UNODC
United Nations Office on Drugs and Crime

COMBATING FALSIFIED MEDICAL PRODUCT-RELATED CRIME

A GUIDE TO GOOD LEGISLATIVE PRACTICES

UNITED NATIONS OFFICE ON DRUGS AND CRIME

COMBATING **FALSIFIED MEDICAL PRODUCT-RELATED CRIME:** A GUIDE TO GOOD LEGISLATIVE PRACTICES

UNITED NATIONS
Vienna, 2019

Acknowledgements

This Guide was prepared by the Organized Crime Branch, Division for Treaty Affairs, United Nations Office on Drugs and Crime, and was funded by France.

This Guide benefited from the invaluable contributions of numerous experts in falsified medical products from all continents of the world, acting in their individual capacity.

The United Nations Office on Drugs and Crime also wishes to thank the Council of Europe, the Economic Community of West African States, the European Union, the International Council of Nurses, the International Criminal Police Organization (INTERPOL), the New Partnership for Africa's Development, the World Customs Organization and the World Health Organization for providing their expertise.

Core team

Hugo Bonar, Antonio De Vivo, Marion Ehalt, Karen Kramer, Riikka Puttonen and Christian Tournié

Legal editing

Colin Craig

Publishing production: English, Publishing and Library Section, United Nations Office at Vienna.

Photo credits cover: © iStock.com/FotografiaBasica

CONTENTS

Introduction **1**

Statement of the problem 1

Definition of falsified medical products 2

Legal framework 2

How to use this Guide 3

Chapter I. General provisions **5**

Objectives and scope of application of this Guide 5

Jurisdiction 6

Glossary of terms 7

Important definitions 8

Chapter II. Prevention of falsified medical products **13**

Regulating the supply chain 13

Research and data collection, exchange and analysis 16

Chapter III. Offences **19**

Elements of criminal offences 19

Offences covered by this Guide 20

A. General offences 21

Manufacture of a falsified medical product 21

Trafficking in falsified medical products 24

Possession of falsified medical products intended (or likely) to be used in manufacturing or placed in the distribution system 25

Offences related to trafficking in falsified medical products by electronic and distance selling 26

Failure to report 27

B. Offences related to the falsification of documents, equipment, implements and materials 28

C. Related offences 29

Conspiracy or criminal association 29

Secondary liability 31
Obstruction of justice 32
Money-laundering 34
D. Penalties, sentencing and other orders 35
Imprisonment 36
Non-custodial penalties and other orders 37
Additional penalties 37
Aggravating and mitigating circumstances 38

Chapter IV. Liability of legal persons 41

Chapter V. Investigations 47

Special investigative techniques 48
Controlled delivery 49
Assumed identities and infiltration 49
Electronic surveillance 50
Seizure and confiscation 50
Collection and analysis of samples and certificates of result of tests, examinations or analyses 51
Disposal 52

Chapter VI. Prosecution of offences 53

Detention pending trial 53
Prosecutorial discretion 53
Alternatives to trial 54
Statute of limitations 54

Chapter VII. National and international cooperation 57

National cooperation 57
International cooperation 59
Mutual legal assistance 60
Extradition 60
Law enforcement cooperation 61
Joint investigations 62

Chapter VIII. Protection of and assistance to witnesses and victims 65

Safety of victims and witnesses 65
Provision of care to victims 66
Compensation and restitution for victims 66
Protective disclosure (whistle-blower protection) 67

Introduction

This Guide was developed in response to Commission on Crime Prevention and Criminal Justice resolution 20/6, entitled "Countering fraudulent medicines, in particular their trafficking". As the Commission has noted, organized criminal groups are involved in all aspects of falsified medical product-related crime. In its resolution 20/6, the Commission underscored the potential utility of the United Nations Convention against Transnational Organized Crime in reinforcing international cooperation to fight such crime and requested the United Nations Office on Drugs and Crime (UNODC), in cooperation with other United Nations bodies and international organizations, to assist Member States in building capacity to disrupt and dismantle the organized criminal networks engaged in all stages of the illicit supply chain, in particular distribution and trafficking.

As explained in detail further on, in this Guide, the term "falsified medical products" is used, along with the definition of that term as adopted by the World Health Assembly in 2017.[1] Nothing in this Guide is to be interpreted as applying to intellectual property rights or as making a distinction between originator medicines and generic medicines.

Statement of the problem

The growing phenomenon of the falsification of medical products threatens the right to life, as enshrined in different international human rights instruments. In its resolution 20/6, the Commission on Crime Prevention and Criminal Justice urged Member States to prevent trafficking in fraudulent medicines by introducing legislation, as appropriate, covering, in particular, all offences related to fraudulent medicines, such as money-laundering, corruption and smuggling, a well as the confiscation and disposal of criminal assets, extradition and mutual legal assistance, to ensure that no stage in the supply chain of fraudulent medicines was overlooked.

According to the limited number of studies on the magnitude of the problem,[2] organized criminal groups engage in falsified medical product-related crime using the same routes and techniques employed in the trafficking in other illicit commodities. In so doing, they exploit gaps and discrepancies in national legislation and criminal justice systems. In many countries, criminal groups use new technologies and platforms such as darknet sites to traffic in falsified medical products and avoid detection by law enforcement authorities.

[1] World Health Organization (WHO), Report by the Director-General on the Member State mechanism on substandard/spurious/falsely-labelled/falsified/counterfeit medical products, Report of the Director-General, document A70/23, annex, appendix 3.

[2] WHO, *A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products* (Geneva, 2017); WHO, *WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products* (Geneva, 2017); and *The Globalization of Crime: A Transnational Organized Crime Threat Assessment* (United Nations publication, Sales No. E.10.IV.6).

Despite the growing nature of the problem, legal systems around the world are facing numerous challenges in effectively combating these crimes. Such challenges include weak or inconsistent legal frameworks and ineffective criminal laws that often fail to criminalize attempt, participation by accessories and the possession and sale of illegally obtained medical products. Online and distance selling of medical products are also growing concerns but are often still inadequately addressed. Many medical product sector-specific laws are inadequate and not harmonized with other laws and international standards. Some laws lack definitions, provide for insufficient penalties and fail to designate offences as predicate offences in anti-money-laundering legislation.

The World Health Organization (WHO) recognizes that falsified medical products are most likely to be found where access to affordable, quality, safe and effective medical products is constrained, standards of governance are low or the tools and technical capacity to ensure good practices in manufacturing, quality control and distribution are limited. While the deleterious impacts of falsified medical products are difficult to quantify, there is no doubt that such products have a multidimensional impact that includes health, economic and socioeconomic consequences. They endanger health, prolong illness, kill, promote antimicrobial resistance and the spread of drug-resistant infections, undermine confidence in health professionals and health systems, create distrust about the effectiveness of medical products, waste resources, cut into the limited budgets of families and health systems and provide income for criminal networks.

Definition of falsified medical products

In its resolution 20/6, the Commission on Crime Prevention and Criminal Justice uses the term "fraudulent medicines". In the past, UNODC has used the terms "fraudulent medicines" and "falsified medicines" interchangeably. Both terms were used with the clear understanding that intellectual property rights were not included.

The term "falsified medical products" is used in this Guide, following the adoption of the term by the World Health Assembly in 2017.[3] As noted by WHO, the term "falsified" appears to adequately include all the various types of deliberate misrepresentation of a medical product in such a way as to enable the specific exclusion of intellectual property rights.[4]

To avoid legislative gaps and minimize risks to public health, a broad definition of medical products is used in this Guide. For the purposes of this Guide, the term "medical products" means medicines, excipients and active substances, as well as medical devices, their parts and materials, and accessories used in conjunction with medical devices. This definition takes into account the very close relationship between medicines and medical devices, as well as the fact that criminals do not distinguish between the two types of medical products in their criminal activities and, ultimately, that both falsified medicines and falsified medical devices cause harm to members of the public.

Legal framework

As recognized by the Commission on Crime Prevention and Criminal Justice with the adoption of its resolution 20/6, there is a need for more initiatives concerning falsified medical product-related crime. It is imperative that initiatives are undertaken in cooperation with each other to combat falsified medical product-related crime and, in particular, the organized criminal activities that facilitate falsified medical products reaching vulnerable consumers.

[3] As specified in WHO document A70/23, annex, appendix 3, para. 7 *(c)*, falsified medical products are medical products that deliberately/fraudulently misrepresent their identity, composition or source. Any consideration related to intellectual property rights does not fall within this definition. Such deliberate/fraudulent misrepresentation refers to any substitution, adulteration, reproduction of an authorized medical product or the manufacture of a medical product that is not an authorized product.

[4] The term "counterfeit" is now usually defined and associated with the protection of intellectual property rights. For reference purposes, the definitions of "trademark counterfeit goods" and "pirated copyright goods" are included as defined under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (WHO document A70/23, annex, appendix 3, para. 8).

In this Guide, the good practices and existing work of Member States and of regional and international organizations are used and built upon. The following instruments, in particular, were used in the preparation of this Guide:

- United Nations Convention against Transnational Organized Crime
- United Nations Convention against Corruption
- Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health (MEDICRIME Convention)
- "Legal framework on the counterfeiting of and illicit trade in medical products for ECOWAS member States" (available in French only at the time of publication of this Guide)
- *African Union Model Law on Medical Products Regulation*
- Directive 2011/62/EU of the European Parliament and of the Council of the European Union of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products

How to use this Guide

This Guide is intended to support States in enacting or strengthening domestic legislation to combat falsified medical product-related crime and, in so doing, contributing to the protection of public health. States may use this Guide as a practical tool as they draft, amend or review relevant national legislation within their constitutional and legislative framework. It is not a model law and does not provide a "one-size-fits-all" model ready to be introduced into a State's legal system. Rather, it is recognized that legislation must be tailored to each State's legal tradition and social, economic, cultural and geographical conditions. States should adapt the sample provisions and guidance provided in this Guide to implement treaty obligations and fit local conditions, constitutional principles, legal culture and structures and existing enforcement arrangements. It is recommended in this Guide that States consult with relevant stakeholders as they engage in the process of drafting, amending or reviewing legislation.

As noted above, legislation on intellectual property rights is specifically excluded from the ambit of this Guide and the term "falsified medical products" has been chosen to avoid any implication otherwise. To assist legislators in drafting legislation relating to falsified medical products, examples of domestic legislative initiatives are referred to throughout this Guide. These examples may sometimes make use of language, such as references to "counterfeit" products, that can also be used in the context of intellectual property rights. To be clear, where reference has been made to such terms, it is to show readers how other legislative initiatives have defined and used those terms for public health protection purposes only, not for intellectual property rights purposes.

The key terms and concepts used in this Guide are set out and explained in chapter I, to assist the reader. Some of the terms used may not fit within the legal tradition of all States and may need adapting. This Guide is intended to be sufficiently flexible so as to help build the necessary legislative framework for combating falsified medical product-related crime in any State.

Throughout the sample provisions contained in this Guide, square brackets are used to indicate certain words or phrases that will need to be adapted to the State in question or to indicate that several possibilities exist in terms of the wording used.

Photo credits: iStock/Motortion

Chapter I.

GENERAL PROVISIONS

Objectives and scope of application of this Guide

The primary objective of this Guide is the protection of public health. The Guide seeks to achieve this objective through providing for the criminalization of certain acts, preventing and combating falsified medical product-related crime and supporting the integrity of the medical product supply system. Given the known involvement of organized criminal groups and the transnational nature of falsified medical product-related crime, this Guide also draws upon the objective of the Organized Crime Convention, namely, promoting national and international cooperation to prevent and combat transnational organized crime. As already mentioned, the protection of intellectual property rights is not covered in this Guide.

Sample provision 1: objective of [*Act/Law/Chapter, etc.*]

The objective of this [*Act/Law/Chapter, etc.*] is to protect public health through:

(a) Providing for the criminalization of certain acts;

(b) Preventing and combating falsified medical product-related crime;

(c) Supporting the integrity of the medical product supply system; and

(d) Promoting national and international cooperation in order to achieve these objectives.

Sample provision 1 is aimed at defining the most important objectives of legislation on falsified medical products. In case of doubt over the interpretation and scope of a given provision, an analysis of the objectives of the legislation may help in best construing the provision. In this context, it is important to note once again that this Guide does not deal with the protection of intellectual property rights.

Sample provision 2: scope of application

1. This [*Act/Law/Chapter, etc.*] applies to offences involving falsified medical products for human or veterinary use, whether generic or originator, including medicines, excipients, active substances, medical devices and their parts and materials, and accessories used in conjunction with medical devices.

2. Intellectual property rights are not covered by this [*Act/Law/Chapter, etc.*].

Sample provision 2 is also aimed at clarifying the scope of application of the sample provisions contained in this Guide. It provides that the provisions of a State's legislation on combating falsified medical product-related crime apply to offences involving medical products, whether generic or originator and whether for human or veterinary use. Distinctions are not made between generic and originator products or between products for human and veterinary use because all of those types of medical products can be falsified and have harmful effects. The term "medical products" is defined broadly to include medicines, excipients and active substances, as well as medical devices and their parts and materials, and accessories used in conjunction with medical devices.

Jurisdiction

States should enact provisions establishing comprehensive jurisdiction for the prosecution and adjudication of falsified medical product-related crime. Jurisdiction refers to the power of a State, through its prosecutors, courts and other institutions, to exercise legal authority over a territory, person or thing. Establishing comprehensive jurisdiction is particularly important in the context of falsified medical product-related crime because it can occur across State borders. Offenders may also move between States and exploit jurisdictional gaps in States' laws to avoid apprehension and prosecution. It is therefore important to clearly articulate the jurisdictional bases upon which national courts can determine proceedings.

