[80]

Example: Malawi Pharmacy and Medicines Regulatory Authority Act No 9 of 2019

69.—(1) The Authority may, where it determines that it is not in the public interest that any medicine or allied substance should be made available to the public, recall the medicine or allied substance which the person has possession of.

Sub article (2)-(6) elaborate on how these functions should be fulfilled

Example: Kenya Guidelines for Recall and Withdrawal of Medical Products and Health Technologies (2022).

Zambia Medicines and Allied Substances Act No. 3 of 2013 Section 46 **-Recall of Medicines**

77. OECD/EUIPO. *Trade in Counterfeit Pharmaceutical Products* (2020), page 73. See also https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa.

78. WHO GSMS, supra note 13, page 58.

79. MC04.07: Documented and implemented procedures and mechanisms exist to prevent, detect, and respond to SFMP. WHO GBT, supra note 51.

80. When recall is not initiated, this could have serious consequences on health and otherwise. For example, in once case in Zambia, condoms and contraceptive tablets imported by a pharmacy, were tested and found to be defective, but still put on the market. See at https://www.thebody.com/article/zambia-honeybee-leaky-condoms.

46. (1) The Authority may, where it determines that it is not in the public interest that any medicine or allied substance should be made available to the public, by notice, in writing, served on any person or in the Gazette, direct that person to return the medicine or allied substance which the person has in that person's possession to—

(a) the manufacturer of the medicine or allied substance.

(b) in the case of any imported medicine or allied substance, to the importer concerned.

(c) deliver it or send it to the Authority or such other person as the Authority may designate.

(2) The Authority may, by notice, in writing, direct the manufacturer or importer of the medicine or allied substance referred to in subsection (1) or the person referred to in paragraph (c) of subsection (1), who has in their possession any quantity of the medicine or allied substance, including the returned quantity to deal with or dispose of that quantity in such manner as the Authority may determine.

(3) A person shall not sell any medicine or allied substance which is the subject of a notice under subsection (1).

(4) A person who contravenes subsection (3) commits an offence and is liable, upon conviction, to a fine not exceeding one million penalty units or to imprisonment for a period not exceeding three years, or to both.

b. Suspension of marketing authorization.

Example: Kenya Pharmacy and Poisons Act- suspension of marketing authorization, recall of batches, warnings to be sent to institutions/ prescribers/population, sanctions, penalties/ prosecutions/ regulation of the manufacture, import, distribution, and sale of medicinal products.

c. Withdrawal – the NRA should have the authority to **withdraw** products from the market and from clinical development or clinical trials.[81]

Example: Malawi Pharmacy and Medicines Regulatory Authority Act No 9 of 2019

129.—(1) The Minister may make regulations for the better Regulations carrying out of the provisions of this Act. (2) Without prejudice to the generality of subsection (1), regulations under that subsection may make provision for— (g) the recall or withdrawal of medicines and allied substances that do not meet the prescribed standards of quality, efficacy and safety;

d. **Safe disposal** - The NRAs should be responsible to make sure that there is adequate **safe disposal** of SFMP, including expired and seized medical products. In some countries, the NRA provides licenses to third parties to carry out destruction, subject to verifiable proof that such destruction has been properly done, backed by the issuance of a destruction certificate, mostly co-signed by the NRA, especially for controlled medical products. However, this practice requires strict supervision and carries a risk that such third parties (or their employees) would use weakness in the system to traffic in SFMP rather than destroy them. The term destruction is not used here as it is only one option for disposal. Disposal may include other options, as long as the product is removed from circulation. Safe disposal should take into account environmental considerations.

Example: The Tanzania Medicines and Medical (Recall, Handling and Disposal of Unfit Medicines and Cosmetics) Regulations, 2015

Example: Tanzania Guidelines for Recall, Handling and Disposal of Unfit Medicinal Products, 3rd Edition, October 2020 provides improved guidance on conducting withdraw and recall of unfit medicinal products based on relative health risks and adverse events that may occur to patients. These guidelines have also over-emphasized the need for appropriate handling and disposal of unfit medicinal products which includes those recalled from the market. The guidelines intend to elaborate step by step procedures for enforcing the provisions stipulated under the Act and TMDA Recall, Handling and Disposal of Unfit Medicines and Cosmetics Regulations, 2015.

In order to detect SFMP, the NRA may conduct routine inspections, targeted risk-based surveys, or investigations of reports of complaints, suspicious observations, unexpected adverse events, or whistle-blower concerns. Regulatory actions in response to SFMP might include rapid alerts, prosecutions, and recalls, quarantines, or withdrawals of affected products.[82]

5) **The legislation should provide for adequate and proportional sanctions, penalties and prosecutions for violations of the applicable legislation.**[83] Examples of possible actions to be taken include suspension of a drug's marketing authorization, recall of certain batches, a warning in national drug bulletins, or a separate warning sent out to a list of institutions and key persons that deal with or prescribe pharmaceutical products. Article 22 of the AU Model Law establishes the rule that the NRA shall issue guidelines stipulating procedures for handling SFMP in collaboration with other relevant institutions, and Article 23 establishes a list of violations. It includes contravening the rules of the NRA in any way; in particular, relating to: marketing authorization; recall, withdrawal and disposal of medical products; control of promotion and advertisements; and scheduling, classification and control of products. As a rule, any of these violations could be the basis for an administrative action by the NRA.

6) **Specific measures for online pharmacies/online sale**

Internet sales refer to different types of sales platforms that advertise falsified medical products to the market or to the consumer, suppliers of domain names that facilitate elec-

81. WHO GBT, supra note 51, page 2.

82. WHO GBT, supra note 51, page 170.

83. WHO GBT, supra note 51, page 2.

tronic sales of falsified medical products, postal carriers of personal and commercial mail packages, and suppliers and processors of finance facilities that enable the distance selling of falsified medical products.

It is estimated that at any given time, there are between 35,000-45,000 online pharmacies in operation, and that 95% of online sellers operate illegally.[84] Considering the proliferation of online pharmacies and the big portion of SFMP sold online, it is crucial to develop strategies to monitor and regulate such online sale, and adopt the necessary laws, rules, regulations, and guidelines.

Several strategies have been identified including creating specific **domain names** for on-line pharmacies, establishing a **common regional logo** for on-line pharmacies (e.g. in the EU), and removing fraudulent websites. There are also restrictions on the types of medicines that may be sold on-line. Since in most countries in the region there is no registration of domain names, this could be a first step to regulate on-line sale.

These actions require clear legislation empowering the supervision of websites while taking into account other legitimate rights such as privacy and freedom of speech. Procedures for authorizations and licensing of pharmacies could include specific references to online sale. Medicine authentication technology, website verification approaches and new detection methods were identified as potential solutions specific to online sales.[85]

In the European Union, government agencies overseeing the market are responsible for the registration process of those entities wanting to sell medicines over the Internet (each country has an official registrar), and also inspections to ensure that such pharmacists or retailers are operating legally and displaying the logo in accordance with the EU Directive on Falsified Medicines.[86]

States may also consider establishing liability for certain types of online intermediaries, after carefully considering all the implications of such liability.[87] Cooperation with the cybercrime unit is important, as offenders sometimes create “mirror” websites that may appear to be legitimate. Awareness raising is also an important element to warn customers against on-line buying of medical products.

Example: Pharmacists Council of Nigeria Act (CAP P.17 LFN 2004) Online Pharmacy Regulations, 2020. It establishes that all internet based Pharmaceutical Service providers in Nigeria should be registered with the Pharmacists Council. It requires a physical location of a registered pharmacy, which will be the place for taking orders and storing medicines. It prohibits the sale of certain drugs on-line.[88]

5. LICENSING ESTABLISHMENTS

Premises, facilities, establishments, and companies throughout the supply chain should possess a license to operate, issued by the appropriate NRA. These facilities include, but are not limited to, manufacturers, distributors, wholesalers, importers, exporters, and retailers. The process of issuing licenses should be based on the implementation of and compliance with "good practice" quality guidelines and regulations (GXP). The AU Model Law relevant provision is article 15: Licensing of Manufacturers, Importers, Exporters, Wholesalers and Distributors. The Model Law does not explicitly refer to licensing of retailers. In some countries NRAs are not responsible for the licensing of retailers, nevertheless, there should be a process that ensures effective regulation of such premises by a competent authority. In general, regulation should cover the entire supply chain.

Legislation should be in place that:

1) Defines a legal framework for licensing activities. There should be a legal basis to establish the licensing system for facilities throughout the supply chain and to authorize the responsible entities to take the necessary actions.

Example: The Ethiopian Food and Medicine Authority is mandated to administer medicines and medical devices (Article 4 of Proclamation 1112/2019). The mandate accorded to the authority constitutes the authority to issue certificate of competence to entities which engage in trading of medicines and medical devices, register, and give market authorization up on ensuring compliance of GMP requirements, dossier assessment, and where appropriate up on fulfilling laboratory test requirements (Art. 4(1,2), Art. 20 of Proclamation 1112/2019). Moreover, the authority is mandated to undertake inspection, PMS vigilance activities and take appropriate measures on products which are not complying with the required standard or produced or put into the market illegally (See Art. 4 of Proclamation 1112/2019).

2) Empowers the NRA to issue, suspend or revoke licenses for establishments, and allows for adequate and proportional sanctions, penalties and prosecutions for violations of the applicable legislation on licensing.[89]

3) Requires that the NRA be informed, for the purpose of notification or approval, in case post-licensure changes or variations are made.

Example: Ghana Public Health Act, 2012, Article 131. Licences and permits

(1) The Authority shall issue a license for

84. Presentation by ASOP. They mention that more than 100,000 website domains were registered within the first month of the Covid-19 public health emergency and the US FDA issues more than 140 warning letters for unapproved or misleading products related to the Covid-19 pandemic. See https://buysaferx.pharmacy/for-the-media/key-data-about-illegal-online-drug-sellers-and-counterfeit-medicines-2/

85. Ahmed J, Modica de Mohac L, Mackey TK, Raimi-Abraham BTA, *critical review on the availability of substandard and falsified medicines online: Incidence, challenges and perspectives*, 6 The Journal of Medicine Access (2002) 1-18.

86. The legal framework is set out in European Commission Directive 2001/83/EC as amended by Directive 2011/62/EU on falsified medicines for human use and by the Implementing Regulation 699/2014 on 24 June 2014.

87. For detailed legal analysis, discussion and examples see UNODC. *Issue Paper: Policymaking and the Role of Online Intermediaries in Preventing and Combating Illicit Trafficking*, (2021), pages 35-62.

88. Available at https://www.pcn.gov.ng/wp-content/uploads/2022/03/Online-Pharmacy-Gazette-2020.pdf.

(a) manufacturing premises,

(b) storage facilities,

(c) importers or exporters, and any other licence or permit determined by the Authority for the purposes of this Part on an application made in the prescribed form.

(2) An application for a licence or permit under this Part shall be made to the Authority and shall be accompanied by the prescribed fees.

(3) A licence or a permit may be renewed for a period of not more than five years.

Licensing generally applies to domestic manufacturers rather than overseas manufacturer. A general limitation to this function occurs when there is no domestic manufacturing of medical products. In this case, the function cannot apply to manufacturers, because none exist in the country. Nevertheless, the function will always apply to distribution practices, including wholesaling. It might be useful to include provisions on manufacturers in the law, to allow for future production in the country.[90]

Another general limitation applies to those countries that depend on the regulatory inspection function (without licensing) to ensure compliance with GXPs at the premises, facilities, establishments and companies throughout the supply chain. Some NRAs rely on the Pharmacy Council to issue these licenses.

Another challenge is the sale in **Informal markets** of medicines and other medical products that might be substandard or falsified. Informal markets appeal to customers – they are cheaper, more accessible, the price is negotiable, patients can buy smaller doses, and they create loyalty to sellers. This is where a lot of the substandard and falsified medicines enter the market. Informal markets are not always unregulated markets, yet the general rule should be regulation throughout the supply chain. The NRA needs to identify strategies to deal with informal markets to regulate the quality of medical products. Developing tools to fight SFMP in informal markets does not necessarily imply legitimizing informal markets, and will depend on the context. From the perspective of criminal law, offences in falsified medical products shall apply to products sold in informal markets.

6. REGULATORY INSPECTION

The purpose of regulatory inspection is to ensure that operations at licensed establishments are carried out in accordance with approved standards, norms, and guidelines and are in compliance with the national medical products legislation and regulations. **NRAs should have the legal mandate to inspect and enforce GXPs throughout the supply chain**, to make decisions concerning the issuance, suspension, renewal, or withdrawal of establishment licenses, and to issue authorizations or certifications for the activities performed by these establishments. Additionally, the NRA should develop policies, regulatory actions, and procedures on the handling of medical products with suspected quality defects and medical products identified as substandard and falsified.[91]

Regulatory inspection in this context should mean inspection of premises, products, manufacturing sites etc. Inspection might also be done remotely and electronically.

To provide for inspection powers, the legislation should:

1) Define a legal framework for inspection and enforcement including:
   a. Allowing inspectors to enter facilities throughout the supply chain at any reasonable time and in any place;
   b. Allowing inspectors to collect evidence, including samples;
   c. Authorizing inspectors to seize and detain medical products, including SFMP and close premises.
2) Empower the NRA to take regulatory action in a case of detection of SFMP;
3) Allow the NRA to transfer the case to law enforcement/ prosecution;
4) Allow for joint investigations.

The AU Model Law includes detailed provisions in Article 17 on regulatory inspections and enforcement.