Most obviously, States may exercise jurisdiction over acts committed within their territories, including their territorial waters (the territoriality principle). This includes the jurisdiction of a State over acts committed outside the State but intended to have a substantial effect within the territory of the State (the objective territorial principle). The right of States to exercise extraterritorial jurisdiction in a number of circumstances is recognized in international law. While the precise scope of such circumstances remains unsettled, the international community has generally recognized the jurisdiction of a State over its nationals, even when outside its territory (the active personality principle) and the jurisdiction of a State over acts injurious to its nationals (the passive personality principle).

As falsified medical product-related crime – in particular, trafficking – can occur across borders, it is suggested in this Guide that States enact provisions establishing jurisdiction over such crime on the basis of both the territoriality principle and the recognized principles of extraterritorial jurisdiction. Sample provision 3 below provides an example of how a State could establish those jurisdictional bases.

Sample provision 3: jurisdiction

(1) [*National courts*] shall have jurisdiction to determine proceedings for offences to which this [*Act/Law/Chapter, etc.*] applies when the offence is committed:

(a) [*Wholly or partly*] within the territory of [*insert name of State*]; or

(b) [*Wholly or partly*] on board a vessel that is flying the flag of [*insert name of State*] or on an aircraft that is registered under the laws of [*insert name of State*] or an aircraft that is registered under the laws of [*insert name of State*] at the time that the offence was committed; or

(c) By a [*insert name of State*] national present in [*insert name of State*] territory whose extradition is refused solely on grounds of nationality.

(2) [*National courts*] shall have jurisdiction to determine proceedings for offences committed outside the territory of [*insert name of State*] to which this [*Act/Law/Chapter, etc.*] applies when:

(a) The [*victim*] is a national [*or permanent resident*] [*or habitual resident*] of [*insert name of State*];

(b) The offence is committed by a national [*or permanent resident*] [*or habitual resident*] of [*insert name of State*];

(c) The offence is committed with a view to the commission of a serious crime within the territory of [*insert name of State*]; or

(d) Such jurisdiction is based on an international agreement binding on [*insert name of State*].

Paragraph 1 of sample provision 3 sets out the territorial jurisdiction for the judicial determination of offences. Paragraphs 1 *(a)* and *(b)* reflect the obligations of States parties under article 15, paragraph 1, of the Organized Crime Convention. Paragraph 1 *(c)* reflects the *aut dedere aut judicare* ("extradite or prosecute") principle set out in article 15, paragraph 3, of the Organized Crime Convention in cases where extradition of nationals is refused. The principle calls on States, in cases of concurring jurisdiction over a crime with other States, to either extradite or prosecute the alleged offender. [5]

Paragraph 2 of sample provision 3 sets out further bases for the exercise of jurisdiction. Paragraph 2 *(a)* establishes jurisdiction over cases where the victim of an offence is a national of the State; it reflects the passive personality principle, which is covered in article 15, paragraph 2 *(a)*, of the Organized Crime Convention. States may also choose to extend the jurisdictional ground set out in paragraph 2 *(a)* of sample provision 3 to permanent and/or habitual residents of the State. Paragraph 2 *(b)* establishes jurisdiction over offences committed by a national (or permanent or habitual resident) of the State, reflecting the active personality principle, and article 15, paragraph 2 *(b)*, of the Organized Crime Convention. Paragraph 2 *(c)* of the sample provision provides for jurisdiction over offences committed outside the territory of the State but with a view to the commission of a serious crime within the territory of the State – that is, the objective territorial principle, as reflected in article 15, paragraph 2 *(c)*, of the Organized Crime Convention.[6] Paragraph 2 *(d)* of the sample provision provides a basis for the judicial determination of cases for which jurisdiction has been conferred by an international agreement binding on the State. Such an agreement could include, for example, a binding resolution by the Security Council.

Glossary of terms

The glossary below contains definitions of several terms used in the sample provisions contained in this Guide. Many of the terms are derived from the Organized Crime Convention, definitions adopted by the World Health Organization or model laws developed by UNODC.

Legislative drafters should ensure that the terminology used is clear, precise and consistently used. The drafting of falsified medical product-related laws should be undertaken in full cognizance of the existing domestic legal framework to avoid contradictions and gaps and to ensure, as far as possible, consistency in the use of terms between different laws.

Terms used in this Guide are to have the meaning assigned to them in the glossary, unless the context requires otherwise. Likewise, words or expressions derived from defined terms should be considered to have corresponding meanings, unless the context requires otherwise. Reference to the singular is also intended to include the plural.

Additional explanations are provided in the glossary for certain definitions having particular importance for this Guide. Those definitions are set out in green boxes and are supplemented by a brief commentary to help clarify their meaning.

Accessory to a medical device means any article that is not a medical device but is intended by its manufacturer to be used together with a particular medical device to specifically enable or assist the device to be used in accordance with its intended purpose.

Active substance means any substance or mixture of substances that is designated to be used in the manufacture of a medicine for human or veterinary use and that, when used in such manufacture, becomes an active ingredient of the medicine.

Document includes any document, whether physical or digital, that travels with, in advance of or following the movement of the medical product for the purpose of demonstrating the legitimacy of that product or supporting a representation of its legitimacy, including records, packaging, patient information leaflets, invoices and delivery dockets, customs-related documents for importation and exportation, and sales documentation.

[5] See also article 16, paragraph 10, of the Organized Crime Convention.
[6] See also UNODC, *Model Legislative Provisions against Organized Crime* (Vienna, 2012), pp. 25–29.

Excipient means any substance that is not an active substance or a finished medicine but is part of the composition of a medicine for human or veterinary use and essential to the integrity of the finished product.

Manufacture means:

(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, or of bringing the medical device, the parts or materials to their final state;

(c) As regards an accessory to a medical device – any part of the process of producing the accessory, including designing the accessory, or of bringing the accessory to its final state.

Parts and materials means all parts and materials that are constructed and designated to be used for or in medical devices that are essential for the integrity thereof.

Person means a natural or legal person.

Serious crime means an offence punishable by a maximum deprivation of liberty of at least four years or a more serious penalty.

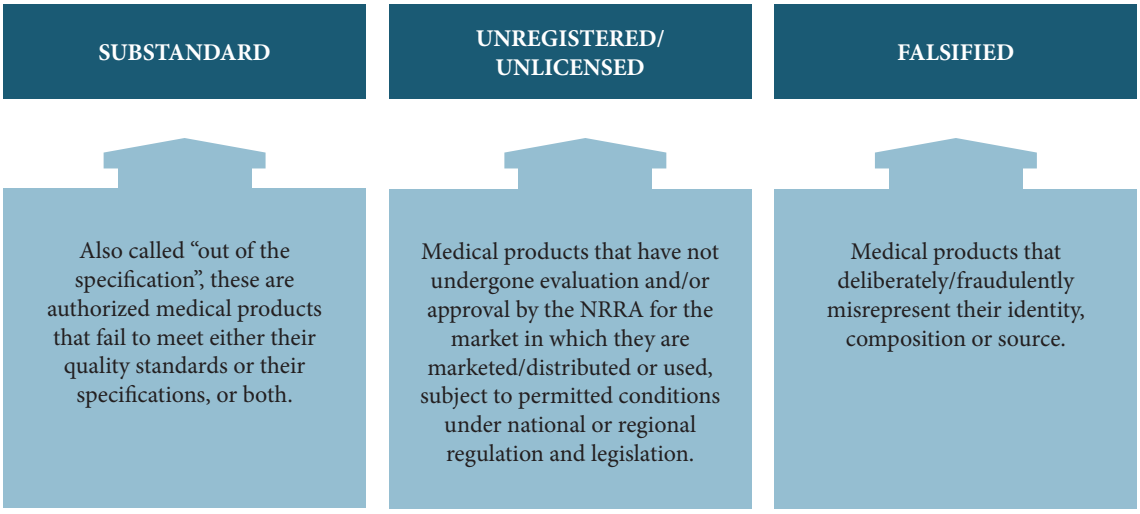
Victim means any natural person suffering adverse physical or psychological effects as a result of having used a falsified medical product.[7]

Important definitions

Falsified medical product means any medical product whose identity, composition or source is intentionally misrepresented.

The definition of "falsified medical product" follows the classification adopted at the World Health Assembly in 2017 (see figure 1).

Figure 1. Classification of medical products used in the context of the World Health Organization Global Surveillance and Monitoring System and the Member States mechanism



Source: WHO document A70/23, annex, appendix 3.

Note: "NRRA" stands for national and/or regional regulatory authorities.

[7] The definition of the term "victim" does not aim to cover all of the potential subjects who are potentially entitled to claim compensation owing to damage suffered as a result of falsified medical product-related crime.

Although there are other categories of medical products of international concern, such as "substandard medical products" (or "out-of-specification medical products") or "unregistered or unlicensed medical products" (products that have not undergone evaluation and/or approval in accordance with the national or regional regulations and legislation for the market in which they are marketed or distributed or used, subject to permitted conditions under national or regional regulation and legislation), only "falsified medical products" are covered in this Guide.[8] Substandard medical products fail to meet quality standards, specifications or both, as set by the State, but that failure is not necessarily intentional.

While these products may pose considerable public health risks and States may wish to introduce criminal offences relating to their manufacture, the manufacture of unintentionally substandard medical products is beyond the scope of this Guide. It is advisable, in the interest of public health, to consider providing for incentives for the pharmaceutical industry to report any unintentional quality defects.

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. While substandard medical products may or may not be falsified medical products, depending on whether their failure to meet the relevant standards was intentional, falsified medical products will always be substandard because the fact of being falsified means that they will fail to meet the applicable quality standards or specifications or both. In this Guide, a separate offence for the intentional manufacture of substandard medicine has not been covered because such acts will already be covered by the manufacture of a falsified medical product, in that they will necessarily entail a false representation as to the identity of the product, and to include a separate offence would be both redundant and confusing.

The falsification of medicines at the production stage raises significant risks to public health, as such products may not properly treat diseases or illnesses and may facilitate resistance to the "authentic" medicine. Intentionally manufacturing a substandard medical product is a fraudulent act and warrants a criminal justice response.

Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human or veterinary use, for one or more of the specific medical purposes of:

(a) Diagnosis, prevention, monitoring, treatment or alleviation of disease;

(b) Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;

(c) Investigation, replacement or modification of the anatomy or of a physiological process or state;

(d) Control or support of conception; or

(e) Disinfection or sterilization of any of the aforementioned products;

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means in or on the human or animal body, but may be assisted in its function by such means.

The definition of "medical device" is intended to include investigational medical devices. States may wish to explicitly provide that investigational medical devices are included in the definition of "medical device" in their legislation.

In drafting domestic definitions of a "medical device", States may also wish to consult the definitions of the term set out in the *WHO Global Model Regulatory Framework for Medical Devices Including In Vitro*

[8] In the "Legal framework on counterfeiting of and illicit trade in medical products for ECOWAS member States", the term "counterfeit" is used instead of "falsified". According to the ECOWAS framework, "counterfeit medicine" means any medicine, whether branded or generic, that is falsely labelled with respect to identity or source and includes a medical substance that may or may not be active or a substance that may be sufficiently active or not or that is misrepresented. This is similar to the definition of "falsified medical product" used in this Guide. The term "counterfeit medical product" is used in the MEDICRIME Convention and the term "falsified medicinal product" is used in directive 2011/62/EU.

Diagnostic Medical Devices[9] and the "Legal framework on the counterfeiting of and illicit trade in medical products for ECOWAS member States".

In the *WHO Global Model Regulatory Framework for Medical Devices Including In Vitro Diagnostic Medical Devices*, "medical device" is defined 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:
>
> *(a)* Diagnosis, prevention, monitoring, treatment or alleviation of disease;
>
> *(b)* Diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
>
> *(c)* Investigation, replacement, modification or support of the anatomy or of a physiological process;
>
> *(d)* Supporting or sustaining life;
>
> *(e)* Control of conception;
>
> *(f)* Disinfection of medical devices;
>
> *(g)* Providing information by means of in vitro examination of specimens derived from the human body.
>
> Such a device does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but may be assisted in its intended function by such means.

"In vitro diagnostic medical device" is defined in that publication as:

> A medical device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

In the "Legal framework on the counterfeiting of and illicit trade in medical products for ECOWAS member States", "medical device" is defined as:

> Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including software accessories designed by the manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for the correct functioning of the device, intended by the manufacturer to be used for human beings for the purpose of:
>
> *(a)* Diagnosis, prevention, monitoring, treatment or alleviation of disease;
>
> *(b)* Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
>
> *(c)* The study, replacement or modification of the anatomy or of a physiological process;
>
> *(d)* Control of conception.
>
> Such a device does not achieve its main intended action, in or on the human body, by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.

Medical product means medicines, excipients, active substances, medical devices, their parts and materials, and accessories used in conjunction with medical devices.

The definition of "medical product" used in this Guide includes medical devices and their parts, materials and accessories. This definition is therefore broader than the definition of "medical product" used by WHO, which does not include medical devices, with the exception of in vitro tests. Medical devices, as well as their

[9] WHO, Geneva, 2017.

parts, materials and accessories, are included in the definition of "medical product" here because, such as medicines, these items can also be falsified and thereby constitute a serious risk for public health.

Medicine means any substance, or combination of substances: (a) presented as having properties for treating or preventing disease in humans or animals; or (b) that may be used in or administered to human beings or animals with a view to either restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or making a medical diagnosis.

The definition of "medicine" is intended to cover investigational medicines. States may wish to explicitly provide that investigational medicines are included in the definition of "medicine" in their legislation. The reference to animals, in addition to humans, in this definition reflects the intention of covering veterinary medicines. In addition to the risks they pose to animals, falsified veterinary medicines may also pose risks to human health when consumed by animals in the human food chain.