Example: Ghana Public Health Act, 2012 (Act 851)

Section 135 (1): An authorised officer may, at a reasonable hour, for the proper performance of a function under this Part

(a) enter any premises where the officer believes an article to which this Part applies is prepared, preserved, packed, stored or conveyed and examine the article and take samples and examine anything that the officer believes is used or is capable of being used for the preparation, preservation, packaging, storing or conveying of the article;

(b) open and examine a receptacle or package which the officer believes contains an article to which this Part applies;

(c) examine the books, documents, or any other records found in a place mentioned in paragraph (a) which the officer believes contains an information relevant to the enforcement of this Part and make copies of them or take extracts from them; and

(d) seize and detain for the period that the officer considers necessary an article by means of or in relation to which it is believed a provision of this Part has been contravened.

(2) An authorised officer acting under this section shall produce the authority to act if required.

(3) Where the owner or a responsible person in occupation of premises is present and refuses to open a container or door on being asked to do so, an authorized officer may by a warrant break open the container or door of the premises where food or drugs may be kept for storage or sale.

89. WHO GBT, supra note 51, page 180.

90. AUDA-NEPAD Guide, supra note 2, page 14.

91. WHO GBT, supra note 51, page 2. RI 01, 01.02, 02.03, 01.05, 05.01

(4) A person who obstructs or impedes an authorised officer in the course of the officer's duties or by a gratuity, bribe, promise or any other inducement prevents or attempts to prevent the due execution by the authorised officer of duties under this Part or of the Regulations commits an offence.

If the NRA inspector detects falsified or substandard medical product, there should be a legal provision that regulatory action can be taken. Regulatory sanctions such as administrative sanctions may have an immediate impact.

5) The powers to investigate conduct related to the manufacture, import, export storage, distribution, sale and use of medical products and institute administrative, civil and/or criminal proceedings (article 6 AU Model Law).

Example: Act to Establish the Liberia Medicines and Health Products Regulatory Authority (LMHRA) of 2010

Section 2. Functions and Duties of the Authority.
(1) The functions and duties of the Authority shall include:…s. Receive and investigate complaints regarding alleged violations of the Act or any regulations promulgated by the Authority, and impose appropriate sanctions in accordance with regulations promulgated by the Authority under this Act, and consistent with the Administrative Procedure Act of the Republic of Liberia and with due process of law;

6) **Laws to establish administrative offences and sanctions**
Article 24 of the AU Model Law establishes that administrative penalties may be imposed as stipulated in Regulations. This function is directly linked to investigation of criminal offences, therefore the NRA should be able to cooperate with other institutions and agencies, for example to investigate the source of falsified medical products, or suspected money laundering in the context of trafficking in SFMP. If the MP is falsified, the NRA may decide to prosecute (collect evidence with police and help police to build the case, with AG's office start the prosecution – NRA contributes to ensure the technical aspects of evidence are not refutable). Cooperation may include joint operations with Interpol, Customs, etc. This may require establishing MoUs and Terms of Reference for joint action.

Example: Rwandan authorities have some experiences with prosecution assisting NRA to investigate According to Article 3(5) of Law N°014/2018 of 04/04/2018 determining the organization, functioning and competence of the National Public Prosecution Authority (NPPA), one of the responsibilities of the NPPA it to investigate and prosecute crimes related to the illegal use of narcotic drugs and psychotropic substances. By virtue of Article 28 of the above-mentioned law, the NPPA has powers to investigate offences under prosecution process and lead investigations carried out by criminal investigators. According to Article 9(3) of Law No.003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority (FDA), it has powers to seize and confiscate any product regulated under this Law not conforming to the provisions of this Law. A national prosecutor may investigate and prosecute a suspect involved in SFMP before a judge without the assistance of an official from FDA. On a flip side, some institutions in Rwanda that deal with sensitive matters like tax, drugs, environment, etc. have been given powers of criminal investigators. In that respect, officials from FDA have powers to seize and confiscate any product regulated under Law No.003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority (FDA) – Refer to Article 9(3) of the FDA Law. In this case, the official from FDA conduct investigations on SFMP, develop a file and submit it to the national prosecutor to conduct prosecution processes before the court. An FDA official that is carrying out criminal investigations related to the SFMHP case works under supervision of a prosecutor.

Example: Act to Establish the Liberia Medicines and Health Products Regulatory Authority (LMHRA) of 2010, PART VIII VIOLATIONS AND ENFORCEMENT

Section 1. Administrative Sanctions

Any person/organization who cause or takes any action, or any failure to act that violates any provision of this Act or any regulation promulgated under this Act may be subject to enforcement action in accordance with the provisions of this Part VIII, Section 1. The civil administrative penalties provided for herein are in addition to any applicable criminal penalties.

3) Administrative Penalties

Any person/organization who causes or takes any action or any failure to act, that violates this Act or any regulation promulgated under this Act may be subject to administrative penalties, as follows:

i. A. penalty of not more than $1,500 United States dollars may be imposed for impeding any inspection or investigation carried out under the Act. …

iv. A penalty of not more than $500 United States dollars may be imposed for any supply, storage, distribution, sale or offer to sell in violation of Part V Section 3.

v. A penalty of not more than $500 United States dollars may be imposed for any manufacturing in violation of Part V, Section 4. …

vii. A penalty of not more than $500 United States dollars may be imposed for any advertising or promotion in violation of Part V, Section 6.

viii. A penalty of not more than $500 United States dollars may be imposed for any donation of medicines or health products in violation of Part V, Section 7.

Example: Ghana Public Health Act, 2012 (Act 851). Part 7

Section 132

(1) The Authority shall, order the closure of any premises where articles regulated by this Part are manufactured, stored, prepared or sold, if the Authority has reason to believe that the articles are exposed to the risk of contamination or deterioration,

and the Authority may make a further order appropriate in the circumstances.

(2) The Authority shall supervise the safe disposal of an unwholesome regulated product at a fee determined by the Authority.

(3) A person shall not dispose of an unwholesome regulated product without the supervision of the Authority.

(4) A person who contravenes subsection (3) shall pay a fine of not more than five thousand penalty units ($5,000) to the Authority.

Administrative sanctions – Any conduct that is regulated under the law and defined as an obligation or a prohibition, may be subject to an administrative fine, when violated. The NRA may issue an administrative fine immediately, and the evidentiary requirements are lower than the ones required in criminal proceedings. Administrative sanctions may be established by law or in regulations (see examples below) and may include revocation of licenses and or permanent closure of business; administrative fines; forfeiture, confiscation, and destruction of products found to be falsified and the equipment, instruments, and other articles used in falsifying them; permanent disqualification of the person concerned, whether natural or juridical, from owning or operating an establishment engaged in any business related to medical products.

Example: Administrative sanctions for manufacture and sale of substandard medicines in Malawi

According to Section 98 of the Pharmacy and Medicines Regulatory Authority Act No. 9 of 2019, a person shall not, in the course of any business carried on by him, manufacture, import, assemble, dispense, sale any medicinal product or medicine which is or substandard.

While conducting pre-distribution quality control testing of samples for the Central Medical Stores in Malawi, the PMRA observed that samples of Atenolol, Glibenclimide, and Cotrimoxazole from one manufacturer were consistently not meeting specifications. Investigations conducted revealed that the root cause was the lack of primary reference standards by the manufacturer as required by testing protocols for these products. For all products which did not have primary reference standards but were under production and had verifiable quality problems on the market, production was **stopped immediately** until reference standards were procured. The list product included Atenolol 50mg tablets, Glibenclamide 5mg tablets, Sulfamethoxazole 800mg/Trimethoprim 160mg). It was also recommended that primary reference standards for all products manufactured be made available within **2 months from the date of communication of the decision**. The laboratory refrigerator for storage of reference standards to be made available within **3 months from the date of communication of the decision**.

The actions above were administrative variations to section 118_2-5 of the PMRA (Closure of pharmacy practice) that calls for closure of pharmacy practice premises (manufacturing, distributor, retailer) when the Authority receives an inspection report that the premises are not compliant with the requirements of this Act. In this case, a written notice of violation is expected to be written by the Authority and the facility is expected to submit a written plan of remedy with timelines of action. The pharmacy practice premises will be closed if the facility does not comply with the plan.

Example: Regulation Governing Good Storage and Distribution Practices of Medical Products (Rwanda FDA Law No 003/2018 Of 09/02/2018, Article 9) Chapter VI: Administrative Sanctions Article 34: Sanctions for violation of these regulations

Any person who contravenes the provisions of these Regulations, shall be liable to the administrative measures and sanctions under Annex A:

1° Manufacturing, importation, sale, storage and distribution of substandard, unapproved, counterfeit/falsified, expired and fraudulent regulated products.

2° Illegal opening of premises closed by the Rwanda FDA.

3° Absence of an authorized personnel in an authorized premise dealing with regulated products.

4° Transport of regulated products in unacceptable conditions.

5° Failing to ensure that narcotics and other controlled substances are kept in a secured cupboard.

6° Failure to provide prescriptions/reports for distribution of narcotics and controlled products at the time of inspection.

7° Any change to the authorization without notifying the Authority within the prescribed timelines.

8° Obstruction of inspectors from Rwanda Food and Drugs Authority.

According to Annex-A: Faults and Administrative Sanctions, the administrative sanction for manufacturing, importation, sale, storage and distribution of substandard, unapproved, counterfeit/falsified, expired and fraudulent regulated products is 25% to 50% of the product value found in violation.

Remedial measures – In some cases, time is given to the manufacturer/MA holder/establishment to correct the situation, and if they do not correct it, the sanctions may be aggravated.

Example: Zambia Medicines and Allied Substances Act No. 3 of 2013

Remedial Measures under- Section 23 - Suspension or cancellation of certificate of registration

(3) The Authority shall not suspend or cancel a certificate of registration under this section if the holder takes remedial measures to the satisfaction of the Authority within the period referred to in subsection (2).

7) Laws to establish civil liability for damages

Civil liability for damages should also be established by

law. Civil liability implies restitutive compensation for users of SFMP that have suffered damages. Civil action may apply in the absence of proven intent. The evidentiary level required is lower, therefore it is an important legal tool for individuals affected. Civil actions could be recommended to provide fair remedy to consumers who might be affected by use of SFMP on the principle of duty of care or professional negligence of the supplier, depending on the genesis of such proven SFMP. If a criminal trial takes place, an order of compensation can be issued at the end of the trial, but in parallel, there may be a civil process to award damages.

Liability in torts - In practice, this may be a cumbersome legal option, since it requires obtaining the services of a lawyer, submitting your case to the courts, which may take years until reaching a final decision. Patients that do not have medical insurance need recourse for immediate compensation. An expedited procedure is needed to determine the harm, the extent of the harm, and adequate compensation. It is recommended that a person harmed by substandard product could approach a specialized committee under the NRA that will investigate and provide a medical opinion. The person's lawyers can proceed to initiate proceedings on the basis of this medical opinion.

In addition to establishing technical committees to review whether the reaction was caused by the substandard product, the law should specify the compensation for such persons (a maximum/a minimum).

Example: Liberia Act to Establish the Liberia Medicines and Health Products Regulatory Authority (LMHRA) of 2010

Section 2. Civil Liability

Any person/organization that causes or takes any action, or any failure to act, enumerated in Part VIII, Section 1, will be liable in tort for any and all damages caused by such action or failure to act.

7. LABORATORY TESTING

The National Regulatory Authority (NRA), through a quality control laboratory, has to ensure that a set of legal provisions and guidelines support the regulatory laboratory testing system by defining the mandate for implementation of activities related to this function. The NRA should have the capacity to assess the quality of medical products and test medical products when a complaint or report are submitted to allow the detection of SFMP.[92] The evidence needed is gathered via lab testing.

A Quality Control Laboratory (QCL) for medical products requires infrastructure and equipment, properly designed and maintained; and a Quality Management System (QMS) that meets international standards, thus WHO Good Practice for Pharmaceutical Quality Control Laboratory (WHO GPPQCL), relevant parts of the WHO Good Manufacturing Practice (WHO GMP) and/or ISO 17025:2017. This includes policies, procedures, document control & records, management responsibility and continual improvement through measurement, analysis and monitoring of processes.

Laboratory testing implies that the NRA should establish appropriate mechanisms for quality assurance,[93] and requires **legislation that:**

1) Defines a legal framework of laboratory testing activities including establishing a national quality control laboratory to perform quality control (QC) testing, and/or to authorize the National Regulatory Authority (NRA) to sub-contract the required testing services.[94]
2) Allows the NRA to recognize and use laboratory testing-related decisions, reports or information from other NRAs or regional and international bodies.[95]

Relevant provisions of the AU Model Law include Article 14: Consideration of Applications for Marketing Authorisation (4); Article 16: Post-Marketing Surveillance and Safety Monitoring (2); Article 20: Quality Control Laboratory (2).

Not all NRAs have laboratory testing performed in their countries. When national laboratories are not available, the NRA may send samples to WHO Prequalified QCLs. These are laboratories that have been assessed and deemed to be adhering to international standards, thus WHO GPPQCL, WHO GMP or ISO 17025:2017. The legal provision on sending samples should be in the law of the sending country, especially when sending to a QCL in a different country.

In ECOWAS, countries lacking testing capacity may approach other countries for assistance. In the EAC some countries may conclude an MOU to send samples to other countries with competent laboratories. Certain tests need to be conducted in WHO qualified labs. Sometimes assistance may be needed to confirm results. Most countries may do screening testing, but resources may be lacking for compendium testing, to confirm whether the API is within the limits or not, and this is when a request for assistance is sent to another country. Lab tests are quite costly, since testing is already done in the origin country, hence screening test at the port of entry could lower the burden.

8. CLINICAL TRIALS OVERSIGHT AND NRA LOT RELEASE

National Regulatory Authorities (NRAs) should have the legal mandate to authorize, regulate and, if necessary, terminate clinical trials (CTs).[96] Article 18 pf the AU Model Law covers Control of Clinical Trials of Medical Products. However, this function is mostly related to product **safety**. Legal provisions and regulations should require that CTs be authorized by the NRA prior to initiation. The NRA should review the protocol and other relevant documentation to be sure safety of participants is considered and that all required aspects are conducted according to GCPs. During emergencies, some products might be used while they are still in development. Thus, there should be very clear rules for emergency approval of medical products in place, considering all the relevant risks.

92. For guidance on laboratory testing see WHO global benchmarking tool plus rev. VI+ ver. 1 - Laboratory Testing (LT), 1 November 2019. Available at https://www.who.int/publications/m/item/07-gbt-plus-rev-vi-plus-ver1-lt.

93. AUDA-NEPAD Guide, supra note 2, page 15.
94. WHO GBT, supra note 51, LT01.01.
95. WHO GBT, supra note 51, LT01.02.
96. WHO GBT, supra note 51, CT01.

NRA **lot release** is a regulatory function for the release of specified biological products and in relation to medical products, applies to vaccines. During Covid-19 pandemic, falsified vaccines posed a real challenge in many countries, as well as vaccines whose efficacy was misrepresented. Most countries in the region do not currently produce vaccines. However, countries in the continent are making progress in building capacity to manufacture vaccines (e.g., Senegal, Ghana, Rwanda, Kenya, South Africa, and Egypt), hence they need to build regulatory capacity for regulation of biologics and vaccines. The lot-release function is currently not mentioned in the AU model law (although it may be reviewed to include this function). It may be relevant to detecting certain aspects of substandard medicines (potency, sterility). This may be already established by the regulations for medical products (under Marketing Authorizations). Based on the WHO recommendations, countries can rely on results from other countries with maturity level 3 and 4 for NRA lot release.

III. THE LEGAL FRAMEWORK FOR CRIMINAL JUSTICE RESPONSE

A. Introduction

1. THE FRAMEWORK FOR CRIMINAL JUSTICE RESPONSE

The regulatory response to SFMP should be complemented by a criminal justice response to ensure effective prevention and deterrence of offenders, as well as guaranteeing the rights of victims. While the regulatory response addresses both substandard and falsified medical products, when it comes to criminal justice response, the general view is that the two should be tackled differently.[97] In the context of criminal law, falsified medical products are medical products that deliberately/fraudulently misrepresent their identity, composition, or source; excluding questions related to intellectual property and treating brand-name medicines and generic medicines in the same manner. Most of the offences listed below are related to falsified medical products (the four key offences), but some may apply to substandard medical products (see detailed discussion under criminal offences below).

Offences in falsified medical products may be committed by organized criminal groups or by opportunistic individuals. According to a recent report on trafficking in medical products in the Sahel published by UNODC, "investigations have revealed the involvement of a wide range of opportunistic actors in trafficking in medical products in the Sahel countries, from employees of pharmaceutical companies, public officials, law enforcement officers and health agency workers to street vendors, all motivated by potential financial gain".[98]

The laws of states should allow the prosecution of these offences both when they manifest as a form of organized crime (including through the offences of participation in an organized criminal group, conspiracy or criminal association), and when committed by opportunistic individuals, including manufactures and employees of pharmaceutical companies. While currently some of these offences are prescribed in regulatory laws, **it is advisable to include them in the general criminal code, or in specific criminal laws to combat manufacturing of and trafficking in falsified medical products.** This will ensure consistency in the interpretation and application of criminal offences.

An effective criminal justice response requires establishing in law adequate criminal offences, procedures and tools to investigate and prosecute offenders, and mechanisms to protect witnesses and victims. At the same time, it also requires sufficient resources for enforcement including the establishment of specialized units, training of specialized law enforcement officers and prosecutors. The legal provisions provide the basis for enforcement, but additional measures are required to make it effective. These measures are beyond the scope of this Manual, but governments should ensure their adoption in order to address all criminal activity related to medical products.

2. APPLICABLE LEGAL RULES

i. The African Union Model Law

The African Union Model Law includes in articles 22-24 provisions on offences and sanctions. Some of these offences are related to contravening the provisions of the law related to the regulatory functions of the NRA, and are therefore not directly related to SFMP. Others establish general prohibitions, but do not provide a detailed description of the elements of the offence (including the necessary mental element). The AU Model Law lists the main activities that should be considered prohibited, yet these need to be redefined as criminal offences, and appropriate sanctions should be established.[99] The foreseen amendments of the Model Law may include more detailed definitions of the different offences, and the necessary mental elements for offences.

ii. The MEDICRIME Convention

The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, 2011 (the MEDICRIME Convention)[100] provides a comprehensive framework for a criminal justice response to falsified medical products for the purpose of preventing and combating threats to public health. The Convention does not address issues of intellectual property rights and includes within its scope all medical products, whether generic or originator medical products. The Convention uses the term 'counterfeit' which was the term in general usage when it was drafted. The term in the context of the Convention is clear in its meaning to equate with the meaning of 'falsified' used by both the WHO and UNODC. It defines the term counterfeit to mean a false representation as regards identity and/or source (Article 4. j). False representation in this context includes not just the medical product's name, but includes any misrepresentation involved, including such matters as composition. It has, therefore, a wide meaning that is not limited to any qualification of a term not mentioned in the definition.

97. 't Hoen & Pascual, supra note 46.

98. UNODC, Trafficking in medical products in the Sahel (2023), page 7.

99. AUDA-NEPAD Guide, supra note 2, pages 16-17.

100. See https://www.coe.int/en/web/conventions/full-list?module=treaty-detail&treatynum=211

The Convention includes aspects such as the criminalization of manufacturing, falsification, trafficking, and keeping in stock of falsified medical products (Articles 5, and 6), as well as the criminalization of the same acts in relation to non-falsified medical products when an authorisation, relating to medicinal products, and compliance with a conformity standard, for medical devices, is required under domestic law and none exists (Article 8). While the3 notion of fraudulent diversion of legitimate medical products is not specifically mentioned, this is intended to be covered by Article 8. The Convention also includes the criminalisation of the falsification of and tampering with documents (Article 7) and the acts of aiding or abetting or attempts relating to the offences established in Articles 5-8 (art. 9). Also included is a requirement for imposing adequate sanctions, including aggravating circumstances (Articles 12-14), international cooperation (Article 21), and protection of victims (articles 19-20). Cooperation measures among the regulatory, law enforcement, and customs authorities is provided for (Article 17), and there is a requirement for the establishment of medical product regulatory authority, and the implementation of specified prevention measures (Article 18) in the Convention.[101] While most Member States of the African Union have not ratified it, it is a useful source of guidance for countries who wish to ensure criminal enforcement against manufacturers and traffickers.[102]

iii. The United Nations Convention against Transnational Organized Crime

The United Nations Convention against Transnational Organized Crime (UNTOC), adopted in 2000, provides a framework for promoting cooperation to prevent and combat transnational organized crime. In 2020, the Conference of the States Parties to the UNTOC Convention adopted Resolution 10/5 on *Preventing and combating the manufacturing of and trafficking in falsified medical products as forms of transnational organized crime*, confirming that the Convention "constitutes a useful tool for international cooperation in preventing and combating the manufacturing of and trafficking in falsified medical products in those cases falling within its scope"; and calling upon States parties "to develop and implement, as appropriate, effective and comprehensive legal frameworks to prevent, prosecute and punish the manufacturing of and trafficking in falsified medical products, consistent with the Convention and taking into consideration the relevant resolutions of the World Health Assembly". Most of the Member States of the African Union are parties to the UNTOC Convention.[103] It therefore provides a useful framework for discussing necessary legislation to respond to offences and ensure effective cooperation between states.

UNODC has developed *Model Legislative Provisions against Organized Crime* (2021, second edition) that support the domestication of the Convention, as well as a *guide to good legislative practices on Combating Falsified Medical product- Related Crime* (2019). The Guide covers the main legal issues and provides examples of relevant national legislation and sample provisions. In 2021 UNODC published an Issue Paper on *Policymaking and the Role of Online Intermediaries in Preventing and Combating Illicit Trafficking*. This is particularly important since according to reports of different organizations (Interpol, OECD), a major portion of transactions in falsified medical products are currently conducted on-line.

B. Criminal Offences

The criminalization of offences would have to be prescribed by clear and accessible law, serve the legitimate aim of public health but also public order and safety – and be necessary to address the problem of falsified medical products in the country/continent, the prescribed penalties being proportionate.

As noted in the UNODC guide:[104] "In general, criminal offences have two components: the physical elements (also known as the *actus reus*) and the mental elements (also known as the *mens* rea). These two types of elements may be referred to by other names in some jurisdictions. Most criminal offences require proof of both physical and mental elements to establish a conviction. The physical elements of an offence relate to the acts that the accused person actually committed. They may include, depending on the legal system, conduct (acts or omissions), results of conduct and special circumstances relating to the conduct. The mental elements of an offence relate to the accused person's state of mind at the time of the offence. For a given offence, proof of a mental element is generally required for each physical element of the offence." "Mental elements generally differ according to the degree of intention or knowledge of facts, probabilities and risks on the part of the defendant or, in some circumstances, the knowledge that can reasonably be imputed to him or her". Those mental elements may be called intent, knowledge, recklessness or gross negligence".

In general terms, depending on the legal tradition of States, the mental element of knowledge may mean that the defendant is practically certain that the conduct will cause a particular result. Recklessness/gross negligence may mean that the defendant consciously disregarded a substantial

101. The MEDICRIME Convention is open to non-Council of Europe States for ratification and a number of African countries have already signed and acceded to the Convention which opens to their full participation in the further development of the Convention and the mutual support with other countries who are Parties to the Convention. The Convention works as a basis for national and international cooperation among States.

102. The Council of Europe published in 2015 a Handbook for Parliamentarians on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (MEDICRIME Convention, CETS No. 211). It discusses the necessary legislation for implementing the Convention (hereinafter: MEDICRIME Handbook).

103. Except Somalia and Congo (Brazzaville). See https://treaties.un.org/pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XVIII-12&chapter=18&clang=_en (UNTOC ratification).

104. The following text is reproduced from UNODC Guide, supra note 3, page 19.

and unjustified risk. In some legal systems, no proof of mental state on the part of the accused may be required. These are offences of strict or absolute liability.[105] The Reference Manual does not recommend the use of strict liability offences. Strict liability may be appropriate in the case of administrative violations (e.g. operating without a valid license).

The **main criminal offences in this chapter (manufacture, trafficking, possession and falsification) apply to falsified medical products**. However, "a substandard medical product can become a falsified medical product when it is manufactured intentionally below the mandated standards of quality or specifications, including where it is manufactured by an authorized, licensed or registered manufacturer. This is because the intentional manufacture of a substandard medical product entails a misrepresentation as to the identity or composition of that medical product".[106] The WHA took a similar position stating that "when the authorized manufacturer deliberately fails to meet these quality standards or specifications due to misrepresentation of identity, composition, or source, then the medical product should be considered 'falsified'".[107] Since criminal law applies "when there is evidence of fraudulent intent or gross negligence (including intentional adoption of risky procedures)", [108] "manufacturers who were knowingly adopting substandard practices would either way be held accountable".[109]

Criminal law would not apply where substandard medical products are the results of unintentional errors in production or storage.

Some argue that "manufacturers modulate their quality assurance system to the regulatory capacity of the country of destination to lower production costs, [...] Harming is not the primary intent of such practices, but the primary intent (cutting costs) implies accepting the risk of harming".[110] Since currently African states are not the main producers of medical products,[111] their control over the production of substandard medical products is still limited. They are more concerned about substandard medical products that may enter their markets than in other regions.[112] Therefore, to be able to apply the law to such cases, it is recommended in the Reference Manual to include an offence of recklessness in the manufacture and storage of medical products (see below under **2.iv**). Other offences may still apply such as failure to report on substandard medical products imported or donated into the country, or corruption in the context of regulation of medical products.

This is the approach in practice in some countries. In Malawi, according to Section 98 of the Pharmacy and Medicines Regulatory Authority Act No. 9 of 2019, "a person shall not, in the course of any business carried on by him, manufacture, import, assemble, dispense, sale any medicinal product or medicine which is falsified or substandard". Although the provision appears to criminalize both falsified and substandard products, legal proceedings taken so far indicate that cases against substandard products are handled administratively while cases involving falsified products are handled criminally.

1. OFFENCES IN FALSIFIED MEDICAL PRODUCTS

Resolution 10/5 of the UNTOC COP called upon States parties to make the manufacturing of and trafficking in falsified medical products, in appropriate cases and in accordance with national legislation, a serious crime as defined in article 2, paragraph (b), of the Organized Crime Convention. In the development of this Reference Manual, legal experts identified four main criminal offences that should be included namely **manufacture, trafficking, possession, and falsification.**[113]

In these offences, the necessary criminal intent is usually intention or knowledge. The Medicrime Convention requires that "each Party shall take the necessary legislative and other measures to establish as offences under its domestic law, when committed intentionally" (Articles 5-7). This Convention, in its Explanatory Report (paragraph 43), states that the interpretation of the word "intentional" is left to domestic law.

However, there may be scenarios where it is difficult to prove intention to falsify, and the manufacturers' claim is that an error resulted in substandard product; although this is hard to accept, especially when consequences had been

105. Text reproduced from UNODC Guide, supra note 3, page 19. Establishing different levels of mental knowledge should also carry different sanctions, depending on the level of culpability, making a difference between intentional, with knowledge, reckless/gross negligent conduct.

106. See UNODC Guide, supra note 3, pages 21-26; and MEDICRIME Handbook, supra note 102, page 9.

107. WHO. Report by the Director-General on the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products, document A70/23, (2017) annex, appendix 3. 2 Working Definitions. Text of footnote 1, page 34.