It is for each State to decide what it defines as a medicine and whether traditional, herbal or homeopathic medicines or food supplements fall under that definition. Research has shown that such products have also been falsified.

Service providers means natural or legal persons involved in the supply chain of falsified medical products, including by electronic and distance selling. They include providers of electronic payment services, banking and money-transfer services and transport and logistical delivery services, as well as Internet service providers, domain name registrars and providers of web-hosting services.

The definition of "service providers" is very broad and is aimed at covering all kinds of service providers that can be potentially involved in the electronic and distance selling of medical products. It is intended to include the different types of sales platforms that advertise falsified medical products to the market or to the consumer, suppliers of domain names that facilitate electronic 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. In general, the issue of the liability of service providers in this field is still an open discussion and legislation varies significantly from State to State.

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.

The definition of "trafficking in falsified medical products" does not cover the removal or diversion of medical products from their intended market, but it would also be possible for States to include such acts in their definition of trafficking in falsified medical products.

Photo credits: iStock/RGtimeline

Chapter II.

PREVENTION OF FALSIFIED MEDICAL PRODUCTS

Regulating the supply chain

As noted in the introduction, WHO recognizes that falsified medical products are most likely to be found where access to affordable, quality, safe and effective medical products is constrained, standards of governance are low or the tools and technical capacity to ensure good practices in manufacturing, quality control and distribution are limited. Falsified products are thus less likely to emerge where there is a well-regulated supply chain for medical products.[10]

Regulatory authorities are the national bodies that have the legal mandate to set objectives and administer the full spectrum of regulatory activities to medical products, including issuing marketing authorizations, monitoring the use of medical products and adverse reactions, performing quality control laboratory testing, promoting the rational use of medical products, conducting good manufacturing practice and good distribution practice inspections, and licensing manufacturers, wholesalers and other entities that participate in the distribution channels of medical products.

Regulatory authorities are responsible for the regulation and control of medical products and contribute to promoting and protecting public health by ensuring that:

(a) Medical products are of the required quality, safety and efficacy;

(b) Health professionals and consumers have the necessary information to enable them to use products rationally;

(c) Medical products are appropriately manufactured, stored, distributed and dispensed;

(d) Illegal manufacturing and trade are detected and adequately sanctioned;

(e) Promotion and advertising are fair, balanced and aimed at rational use;

(f) Access to medical products is not hindered by unjustified regulatory work. [11]

[10] The supply chain can be defined as a system of organizations, people, activities, information and resources involved in moving a product (including finished medical products, their excipients, active substances, parts and materials) from the supplier to the end user. In the context of this Guide, patients or consumers are not considered part of the supply chain.

[11] Adapted from WHO, Essential medicines and health products, "Assessing national medicines regulatory systems". Available at www.who.int/medicines/areas/quality_safety/regulation_legislation/assesment/en.

A sustainable, well-functioning regulatory system will ensure independent and competent oversight of medical products, not only preventing the occurrence of falsified medical products but also offering the necessary structure to detect them and to support appropriate responses, including both reactive responses, such as recalls, and preventive responses.[12]

Prevention activities carried out by regulatory authorities should be aimed at ensuring that every medical product is of the necessary quality, safety and efficacy, and at securing the integrity of the supply chain, which should include only authorized companies and individuals. Regulatory authorities are expected to constantly develop and enhance the regulatory framework and practices, engage with different national and international stakeholders to exchange information, ensure the traceability of medical products and promote education and awareness-raising activities tailored to the State's needs and circumstances and targeted at a broad range of interested parties.

Ensuring the integrity of the supply chain plays an important role in preventing the falsification of medical products. States may wish to consider establishing track-and-trace systems for medical products, which would provide a guarantee of integrity throughout the supply system for the benefit of consumers. Authentication technologies can provide consumers with an opportunity to check the authenticity of medical products. In some States, mobile authentication applications are used for that purpose. Mobile applications could also be used to allow consumers to report suspected falsified medical products to regulatory authorities. Facilitating consumer feedback would also have the benefit of promoting awareness of falsified medical product-related crime and improving the detection of such products.

Prevention programmes and awareness-raising campaigns for the public are important in order to support consumer protection, understanding and involvement in ensuring their safety and preventing the consumption of falsified medical products. Such programmes should take into account the local specifics of crime (demographics of victims, types of products, distribution channels, etc.) and use appropriate means to reach the target audience (Internet, TV, newspapers, social media, etc.). Involving civil society organizations in providing training to relevant stakeholders, supporting awareness-raising campaigns and working closely with the media could assist in achieving those goals.

The effective detection of falsified medical products is facilitated by regulatory authorities because such authorities are able to correctly identify which medical products in a given supply chain comply with applicable regulatory requirements. Regulatory authorities can assist in the detection of falsified medical products by performing risk-based inspections and monitoring the market, participating in border control activities for imported, exported and transiting medical products, conducting investigations either alone or in cooperation with other authorities, providing access to testing laboratories and screening technologies, and managing both national and international reporting systems.

Health regulatory authorities should also be able to inspect bonded warehouses and free-trade zones to ensure that all medical products being stored in such locations retain their integrity and do not enter the distribution system in the internal market of the State without being imported in accordance with the law of the State. A further concern is the repackaging of medical products within such bonded warehouses and free-trade zones for redistribution outside of regulatory control. Such systems for the repackaging and storing of medical products are commonly known as fulfilment centres and have been linked to the supply of falsified medical products around the world. States should consider measures to ensure oversight by the competent regulatory authorities of medical products stored in bonded warehouses and customs zones to prevent falsified medical products from being illegally supplied either within the State or to other States. It may be appropriate to establish mechanisms of cooperation between health regulatory authorities and shipping companies, postal service providers, Internet service providers and providers of other online services in order to further prevent falsified medical product-related crime.

[12] WHO, WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems, "National regulatory system (RS): indicators and fact sheet", revision VI, version 1 (November 2018); and WHO, WHO Global Benchmarking Tool (GBT) for evaluation of national regulatory systems, "Market surveillance and control (MC) indicators and fact sheets", revision VI, version 1 (November 2018). Available at www.who.int/medicines/regulation/benchmarking_tool/en.

The theft and diversion of medical products puts the integrity of such products at risk. States should take action to ensure that persons responsible for the safe custody of medical products at all stages of the supply chain adequately safeguard these products against theft and fraudulent diversion. Any person who engages in conduct permitting the diversion of medical products should be considered to be the original exporter for the purposes of this Guide.

Finally, regulatory authorities also have a role in responding to falsified medical products by issuing health alerts to the public, collaborating with law enforcement authorities and the judiciary when crime is detected and effectively ensuring the collection, recall and disposal of falsified medical products. If a falsified medical product is made or sold by a licensed company, regulatory authorities may sanction the company. Some regulatory authorities may even have a legal mandate to sanction companies not licensed by them. Each incident involving falsified medical products should be reviewed by regulatory authorities with a view to identifying weaknesses in the regulatory system and vulnerabilities in the supply chain and making appropriate changes to improve the safety of consumers.

States should ensure that they have the necessary institutional structure for effectively regulating the supply chain of medical products. The structure of a relevant regulatory authority or regulatory authorities for the purposes of this Guide is a matter for each State. Regulatory functions could be vested in a unit within an existing authority, or a State could create a separate authority to fulfil such functions.

WHO has developed quality assurance guidelines for medicines for use by regulatory authorities. The guidelines are grouped into the categories of development, production, distribution, inspection, quality control and other regulatory guidelines. Within the manufacturing and distribution categories, WHO has, for example, developed guidance documents on good manufacturing practices and good distribution practices for medicines.

Example: Legal framework on the counterfeiting of and illicit trade in medical products for ECOWAS member States

Article 14

(1) Each Member State shall take the legislative and other measures necessary for securing the safety and quality of medical products and to ensure the security of the distribution of such products.

(2) With the aim of preventing the counterfeiting of medical products, active substances, excipients, parts, materials and accessories, each Member State shall take the necessary measures to provide for:

(a) The training of health-care professionals, service providers, police officers, judges, magistrates, prosecutors, customs authorities, other security officers and relevant regulatory authorities;

(b) The organization of awareness-raising campaigns for the general public in order to disseminate information about counterfeit medical products;

(c) The prevention of illegal manufacture and supply of counterfeit medical products, active substances, excipients, parts, materials and accessories by establishing well-equipped and functional laboratories;

(d) The use of appropriate technologies to detect counterfeit medical products.

Example: Cambodia – Decision establishing the Committee for Eliminating Counterfeit Medicines and Illegal Health Services for Poverty Reduction

Article 2

The role and responsibilities of the Committee for Eliminating Counterfeit Medicines and Illegal Health Services for Poverty Reduction are the following:

(a) To strengthen interministerial cooperation to eliminate counterfeit medicines and illegal health services in Cambodia;

Example: Cambodia – Decision establishing the Committee for Eliminating Counterfeit Medicines and Illegal Health Services for Poverty Reduction *(continued)*

(b) To investigate the sources of those counterfeit medicines and illegal health services;

(c) To take effective action for regular inspections and to seize, destroy or prevent counterfeit medicines and illegal health services;

(d) To disseminate information among and educate the public and promote public awareness of the risks of consuming counterfeit medicines and using illegal health services;

(e) To prepare the file to be forwarded to the relevant court.

Research and data collection, exchange and analysis

Information collection, exchange and analysis are essential to developing sound, evidence-based policy on preventing and combating falsified medical product-related crime, and transnational organized crime in general.

Developing a comprehensive understanding of illicit markets within a State is crucial for that State to tailor its policies to its specific situation. Article 28 of the Organized Crime Convention recognizes the importance of data collection, exchange and analysis to preventing and combating organized crime, including the importance of assessing the effectiveness and efficiency of policies and measures to combat crime.

At the global level, States may consider sharing information on detections of falsified medical products through existing platforms, such as the WHO Global Surveillance and Monitoring System for substandard and falsified medical products.

At the national level, the exchange and sharing of information and data may require putting in place new institutional arrangements. Some States may decide to entrust responsibilities to the ministry of health or to an independent authority such as the scientific and academic communities. In other cases, distribution of responsibilities among different institutions may be needed. It is, however, important to develop a coordinated system that allows for the collection of relevant data from different sources, such as health-care services, law enforcement agencies and other stakeholders.

Sample provision 4 below establishes a scheme for the collection of statistical and other data and information on issues related to falsified medical products, as well as the facilitation of research into the causes, prevalence and impact of falsified medical products and the circumstances in which incidents involving falsified medical products occur. This could extend to, for example, data and information on the modi operandi of criminal networks involved in the trafficking in falsified medical products and the routes used for such trafficking.

Sample provision 4: research, data collection and analysis

The [*insert name of relevant institution*] shall provide for:

(a) The collection of statistical and other data and information on issues related to falsified medical products; and

(b) The facilitation of research into:

(i) The causes, prevalence and impact of falsified medical products; and

(ii) The circumstances in which incidents involving falsified medical products occur.

Several States have established research institutes that may fulfil these functions and share analytical expertise with other, similar institutions. While establishing a dedicated research institute may be beyond the resources of some States, it is also possible to make important data available through, for example, partnerships between the State and existing scientific and academic institutions, such as universities.

For additional information, see the *Model Legislative Provisions against Organized Crime*, chapter II, article 5, which sets out model legislative provisions relating to the collection and analysis of data on organized crime.

Example: Afghanistan – Law on the Campaign against Intoxicants and Drugs and on their Control

Article 65

12. The Ministry of Foreign Affairs shall adopt measures in consultation with the Ministry of Counter Narcotics in order to achieve the following objectives:

(a) Attract assistance from foreign and national non-governmental organizations and international organizations for farmers and to equip and expand hospitals and rehabilitation centres for drug addicts;

(b) Collect reports, publications and information material related to the struggle against drugs from regional and international organizations, and translate and distribute them.

Example: China – Regulations for the Implementation of the Drug Administration Law

Article 2

The drug regulatory department of the State Council shall establish a national drug-testing institute. The drug regulatory departments of the people's governments of the provinces, autonomous regions and municipalities directly under the Central Government may establish drug-testing institutes within their respective administrative areas. Plans for the establishment of local drug-testing institutes shall be proposed by the drug regulatory departments of the people's governments of the provinces, autonomous regions and municipalities directly under the Central Government and submitted to the people's governments of the provinces, autonomous regions and municipalities directly under the Central Government for approval. The drug regulatory department under the State Council and the drug regulatory department of the people's government of a province, autonomous region and municipality directly under the Central Government may, when necessary, designate the testing institutes fulfilling the requirements for drug testing to undertake drug testing.

Photo credits: iStock/kadmy

Chapter III.

OFFENCES

Elements of criminal offences

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.

The types of mental states recognized by the criminal laws of various States and the terms used to describe those mental states vary significantly between jurisdictions. These differences in terminology and underlying legal principles make it difficult to make generalizations about mental elements across the spectrum of legal traditions and legal systems. It can, however, be said that 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. In some legal systems, some offences can be established without proof of any mental state on the part of the defendant. These offences are referred to as offences of strict or absolute liability.

In this Guide, unless otherwise specified, it is contemplated that proof of a mental element or mental elements equivalent to intention or, in some jurisdictions, knowledge is to be required for a conviction for committing an offence covered by the Guide. For many of the falsified medical product-related offences included in this Guide, such as possession of falsified medical products and document fraud, a position is not adopted in the Guide on the wording that States should use to establish the requirement of proof of the requisite mental state. This is due to the fact that the wording of mental elements may vary from country to country in accordance with their legal traditions. States may consider adopting stricter measures and may also allow proof of less strict mental elements to suffice for establishing a conviction for the commission of particular crimes.[13]

[13] See also Organized Crime Convention, article 34, paragraph 3 ("Each State party may adopt more strict or severe measures than those provided for by this Convention for preventing and combating transnational organized crime".)