108. Olliaro et al., supra note 5, page 266.

109. Olliaro et al., supra note 5, page 265.

110. Ibid. page 264.

111. See The Institute for Economic Justice, *The Localisation of Medical Manufacturing in Africa* (LoMMiA Research Report - November 2022). Available at https://www.iej.org.za/wp-content/uploads/2022/11/IEJ-LoMMiA-report_Nov2022.pdf. According to the report, there is very limited capacity for manufacturing active pharmaceutical ingredients (APIs) for drugs and active drug substances for vaccines in Africa. However, this might change in the future.

112. See for example the views expressed in the following article: Philip Osarobo Odiase. *Recalibrating African health laws to combat substandard and falsified medical products: Beyond COVID-19*, 1(2) International Journal of Civil Law and Legal Research 2021; 01-09.

113. See UNODC Guide, supra note 3, pages 21-26. These are also the four main offences in the MEDICRIME Convention: see MEDICRIME Handbook, supra note 102, pages 43-48.

114. Olliaro E, Olliaro P, Ho CWL, Ravinetto R. Legal Uncertainty-The Gray Area around Substandard Medicines: Where Public Health Meets Law. 102(2) Am J Trop Med Hyg. (2020) 262-267. See examples of Miltefos® and Isotab® on pages 262-264.

115. See UNODC Guide, supra note 3, pages 19-20. It also notes that "States should exercise great caution in lowering the threshold because of the prejudice to the rights of defendants that it may entail. International and regional human rights instruments may express human rights guarantees in either absolute or qualified terms. Absolute rights are, however, the exception, and most rights can be limited, provided that certain conditions are met. While the language used to qualify human rights may differ between and within instruments, in general, limitations may be imposed on human rights where they are prescribed by clear and accessible law, serve a legitimate aim and are necessary for meeting, and proportionate to, that legitimate aim. A legitimate aim may include respect for or protection of the rights of others or certain public interests, such as public order, public health, public safety and national security". See also Issue Paper: The United Nations Convention against Transnational Organized Crime and International Human Rights Law (2022), available at https://sherloc.unodc.org/cld/uploads/pdf/21-01901_Human_Rights_eBook.pdf.

quite severe, such as the death of patients.[114] Lowering the requisite mental element for the offences of manufacturing of and trafficking in falsified medical products from intent or knowledge to recklessness/gross negligence, in accordance and consistent with the country's legal tradition, and in line with international human rights law, may capture such scenarios.[115]

i. Manufacture

The establishment of a criminal offence of manufacturing a falsified medical products requires defining in law what is included in 'manufacture' and what is 'falsified'.

Example: The Tanzania Medicines and Medical Devices Act Section 76

(1) No person shall manufacture, import, supply, possess or offer for sale any counterfeit drug, herbal drug or medical device.

(2) Any person who deals in or manufactures counterfeit drugs, herbal drugs, medical devices, commits an offence and upon conviction is liable to fine of not less than five million shillings or to imprisonment for term of not less than two years or to both such fine and imprisonment.

(3) For the purposes of this Act, a drug, medical device or herbal drug shall be deemed to be counterfeit if (a) it is manufactured under a name which belongs to another drug; (b) it is an imitation of, or is a substitute for, another drug, medical device or herbal drug resembles another drug or medical device likely to deceive or bears upon its label or container the name of another drug, medical device or herbal drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug, medical device or herbal drug; (c) the label or container bears the name of an individual or company purporting to be a manufacturer of the drug, medical device or herbal drug; which individual or company is fictitious or does not exist; (d) it has been substituted wholly or in part by another drug substances; or (e) it purports to be it is a product of manufacturer of whom it is not truly product.

(4) **It shall be a defence in any prosecution for an offence** under subsection (1), if it is proved to the satisfaction of the court that the accused, not being a person selling the drug, medical devise or herbal drug to which the false or misleading advertisement which is the subject of the prosecution relates, did **not know and could not reasonably be expected to have known**, the advertisement was in any respect' "false" or "misleading" unless it is proved that, the accused failed on demand by the Director General, an inspector or a police officer, to furnish the name and address of the person at whose instance the advertisement was published or distributed or was brought to the notice of the public.

The definitions of manufacture adopted by WHA and by the AU Model Law,[116] are quite wide and also include activities such as storage and distribution, which should probably be criminalized under possession or trafficking. It is therefore suggested to use the definition developed by UNODC below.

"Manufacture" is defined to mean:[117]

(a) As regards a medicine, an excipient or an active substance – any part of the process of producing the medicinal product, or an active substance or excipient of such a product, or of bringing the medicinal product, active substance or excipient to its final state;

(b) As regards a medical device – any part of the process of producing the medical device, or the parts or materials of the medical device, including designing the medical device, the parts or materials, and of bringing the medical device, the parts or materials to their final state;

Falsified means deliberately/fraudulently misrepresented in identity, composition, or source. A substandard medical product can become falsified when it is manufactured intentionally below the mandated standards of quality or specifications. The UNODC Guide therefore does not include a separate offence for the intentional manufacture of substandard medical products since "to include a separate offence would be both redundant and confusing".[118]

Example from Malawi: manufacture and sale of falsified medicines

According to Section 98 of the Pharmacy and Medicines Regulatory Authority Act No. 9 of 2019, a person shall not, in the course of any business carried on by him, manufacture, import, assemble, dispense, sale any medicinal product or medicine which is falsified. In 2016, one of the pharmaceutical manufacturing companies stopped the manufacturing of OTC Novidar-SP (Sulphadoxine-Pyrimethamine) following the change in medicine schedule from OTC to prescription Only Medicine as they projected they would not make good business with the re-scheduling. In July, 2019, PMRA received complaint from the manufacturer that falsified Novidar-SP was on the market in the southern region of Malawi. The PMRA inspectors together with investigators from the Malawi Police Service initiated an investigation to uncover the source of the illegal supply of the falsified Novidar-SP. The investigation led to the location of a printing services unit that supplied the packaging and labelling materials of the falsified Novidar-SP to a makeshift manufacturing unit in a town ship in Blantyre-Malawi. The artwork was copied from original package of Novidar-SP produced by manufacturer. The tablets that were packed in the product were cotrimoxazole diverted from public supply chain. This was therefore a case of falsified packaging material purported to contain

116. AU Model Law, article 4; WHO Quality Assurance of Medicines Terminology Database - List of Terms and related guideline at https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/mqa-terminology-sept-2020.pdf?sfvrsn=48461cfc_10&download=true

117. UNODC Guide, supra note 3, page 21.

118. See UNODC Guide, supra note 3, pages 21-26.

Sulphadoxine-Pyrimethamine where the tablets were actually cotrimoxazole. **The offenders were convicted in manufacture and sale of falsified medicines** in violation of the provisions of the Pharmacy and Medicines Regulatory Authority under sections **95, 98, 100, 104(1) as read with 104(3), 106(1) and 106(2) of PMRA Act No 9 of 2019**. The offenders were fined an equivalent of USD 400.

ii. Trafficking in FMP

Trafficking in falsified medical products is mentioned both in the Medicrime Convention and the AU Model Law in article 23 (selling a medical product upon the container of which a false or misleading statement in connection with the contents is written). The UNODC Guide proposes the following definition for trafficking: **"Trafficking in falsified medical products** means importing, exporting, storing, transporting, donating, dispatching, dispatching in transit, dispatching in free-trade zones, trans-shipping, distributing, brokering, offering, keeping for offer, selling or supplying a falsified medical product, whether on one's own behalf or for a third party."[119]

A person who intentionally traffics in a falsified medical product commits an offence punishable by [ ].

States can include in their laws all or some of these acts, depending on their national laws and the circumstances usually associated with the commission of offences, for example in the context of regional free-trade zones. In African countries, SFMP may be associated with donations therefore they should prescribe procedures that national regulatory authorities should follow when dealing with donations. For example, when donations are made in times of crises, there should be minimum procedures followed by national regulatory authorities to ensure the safety of the medical products before distribution (see under section II).

As mentioned above, nowadays selling is often done online, by on-line pharmacies. Therefore, legislators need to ensure that selling and supplying also include on-line selling.[120]

The offence needs to be committed intentionally; hence, it requires knowing that the product is falsified. As in the case of manufacturing, the selling of a medical product while knowing that it is substandard implies knowledge that it is falsified i.e., its identity, composition or source is misrepresented.

Case-law Example: Benin

Judgment n° 43/1FD-18, Tribunal de première instance de première classe de Cotonou, Benin of 2018 Several persons of Beninese, French and Indian nationalities were found guilty of selling of falsified medicines, and received high fines and imprisonment of 4 years each. (Source: UNODC Sherloc case-law database).[121]

Case-Law Example Nigeria: Eromosele v Federal Republic of Nigeria (L 550 of 2013) [2016] NGCA 27 (30 May 2016); Court of Appeal

Two Nigerian citizens were sentenced to seven years in prison in a case involving the deaths of children from a falsified teething medicine ("my Pikin"). After children started dying in 2008, the paracetamol-based syrup was found to contain diethylene glycol, used as an engine coolant. The officials from the company which manufactured and sold the falsified syrup were found guilty by a court in Lagos and convicted again in the appeal in manufacture, distribution, and selling of falsified medical products, but acquitted from conspiracy.[122] The judge also ordered that the company be closed and its assets forfeited to the state. According to news reports this was replaced by a fine of 1Million in lieu of dissolution of the company.[123]

iii. Possession

In a manner similar to the criminalization of knowingly possessing illegal substances/drugs, possession of falsified medical products should also be criminalized to cover situations where the falsified medical products are discovered prior to sale. The idea is to criminalize possession when there is an intention to commit an offence. Article 6 of the Medicrime Convention includes as an offence "keeping in stock" of falsified medical products.

The UNODC Guide proposes to criminalize possession of a falsified medical product that is intended for distribution/sale, and also when it is intended to be used in a manufacturing process or its placement in the distribution system for supply, but not for personal use:[124] "Any person who [*with the requisite mental state*] possesses a falsified medical product where it is intended [or likely] that the falsified medical product will be used in a manufacturing process or placed in the distribution system for wholesale or retail supply commits an offence […]" - **Sample provision 8: possession of a falsified medical product.**[125]

The offence requires knowledge that the medical product is falsified, and an intention to sell it.

The UNODC Guide proposes considering criminalising also the possession of equipment, implements and materials with the intention to use them for manufacture or trafficking in FMP. It should be noted that there could be overlap between the offences of 'trafficking' and 'possession' in cases where a person is found in possession of falsified medical products for purposes of trafficking (the definition of trafficking includes the act of 'storing'). Prosecutors could be guided to have al-

119. See UNODC Guide, supra note 3, page 11.

120. Another option is to define specific offences of trafficking by electronic and distance selling. See UNODC Guide, supra note 3, pages 26-27. This is a question of legal drafting to be decided by national decision makers.

121. Available online at https://sherloc.unodc.org/cld//case-law-doc/fraudulentmedicinecrimetype/ben/2018/jugement_n_431fd-18.html?lng=en&tmpl=sherloc

122. Available at https://nigerialii.org/ng/judgment/court-appeal/2016/27.

123. See https://punchng.com/appeal-court-orders-pikin-seller-pay-n1m-fine/.

124. See UNODC Guide, supra note 3, pages 25-26.

125. UNODC Guide, supra note 3, page 25.

ternative offence of possession when indicting an offender (for example, when there isn't sufficient evidence for trafficking).

Most states do not have specific offences of possession of falsified medical products, and additional research might be needed prior to establishing them, for example on the question of the minimum quantity required for possession.

Example: the use of count of "possession" under the Tanzania Medicines and Medical Devices Act [CAP.219)

Prohibition of sale of adulterated or unfit drugs, medical devices and herbal drugs

75.-(1) No person shall-

(b) sell or supply, or offer or expose for sale or supply, or have in his possession for the purpose of sale or supply, any drug, medical devices, herbal drug or poison product whose composition has been affected by the addition thereto or subtraction there from of any substance;

Example of the use of count of "possession" under The Zanzibar Food, Drugs and Cosmetics Act No. 2 of 2006 77. (1) No person shall manufacture, import, supply, possess or offer for sale any counterfeit drug, herbal or medical devices.

iv. Falsification of documents

Falsification of documents is a key aspect of falsifying medical products, and therefore justifies establishing a specific offence. While the criminal law may already include a general offence of falsifying official documents, it is recommended to include a specific offence related to medical products, both in the AU Model Law and in the MEDICRIME Convention.

According to Article 23 of the AU Model Law, Any person who: - 3) **Makes any false or misleading statement in connection with any medical product** or scheduled substance: - a) In an application for marketing authorization thereof; or b) In the course of an application for a manufacturing, importing, exporting, storage, sale or distribution license thereof; or c) In the course of the sale thereof; 6) In any other manner, contravenes the provisions of this Law, shall be guilty of an offence.

States may take different approaches to defining the offence of falsification of documents as a general offence. If they wish to establish specific offences in the context of falsified medical products, they may also establish offences in documents and other falsified equipment and materials. The UNODC Guide includes proposed provisions.[126]

It is also important to note that some uses of falsified documents may be considered administrative offences under administrative law, which may offer in certain cases a more adequate response. Criminal provisions may be applied in the context of the activities of organised criminal groups or large-scale operations of falsification.

Example: Zambia Medicines and Allied Substances Act No. 3 of 2013

Article 58. (1) A person who fraudulently obtains a licence, permit, authorisation or registration under this Act or makes any false or misleading statement in connection with any medicine or allied substance commits an offence and is liable, upon conviction, to a fine not exceeding one million penalty units or to imprisonment for a period not exceeding three years, or to both.

2. RELATED CRIMINAL OFFENCES

i. secondary liability of accessories to an offence

As a general principle, criminal law recognizes principal offenders and accessories. Accessories to an offence should also be liable, though at times may be subject to a lesser sentence. This is usually defined in the general part of the criminal law, and there are varied approaches among national jurisdictions. In the context of offences in falsified medical products, the law should also include related crimes such as aiding and abetting the commission of an offence, conspiracy to commit an offence, criminal association, organizing and directing the commission of an offence.[127] Different countries have different penalties for aiding and abetting. Organizing or directing may be considered as an independent offence or as aggravating circumstance in sentencing. Model provisions are available in several UNODC publications,[128] so it was deemed not necessary to reproduce them in the Reference Manual.

UNTOC Article 5 establishes the criminalisation of participation in, association with or conspiracy to commit, organizing, directing, aiding, abetting, facilitating, or counselling the commission of serious crime.

Example: Tanzania case for falsified medicine In the Resident Magistrate Court of Kisutu at Kisutu[129]

Economic Criminal Case No 5 of 2014 Republic versus Managing Director of TPI co Ltd & Others

The accused company was charged among other things for supply of falsified anti-retroviral tablets branded TT-VR 30 bi-layer round shaped on the auspicious of a framework agreement to supply a genuine and registered anti-retroviral TT-VIR 30 white colour oblong shaped caplets with inscription 'TPI' on one side and 'T30' on the other. The anti-retroviral tablets branded TT-VR 30 bi-layer round shaped tablets were the falsified products but supplied and

126. UNODC Guide, supra note 3, page 29. Sample provisions 13 and 14.

127. See UNODC Guide, supra note 3, pages 29-31.

128. For the latest, see UNODC *Model Legislative Provisions against Organized Crime*. second edition (2021)

129. Example provided by Iskari Fute the Principal State Attorney representing the office of the Attorney General, Tanzania.

sold to Central Medical Store as the registered TT-VIR 30 white colour oblong shaped caplets.

The accused company sold and delivered both fake and genuine products to the Central Medical Store with same packing list as Anti-Retroviral (ARVs), TT-VIR 30 tablets, batch number OC.01.85. The payment had been duly honoured by the accused company upon invoice raised including the falsified anti-retroviral tablets branded TT-VR 30 with batch number OC.01.85.

However, as the burden of proof on the offence in criminal case lies on the prosecution side, two questions of law arose before the court to wit:

a) Whether the anti-retroviral tablets branded TT-VR 30 bi-layer round shaped were a falsified product; and

b) Whether the accused company had capacity to manufacture or supply TT-VR 30 bi-layer round shaped.

On the first question of law, the Prosecution side failed to produce before the Court of law a sample of a genuine registered anti-retroviral TT-VIR 30 white colour oblong shaped caplets with inscription 'TPI' on one side and 'T30' on the other as the same was not available at the storage of he submitted dossier for registration by Tanzania Medicines and Medical Devices Authority (TMDA). The court was not able to make a comparison of the two to determine on which one out of the two disputed products can collaborate the evidence by the prosecution side that was watertight to win the conviction.

On the second issue, the prosecution side failed to provide evidence as to the technological capacity of the accused company to manufacture or supply TT-VR 30 bi-layer round shaped tablets since the machines of the manufacturing plant was only equipped with machines capable of manufacturing and producing TT-VIR 30 oblong shaped caplets.

Following these two questions being not proved beyond reasonable doubt, the accused company was acquitted and set free.

ii. Obstruction of Justice

Considering the importance of inspections in detection of SFMP, states may wish to adopt a specific offence on obstruction of inspections. The criminal law may already include more general provisions on obstruction of investigations and prosecutions. The UNODC Guides notes that "in jurisdictions in which enforcement powers are exercised by competent authorities other than the police, states should ensure that specialized provisions on obstruction of justice cover officers acting on behalf of those authorities."[130]

Article 23 of the AU Model Law establishes as an offence any person who "obstructs or hinders any inspector in the exercise of his or her powers or the performance of his or her duties under this law".

UNODC Sample provision 19: obstruction of justice:

> A person who, in a proceeding in relation to any offence covered by this [Act/Law/Chapter, etc.], uses force, threats or intimidation or offers, promises or gives any undue gift, concession or other advantage in order to: (a) Induce false testimony; (b) Interfere in the giving of testimony or production of evidence; or (c) Interfere with the duties or performance of law enforcement, prosecution or judicial authorities or competent authorities, [including those responsible for forensic analysis and the regulation of medical products]; commits an offence.

Example: Sierra Leone's The Pharmacy and Drugs Act, 2001, Section 54

54. No person shall obstruct an inspecting officer exercising powers under and in accordance with this Part or fail to comply with a requirement made by him in exercise of those powers.

iii. Failure to report

To prevent the spread of SFMP, manufacturers, distributors, brokers, suppliers, or retailers should be subject to administrative and/or criminal sanctions if they fail to report them. The same should apply to health-care practitioners providing medical products to consumers with actual knowledge that they are falsified. The mandatory duty to report is established in the regulatory framework. The duty arises when the person comes to know of SFMP or has reasonable suspicion.

For all regulated products, if the product is already in circulation, and an error is identified, there should be a recall process followed, after informing the NRA. The consequences of such medicines being used by patients are dire, and the NRA therefore needs to be efficient enough to provide a response when they receive a report on substandard or falsified medicine. In practice, NRAs might be cautious about recalls in order not to alarm the society – they must do a risk/benefit analysis otherwise the NRA becomes culpable. Sometimes, the NRA is also concerned with the reputation of the manufacturer. It is hard to link the cause of death to the consumption, so there is a need for expert witnesses.

The UNODC Guide proposes to establish a specific offence. **Sample provision 11: failure to report**

> A manufacturer, distributor, broker, supplier or retailer of medical products or a health-care practitioner providing medical products to consumers with [***actual knowledge or reasonable suspicion***] that they have transacted in a falsified medical product, who fails to report to the [*insert name of competent authority*] commits an offence.[131]

The report should be on the falsified medical product, not the transaction. The duty to report arises before the transaction. This provision is not intended to apply to the main offender who is involved in the falsifying, as the principle of Ne bis in idem applies– you cannot prosecute a person twice for the same offence.

The reporting obligation for substandard medical products is established in the regulatory system. However, if a person knows a medical product is substandard but does

130. UNODC Guide, supra note 3, pages 32-34.

131. UNODC Guide, supra note 3, page 27.

disclose it, in many cases it would mean that he or she knowingly (with the requisite mental state) misrepresented the identity, composition or source. The medical product is hence falsified, as per the definition.

By virtue of the training of health professionals, especially pharmacists that are trained custodians of medicines and medical products, who know that as part of the stability studies that are carried out to determine the shelf-lives of medical products (life span within which a medicine can be safely administered and used), if/when medical products have been known to be stored/handled for an unacceptable period (as per the manufacturer's recommended storage conditions) and if the health professional still goes ahead to administer or dispense such medical products for consumption, such health professionals should be held liable. To avoid such culpability, the health professional should consider his/her responsibility to report to be critical in this respect.

There are obligations to report on substandard medical products that are detailed in the regulatory system including procedures for reporting (for example, the Zanzibar regulations on the reporting of suspicious MP include a specific form for reporting). These are usually complied with, especially by established manufacturers multinationals. For them it is very important to maintain reputation. Therefore, when they have reason to suspect, they will send the report to the NRA (see detailed discussion under reporting duties in the regulatory section).

iv. Recklessness/gross negligence in handling medical products

Different consequences of using substandard and falsified medical products may affect the sanctions, but "manufacturers who were knowingly adopting substandard practices would either way be held accountable".[132] The UNODC Guide notes that "if deemed appropriate, States may decide to criminalize conduct resulting in unintentional quality defects or the violation of safety procedures and standards when committed with the adequate mental state, such as recklessness or negligence".[133] The Reference Manual therefore recommends the adoption of such specific offences. Legislators could consider the following language:

> *Any persons who is reckless/grossly negligent in the manufacturing, storing, transporting, or otherwise handling of medical products, shall be liable to an offence punishable by __ years of imprisonment and a fine of __. If such recklessness/gross negligence resulted in the death of another person, or serious harm to a person, the sentence shall be __ years of imprisonment and a fine of __ (establish a higher punishment).*

Adding such an offence to the criminal law allows for prosecution of severe cases of manufacturer recklessness and also provides protection to victims who could then be entitled to compensation at the end of the criminal trial.

3. OFFENCES RELATED TO ORGANIZED CRIME AND CORRUPTION

The UNOTC COP in its resolution 10/5 urged States parties to "criminalize corruption and the laundering of proceeds of crime, in accordance with national legislation, including when related to the manufacturing of and trafficking in falsified medical products." UNTOC article 5. Criminalization of participation in an organized criminal group, Article 6. Criminalization of the laundering of proceeds of crime.

The law should also criminalize membership in an organized criminal group to deter participation in organized criminal activity for the trafficking of falsified medical products and to allow the prosecution of offenders when there is evidence of their participation in such a group.

Some countries have specific offence of **conspiracy**. This is one of the two options under article 5 of UNTOC on participation in an organized criminal group (more used in common law tradition). The other one is criminal association (more used in civil law tradition).

UNODC Guides provide detailed recommendations on such legal provisions,[134] therefore the Reference Manual only highlights specific aspects related to offences in falsified medical products.

i. Corruption

Corruption within the supply chain of medical products often facilitates the trafficking and contributes to weakened regulatory systems. It is therefore necessary to ensure that the criminal law adequately addresses corruption offences. The UN Convention against Corruption (UNCAC) defines specific offences related to corruption (in chapter III), that States parties should criminalize.[135]

Health-sector corruption is multi-jurisdictional and may involve transnational criminal networks, such as the international trafficking in falsified medical products, or organized criminal groups that are directly involved in health fraud schemes in multiple countries. Corruption that facilitates falsified and substandard medicines is one form of such corruption, which also delays the achievement of SDG target 3.8.1: Coverage of essential health-care services.[136]

In the context of manufacturing and trafficking in falsified medical products, it was recommended that countries adopt rigorous measures to fight corruption by public officers involved in manufacture of and trafficking in falsified medical products, including the establishment of mobile enforcement and integrity units.[137]

In connection with the work of NRAs, staff, Board and Committee members may be required to declare any interests

132. Olliaro et al., supra note 5, page 265.

133. UNODC Guide, supra note 3, pages 19-20.

134. UNODC *Model Legislative Provisions against Organized Crime* second edition, (2021).

135. See United Nations Convention against Corruption, 2003. Available at https://www.unodc.org/unodc/en/corruption/uncac.html .

136. Mackey TK, Vian T, Kohler J. *The sustainable development goals as a framework to combat health-sector corruption*. 96(9) Bull World Health Organ. (2018) 634-643.

137. Inter-Governmental Action Group against Money Laundering in West Africa, *Typologies Report: Money Laundering Resulting From the Counterfeiting Of Pharmaceuticals in West Africa* (2017).

related to medical products or to any decision-making of the Authority; any identified conflicts of interest must be managed in accordance with established guidelines.[138]

Examples: South African Medicines and Medical Devices Regulatory Authority Act NO. 132 OF 1998 as amended, article 14, requires declaring a conflict of interest in the Board.

Liberia Act to Establish the Liberia Medicines and Health Products Regulatory Authority (LMHRA) of 2010, article 2 – one of the functions of the NRA is to manage any potential conflict of interests.

In Zambia, a case of corruption in the manging of medical products was exposed. It involved condoms and contraceptive tablets imported by a pharmacy, tested by the Zambia Bureau of Standards (ZABS) and found to be defective, but still put on the market. Only after complaints from users, the case was handled as corruption case. In January 2021, the Minister of health was fired and an investigation was launched.[139]

ii. Money laundering

Large sums of money are generated and laundered through the manufacturing of and trafficking in falsified medical products in Africa. The motivation for trafficking in falsified medical products is the considerable profit generated from it, therefore, it is also crucial to enact laws that criminalize money laundering, and allow for seizure and confiscation of assets and funds.[140] Ideally, this will deter the criminals from continuing the trafficking and will divert the proceeds of crimes towards other uses, such as the compensation of victims affected by the use of SFMP. One important element for addressing money laundering is defining manufacturing of and trafficking in FMP as a **predicate offence** (see definition above). UNTOC article 7 list measures to combat money laundering that States parties should adopt.

C. Sanctions

Adequate sanctions should be established in the law to deter traffickers and manufacturers of falsified medical products, considering aggravating and mitigating circumstances, including previous convictions. The penalty should also be sufficient considering the gravity of the offence, and the requirements under extradition treaties.[141] UNTOC defines serious offence as subject to maximum penalty of at least 4 years of imprisonment. The important point in relation to sanctions is that UNTOC can be used by States parties as a legal basis for international cooperation, and for that to happen, the national law needs to have as a maximum at least four years. Most Member States of the AU are parties to the Convention.

The current sanctions provided in national legislation on falsified medical products are on the lower side and not very deterrent to curb the commission of offences. Often offences in substandard and falsified medical products are grouped together with similar sanctions. The Reference Manual does not prescribe the actual monetary and imprisonment penalties; however, guidance would be given on the factors to consider when drafting the legislation. In general, the main goals of criminal law should be considered in evaluating sanctions. These include protection of society (by removing dangerous individuals), deterrence (of potential offenders), accountability (of offenders) and retribution for their actions, rehabilitation of offenders and prevention of their recidivism, and restoration (repairing relationships and protecting victims).

Types of sanctions

Article 24 of the AU Model Law lists as criminal sanctions fines and imprisonment.[142] Another element of the sanction could be compensation of victims as part of the sentence. It could also include confiscation of proceeds of the crime and of property, equipment or other instrumentalities used in or destined for use in offences.[143] In the case of legal entities, this may include suspension, revocation, cancellation of a license; as well as the dissolution of companies (see article 12 of the Medicrime Convention). Publishing the names of companies that were involved in offences is another "soft sanction" that can be quite effective, as companies try to avoid such publicity.