In respect of the sample provisions for manufacturing of and trafficking in falsified medical products, however, the language of intent used in this Guide is used expressly to describe the relevant mental elements. As mentioned above, unintentional manufacturing of substandard medical products does not fall within the scope of this Guide. However, 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.

While lowering the requisite mental elements for a crime facilitates the obtaining of criminal convictions, States should exercise great caution in lowering this threshold because of the prejudice to the rights of defendants that it may entail. Moreover, in some legal systems, the removal of the requisite mental element to create offences of strict liability is impermissible except in limited circumstances. The rights of defendants must always receive due consideration in the process of legal drafting, including in determining the requisite mental elements for offences covered by this Guide.

Where proof of intention is required to establish guilt for a criminal offence, finding direct evidence of intention can be hard, if not impossible, for prosecutors in most cases. States should make sure that proof of intention can also be inferred from factual circumstances. Article 5 of the Organized Crime Convention requires States parties to make this possible by introducing appropriate provisions in their legislation. In some States, it may already be clear from existing national laws on evidence or criminal procedure that inferences as to the mental state of the accused at the time of the offence can be made from circumstantial evidence.

Sample provision 5 below provides an example of how this could be achieved in the context of a law establishing falsified medical product-related offences. The inclusion of a provision along the lines of sample provision 5 in such a law would only be necessary if proof of intention could not already be inferred from objective factual circumstances under the general law of the State.

Sample provision 5: proof of intention

For offences under this [*Act/Law/Chapter, etc.*], the knowledge, intention, aim, purpose or agreement referred to in each offence may be inferred from objective factual circumstances.

Offences covered by this Guide

Falsified medical product-related crimes occur along a supply chain that runs from the manufacturer of the falsified medical product to distributors and sellers and, ultimately, the end consumer. Related criminal activities, including corruption, money-laundering, document fraud and obstruction of justice, are also undertaken by criminals along this supply chain to facilitate and protect the illicit profits obtained. This broad range of criminal activities necessitates a broad criminal justice response. Section A of this chapter sets out a number of offences directly related to falsified medical products. These are:

(a) Manufacture of a falsified medical product;

(b) Trafficking in falsified medical products;

(c) Possession of falsified medical products intended (or likely) to be used in manufacturing or placed in the distribution system;

(d) Offences related to trafficking in falsified medical products by electronic and distance selling;

(e) Failure to report.

Section B of this chapter sets out offences related to the falsification of documents, equipment, implements and materials relevant to falsified medical products.

A comprehensive examination of all possible related offences is beyond the scope of this Guide.[14] Nevertheless, legislation establishing offences related to falsified medical products should also be crafted to criminalize certain related criminal activities. Section C of this chapter contains legislative guidance on several such offences, including participation in an organized criminal group, obstruction of justice and money-laundering, and also provides guidance on establishing forms of secondary liability for the offences covered by the Guide.

It may be noted that the same criminal act may entail the breach of more than one of the criminal offences covered by this Guide. This is deliberate. To help ensure that criminal activities are punished when appropriate, the offences in this Guide seek to criminalize falsified medical product-related crimes from a variety of angles. In taking such an approach, some overlap between offences is inevitable. How States deal with prosecuting offenders in the case of multiple partially overlapping offences is a matter for each State in accordance with its legal tradition. In some States, multiple partially overlapping charges are possible on a criminal indictment. In other States, that is not possible.

The sample provisions contained in this chapter do not stipulate the applicable penalty for each offence. Determination of the appropriate penalties has been left to each State, in accordance with its legal system and culture, within the limits established under international law. How penalties should be structured within a given law is also left to the individual State. Some States may elect to include the penalty applicable to each offence within the provision establishing the offence. Other States may decide to set out the applicable penalties for each offence within a special penalties provision, separate from the offences themselves. Section D of this chapter contains some general guidance on issues relevant to penalties and sentencing in relation to the offences covered by this Guide.

A. General offences

Manufacture of a falsified medical product

The harm caused by falsified medical products begins with the manufacture of such products. Sample provision 6 criminalizes the manufacturing or procuring the manufacture of a falsified medical product when done intentionally. This offence includes the intentional manufacture of a substandard medical product and applies regardless of whether the manufacturer is authorized under the laws of the State to manufacture any medical product.

The requirement of intention excludes criminal liability for unintentional quality defects caused during manufacture. Sample provision 6 does not criminalize the manufacture of medical products that are substandard owing to an unintentional failure to meet the good manufacturing practice guidelines set by a regulatory authority. The unintentional manufacture of substandard medical products is more appropriately addressed through the education and training of manufacturers, not criminalization.

Sample provision 6: manufacture of a falsified medical product

A person who intentionally manufactures or procures the manufacture of a falsified medical product commits an offence punishable by [*insert penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties*].

"Manufacture" is defined in the glossary of terms in chapter I, to mean:

(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;

[14] For further information on the criminalization of corruption, see the relevant publications available at www.unodc.org.

(c) As regards an accessory to a medical device – any part of the process of producing the accessory, including designing the accessory, or of bringing the accessory to its final state.

Manufacture is thus defined broadly and includes steps taken as part of the process of producing a medical product or bringing it into its final state, even where the steps taken do not complete the production of the medical product or bring it to its final state. The definition of manufacture, as used in provision 6, is intended to include the adulteration of a medicine with undeclared and unauthorized ingredients and excipients. Pursuant to the MEDICRIME Convention, adulteration of a medicine should be understood as making a medical product poorer in quality by injuriously adding or substituting another undeclared substance.[15]

"Manufacture" of a medical product for the purposes of sample provision 6 should also be understood to include tampering with the medical product. Tampering with a medical product results in a different product from the original product authorized for manufacture by the State. In such circumstances, the person tampering with the medical product is considered to be the new manufacturer. Criminal liability for breach of sample provision 6 thus attaches to the person tampering with the medical product and not to the original manufacturer.

States may wish to introduce several offences along the lines of the offence set out in sample provision 6, with differing severity according to factors such as the nature of the falsified medical product involved in the offence and the nature and seriousness of the offender's conduct. Introducing different offences for different types of offending is one way in which legislators can ensure that the penalties given for intentionally manufacturing a falsified medical product are proportionate to the circumstances of each case. Another way this can be ensured is through providing the judiciary with adequate discretion for the determination of appropriate penalties.

Several examples of offences of manufacturing falsified medical products are set out below. Some of the examples also cover the import and export of falsified medical products. In this Guide, such activities are covered by the separate offence of trafficking in falsified medical products, which is set out in the following subsection. States are free to choose their preferred approach for criminalizing these activities but should ensure that their legislation covers acts of manufacturing, trafficking, importing and exporting.

Example: "Legal framework on the counterfeiting of and illicit trade in medical products for ECOWAS member States"

Article 4

Any person who:

(a) Manufactures, produces or causes to be produced, imports, transports, exports, trans-ships, offers for sale, including electronic sale, distributes, sells or is in possession of;

(b) Sells or displays for the purpose of sale or supply; or

(c) Conspires, aids or encourages a third party to manufacture, commercialize, offer for sale, including electronic sale, import, transport, export, trans-ship, sell, supply, distribute or display for the purpose of sale;

any counterfeit medical product or unwholesome medical product, in any form whatsoever, or attempts any of these prohibited acts, commits an offence under this legislation and shall, accordingly, be prosecuted.

[15] "Explanatory report to the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health", para. 44.

Example: Russian Federation – Federal Law on Circulation of Medicines

Article 45 (Manufacturing of medicines)

It is forbidden to manufacture:

1. Medicines not included in the State register of medicines, except for medicines manufactured for clinical trials and for export;
2. Counterfeit medicines;
3. Medicines with no licence for manufacturing of medicines;
4. Medicines in violation of good manufacturing practice.

Example: India – Penal Code

274. Adulteration of drugs

Whoever adulterates any drug or medical preparation in such a manner as to lessen the efficacy or change the operation of such drug or medical preparation, or to make it noxious, intending that it shall be sold or used for, or knowing it to be likely that it will be sold or used for, any medical purpose, as if it had not undergone such adulteration, shall be punished with imprisonment of either description for a term which may extend to six months, or with a fine which may extend to 1,000 rupees, or with both.

275. Sale of adulterated drugs

Whoever, knowing any drug or medical preparation to have been adulterated in such a manner as to lessen its efficacy, to change its operation or to render it noxious, sells the same, or offers or exposes it for sale, or issues it from any dispensary for medicinal purposes as unadulterated, or causes it to be used for medicinal purposes by any person not knowing of the adulteration, shall be punished with imprisonment of either description for a term which may extend to six months, or with a fine which may extend to 1,000 rupees, or with both.

276. Sale of drug as a different drug or preparation

Whoever knowingly sells, or offers or exposes for sale, or issues from a dispensary for medicinal purposes, any drug or medical preparation, as a different drug or medical preparation, shall be punished with imprisonment of either description for a term which may extend to six months, or with a fine which may extend to 1,000 rupees, or with both.

Example: Botswana – Drugs and Related Substances Act

Part II

Section 15. Offences generally

(1) Any person who contravenes or fails to comply with any of the provisions of this act, or who:

(a) Manufactures, imports, exports, distributes or sells drugs without first obtaining the Director's approval in respect of such drugs;

(b) Prescribes any Schedule 1 or Schedule 2 drug without being authorized thereto by this Act or by the Director;

(c) Dispenses any Schedule 1A, B or C drug or any Schedule 2 or 3 drug otherwise than in accordance with the provisions of section 9 (3);

(d) Advertises any drug otherwise than in accordance with the provisions of section 11; or

(e) Obstructs or fails to comply with any reasonable request or demand made by the Director, in the exercise of his powers and the performance of his duties under this Act;

Example: Botswana – Drugs and Related Substances Act *(continued)*

shall be guilty of an offence and, without prejudice to his liability in accordance with the provisions of subsection 2 or of section 16, shall be liable to a fine of 10,000 pula and to imprisonment for two years.

(2) Any person who manufactures, imports, exports, distributes, sells, prescribes, dispenses or advertises any drug banned in accordance with a notice by the Minister under section 3, subsection 1, or any drug or other substance falsely purporting to be, or intended to or likely to induce anyone to a mistaken belief that it is, a registered drug shall be guilty of an offence and, without prejudice to his liability in accordance with the provisions of section 16, shall be liable to a fine of 20,000 pula and to imprisonment for five years.

Trafficking in falsified medical products

Criminalization of domestic and cross-border trafficking is an essential component of any criminal law combating falsified medical products. The purpose of criminalizing trafficking in falsified medical products is not only to protect the domestic market from the entry of such products, but also to prevent their export to other markets. To allow States to exercise their jurisdiction over a broad range of acts, the term "trafficking in falsified medical products" is broadly defined in the glossary of terms above, as 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. Taking a broad approach to the criminalization of trafficking can serve as a powerful tool in combating domestic and cross-border trafficking. Sample provision 7 below covers all falsified medical products, in accordance with the definition set out in the glossary of terms, and is also intended to cover investigational medicines and medical devices.

Sample provision 7: trafficking in falsified medical products

A person who intentionally traffics in a falsified medical product commits an offence punishable by [*insert penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties*].

States may also encounter within their jurisdiction medical products that have not been licensed, registered or permitted by their regulatory authority. Not all cases of unlicensed, unregistered or unpermitted medical products pose threats to public health, as countries may have in place mechanisms that allow for the distribution of such medical products under specific conditions usually established by regulatory authorities. For example, in some circumstances, medical products may be procured by WHO and distributed within States without being registered. Most States have laws or regulations allowing for waivers of licensing or registration requirements to be granted in such circumstances. However, if unlicensed, unregistered or unpermitted medical products are falsified, substandard or fraudulently introduced into the supply chain (that is, by theft or diversion), they may pose a serious risk to public health. To the extent that such medical products do not involve a misrepresentation as to their identity, composition or source, they will fall outside the scope of this Guide as they do not fall within the definition of "falsified medical product" used herein. This may be the case where, for example, a State does not have a licensing system for medical devices.

States may wish to adopt separate offences criminalizing activities with respect to unlicensed or unregistered medical products. Some States have, for example, adopted the offences of supplying an unlicensed or unregistered medicine or placing onto the market or putting into service a medical device that does not bear the correct conformity standards mark or comply with essential requirements.

In that case, the placing on the market would apply without the actual sale taking place, as long as the product is available for the distribution system in the State. This could be achieved by a State stipulating in their legislation that placing on the market includes the act of keeping for supply.

Such an approach would cover situations that are potentially similar to the manufacture of falsified medical products, insofar as they pose an equally serious threat to public health but are nevertheless distinct because the medical products involved are not, or at least not necessarily, falsified. These products are intentionally manufactured, kept in stock for supply, imported, exported, supplied, offered for supply or placed on the

market without authorization (in the case of medicinal products) or without complying with the conformity requirements (in the case of medical devices) of the domestic law of the State. The identity, composition and source of the medical product are not necessarily misrepresented. A medical product can be genuine but put on the market without the required authorizations.

Given the serious risks that unlicensed or unregistered medical products may pose to public health, States may wish to adopt penalties for the commission of offences comparable to those of trafficking in falsified medical products, taking into account the specific facts and circumstances of each case.

Example: Bangladesh – Drug Act

Chapter III, section 10 (Prohibition of import of certain drugs)

From such date as may be fixed by the Government by notification in the official Gazette in this behalf, no person shall import:

(a) Any drug which is not of standard quality;

(b) Any misbranded drug;

(c) Any drug for the import of which a licence is prescribed, otherwise than under, and in accordance with, such licence;

(d) Any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof either the true formula or list of ingredients contained in it in a manner readily intelligible to members of the medical profession;

(e) Any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;

(f) Any drug the import of which is prohibited by rule made under this chapter.

Provided that nothing in this section shall apply to the import, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis or for personal use.

Provided further that the Government may, after consultation with the Board, by notification in the official Gazette, permit, subject to any conditions specified in the notification, the import of any drug or class of drugs not being of standard quality.

Explanation: the formula or list of ingredients mentioned in clause (d) shall be deemed to be true and in sufficient compliance with that clause if, without disclosing a full and detailed recipe of the ingredients, it indicates correctly all potent or poisonous substances contained therein, together with an approximate statement of the composition of the medicine.

Possession of falsified medical products intended (or likely) to be used in manufacturing or placed in the distribution system

It is recommended in this Guide that States introduce provisions criminalizing the possession of falsified medical products 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. Offences of this kind may be useful to prosecutors where there is evidence of criminal activity related to falsified medical products but there does not appear to be sufficient proof of an act of trafficking.

Sample provision 8: possession of a falsified medical product

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 punishable by [*insert penalty sufficient to take into account the gravity of the offence*].

To be convicted of this offence, a defendant must have the requisite mental state in relation to both the fact of possession and the fact that the possession was of a falsified medical product. There is also a further mental element of intention in relation to the use of the falsified medical product in a manufacturing process or its placement in the distribution system for supply. As with the other offences covered in this Guide, proof of intention here may be inferred from objective factual circumstances. Some States may wish to allow proof that, in the circumstances, it is likely that the falsified medical product will be used in a manufacturing process or placed in the distribution system for supply as an alternative to proof of intention. The words "or likely" are therefore included in square brackets in sample provision 8 to reflect that choice for legislators.

The limitation of the offence in sample provision 8 to possession in circumstances 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 precludes criminal liability for possession for personal consumption or use and possession by law enforcement officers or other competent investigative authorities for law enforcement or investigative purposes. As such, it is not necessary for a State to establish specific exemptions for such circumstances. The fact that sample provision 8 does not cover mere possession for personal consumption or use is without prejudice to any law enforcement powers authorizing the seizure of falsified medical products in such circumstances as those products may still pose health risks, even if their possession does not constitute an offence in the circumstances.

Offences related to trafficking in falsified medical products by electronic and distance selling

Buyers and sellers are increasingly using electronic venues, including the darknet, to arrange the sale of falsified medical products. Legislation combating falsified medical product-related crime must keep pace with the changing nature of this kind of crime in the digital age, including by adequately addressing illicit electronic and distance selling. The sale of falsified medical products using electronic means will ordinarily be regulated by general provisions covering sale or trafficking. In some jurisdictions, selling may not automatically include selling by electronic means. Where this is the case, States may introduce specific provisions stating that trafficking includes selling by electronic means.

Electronic and distance selling are often facilitated by a number of natural or legal persons, including electronic payment service providers; providers of banking, finance, payment and money-transfer services; providers of transport, mail, logistical delivery, storage and repackaging services; Internet service providers and providers of web-hosting services; and owners of and persons operating on social media and other Internet sites.

Sample provisions 9 and 10 below establish two different criminal offences relating to trafficking in falsified medical products by electronic and distance selling. Sample provision 9 establishes as a criminal offence the intentional trafficking and the facilitating of trafficking in a falsified medical product where this occurs by electronic or distance selling.

Sample provision 10 establishes as an offence the provision of services to another person where the service provider is aware or has reasonable grounds to suspect or believe that the service will be utilized for trafficking in falsified medical products by electronic or distance selling. This offence may overlap to some extent with the offence of facilitating trafficking by electronic or distance selling contained in sample provision 9.

Sample provision 10 is intended to cover the variety of different natural and legal persons that provide services necessary for electronic and distance selling. Provisions establishing appropriate penalties for this offence should take into account the broad range of service providers that could potentially commit the offence. Penalties for legal persons should both reflect the seriousness of the crime and be sufficient to act as an effective deterrent. This is a relatively new area of law. Therefore, it is of paramount importance that States meticulously consider and clearly establish the extent of the liability of service providers and introduce guidance for such providers to that effect.

As set out in sample provision 2, nothing in sample provision 9 or 10 below is intended to cover intellectual property rights.

Sample provision 9: trafficking in falsified medical products by electronic and distance selling

A person who intentionally traffics or facilitates the trafficking in a falsified medical product by electronic or distance selling commits an offence punishable by [*insert penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties*].

Sample provision 10: offences by service providers involved in trafficking by electronic and distance selling

A person who intentionally provides services to any person who is trafficking in a falsified medical product, where there are reasonable grounds for the service provider to suspect or believe that such service is utilized for trafficking in falsified medical products by electronic or distance selling, commits an offence punishable by [*insert penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties*].

Sample provision 10 criminalizes the intentional provision of services to a person trafficking in a falsified medical product where there are reasonable grounds for the service provider to suspect or believe that such service is being utilized for trafficking in falsified medical products by electronic or distance selling. "Service providers" is defined in the glossary of terms, as natural or legal persons involved in the supply of goods, including by electronic and distance selling. They include providers of electronic payment services, banking and money-transfer services and transport and logistical delivery services, as well as Internet service providers, domain name registrars and providers of web-hosting services.

Service providers may also have existing contractual regulations and agreements with their clients that govern this issue. For example, in the context of domain name registrars, the Uniform Domain Name Dispute Resolution Policy of the International Corporation for Assigned Names and Numbers (ICANN) provides that a person registering a domain name undertakes not to knowingly use the domain name in violation of any applicable laws or regulations. It is the registrant's responsibility to determine whether its domain name registration infringes or violates someone else's rights. Rule 3.18 of the ICANN Registrar Accreditation Agreement provides that the registrar is to maintain an "abuse contact" to receive reports of abuse, including reports of illegal activity, and is to take reasonable and prompt steps to investigate and respond appropriately to such reports. Illegal activity is defined in rule 1.13 of that agreement as "conduct involving use of a registered name sponsored by the registrar that is prohibited by applicable law and/or exploitation of the registrar's domain name resolution or registration services in furtherance of conduct involving the use of a registered name sponsored by the registrar that is prohibited by applicable law". However, not all service providers take active steps to pursue persons using their services for criminal purposes.

Failure to report

Effective action to combat falsified medical products must be proactive and not merely reactive. Proactive measures to guarantee the integrity of the supply chain of medical products are thus crucial to mitigating the public health risks posed by falsified medical products. To assist authorities in the detection of falsified medical products, States are encouraged to introduce a proactive reporting system requiring actors at all stages of the supply chain of medical products to report transactions in falsified or suspected falsified medical products. Sample provision 11 below sets out an offence of failure to report under such a reporting system.

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.

States may wish to narrow or broaden the scope of the actors covered by this offence in accordance with their legal system and values. Sample provision 11 is intended, however, to exclude consumers from the duty to report.

Sample provision 11 provides States with a choice between "actual knowledge" and "reasonable suspicion" for the appropriate mental element for the offence of failure to report. On the one hand, proof of actual knowledge would represent a higher evidentiary burden for prosecutors but would ensure greater protection of the rights of the defendants. On the other hand, the lower threshold of reasonable suspicion could help support successful prosecutions but would provide less protection to the rights of defendants.

As part of a proactive reporting system, States may wish to complement sample provision 11 with provisions on when the regulatory authority may grant a licence, registration or authorization to manufacturers, distributors and wholesalers. The provisions could, for example, establish conditions on the granting of a licence, registration or authorization requiring that transactions in falsified or suspected falsified medical products be reported to the regulatory authority.

States should also consider establishing a time limit within which the report must be made to the relevant authority following a relevant person suspecting or becoming aware that they have transacted in a falsified medical product.

Example: Bosnia and Herzegovina – Criminal Code

Article 230

(1) Whoever, having knowledge of the identity of the perpetrator of a criminal offence for which a punishment of long-term imprisonment can be imposed under the law of Bosnia and Herzegovina, or whoever having merely knowledge of the perpetration of such an offence, fails to report the fact, although the timely discovery of the perpetrator of the offence depends on such report, shall be punished by a fine or imprisonment for a term not exceeding three years.

(2) The punishment referred to in paragraph 1 of this article shall be imposed on an official or responsible person who fails to inform of a criminal offence he has discovered while performing his duties, if for the offence a punishment of imprisonment for a term of five years or a more severe punishment can be imposed under the law of Bosnia and Herzegovina.

(3) No punishment for failure to inform of the criminal offence referred to in paragraphs 1 and 2 of this article shall be imposed on a person who is the spouse, cohabiting partner, first-line blood relative, brother or sister, adoptive parent or adopted child or their spouse or cohabiting partner, or defence lawyer, medical doctor or confessional priest of the perpetrator.

B. Offences related to the falsification of documents, equipment, implements and materials

Permits, certificates and other documents related to medical products are susceptible to being used fraudulently by criminals involved in falsified medical product-related crime. Criminals use fraudulent permits and certificates to present falsified medical products as legitimate in order to allow them to enter the supply chain. Fraudulent documentation may also be used to facilitate the entry of unlicensed, unregistered or non-permitted medical products into the supply chain. Criminals may commit document fraud relating to permits and certificates in a number of ways. In some cases, they forge entire permits and certificates; in others, they alter genuine permits and certificates. Criminals may also obtain genuine permits and certificates through fraudulent misrepresentations to issuing authorities. Additionally, document fraud can occur when persons other than the rightful holder use lawfully obtained genuine permits or certificates. States must tackle each of these forms of document fraud. Sample provisions 12, 13 and 14 below address these aspects of document fraud. States may wish to align their approach to such offences with existing offences relating to fraud, forgery and false claims.

Sample provision 12: falsification of documents

A person who intentionally:

(a) Tampers with an authentic document; or

(b) Makes a fraudulent document; or

(c) Possesses or uses a fraudulent or tampered document; or

(d) Supplies a fraudulent document;

for the purpose of [*committing an offence to which this [Act/Law/Chapter, etc.] applies*] commits an offence.

Sample provision 13: fraudulent conduct in connection with documents

Any person who [*with the requisite mental state*]:

(a) Makes a false or misleading statement; or

(b) Submits a fraudulent document;

to [*insert name of competent authority/ies*] in, or in connection with, an application for or the use of a [*insert relevant terminology for documents*], commits an offence.

Sample provision 14: acts in connection with equipment, implements and materials

A person who [*without designation or authorization*] controls, possesses, designs, imports, exports, procures, produces, sells, donates, keeps for supply or supplies any person with any packaging material, including labels, information leaflets and advertising materials, or any tool or die, machinery, instrumentation, software, parts or materials or equipment, with the knowledge or intent that it is for the purpose of facilitating the manufacture of or trafficking in a falsified medical product, commits an offence.

In addition to offences related to the falsification of documents, equipment, implements and materials, States should take steps to ensure that due diligence checks are conducted by all actors in the supply chain to ensure that actors supplying and receiving medical products are entitled to supply or receive, as appropriate, those products in accordance with the domestic laws. Due diligence checks should include checks on both the medical product and associated documentation to confirm their authenticity and provenance.

C. Related offences

Conspiracy or criminal association

Article 5 of the Organized Crime Convention requires that States parties adopt legislative measures to criminalize participation in an organized criminal group. Article 5, paragraph 1 *(a)*, gives States parties a choice of either or both of two different models for achieving this. These models reflect the differing approaches traditionally taken in common-law and civil-law jurisdictions to criminalize participation in organized criminal groups. The agreement-type offence in article 5, paragraph 1 *(a)* (i), reflects the conspiracy model traditionally taken in common-law jurisdictions, whereas the offence in article 5, paragraph 1 *(a)* (ii), reflects the criminal association model traditionally taken in civil-law jurisdictions.[16]

Sample provisions 15 and 16 below reflect those two alternative models of criminalizing participation in an organized criminal group. The provisions are based on the wording of article 5, paragraph 1 *(a)*, of the Organized Crime Convention but have been adapted to relate to the offences contained in this Guide. Just as in the case of the two models contained in the Organized Crime Convention, States have a choice of whether to introduce one or both of the offences.

[16] See the *Legislative Guide for the Implementation of the United Nations Convention against Transnational Organized Crime* (the most recent version is available from the Sharing Electronic Resources and Laws on Crime (SHERLOC) knowledge management portal (https://sherloc.unodc.org)); and John David McClean, *Transnational Organized Crime: A Commentary on the UN Convention and its Protocols*, Oxford Commentaries on International Law Series (Oxford, Oxford University Press, 2007), pp. 62–64.

Sample provision 15: conspiracy

Any person who agrees with one or more other persons to commit any [*serious*] offence covered by this [*Act/Law/Chapter, etc.*] [*involving an organized criminal group*] in order to obtain, directly or indirectly, a financial or other material benefit, commits an offence.

[*To be included if required by domestic law:*] For a person to be convicted under this section, an act other than the making of the agreement must be undertaken by one of the participants in furtherance of the agreement.

To establish criminal liability for the conspiracy offence covered by sample provision 15, the following elements must be proved:

(a) An agreement to commit an offence covered by this Guide;

(b) That the agreement was between the accused and at least one other person; and

(c) Where required by domestic law, an overt act in furtherance of the agreement.

States may choose to include an additional physical element, namely that the agreement involved an organized criminal group. In addition to the physical elements of the offence, there are two mental elements for:

(a) An intention to agree with one or more other persons to commit the offence; and

(b) The purpose of the agreement being to obtain a financial or other material benefit.