In some laws in the region, offences related to trafficking in falsified medicines are subject mostly to fines, and very low imprisonment sentences, such as one month. One example for that is the case from Malawi (see above under trafficking), where offenders falsified a medical product for pregnant women (they falsified the packaging as well as

138. See WHO, *Managing conflicts of interest: A how-to guide for public pharmaceutical-sector committees in low- and middle-income countries* (2022).

139. See a news report on the case at https://www.thebody.com/article/zambia-honeybee-leaky-condoms.

140. For sample legislative provision See UNODC. Guide, pages 34-35.

141. UNODC Guide, supra note 3, page 21 and pages 35-40. MEDICRIME Handbook, supra note 102, pages 51-55. MEDICRIME Convention, Article 21.3.

142. Which may also include alternatives to imprisonment, when appropriate. See United Nations Standard Minimum Rules for Non-custodial Measures Adopted by General Assembly resolution 45/110 of 14 December 1990 (the Tokyo Rules) for guidance. See also UNODC Handbook of basic principles and promising practices on Alternatives to Imprisonment (2007). Available at https://www.unodc.org/pdf/criminal_justice/Handbook_of_Basic_Principles_and_Promising_Practices_on_Alternatives_to_Imprisonment.pdf.

143. See Article 12 of UNTOC, and UNODC Manual on International Cooperation for the Purposes of Confiscation of Proceeds of Crime (2012), at https://www.unodc.org/documents/organized-crime/Publications/Confiscation_Manual_Ebook_E.pdf.

the contests, which included a different API) and received a fine equivalent to 400 USD. Considering the serious impact on public health, and the vulnerability of victims, administrative sanctions/fines should be reserved for technical infraction of regulatory rules. Compensation for victims is also an important aspect of the sentence to ensure restitution for damages suffered. Its use in criminal cases related to falsified medical products should also be encouraged.

Example: Nigeria Counterfeit and Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act Cap C.34 Lfn 2004 was amended in 2016 to introduce harsher penalties:

3. Penalties

(1) Any person who commits an offence under-

(a) section 1 of this Act, is liable on conviction to a fine not exceeding N500,000 or imprisonment for a term of not less than five years or more than fifteen years or to both such fine and imprisonment;

(b) section 2 (1) of this Act, is liable on conviction to a fine not exceeding N500,000 or imprisonment for a term of not less than two years or to both such fine and imprisonment.

(2) Where an offence under section 1 or 2 of this Act has been committed by a body corporate, every person who at the time of the commission of the offence was a proprietor, director, general manager, secretary or other similar officer, servant or agent of the body corporate (or a person purporting to act in any such capacity), he, as well as the body corporate, shall be deemed to be guilty of the offence and may be proceeded against and punished accordingly.

Considerations in sentencing

To ensure that adequate sentences are imposed on offenders, sentencing guidelines could be developed to guide judges. Awareness raising is important, as most judges are not aware of the public health impact of the offence and the harm done to the victims. Sentencing guidelines may include aggravating and mitigating circumstances (see article 13 of the Medicrime Convention and UNODC Guide). At the time of application of sanctions, penalties will have to be proportionate to the offence committed with due consideration given to the circumstances of the offence. The same degree of sanction will not apply uniformly in all cases. Consideration will have to be given to the levels of culpability and the *mens* rea of a perpetrator. The criminal laws of countries may already include lists of such circumstances that apply generally. It is suggested to add the following considerations in relation to SFMP, which may be applied as aggravating or mitigating circumstances, depending on the situation.[144]

- Whether the offence caused the death of the victim or harmed his or her health or caused no discernible harm;
- Whether the offence was committed by means of a large scale communication device;
- Whether the perpetrator has already been convicted of a similar offence, or has no criminal record;
- Whether the offence was committed as part of an activity of an organized criminal group;
- Whether the offender had a leading role or a minor role in the commission of the offence;
- Whether the offender showed remorse for the commission of the offence (or not);
- Whether the offence involved life-saving medicines;
- The number or quantity of medical products involved in the offence;
- The size of any financial or other material loss to another person as a result of the offence;
- Whether the person voluntarily cooperated by providing information or otherwise assisted competent authorities, including in investigating and prosecuting falsified medical product-related crime; or refused to cooperate with authorities; or even attempted to obstruct the administration of justice during the investigation, prosecution or sentencing stages;
- Whether the offence was committed by a government official;
- Whether the offence was committed by a person abusing the trust conferred by his/her professional capacity; or in his/her capacity as a manufacturer or supplier;
- Whether the offender was or is suffering from reduced mental capacity at the time of commission of the offence or the time of sentencing;
- The age of the offender at the time of commission of the offence or at the time of sentencing.

In some cases, and depending on whether this is permissible in national law, the prosecution may agree to a plea bargain. This usually implies that the offender pleads guilty to the offence, and at times assists the authorities with the investigation and in return, the prosecution agrees to a reduced sentence.[145] It is used to save precious time at court, to spare traumatized victims from testifying, achieve faster resolution of the case and reduce prison congestion. However, there may be backlash from the public when the perception is that rich offenders are treated differently, or that the punishment does not fit the crime. The views of victims should therefore be considered in deciding plea bargains. In some countries the practice is included in sentencing guidelines or court proceedings, in others this is part of the procedural code. Please bargains may be permitted only for specific offences, and may be subject to conditions.[146] **Therefore, legislators need to decide whether to allow plea bargains in offences in falsified medical products, and under which conditions.**

Custodial sentence - It was proposed to adopt a maximum sentence of imprisonment of at least four years, for

144. See UNODC Guide, supra note 3, pages 38-39. Most of the mitigating circumstances mirror the aggravating circumstances.

145. See Article 26 of UNTOC: Measures to enhance cooperation with law enforcement authorities

146. For example, in Zambia, full disclosure is required by the offender, and if it is not met, the agreement may be rejected. See Government of Zambia Act No. 20 of 2010 An Act to provide for the introduction and implementation of plea negotiations and plea agreements in the criminal justice system and for matters connected with, or incidental to, the foregoing (2010). In Article 12. Available at https://www.parliament.gov.zm/sites/default/files/documents/acts/The%20Plea%20Negotiations%20%26%20Agreements%202010.PDF.

the four main offences in falsified medical products, to keep it in line with UNTOC.

Fines - the amounts prescribed for fines should have a deterrent effect to prevent the commission of offences. Therefore, they should consider the profits of manufacturers and the proceeds of organised criminal groups.

Victims' Compensation - Victims should be compensated for the injury suffered because of commission of offences related to medical products that are falsified; the definition of 'victim' would have to be provided for to determine the persons eligible for the compensation. Countries may consider setting up funds for compensation of victims (e.g., from proceeds of crime); and the administration of the compensation funds should be provided in each country's legislation (see detailed discussion below under victims' protection).[147]

D. Jurisdiction over offences

Criminal laws usually establish jurisdiction over offences committed within the territory of the state. This jurisdiction may also be expanded to apply to offences committed on board a vessel carrying its flag or an aircraft registered under its laws, committed by its nationals, or committed against its nationals.

This is usually included in the general part of the criminal law, therefore the same should apply to the offences covered here. In the case of manufacturing of and trafficking in FMP, it is important that the law covers transport by air or sea, to prevent a jurisdictional gap. Additional rules may be required to establish jurisdiction over offences committed by on-line service providers,[148] probably through active or passive nationality (bases currently not available in most countries).

Article 15 of UNTOC establishes the following as possible bases for jurisdiction:

(a) The offence is committed in the territory of the State;

(b) The offence is committed on board a vessel that is flying the flag of the State or an aircraft that is registered under the laws of the State at the time that the offence is committed;

(c) The offence is committed against a national of the state Party;

(d) The offence is committed by a national of the State or a stateless person who has his or her habitual residence in its territory;

(e) The offence is committed outside its territory with a view to the commission of a serious crime within its territory;

(f) When the alleged offender is present in its territory and it does not extradite the person;

In addition, the UNODC Guide proposes to also allow jurisdiction when:

(g) Such jurisdiction is based on an international agreement binding on the State. This could be interpreted to include a binding resolution by the Security Council under the UN Charter.

E. Liability of legal persons

Domestic criminal laws usually include provisions to establish criminal liability of legal persons in certain conditions or in relation to certain offences. It is important that such liability be established in the context of falsified medical products.[150] At a minimum, the law should include a definition of legal persons, the scope of liability of legal persons and sanctions for legal persons. It may also establish principles such as due diligence for legal persons. Liability of directors is an important issue to be considered.[151] Another legal issue is the liability of branches of big corporations that produce medical products, in which the prosecution will need to decide whom to prosecute. The sanctions may include fines but also dissolving the company in accordance with the applicable law.[152]

Article 10 of UNTOC establishes liability of legal persons. It is a mandatory provision but under-utilized by States parties. It reads: "1. Each State Party shall adopt such measures as may be necessary, consistent with its legal principles, to establish the liability of legal persons for participation in serious crimes involving an organized criminal group and for the offences established in accordance with articles 5, 6, 8 and 23 of this Convention. 2. Subject to the legal principles of the State Party, the liability of legal

147. See for example the case of Health Products Regulatory Authority v Taj Accura Pharmaceuticals Ltd (DC, 22 June 2018) from Ireland. Charges were brought against the company Taj Accura, one of its directors, Defendant 2, and a shadow director, Defendant 3. The charges related to selling, selling by wholesale, brokering by wholesale, importing, exporting, placing into circulation and introducing into Ireland falsified medicinal products for the treatment of cancer (that were also sold in several other countries). The accused were ordered to pay fine of EUR 1000 each. See the case on UNODC Sherloc database: https://sherloc.unodc.org/cld/case-law-doc/fraudulentmedicinecrimetype/irl/2018/health_products_regulatory_authority_v_taj_accura_pharmaceuticals_ltd_dc_22_june_2018.html

148. See UNODC Guide, supra note 3, pages 6-7; MEDICRIME Handbook, supra note 102, pages 49-50.

149. UNODC Guide, supra note 3, pages 6-7.

150. See UNODC Guide, supra note 3, pages 41-46; MEDICRIME Handbook, supra note 102, page 51.

151. See UNODC sample provision 21, which broadens the scope of liability. UNODC Guide, supra note 3, page 42.

152. UNODC Guide, supra note 3, page 43.

persons may be criminal, civil or administrative. 3. **Such liability shall be without prejudice to the criminal liability of the natural persons who have committed the offences.** 4. Each State Party shall, in particular, ensure that legal persons held liable in accordance with this article are subject to effective, proportionate, and dissuasive criminal or non-criminal sanctions, including monetary sanctions. "

In some countries **person** means both individual person and a legal person. The AU Model Law speaks about a person in terms of liability, but does not define it. Therefore, it is suggested to clarify the definition of a person in law. Specific measures could also be adopted against online pharmacies to ensure they can be held accountable for offences related to medical products.[153]

Example: Kenya Pharmacy and Poisons Act Section 50 deals with offences by corporate bodies.

If a corporate body is found liable for a criminal offence, then; they can be declared unfit to be in the register; cease to be a seller; be disqualified for a period to be determined by the board.

Example: Zambia Medicines and Allied Substances Act No. 3 of 2013

Section 67 - Offences by body corporate or unincorporate body. "Where an offence under this Act is committed by a body corporate or an unincorporate body, every director or manager of the corporate or unincorporate body is liable, upon conviction, as if the director or manager had personally committed the offence, unless the director or manager proves to the satisfaction of the court that the act constituting the offence was done without the knowledge, consent or connivance of the director or manager or that the director or manager took reasonable steps to prevent the commission of the offence."

F. Investigation and prosecution of offences

In order to effectively investigate and prosecute offences related to trafficking in falsified medical products, Member States should ensure that prosecutors and investigators have the necessary tools and knowledge. This may include the creation of specialized units. For example, in Ghana, the Organized Crime Department is responsible for taking actions related to the investigation and prosecution of criminal offences. Another option is to have mixed expertise in the units (lawyers, cyber experts etc.).

1. PROSECUTORIAL DISCRETION

As UNODC Guide notes: "In many States, prosecutors are afforded discretion as to whether to prosecute offences, either by law or through administrative procedures. Conditions applying to the exercise of such discretion may include the community's interest in prosecuting or not prosecuting an offence and the need to bring offenders to justice and deter the commission of similar offences. Prosecutorial discretion may relate not only to the decision to initiate and continue a prosecution but also to decisions to accept plea bargaining arrangements, where permitted".[154]

In light of the importance of prosecuting offences involving falsified medical products, where prosecutors exercise such discretion, they should be allowed to prosecute even in the absence of a victim's complaint in those jurisdictions which require such a complaint (article 15 of the Medicrime Convention).[155] If such a general authorization already exists in national laws, it may not be necessary to include it. In those countries where the victim's complaint is required, an exception should be made for the offences covered here. It is recommended that principles for prosecutors, on how to apply their discretion, be included in guidelines or regulations, to ensure fairness and consistency.[156]

In the context of falsified medical products, authorities may have discretion in some systems, to decide when to initiate criminal proceedings, and when to refer the case to administrative or civil proceedings. Authorities may consider factors such as "severity (e.g., fatal, life-threatening, and long-term sequelae), size (e.g., number of victims) of the harm caused, and nature/size of the potential harm (in case the medicine is detected and confiscated before reaching and harming people)."[157] Other considerations may be the capacity of the offender, the quantities of medicines, whether it is a repeat offender, and whether damage was caused to patients. Some of these issues may be captured under aggravated sanctions. The discretion would then be of the judge in the case.

Civil litigation could be a better option where there is lack of sufficient evidence for criminal prosecution (where the evidentiary bar is higher – beyond reasonable doubt), so that the victim can at least be compensated.