Sample provision 15 does not include the word "intention". Nevertheless, the wording of the provision implies a mental element of intention. The act of agreement to commit an offence can only be committed intentionally.

Sample provision 16: criminal association

(1) Any person who intentionally takes an active part in criminal activities of an organized criminal group, knowing either the aim and general activity of the organized criminal group or its intention to commit one or more offences covered by this [*Act/Law/Chapter, etc.*], commits an offence.

(2) Any person who intentionally takes an active part in [*any other*] activities of an organized criminal group in relation to this [*Act/Law/Chapter, etc.*]:

(a) With knowledge of either the aim and general activity of the organized criminal group or its intention to commit the crimes in question; and

(b) Knowing that their acts or omissions will contribute to the achievement of the criminal aim described above;

commits an offence.

(3) For the purpose of establishing criminal liability under [*paragraph 2*], the acts or omissions engaged in need not otherwise be illegal.

Sample provision 16 contains two criminal association offences. The first of these offences concerns participation in the criminal activities of an organized criminal group and the second relates to participation in other activities of the organized criminal group. The physical element of the offence in paragraph 1 is the accused taking an active part in criminal activities of an organized criminal group. The mental elements of the offence in paragraph 1 are:

(a) An intention to take an active part; and

(b) Knowledge of either:

(i) The aim and general criminal activity of the organized criminal group; or

(ii) The intention of the organized criminal group to commit one or more offences covered by this Guide.

The physical element of the offence in paragraph 2 is the accused taking an active part in any other activities of an organized criminal group. The mental elements of the offence in paragraph 2 are:

(a) An intention to take an active part;

(b) Knowledge of either:

(i) The aim and general criminal activity of the organized criminal group; or

(ii) Its intention to commit the crimes in question; and

(c) Knowledge that the acts or omissions of the accused will contribute to the achievement of the criminal aim described above.

The "other" activities for the purposes of the offence in paragraph 2 need not otherwise be illegal for the elements of the offence to be met. States may wish to clarify this fact in their legislation. Further information about each model of criminalizing participation in an organized criminal group can be found in the *Legislative Guide for the Implementation of the United Nations Convention against Transnational Organized Crime*.

Secondary liability

In addition to principal offenders, there are a number of actors involved in falsified medical product-related crime who organize, direct, aid and abet the commission of offences. Legislation combating falsified medical product-related crime should criminalize the conduct of these secondary offenders. In many jurisdictions, secondary liability is established for all criminal offences by provisions in general criminal law. In such jurisdictions, specific provisions on secondary liability may not be necessary. Where this is not the case, legislation should expressly establish secondary liability.

Sample provisions 17 and 18 below extend liability for involvement in falsified medical product-related crime to secondary offenders. The provisions are based on article 5, paragraph 1 *(b)*, of the Organized Crime Convention, which requires that States parties criminalize the organizing, directing, aiding, abetting, facilitating or counselling the commission of a serious crime involving an organized criminal group.

Sample provision 17 establishes secondary liability for organizing, directing, promoting, supervising or managing the commission of any offence covered by this Guide. Sample provision 18 establishes secondary liability for aiding or abetting the commission of any offence covered by this Guide. Both offences require proof of intention, so sample provision 18, for example, would not cover involuntary or inadvertent assistance. The provisions enable the prosecution of leaders, organizers and accomplices, as well as persons involved at lower levels.

States may also opt to combine the two provisions. Whatever the approach taken, States may elect to establish higher penalties for organizing or directing than for aiding, abetting, facilitating or counselling because of the higher-level nature of such conduct. In some cases, it may be appropriate for the penalties for organizers and directors to be higher than those given to principal offenders.

Sample provision 17: organizing or directing

A person who intentionally organizes or directs the commission of any of the offences provided for in this [*Act/Law/Chapter, etc.*], involving an organized criminal group, commits an offence.

Sample provision 18: aiding, abetting, facilitating or counselling

A person who intentionally aids, abets, facilitates or counsels the commission of any of the offences provided for in this [*Act/Law/Chapter, etc.*], involving an organized criminal group, commits an offence.

In addition to these forms of secondary liability, States should ensure that liability for attempt in relation to the offences covered by this Guide is established under domestic law. The general criminal law of many States provides automatically for liability for attempt. Where this is not the case, States should introduce specific provisions to achieve it in the context of falsified medical product-related offences.

Obstruction of justice

Falsified medical product-related crime is a profitable enterprise for organized criminal groups. To maintain and expand their criminal operations, organized criminal groups use threats, coercion and violence against judges, prosecutors, law enforcement officers and other officials, jurors and witnesses to attempt to pervert the course of justice. To effectively tackle this form of crime, States need adequate provisions criminalizing the obstruction of justice. The offence covered by sample provision 19 below criminalizes attempts to obstruct justice in relation to a proceeding for any offence covered by this Guide.

States should assess the need to include in their legislation a specific provision criminalizing the obstruction of justice by considering existing offences on the subject. Whether attempts to obstruct justice in relation to officers responsible for forensic analysis and the regulation of medical products and officers with similar responsibilities would be covered by existing offences is of particular importance in this regard. Some States already have comprehensive provisions that extend protection to such officers and that would cover the conduct criminalized in sample provision 19. States that have instead opted to include specialized provisions on obstruction of justice in specific laws may wish to consider including in their legislation an offence similar to that contained in sample provision 19.

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.

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: Ireland – Irish Medicines Board Act (1995) as amended by the Irish Medicines Board (Miscellaneous Provisions) Act (2006)

Section 32B

(7) Any person who:

(a) Obstructs or interferes with an authorized officer, a member of the Garda Síochána, or a person with expertise relating to any relevant thing, in the course of performing a function conferred on him or her by this Act or a warrant under subsection 6;

(b) Impedes the performance by the officer, member, or person with expertise, as the case may be, of such function or fails or refuses to comply with a request or requirement of, or to answer a question asked by, the officer, member, or person with expertise, as the case may be, pursuant to this section; or

(c) In purported compliance with such request or requirement or in answer to such question gives information to the officer, member, or person with expertise, as the case may be, that he or she knows to be false or misleading in any material respect;

shall be guilty of an offence.

Example: Australia – Criminal Code Act (1995), schedule 1

Section 149.1

(1) A person commits an offence if:

(a) The person knows that another person is a public official; and

(b) The first-mentioned person obstructs, hinders, intimidates or resists the official in the performance of the official's functions; and

(c) The official is a Commonwealth public official; and

(d) The functions are functions as a Commonwealth public official.

Penalty: Imprisonment for two years.

(2) In a prosecution for an offence against subsection 1, it is not necessary to prove that the defendant knew:

(a) That the official was a Commonwealth public official; or

(b) That the functions were functions as a Commonwealth public official.

(3) For the purposes of this section, it is immaterial whether the defendant was aware that the public official was performing the official's functions.

(4) Section 15.3 (extended geographical jurisdiction – category C) applies to an offence against subsection 1.

(5) The definition of "duty" in section 130.1 does not apply to this section.

(6) In this section:

"function":

(a) In relation to a person who is a public official — means any authority, duty, function or power that is conferred on the person as a public official; or

(b) In relation to a person who is a Commonwealth public official — means any authority, duty, function or power that is conferred on the person as a Commonwealth public official.

Example: Brunei – Misuse of Drugs Act

Obstruction of inspection or search

27. It shall be an offence for a person to:

(a) Obstruct any officer of the Bureau, any police officer or officer of customs or other public officer in the exercise of any power under this Act;

(b) Fail to comply with any lawful requirements of any officer of the Bureau, any police officer or officer of customs or other public officer in the execution of his duty under this Act;

(c) Fail, without reasonable excuse, to furnish such information in his possession as may be required by an officer of the Bureau, a police officer or officer of customs or other public officer; or

(d) Furnish to any officer of the Bureau, any police officer or officer of customs or other public officer any information which he knows or has reason to believe to be false.

Example: Malawi – Pharmacy, Medicines and Poisons Act

61. Mode of inspection

(1) Any person who:

(a) Wilfully obstructs an inspector in the discharge of his duties; or

(b) Wilfully fails to comply with any requirement properly made to him by an inspector; or

(c) Without reasonable cause fails to give to the inspector any assistance or information which the inspector may reasonably require of him for the purpose of the performance of his duties under this Act, shall be guilty of an offence.

Money-laundering

Falsified medical product-related crime is a lucrative enterprise for high-level offenders. Money earned from falsified medical product-related crime is often laundered in an attempt to conceal its illicit origins. The risk that this poses to legal markets and public health cannot be underestimated. States should ensure that measures are in place to criminalize the laundering of money obtained from falsified medical product-related crime. Article 6 of the Organized Crime Convention requires States parties to introduce measures to criminalize money-laundering. Article 6, paragraph 1, contains a number of subparagraphs that require States parties to introduce criminal offences relating to various aspects of money-laundering. The first of these, article 6, paragraph 1 *(a)* (i), requires States parties to criminalize the intentional conversion or transfer of property, knowing that such property is the proceeds of crime, for the purpose of concealing or disguising the illicit origin of the property or of helping any person who is involved in the commission of the predicate offence to evade the legal consequences of his or her action.

The link between this offence of money-laundering and other forms of organized crime is provided in the term "predicate offence". The concept of predicate offences is essential to the criminalization of money-laundering in many jurisdictions. In article 2, paragraph *(h)*, of the Organized Crime Convention, "predicate offence" is defined as 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 the Convention. Article 6, paragraph (2) *(a)*, requires that each State party seek to apply the offences in article 6, paragraph 1, to "the widest range of predicate offences". Article 6, paragraph 2 *(b)*, specifically requires that States parties include as predicate offences all serious crimes, as defined in article 2 of the Convention, and the offences specifically provided for in articles 5, 8 and 23 of the Convention.

States have taken different approaches to defining the term "predicate offence". Some States have defined "predicate offence" by reference to an exhaustive list of offences. Other States have defined "predicate offence" broadly, as including all crimes, all serious crimes or all crimes subject to a maximum penalty at or above a certain threshold. For those States utilizing a list of predicate offences, article 6, paragraph 2 *(b)*, of the Organized Crime Convention requires that this list include, at a minimum, a comprehensive range of offences associated with organized criminal groups.

Pursuant to the provisions of article 6 of the Organized Crime Convention, States parties must include as predicate offences for the purposes of money-laundering legislation all of the offences covered by this Guide that are deemed to be serious crimes. Where this would not automatically be provided for under existing legislation, States may decide to expressly state, in legislation on falsified medical products introduced pursuant to this Guide, that either all of the offences are predicate offences to money-laundering or that falsified medical product-related crimes constituting serious crimes are predicate offences. An example of a provision designating such offences as predicate offences for money-laundering is provided in sample provision 20 below.

Sample provision 20: money-laundering

Offences contained in this [*Act/Law/Chapter, etc.*] [*punishable by a maximum penalty of [insert maximum penalty] or greater*] are to be considered predicate offences for money-laundering.

Regardless of the manner in which States parties choose to identify predicate offences, it should not be necessary that a person be convicted of a predicate offence when proving that particular property is the proceeds of crime.

Comprehensive guidance on money-laundering legislation is beyond the scope of this Guide, but readers may refer to other UNODC publications on the matter. In 2005, UNODC and the International Monetary Fund (IMF) published *Model Legislation on Money Laundering and Financing of Terrorism*, for use by legislative drafters in civil-law jurisdictions. In 2016, UNODC, the Commonwealth Secretariat and IMF published *Common Law Legal Systems Model Legislative Provisions on Money Laundering, Terrorism Financing, Preventive Measures and Proceeds of Crime*, for use by legislative drafters in common-law jurisdictions. Both publications contain detailed model legislative provisions on money-laundering, confiscation and international cooperation in relation to the proceeds of crime.

D. Penalties, sentencing and other orders

Legislation on falsified medical product-related crime should include appropriate penalties and sentences for the commission of the offences. As approaches to setting penalties and sentencing offenders vary greatly between States, according to their legal tradition, this Guide does not provide any sample provisions on penalties and sentencing. Rather, in this section, a number of relevant issues are set out for consideration by States in drafting legislative provisions relating to penalties and sentencing.

The overriding consideration in determining appropriate penalties for the offences covered in this Guide is that the penalties should be proportional, effective and dissuasive. Generally speaking, the offences covered by this Guide should be considered serious crimes. The offences not only pose serious risks to public health and damage both the legal market and consumers' trust in the integrity of the supply chain but are also a serious threat to the rule of law and stability within States. It is imperative that the penalties for the offences reflect their serious nature and are comparable to the sanctions for other serious crimes,[17] within the limits established under international law.[18] At the same time, not all of the offences covered by this Guide are equally grave. The penalty for each offence must be proportionate to its seriousness. Furthermore, the circumstances of each offence and of each offender are infinitely variable. Sentences available to judges need to be flexible enough to take into account the individual circumstances of each case.

This section covers a number of considerations appropriate to the setting of maximum sentences of imprisonment in falsified medical product-related legislation. It also contains a discussion of non-custodial alternatives to imprisonment, as well as several further penalties that could be imposed on offenders in addition to those penalties, such as confiscation and disqualification orders. Lastly, it contains a discussion of aggravating and mitigating circumstances relevant to sentencing. Penalties for legal persons are discussed in chapter IV (Liability of legal persons).

Example: China – Regulations for Implementation of the Drug Administration Law

Article 79

Where anyone that, in violation of the provisions set forth in the Drug Administration Law and in the Regulations, commits any of the following acts, shall be given heavier punishments by the drug regulatory department based on the extent of punishment set forth in the Drug Administration Law and in the Regulations:

(1) Passing narcotics, psychotropic substances, medicinal toxic drugs and radioactive pharmaceuticals off as other drugs or vice versa;

(2) Producing or selling counterfeit or substandard drugs of which the main users are pregnant or parturient women, infants and children;

[17] See Organized Crime Convention, article 11, paragraph 1.