When offences are committed as part of organized criminal activity, prosecutors could consider including the relevant offences such as conspiracy, or participation in organized criminal group. This will allow the judge to impose the maximum available penalties for organised crime. This is especially relevant when the sanctions for an offence related to falsified medical products are very low.

153. For detailed discussion see also UNODC. *Issue Paper: Policymaking and the Role of Online Intermediaries in Preventing and Combating Illicit Trafficking,* (2021), pages 35-43, page 64.

154. UNODC Guide, supra note 3, pages 53-54.

155. See UNODC Guide, supra note 3, pages 41-46; MEDICRIME Handbook, supra note 102, page 53-54.

156. For additional discussion on the discretionary powers of prosecutors see UNODC and IAP publication on the Status and Role of Prosecutors (2014) available at https://www.unodc.org/documents/justice-and-prison-reform/14-07304_ebook.pdf . 157. UNODC Guide, supra note 3, page 43.

157. Olliaro et al., supra note 5, page 266.

2.TOOLS FOR INVESTIGATION

The law should provide investigators with adequate powers and tools to conduct effective investigations since collection of evidence is key for prosecution. This may include, *inter alia*: freezing and seizure of proceeds of crime and falsified medical products, as well as request for assistance from other countries, recall, obtaining samples, etc.[158] Such powers may be provided for in the criminal law in general, or in specific laws, for example in the context of inspection powers of the NRA (see above under section II). Given the nature of medical products, the NRA may need to guide the investigation by the police. For example, in Ghana, one chief inspector and two inspectors seconded to the NRA are able to support their colleagues to draft charges and prosecute.

In addition, UNODC recommends specifically in the context of falsified medical products to include legal provisions on the taking of samples and using certificates to certify the results of such tests, serving as evidence in court.[159] This might already be covered under inspection powers of regulatory inspectors, therefore **consistency of the criminal procedures with the regulatory ones is extremely important** (see discussion under inspection, page 23 above).

Article 20 of UNTOC lists special investigative techniques that may be adopted:

1. Controlled delivery which may include methods such as intercepting and allowing the goods to continue intact or be removed or replaced in whole or in part.

2. Electronic or other forms of surveillance and undercover operations, by its competent authorities in its territory for the purpose of effectively combating organized crime.

States may conclude bilateral or multilateral agreements or arrangements for using such special investigative techniques in the context of cooperation at the international level. It may also be established by law, or done on an ad-hoc case-by-case basis.

Example: Malawi Pharmacy and Medicines Regulation Act

Section 80 (5). An inspector may, for the purpose of enforcing the provisions of this Act, at any reasonable time, and on the authority of a warrant, enter any premises including pharmacy practice premises, container, vessel, vehicle, aircraft or other conveyance that the inspector has reasonable grounds to believe is used for the commission of an offence or purposes contrary to the provisions of this Act, and—

(f) take samples of any medicine or allied substance as may be necessary for the purposes of testing, examination or analysis;

(g) take extracts from, or make copies of, any book, record or document found on the premises that has a bearing on an inspection or investigation; Samples can either be used as exhibits in court as a supplement to expert evidence given on the results of testing the samples. The Criminal procedure and evidence code provides for admissibility of documents related to tests.

3. LAW ENFORCEMENT COOPERATION

Considering the transnational nature of trafficking in falsified medical products it is important that the law allows for cooperation amongst law enforcement officers, including joint investigations. Information sharing between agencies and mainly cross border ones is key to ensuring that SFMP are not transferred to another country upon being rejected on one. Interpol national central bureaus in countries should work in collaboration with NRA/NDAs for closer cooperation.

In both UNCAC Art 48 and UNTOC Art 27 State parties are required to strengthen the channels of communication among their law enforcement authorities and provide each other with items or substances for purposes of analysis and investigation. Other special investigative techniques include controlled delivery and surveillance.[160]

Article 19 of UNTOC allows for Joint investigations: "States Parties shall consider concluding bilateral or multilateral agreements or arrangements whereby, in relation to matters that are the subject of investigations, prosecutions or judicial proceedings in one or more States, the competent authorities concerned may establish joint investigative bodies. In the absence of such agreements or arrangements, joint investigations may be undertaken by agreement on a case-by-case basis. The States Parties involved shall ensure that the sovereignty of the State Party in whose territory such investigation is to take place is fully respected."

4. INTERNATIONAL CO-OPERATION IN CRIMINAL MATTERS

Considering the transnational nature of trafficking in falsified medical products, in order to allow effective prosecutions, the law should permit the use of tools for cooperation in criminal matters with other countries. This includes extradition and mutual legal assistance, as well as transfer of proceedings and transfer of prisoners.

UNTOC COP in its resolution 10/5 invited States parties "to strengthen coordination and cooperation among their national authorities involved in the prevention of and fight against the manufacturing of and trafficking in falsified medical products, including through effective international cooperation, such as mutual legal assistance and extradition mechanisms, and other international cooperation arrangements for investigation and prosecution, including joint investigations, when appropriate and in accordance with national law, making use of best practices such as the effective use of international and regional law enforcement and judicial cooperation networks".

International cooperation in criminal matters is an important complex legal issue, and there are many legal tools and guides for Member States.[161] The Reference Manual encourages states to ensure they have the legal tools in place to allow for cooperation in criminal matters related to falsified medical products.

Articles 16-18 of UNTOC provide a detailed framework for such cooperation, and can also be used as a basis for coo-

158. For detailed information on these investigations tools see UNODC Guide, supra note 3, pages 47-52. On page 47 see some more tools.

159. Sample provisions 25 and 26, UNODC Guide, supra note 3, pages 51-52.

160. For detailed proposals see UNODC Guide, supra note 3, pages 61-62.

161. See UNODC Manual on Mutual Legal Assistance and Extradition (2012), as well as UNODC Model Laws and Model Treaties on extradition and MLA.

peration between States parties to the Convention, if they decide to do so.[162] Since not all countries use the Convention as a legal basis for cooperation, another option is the conclusion of bilateral treaties for extradition and MLA (see model treaties on extradition and MLA). Another approach is the adoption of general laws on extradition and MLA. If such provisions are not already included in the law, they should also be considered in any legal reform.

The MEDICRIME Convention provides for that Convention to act as a legal basis for extradition or mutual legal assistance in criminal matters in respect of offences established in accordance with that Convention (Article 21).

Regional treaties for cooperation in criminal matters can also provide the necessary legal framework. For example, the IGAD Convention on Mutual Legal Assistance, and the IGAD Convention on Extradition. These conventions were adopted by the IGAD Council of Ministers at their 33rd ordinary session in Djibouti on 7–8 December 2009.[163] The Conventions aim to promote cooperation in the prevention and suppression of crime, tracing and confiscating the proceeds of crime more effectively among the member states. These two instruments provide a platform to the Member States for the "obtaining of evidence and exchange of information" to investigate, prosecute and convict the culprits of all forms of criminal activities. All IGAD Member States signed the two Conventions, but only Djibouti and Ethiopia have ratified the Conventions. Entry into force shall be upon ratification by three Member States. Some regional treaties of the economic regions establish international cooperation, as well membership in Interpol.

In addition to regional treaties, in the specific context of SFMP in Africa, it is suggested that states enter into bilateral and multilateral treaties especially with origin countries outside the continent to facilitate effective prosecution.[164] All legal instruments related to international cooperation should ensure that offences related to falsified medical products are extraditable offences (in line with national laws) and can provide the basis for sending and receiving requests for MLA.

G. Victims and witness protection

1. VICTIMS' PROTECTION, COMPENSATION, RESTITUTION, AND PARTICIPATION IN THEPROCESS

The impact of the use of SFMP on human lives is considerable, and some of its users may suffer long term health consequences. It is therefore important to establish legal rules that will recognize their rights to compensation, protection, and restitution, in particular as to medical expenses, and to establish appropriate funding mechanisms to provide for such rights. Victims of crime will be those affected by the offences established in the law in accordance with the recommendations above (B. criminal offences).

The definition of victims may be expended to include family members of victims who died as a result of such use (as suggested by the UN Declaration of Basic Principles of Justice for Victims of Crime and Abuse of Power),[165] or other categories of victims as may be deemed appropriate in the context of the region and each country, taking into account the wider implications of the definition of a victim of a crime when deciding on the definition (for example, including in the definition someone whose legal interests protected by criminal law might have been violated through a criminal offence).[166]

The rights of victims of crimes in international law, including different definitions of victims were established in the MEDICRIME Convention; the United Nations Declaration of Basic Principles of Justice for Victims of Crime and Abuse of Power (1985); the UN Convention against transnational organized crime (article 25) and other sources. Countries are encouraged to draw inspiration from these conventions. Some of these rights may already be recognised in the national constitutions.

The following rights of victims should be recognised:

- **Right to compensation** and restitution. Currently most of the legal frameworks do not have provisions for compensation, and it is not seen as a priority. Compensation should also be provided to users of substandard medical products as well. When it comes to the impact on the health of patients, there is no justification to differentiate. However, the criminal procedure would not allow for compensation for victims of substandard medical products, unless a specific offence applies (e.g. offence of gross negligence during the manufacture or storage of medical products that resulted in substandard product – see above in section B.2.iv).

  When users of substandard medical products were harmed, they should be provided with procedures for obtaining compensation from the manufacturer, since they will not be considered victims of crime, unless an offence was committed. This is covered above under civil liability. There is a cause of action in civil law. We could encourage countries to have some minimum compensation in civil cases as guidance for judges. This may be established through product liability (manufacturers always have a representative in the country). Victims of falsified medical products may seek compensation at the end of the criminal trial. States should ensure that the legal framework provides for compensation of victims when deemed appropriate.[167] However, when the

162. UNODC Guide, supra note 3, pages 57-62.

163. See the texts of the conventions at https://igadssp.org/index.php/documentation/1-igad-convention-on-extradition/file and https://igadssp.org/index.php/documentation/2-igad-convention-on-mutual-legal-assistance-in-criminal-matters/file .

164. Philip Osarobo Odiase. *Recalibrating African health laws to combat substandard and falsified medical products: Beyond COVID-19*, 1(2) International Journal of Civil Law and Legal Research 2021; 01-09. Page 6. He mentions that according to studies, "some states have been unanimously identified as major provenance economies of SFMP".

165. For detailed proposals see UNODC Guide, supra note 3, pages 61-62.

166. UNODC Model legislative provisions UNTOC (2021), page 121.

167. See for example the COVAX no-fault compensation program for AMC eligible economies (the "Program"), in relation to Covid-19 vaccines. Available at https://www.who.int/initiatives/act-accelerator/covax/no-fault-compensation .

offender cannot be identified, there might be a gap in protection. Therefore, there is a need to consider ensuring access to medical services when the victims have no health insurance or universal coverage. The law may appoint an authority to be the responsible body to the rights of victims of the use of substandard and falsified medical products.

- There is a need to recognise the government's duty to protect the lives of its citizen when the alleged harm caused by substandard and falsified medical products was the result of the negligence of its own regulators.
- States may consider establishing a general fund for compensation of victims and clearly define who is entitled under the scheme. Confiscated proceeds of crime may be used to pay for care of people seriously affected by SFMP (see article 14(2) of UNTOC): "States Parties shall, to the extent permitted by domestic law and if so requested, give priority consideration to returning the confiscated proceeds of crime or property to the requesting State Party so that it can give compensation to the victims of the crime or return such proceeds of crime or property to their legitimate owner".
- **States could recognize a right to free legal aid by the state** for the purpose of navigating the criminal justice process and for filing civil claims. Free legal aid is key since victims need a lawyer's assistance to pursue compensation from the manufacturer. Otherwise, the poor will never be compensated. Another aspect is to allow public interest litigation by victims' rights NGOs.
- **Right to be heard in legal proceedings**, especially before sentencing. Rules should also allow for the participation of victims of crimes in the proceedings, either as witnesses, or in the sentencing stage.[168]
- **Right to information about their rights** and about the criminal proceedings, including at the post-sentencing stage.
- **Right to physical protection**, especially when victims are also witnesses at trial.

2. WITNESS' PROTECTION

Witnesses should be provided effective measures for their safety, and protection from intimidation and retaliation. If such general protection is not already provided in criminal law, it should be provided for witnesses in cases related to falsified medical products.

There are different types of witnesses, such as informants, bystanders, expert witnesses, and justice collaborators. UNODC defines **witness** as "any person, irrespective of his or her legal status (informant, witness, judicial official, undercover agent or other), who is eligible, under the legislation or policy of the country involved, to be considered for admission to a witness protection programme".[169]

There are different measures for witness protection, ranging from judicial protection such as conducting the proceedings in camera, confidentiality of names of witnesses and measures such as changing of identity and relocation to other countries.[170] Some countries may have it under their criminal procedure codes.

Informants require confidentiality and protection of their anonymity (for example, in DRC, article 73 of the penal code protects secret informants). In cases of inquiries related to falsified medical products, the informants could be persons involved in the supply chain, such as pharmacists or persons responsible for storage. They might also be persons operating within organised criminal groups. In both cases, they will require some level of protection. The UNTOC lists some possible measures in article 24, such as physical protection and relocation of witnesses and their relatives, giving testimony through video link, etc. Additional measures may be adopted by the government in its laws.

Whistle-blower protection

"**Whistle-blower** may be broadly defined as a member of an organization who reports an illegal, unethical or illegitimate practice under the control of the organization to individuals or institutions that may be able to respond or to the public".[171] Article 33 of the UN Convention against Corruption recommends that states adopt measures "to provide protection against any unjustified treatment for any person who reports in good faith and on reasonable grounds to the competent authorities any facts concerning offences" established under the Convention.

The case of whistle-blowers is specific, and protection is needed as they are key in the prosecution while their lives might be in danger (see UNODC Model Provisions on UNTOC, article 28). The concerns of whistle-blowers are different from those of witnesses, as their decision to report offences affects their place of work. Therefore, their protection may require specific measures such as anonymity, legal protection against loss of employment, legal remedies for reprisals, protection from unfair dismissals, and protection from libel suits.[172]

Legislation to protect whistle-blowers would normally be applicable to persons reporting on corruption generally, and not only in the context of a specific crime. In some countries the whistle-blower gets a reward if the proceedings are concluded successfully. There are also hotlines to report information 24/7 and if an anonymous tip leads to an arrest, there is a small reward, to encourage people to report any facts concerning offences. In other countries this might raise issues with the credibility of their testimony. There might also be specific policies of NRAs to encourage reporting on suspicions related to violations of the regulatory laws on medical products.

168. See also UNODC Guide, supra note 3, pages 16-18.

169. See UNODC, *Good practices for the protection of witnesses in criminal proceedings involving organized crime* (2015), available at https://www.unodc.org/documents/middleeastandnorthafrica/organised-crime/Good_Practices_for_the_Protection_of_Witnesses_in_Criminal_Proceedings_Involving_Organized_Crime.pdf

170. See UNODC Legislative Guide on UNTOC, Protection of witnesses and victims, available on SHERLOC.

171. UNODC Model Legislative Provisions against Organized Crime (2021), page 125.

172. See analysis of the provision at https://www.whistleblowers.org/wp-content/uploads/2018/10/un-convention-article-33.pdf . See also UNODC UNCAC Resource Guide on Good Practices in the Protection of Reporting Persons (2015).

Example: Tanzania Whistle Blower and Witness Protection Act, Cap 446 (revised 2022). Enacted to provide for the protection of whistle-blowers and witnesses against potential retaliation or victimization; to provide for a legal mechanism to reward and compensate whistle-blowers and witnesses and to provide for other related matters. For the purpose of effecting reward and compensation under the Act, competent authorities within public and private institutions must set aside budget to that effect.

The Tanzania Medicines and Medical Devices Act, Chapter 219, RE 2021 provides for protection of informers in section 119.

119.-(1) Subject to this subsection, no complaint made in respect of an offence under this Act shall be admitted in evidence and no witness in any proceedings for an offence under this Act shall be obliged or permitted to disclose the name or address of any informer or state any matter which might lead to his discovery, and, if any books, documents or any other papers which are in evidence or liable to inspection in those proceedings contain any entry in which any informer is named or described or which might lead to his discovery, the court shall cause all those passages to be concealed from view or to be obliterated so far as may be necessary to protect the informer from discovery, but no further.

(2) Where the court, after full inquiry into the case, is satisfied that the informer wilfully made in his information a statement which he knew or believed to be false in a material particular, or which he did not believe to be true, or if it appears to the court that justice cannot be fully done, it may require the production of the original information and permit inquiry and require full disclosure concerning the informer.

The Tanzania Medicines and Medical Devices Authority (TMDA) Whistleblowing Policy of March 2020[173] provided for a confidential, open or anonymous reporting process for the TMDA's employees and other stakeholders to report suspicions or evidence of malpractice, or concerns regarding serious violations of the TMDA's Act, regulations and any serious misconduct. There is also an electronic whistle-blower reporting form available at

https://www.tmda.go.tz/whistleblower#:~:text=In%20case%20of%20any%20form,action%20to%20protect%20the%20whistleblower

Example: Act of the Parliament of The Republic of Ghana Entitled the Whistleblower Act, 2006 Act to provide for the manner in which individuals may in the public interest disclose information that relates to unlawful or other illegal conduct or corrupt practices of others; to provide for the protection against victimization of persons who make these disclosures including legal assistance, police protection, protections against civil and criminal action. The law allows the issuance of an order to stop harassment, police protection, identity change, and location change. The law also provides for a Fund to reward individuals who make the disclosures and to provide for related matters.

IV. CONCLUSIONS

A. Summary

The Reference Manual acknowledges and builds upon the efforts made to improve the regulatory systems for medical products in the region and provide guidance to the Member States of the African Union. These efforts include the African Union Model Law on Regulation of Medical Products (2016), the WHO Global Benchmarking Tool for Evaluation of National Regulatory System of Medical Products (2021), and the UNODC Guide to Good Legislative Practices on Combating Falsified Medical product- Related Crime (2019).

The Reference Manual brings together for the first time in a comprehensive manner both the regulatory side and criminal elements, and this is a useful addition to the existing tools. It is important to note that addressing criminal law in isolation is not enough, and the same is true for the regulatory action. The goal of the Reference Manual is to assist countries in the process of reviewing their laws or policies in relation to SFMP, and aims to address existing gaps in policies, practice, and legislation.

The Reference Manual highlights the importance of addressing the menace of SFMP on the one hand, and ensuring access to medical products on the other hand. It adopts the WHA definitions, which imply different approaches to substandard and falsified medical products. The functional areas of NRAs' work were covered in the same manner as the WHO GBT 9 key functions, which is helpful for NRAs in the region working towards achieving a higher maturity level recognition from WHO. The Reference Manual addresses contemporary issues such as the on-line sale of SFMP, informal markets for medical products, and safe disposal of SFMP while considering environmental concerns. It also discusses the importance of reporting on SFMP and how to incentivize such reporting by professionals and by the general public.

The Reference Manual acknowledges the work already done in the eleven countries covered by Medisafe and allows for the sharing of knowledge with other AU Member States. It also acknowledges the efforts made at the regional level, and encourages regional harmonization. It highlights the importance of cooperation at the continental, regional, bilateral, and national levels. Regional cooperation is needed to maximize the chance of achieving success in addressing this issue, especially given its correlation with transnational organized crime. Regional NRA cooperation could be encouraged through recognition and reliance on decisions related to SFMP by other NRAs. NRAs should also reinforce cooperation at the national level, with other existing bodies empowered by legislation to deal with certain aspects of SFMP, such as customs, police etc., through administrative arrangements.

The Reference Manual reflects on the adequate use of administrative rules, civil and criminal law, offences, sanctions and their respective elements and standards. On the criminal justice side, the distinction between substandard and falsified medical products was highlighted as well as the need to address organized crime through serious and proportionate sanctions. Providing compensation for victims of offences and those otherwise harmed by the use of SFMP was identified as a main priority. Tools for investigation and the protection of witnesses and whistle-blowers were required for prosecuting offenders.

Finally, it is extremely important that governments commit resources to support mechanisms and procedures established by law and to allow the NRAs and other competent agencies operationalize all the functions mentioned in the Regulatory System. While the Reference Manual focuses on the legal structures that need to be in place, there is a need to emphasize the commitment of governments to provide resources for enforcement, in order to ensure success at the country level.

B. Checklist for legislators

The following checklist aims to assist legislators in verifying that their legal framework includes all the necessary elements for a comprehensive framework to respond to SFMP, and for quick navigation through the Reference Manual.

Do you have in your legislation/regulations/guidelines:	page	yes	no	partially
The Regulatory System				
1) A law to establish a national regulatory agency for medical products (NRA).				
2) A clear authorization of the institutions involved in regulation, their mandates, functions, roles, responsibilities, and enforcement powers.				
3) Administrative arrangements and channels of communication and coordination amongst the institutions involved.				

Do you have in your legislation/regulations/guidelines:	page	yes	no	partially
Marketing authorization				
4) A regulatory framework for registration and marketing authorization.				
5) A clear definition in a list (that may be updated from time to time) of the regulated medical products.				
6) A requirement for the receipt of a registration or marketing authorization (MA) before placing the product on the market.				
7) Detailed regulations or guidelines on the requirements for obtaining MA.				
8) A requirement of demonstration of the product quality, safety and efficacy prior to registration or MA.				
9) Limits on the duration of the validity of the MA and periodic reviews/renewals of MAs.				
10) The powers to withhold, suspend, withdraw, or cancel an MA if there are concerns regarding quality, safety, or efficacy issues.				
11) Legal provisions to cover circumstances under which the routine MA procedures may not be followed for public health reasons such as for compassionate use, donations, emergencies.				
12) The powers to recognize and/or rely on MA-relevant decisions, reports or information from other NRAs or regional/international bodies.				
Vigilance				
13) Law to establish the national medical products vigilance system (define the responsible entities as well as the roles, responsibilities, accountability, and obligations of these entities).				
14) Provisions to ensure that distributors, importers, exporters, healthcare institutions, consumers and other stakeholders are encouraged to report adverse drug reactions (ADRs) and AEs to the MAH and/or NRA.				
15) The powers to require manufacturers and/or MAHs to conduct specific studies on safety and effectiveness under specific conditions.				
16) The powers to require the manufacturer to review vigilance data to determine if their labelling requires updating to inform users of new or increased (safety) risk related to use of the medical product.				
17) Guidelines to provide for mandatory reporting and submission of periodic safety updates by the manufacturers and distributors.				
18) Guidelines to provide for voluntary reporting by health care professionals and the public.				
19) Guidelines for reporting on medical devices.				
20) SOPs or Regulations to establish a national reporting system.				
21) Authorization in the law/regulations to allow for reporting to regional and international bodies, such as the future African Medicines Authority, and the WHO Global Surveillance and Monitoring System (GSMS).				
22) Provisions allowing recognition and/or reliance on vigilance-related decisions, reports, or information from other countries or regional or international bodies.				
Market surveillance and control				
23) Laws to regulate import activities including • Permanent regulatory intervention at designated entry and exit ports where medical products are being moved. • Product inspection at ports of entry. • Regulations on the processes for transport of medicines and medical products through customs and at borders. • Additional Import permits required to import medical products • Ensuring that the incoming batch matches the import documents.				
24) Laws authorizing market surveillance and control activities which include product sampling from different points of the supply chain.				
25) Laws to control promotion, marketing, and advertising of medical products to avoid communication of false or misleading information.				
26) Laws defining the role of the NRA in dealing with SFMP, and empowering them to take regulatory action. The NRA should have administrative powers to take action on recall, suspension, withdrawal and/or safe disposal of substandard and falsified medical products. Possible actions may also include the issuance of a separate warning set to a list of institutions and key persons dealing with handling medical products.				
27) Law establishing adequate and proportional administrative sanctions, penalties, and prosecutions for violations of the applicable legislation.				
28) Relevant legislation/rules for on-line pharmacies with requirements such as domain registration and links to physical location.				

Do you have in your legislation/regulations/guidelines:	page	yes	no	partially
Licencing establishments				
29) A legal framework for licensing activities				
30) Law to empower the NRA to issue, suspend or revoke licenses for establishments, and allows for adequate and proportional sanctions, penalties and prosecutions for violations of the applicable legislation on licensing.				
31) Law requiring that the NRA be informed, for the purpose of notification or approval, in case post-licensure changes or variations are made.				
Regulatory inspection				
32) A legal framework for inspection and enforcement including: a. Allowing inspectors to enter facilities throughout the supply chain at any reasonable time and in any place; b. Allowing inspectors to collect evidence, including samples; c. Authorizing inspectors to seize and detain medical products, including SFMP and close premises.				
33) Law to empower the NRA to take regulatory action in the case of SF.				
34) Law to allow the NRA to transfer the case to law enforcement/prosecution.				
35) Rules/guidelines for joint investigations.				
36) The powers to investigate conduct related to the manufacture, import, export storage, distribution, sale and use of medical products and institute administrative, civil and/or criminal proceedings.				
37) Law establishing administrative offences and sanctions related to violations of the applicable regulatory laws.				
38) Law establishing civil liability for damages caused by SFMP.				
Laboratory testing				
39) A legal framework of laboratory testing activities including establishing a national quality control laboratory to perform quality control (QC) testing, and/or to authorize the National Regulatory Authority (NRA) to sub-contract the required testing services.				
40) Law that allows the NRA to recognize and use laboratory testing-related decisions, reports or information from other NRAs or regional and international bodies.				
The criminal justice system				
Does your criminal code include the following:				
41) The four main criminal offences in falsified medical products that should be included, namely: manufacture, trafficking, possession, and falsification. 42) Secondary liability for such offences;				
43) Adequate sanctions for these offences, i.e., at least 4 years imprisonment as the maximum sentence, as well as severe fines. 44) Provision for compensation of victims at the end of the criminal trial.				
45) An offence of obstruction of justice; 46) An offence of failure to report suspected medical products.				
47) An offence of recklessness/gross negligence in handling medical products				
48) Offences related to organized crime, corruption and money laundering.				
49) Jurisdiction over offences committed outside of your territory.				
50) Liability for offences committed by legal persons.				
51) Guidelines for prosecutors on prosecution of cases involving falsified medical products				
Tools for Investigation				
52) Do you have in the law the necessary tools for investigation including for freezing and seizure, collection of evidence, taking samples etc.? Are the criminal procedures consistent with the regulatory ones and allow for cooperation of the police with the NRA? (See question 32 above). 53) Does your law allow for joint investigations? Controlled delivery? Exchange of information with law enforcement officers from other countries?				
International cooperation				
54) Do you have specific laws to enable all forms of international cooperation in criminal matters, i.e., extradition, mutual legal assistance, and transfer of prisoners?				
55) Are offences related to falsified medical products considered extraditable offences? Can they be used as a basis for sending and receiving requests for MLA?				
Victims and Witnesses				
56) Do you have laws to protect the rights of victims, in particular: a. to provide access to free legal aid; b. to allow for public interest litigation by NGOs; c. to provide compensation and reparation; d. to establish liability of the state for violation of rights and damage caused by negligence the regulator.				
57) Do you have laws to provide for Witness protection?				
58) Do you have Laws to provide for whistle-blower protection?				

Funded by
the European Union

medisafe

EXPERTISE
FRANCE
GROUPE AFD