[18] Some instruments prohibit or restrict the use of certain penalties. For example, the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment, or the safeguards guaranteeing protection of the rights of those facing the death penalty. Other instruments set out basic principles on the role of lawyers, prosecutors and judges.

Example: China – Regulations for Implementation of the Drug Administration Law *(continued)*

(3) Producing or selling biological and blood products which are defined as counterfeit or substandard drugs;

(4) Producing, selling or using counterfeit or substandard drugs, thus inducing harmful results to people;

(5) Producing, selling or using counterfeit or substandard drugs again after being punished; or

(6) Refusing or evading supervision and inspection, or forging, destroying or concealing relevant evidentiary materials, or using sealed and seized articles without authorization.

Example: Liberia – Medicines and Health Products Regulatory Authority Act

Section 3: criminal penalties

Any person/organization who causes or takes any action, or any failure to act, enumerated in part VIII, section 1, may be subject to criminal prosecution in accordance with the provisions of this part VIII, section 2, or the Penal Code of the Republic of Liberia, whichever act provides a greater length of imprisonment or higher fine. The criminal penalties provided for herein are in addition to any applicable civil administrative penalties.

Initial violation: any person/organization who causes or takes any action or any failure to act enumerated in part VIII, section 1, shall be guilty of a first-degree misdemeanour.

Second and further violations; violation with intent to defraud or mislead: notwithstanding the provisions of part VIII, section 3.1, any person/organization who commits any such violation after a conviction under this section has become final, or commits such a violation with the intent to defraud or mislead, shall be guilty of a third-degree felony.

Imprisonment

The most serious offences covered by this Guide should be punishable by sentences of imprisonment proportional to the seriousness of the offence and high enough to serve as effective deterrents. Beyond proportionality and deterrence, there are several considerations that States should take into account in setting maximum sentences of imprisonment for those offences.

First, the Organized Crime Convention contains a number of tools available to States parties in relation to the prevention, investigation and prosecution of "serious crime". Article 3 of the Convention provides that the Convention shall apply to serious crime. Article 2 of the Convention defines "serious crime" as conduct constituting an offence punishable by a maximum deprivation of liberty of at least four years or a more serious penalty. In other words, for the Organized Crime Convention to apply to the most serious falsified medical product-related offences covered in this Guide, States should provide for maximum penalties of at least four years' imprisonment for each of those serious offences.

Second, in some States, designation of predicate offences for the purpose of money-laundering legislation is determined by reference to the maximum penalty of the offence in question. In such States, legislative drafters should ensure that the maximum penalties for offences intended for designation as predicate offences are sufficiently high to meet that threshold (see also the discussion on money-laundering in chapter III, section C).

Finally, in some States, eligibility of an offence to serve as a basis for extradition is determined by reference to the maximum penalty of the offence in question. Where this is the case, legislative drafters should ensure that the maximum penalties for offences serious enough to warrant extradition are sufficiently high for extradition to be possible under the State's extradition treaties and domestic legislation (see also the discussion on extradition in chapter VII). Some of the offences covered by this Guide may not be deemed by a State to be sufficiently serious to warrant extradition. The offence of possession of a falsified medical product set out in sample provision 8 above may be one such offence.

Non-custodial penalties and other orders

Legislation on offences covered by this Guide should also take into consideration the desirability of alternatives to custodial sentences in certain circumstances. The types of non-custodial sentences that may be given to offenders and the availability of each type of non-custodial sentence are matters for each State to determine in accordance with their legal framework for sentencing. Guidance on alternatives to imprisonment can be found in the United Nations Standard Minimum Rules for Non-custodial Measures (the Tokyo Rules) and in rules 57 to 66 of the United Nations Rules for the Treatment of Women Prisoners and Non-custodial Measures for Women Offenders (the Bangkok Rules), as well as in the *Handbook of Basic Principles and Promising Practices on Alternatives to Imprisonment*[19] and *Handbook on Strategies to Reduce Overcrowding in Prisons*.[20]

Under rules 2.3 and 3.1 of the Tokyo Rules, the criminal justice system should provide for a wide range of non-custodial measures, from pretrial to post-sentencing provisions, and the introduction, definition and application of non-custodial measures is to be prescribed by law. Under rule 5.1, the authorities dealing with criminal cases should be empowered to discharge the offender in appropriate circumstances and to impose non-custodial measures for minor cases. As set out in rule 8.2, non-custodial penalties may include verbal sanctions, such as admonitions, reprimands or warnings; conditional discharge; status penalties; economic sanctions and monetary penalties, such as fines and day-fines; confiscation or expropriation orders; compensation to the victim or compensation orders; suspended or deferred sentences; probation and judicial supervision; community service orders; referral to an attendance centre; house arrest; any other mode of non-institutional treatment; and any combination of such measures.

Like other penalties for falsified medical product-related crime, maximum fines must adequately reflect the seriousness of the offences and be high enough to act as effective deterrents. In some circumstances, fines may be imposed in addition to a sentence of imprisonment. In determining the appropriate value for maximum fines for offences covered by this Guide, legislators should bear in mind that falsified medical product-related crime can be an extremely lucrative business for offenders. If fines are not high enough, there is a danger that they simply become incorporated into the operating costs of organized criminal groups without acting as a deterrent. In some cases, a fine alone will not serve as an effective deterrent without confiscation of the proceeds of crime. Confiscation of proceeds of crime and property, equipment and other instrumentalities used in or destined for use in criminal offences is addressed in article 12 of the Organized Crime Convention.

In determining the appropriate fine in a given case, courts should also consider the value of the medical products involved in the offence, the financial or material benefit obtained by the offender and the damage to public health. States should also consider implementing measures to prevent the real value of fines being reduced over time by inflation. One approach could be to tether fine values to penalty units, which then can be adjusted in step with inflation.

States may also wish to provide courts with powers to make compensation or restitution orders to victims of falsified medical product-related crime. In some States, the availability of compensation or restitution orders is contingent upon the accused being convicted of a relevant criminal offence but, in other States, victims may be able to obtain compensation or restitution from an offender regardless of whether that offender has been convicted of an offence. Compensation or restitution is discussed further in chapter VIII.

Additional penalties

Depending on the circumstances of the case, a sentence of imprisonment or a non-custodial alternative to imprisonment alone may be insufficient and it may be necessary for a court to impose additional penalties. Additional penalties could include, but are not limited to, orders confiscating proceeds of crime or property, equipment or other instrumentalities used in or destined for use in offences;[21] orders disqualifying or

[19] United Nations publication, Sales No. E.07.XI.2.

[20] UNODC, Criminal Justice Handbook Series (Vienna, 2013).

[21] See UNODC, *Manual on International Cooperation for the Purposes of Confiscation of Proceeds of Crime* (Vienna, 2012); see also the definition of "confiscation" in article 2 of the Organized Crime Convention.

prohibiting a person from exercising one or more social, commercial or professional activities; orders excluding a person from public bidding or from entitlement to public benefits or aid; orders disqualifying a person from participation in public procurement; and orders disqualifying a person from applying for or being granted a permit or a certificate from a relevant competent authority.

Aggravating and mitigating circumstances

The circumstances in which any two offences occur will inevitably differ. It follows from the requirement that sentences be proportional to the seriousness of the offending that sentences must take into account the material circumstances of the offending. Circumstances that tend to increase the culpability of the offender or otherwise warrant higher sentences are known as aggravating circumstances. Circumstances that tend to lower the culpability of the offender or otherwise warrant lower sentences are known as mitigating circumstances.

Different approaches to aggravating and mitigating circumstances are taken in different jurisdictions. In some jurisdictions, legislative provisions require stricter penalties, such as higher minimum and/or maximum sentences, where particular aggravating circumstances are present. In other jurisdictions, statutory provisions set out relevant factors to be taken into account by sentencing judges in deciding upon the appropriate sentence. In some cases, specific lists of aggravating and mitigating circumstances will be provided for in the legislation for particular offences. In other cases, sentencing judges will rely upon general lists of factors relevant to sentencing for all criminal offences. Some jurisdictions use a mix of these approaches, depending on the legislation and the offence in question. The approach a State takes to aggravating and mitigating circumstances in relation to falsified medical products is a matter for each State to determine, taking into account its own legal tradition. Should a State choose to establish statutory aggravating circumstances or legislate lists of factors for use by sentencing judges in relation to falsified medical product-related offences, a number of suggested aggravating and mitigating circumstances are set out below.

Factors that may be considered to increase the culpability of an offender or otherwise warrant higher penalties may include:

(a) Any injury or death caused by a falsified medical product involved in the offence;

(b) The offence causing a serious impact on public health or a society or economy;

(c) The number or quantity of medical products involved in the offence;

(d) Whether the offence involved life-saving medicines;

(e) Whether the offender previously committed a falsified medical product-related offence and whether or not the offender was charged or convicted in relation to such an offence;

(f) The size of any financial or other material benefit to the offender or any other person as a result of the offence;

(g) The size of any financial or other material loss to another person as a result of the offence;

(h) Whether the offence was committed as part of an activity of an organized criminal group;

(i) Whether the offender had a leadership or managerial role in the organized criminal group;

(j) Whether the offence was part of a pattern of ongoing criminal activity;

(k) The time and money spent by enforcement agencies to investigate and bring the offender to trial;

(l) Whether the offender attempted to obstruct the administration of justice during the investigation, prosecution or sentencing stages;

(m) Whether the offence was committed by a government official;

(n) Whether the offence was committed by a person in a position of trust or authority, including the holder of a relevant permit or certificate.

If an aggravating circumstance is already an element of the offence, or an element of another offence for which the accused has been convicted arising from the same offence, it should not be regarded as an aggravating factor for the offence in question. Several of the aggravating circumstances listed above are elements of offences covered in this Guide; it would not be appropriate to use them to enhance the offender's sentence in circumstances where an offender has been or is being sentenced for such an offence. For example, the aggravating circumstance of commission of the offence as part of the activity of an organized criminal group should not apply where the offender has also been convicted of the offence of participation in an organized criminal group. A second example would be that an offender could not be liable for organizing or directing the commission of an offence and be given an even higher sentence because of his or her leadership or managerial role within the organized criminal group.

Factors that may be considered as reducing the culpability of an offender or otherwise warranting lower penalties may include:

(a) If the offender had a lower or minor role in the commission of the offence;

(b) If the offender had no prior criminal record;

(c) If the offender was of prior good character;

(d) If the offender showed remorse for the commission of the offence;

(e) If the person voluntarily cooperated by providing information or otherwise assisted competent authorities, including in investigating and prosecuting falsified medical product-related crime;

(f) If the offence caused no discernible harm;

(g) The number or quantity of falsified medical products involved in the commission of the offence;

(h) The age of the offender at the time of commission of the offence or at the time of sentencing;

(i) Whether the offender was or is suffering from reduced mental capacity at the time of commission of the offence or the time of sentencing.

Example: "Legal framework on the counterfeiting of and illicit trade in medical products for ECOWAS member States"

Article 12

(1) Each member State shall take the necessary legislative and other measures to ensure that the following circumstances, insofar as they do not already form part of the constituent elements of the offence, may, in conformity with the relevant provisions of domestic law, be considered as aggravating circumstances in determining the sanctions in relation to the offences established in accordance with this legislation:

(a) The offence caused the death of, or serious damage to the physical or mental health of, the victim;

(b) The offence was committed by persons abusing the confidence placed in them in their professional capacity;

(c) The offence was committed by persons abusing the confidence placed in them as manufacturers or suppliers;

(d) The offences of supplying and offering to supply were committed having resort to means of large-scale distribution, such as information systems, including the Internet;

(e) The offence was committed in the framework of a criminal organization;

(f) The perpetrator was previously convicted of offences of the same nature.

Example: United Kingdom of Great Britain and Northern Ireland – Criminal Justice Act 2003

Section 143

(1) In considering the seriousness of any offence, the court must consider the offender's culpability in committing the offence and any harm which the offence caused, was intended to cause or might foreseeably have caused.

(2) In considering the seriousness of an offence ("the current offence") committed by an offender who has one or more previous convictions, the court must treat each previous conviction as an aggravating factor if (in the case of that conviction) the court considers that it can reasonably be so treated having regard, in particular, to:

(a) The nature of the offence to which the conviction relates and its relevance to the current offence; and

(b) The time that has elapsed since the conviction.

Chapter IV.

LIABILITY OF LEGAL PERSONS

Falsified medical product-related crime can be committed by organizations with legal personality. Legal personality is a characteristic of organizations that have some, but not necessarily all, of the rights and obligations of a natural person in a particular jurisdiction. A corporation is the classic example of a type of organization with legal personality, but, depending on the law of a given State, a range of other types of entities, such as companies, associations, societies, partnerships, local governments, trade unions, municipalities and public bodies, may be defined as legal persons. Sophisticated organized criminal groups often use complex corporate structures to conceal the identities of human actors, both organizers and clients, involved in falsified medical product-related crime.

Effectively combating falsified medical product-related crime requires that legal persons be held responsible for their culpable acts and omissions. Article 10 of the Organized Crime Convention requires that States parties adopt such measures as necessary to establish the liability of legal persons for participation in serious crimes involving an organized criminal group. The legal nature of their liability is left to each State to decide, with article 10, paragraph 2, specifying that liability for legal persons may be criminal, civil or administrative. Moreover, two or even all three of these forms of liability of legal persons may be recognized under a single legal system. Article 10, paragraph 3, clarifies that liability of legal persons must be without prejudice to the criminal liability of natural persons involved in the offences.

Criminal liability is the most serious form of liability a State can impose on legal persons. It is generally associated with trials in criminal courts, a high potential for sanctions and a significant level of procedural protections for defendants. The criminal liability of a legal entity has the potential to cause costly reputational damage to the entity and may also deter legal persons from engaging in unlawful conduct.[22]

Civil and administrative liability for legal persons are options available to legal systems that do not recognize the capacity of legal persons to commit criminal offences. Each of these terms has a different meaning, but in some States, they are used interchangeably. Civil liability refers to the potential for civil penalties to be imposed by courts or similar bodies. Administrative liability is generally associated with liability imposed by a regulator, but in some legal systems, judicial bodies may impose administrative penalties. Similar to civil liability, administrative liability does not result in a criminal conviction. Civil and administrative liability are both generally associated with lower standards of proof than criminal liability.

Where criminal, civil or administrative liability of legal persons involved in falsified medical product-related crime is not already provided for under domestic law, States should include specific provisions establishing

[22] UNODC, *Legislative Guide for the Implementation of the United Nations Convention against Transnational Organized Crime and the Protocols Thereto* (United Nations publication, Sales No. E.05.V.2), p. 116.

such liability in legislation dealing with such crime. The choice of whether to establish criminal, civil or administrative liability should be made by each State, taking into account its legal tradition and culture and whether its legal system recognizes the capacity of legal persons to commit criminal offences. Sample provision 21, presented below, provides a basic example of a specific provision establishing liability for legal persons in respect of the offences covered by this Guide. Under sample provision 21, drafters of legislation are provided with three possible options for establishing liability of legal persons.

States should also consider whether a legal person's due diligence may serve as a defence or mitigating factor in a prosecution. Due diligence refers to the steps that a legal person takes to ensure compliance with a particular law. States have taken different approaches to the impact of a legal person's due diligence on its treatment in an enforcement action. In some States, proof of due diligence provides an absolute defence to liability for legal persons. In other States, due diligence may be a factor relevant to the exercise of prosecutorial discretion in bringing a case against a legal person or may provide a mitigating factor in sentencing. The party that bears the burden of proof of due diligence (or lack thereof) may also differ among States.

Sample provision 22, below, provides an example of a defence of due diligence that a State could introduce to exclude the liability of a legal person for offences covered in this Guide in cases where the legal person can prove that it exercised due diligence to prevent the commission of the offence.

What constitutes due diligence will differ from State to State and from case to case. In general, the exercise of due diligence will involve a system of risk management to prevent and detect misconduct. An adequate risk management system will generally include systems for accessing information, assessing risk based on that information and mitigating risk based on that assessment.[23] The mere existence of policies, procedures and systems to prevent and detect misconduct generally will not, however, be sufficient to absolve a legal person from liability.[24] Whether a legal person has exercised due diligence will always depend on the facts and circumstances of the individual case.

In establishing liability of legal persons, States must also introduce appropriate penalties and sanctions. Penalties associated with criminal liability of legal persons may include orders calling for the legal person to be dissolved; excluded from public bidding or entitlement to public benefits or aid; disqualified or prohibited from participating in public procurement or the practice of particular commercial, social or professional activities; or disqualified from creating another legal person; as well as orders requiring the legal person to publish the judgment of the court, or to close one or more of its establishments. A number of examples of orders that could be made upon the conviction of a legal person are set out in sample provision 23 below.

Sample provision 21: liability of legal persons

(1) Legal persons [*other than the State*] may be subject to [*criminal/civil/administrative*] liability for offences established in accordance with this [*Act/Law/Chapter, etc.*].

(2) The liability of any legal person does not preclude the liability of a natural person.

[*Option 1*]
(3) A legal person is guilty of an offence committed by a representative of the legal person acting within the scope of his or her authority and, at least in part, for the benefit of the legal person.

[*Option 2*]

(3) For the purpose of imposing liability on a legal person, any conduct or associated state of mind of a representative of the legal person is deemed to be that of the legal person where the conduct is within the authority of the representative and, at least in part, for the benefit of the legal person.

[23] See regulation (EU) No. 995/2010 of the European Parliament and of the Council of 20 October 2010 laying down the obligations of operators who place timber and timber products on the market (*Official Journal of the European Union*, L 295, 12 November 2010), preamble, articles 4 and 6; United Kingdom, Ministry of Justice, "The Bribery Act 2010: guidance about procedures which relevant commercial organizations can put in place to prevent persons associated with them from bribing (section 9 of the Bribery Act 2010)" (London, 2011), pp. 27–28.

[24] United States, Department of Justice, *Justice Manual*, Title 9-28.800 (Washington, D.C., 2018).

(4) A representative means [*a director, partner, employee, member, agent or contractor*].

[*Option 3*]

(3) A legal person is guilty of an offence where a [*senior officer employed by*] [*officer exercising control over*] the legal person, or acting on behalf or for the benefit of the legal person:

(a) Commits the offence;

(b) [*Authorizes or permits the commission of the offence*]; or

(c) [*Knowing an offence is likely to be committed, fails to take all reasonable steps to prevent the commission of the offence*].

(4) A senior officer means an employee, agent or officer of the body corporate with duties of such responsibility that his or her conduct may objectively be assumed to represent the legal person's policy.

Sample provision 22: due diligence

It is a defence to liability under [*sample provision 21*] for the legal person to prove that it exercised due diligence to prevent the commission of the offence.

Sample provision 23: sanctions for legal persons

Upon convicting a legal person for an offence under this [*Act/Law/Chapter, etc.*], a judge may make an order that includes any of the following sanctions:

(a) A fine up to a maximum of:

(i) [*Maximum amount*]; or

(ii) [*x*] times the total value of the benefit obtained or damage caused that is reasonably attributable to the offence; or

(iii) [*If the court cannot determine the total value of the benefit or damage*] [*x*] per cent of the annual turnover of the legal person during the 12 months prior to the commission of the offence;

(b) Confiscation of proceeds of crime or property, equipment or other instrumentalities used in or destined for use in offences covered by this [*Act/Law/Chapter, etc.*];

(c) Requiring the legal person to publish the judgment by the court, including, as appropriate, the particulars of the offence and the nature of any penalty imposed;

(d) Requiring the legal person to take prescribed actions or establish or carry out prescribed projects for the public benefit;

(e) Requiring the legal person to be placed under judicial supervision for a maximum period of [*x*] years;

(f) Prohibiting the exercise, whether directly or indirectly, of one or more social or professional activities [*permanently*] [*for a maximum period of [x] years*], including with regard to occupying a public office;

(g) Requiring the [*temporary*] [*permanent*] closure of one or more establishments of the legal person used to commit the offence(s) in question;

(h) Excluding the legal person from public bidding;

(i) Excluding the legal person from entitlement to public benefits or aid;

(j) Disqualifying the legal person from participation in public procurement, whether on a temporary or permanent basis;

(k) Disqualifying the legal person from applying for or being granted a [*insert relevant terminology for the appropriate licence/authorization/concession, etc.*] from [*insert name of competent authority*];

(l) Disqualifying the legal person from the practice of other commercial activities or from the creation of another legal person;

Sample provision 23: sanctions for legal persons *(continued)*

(m) If the activity of the legal person was entirely or predominantly used to carry out criminal offences or if the legal person was created to commit an offence under this [*Act/Law/Chapter, etc.*], requiring that the legal person be dissolved; and

(n) [*Any other sanction the court considers just*].

Legislative provisions establishing the liability of legal persons should combine both the need for effective enforcement and the need to attribute organizational fault. A number of different theories of liability of legal persons have been proposed and underpin the approaches taken in the legislation of different States. The nominalist theory of liability holds that, as a legal person is a legal construct that can only act through individuals, the liability of the entity is dependent upon the liability of individuals. For example, a company may be held liable for a criminal offence committed by one of its officers or employees. Such liability is said to be "derivative" because it links the liability of the legal person to the liability of the individual; it does not seek to attribute fault to the organization itself.

Derivative liability has the advantage of relative simplicity. It fits well within the traditional criminal law model, focusing on the acts and mental states of an individual as a proxy for the fault of the legal entity. Under this model, a corporation will, however, escape liability if fault cannot be established in relation to a relevant individual. This is particularly problematic in large organizations where responsibility is diffuse and individual responsibility may be difficult to prove.

The simplest form of derivative liability is "vicarious liability". Vicarious liability is based on the principle *respondeat superior* ("let the principal answer") and renders the legal person liable for the conduct of an individual employee or agent acting within the scope of his or her employment or agency. There is no requirement that the employees or agents be of a certain level of seniority or responsibility; it is sufficient that they were acting within the scope of their employment or agency at the time of the offence. Typically, the conduct must also be in part for the benefit of the organization. Thus, the organization may not be liable if the employee or agent was acting entirely in his or her own interest.

An alternative form of derivative liability is the so-called "attribution" or "identification" model, which is similar to vicarious liability in that fault must be found in an individual. However, in contrast to the primary definition of vicarious liability, under the attribution model, it is not enough that fault can be attributed to an employee or agent of the legal person; the employee or agent must be of sufficient standing that he or she may be said to represent the entity. In common-law systems, such a person is referred to as the "directing mind and will" of the company, and it is only his or her actions for which the company is liable.

Under the organic theory of corporate liability, rather than considering the legal person to be vicariously liable for the conduct of a natural person, a legal fiction is adopted which holds that the natural person is the company for particular purposes and the company is liable in its own right. In this way, it may be said that the principle of personal responsibility is maintained for legal persons.

Although this approach involves some effort to attribute organizational fault by focusing on senior employees, the difficulty is in identifying who should represent the legal person for these purposes. Obvious examples include the board of directors and other senior officers of a company, such as the chief executive officer or the managing director. However, in modern, decentralized organizations, considerable authority is often vested in middle managers. For this reason, some jurisdictions have adopted a more liberal approach, focusing on the person's actual role within the organization, rather than his or her formal job title. This approach is found, for example, in the Criminal Code of Australia, which provides, in its schedule I, section 12.3, that the mental state of a "high managerial agent" can be attributed to a body corporate. In that Criminal Code, a "high managerial agent" is defined as "an employee, agent or officer of the body corporate with duties of such responsibility that his or her conduct may fairly be assumed to represent the body corporate's policy". The advantage of this approach is that legal persons cannot avoid liability by relying on the formal titles of employees acting on their behalf. Who is considered to be the "directing mind and will" of a company may also depend on the nature of the offence in question.

Example: France – Penal Code

Article 121-1

No one is criminally liable except for his or her own conduct.

Article 121-2

Legal persons, with the exception of the State, are criminally liable for the offences committed on their account by their organs or representatives, according to the distinctions set out in articles 121-4 and 121-7.

However, local public authorities and their associations incur criminal liability only for offences committed in the course of their activities which may be exercised through public service delegation conventions.

The criminal liability of legal persons does not exclude that of any natural persons who are perpetrators or accomplices to the same act, subject to the provisions of the fourth paragraph of article 121-3.

Article 435-6

Legal persons may incur criminal liability pursuant to the conditions set out under article 121-2 for the offences set out under articles 435-2, 435-3 and 435-4.

The penalties incurred by legal persons are:

(1) A fine, in the manner prescribed by article 131-38;

(2) For a maximum period of five years:

- Prohibition to undertake directly or indirectly the professional or social activity in which or on the occasion of which the offence was committed
- Placement under judicial supervision
- Closure of the establishment or one of the establishments of the enterprise which was used to commit the offence
- Disqualification from public tenders
- Prohibition to draw cheques, except those allowing the withdrawal of funds by the drawer from the drawee or certified cheques, or to use payment cards

(3) Confiscation, in accordance with the conditions laid down under article 131-21, of the thing which was used or intended for the commission of the offence, or of the thing which is the product of it, except for articles liable to restitution;

(4) The public display or dissemination of the decision, in accordance with the conditions set out under article 131-35.

Example: Switzerland – Criminal Code

Article 102

Liability under the criminal law

1. If a felony or misdemeanour is committed in an undertaking in the exercise of commercial activities in accordance with the objects of the undertaking and if it is not possible to attribute this act to any specific natural person due to the inadequate organization of the undertaking, then the felony or misdemeanour shall be attributed to the undertaking. In such cases, the undertaking shall be liable to a fine not exceeding 5 million francs.

2. If the offence committed falls under articles 260 ter, 260 quinquies, 305 bis, 322 ter, 322 quinquies or 322 septies, paragraph 1, or is an offence under article 4 (a), paragraph 1 (a), of the Federal Act of 19 December 1986 on Unfair Competition, the undertaking shall be penalized irrespective of the criminal liability of any natural persons, provided the undertaking is responsible for failing to take all the reasonable organizational measures that were required in order to prevent such an offence.

3. The court shall assess the fine in particular in accordance with the seriousness of the offence, the seriousness of the organizational inadequacies and of the loss or damage caused and based on the economic ability of the undertaking to pay the fine.

Example: Switzerland – Criminal Code *(continued)*

4. Undertakings within the meaning of this title are:

(a) Any legal entity under private law;

(b) Any legal entity under public law with exception of local authorities;

(c) Companies;

(d) Sole proprietorships.

Example: Australia – Therapeutic Goods Act 1989

55. Conduct by directors, servants and agents

(1) Where, in proceedings for an offence against this Act, or for a contravention of a civil penalty provision, it is necessary to establish the state of mind of a body corporate in relation to particular conduct, it is sufficient to show:

(a) That the conduct was engaged in by a director, servant or agent of the body corporate within the scope of his or her actual or apparent authority; and

(b) That the director, servant or agent had the state of mind.

(2) Any conduct engaged in on behalf of a body corporate by a director, servant or agent of the body corporate within the scope of his or her actual or apparent authority is to be taken, for the purposes of a prosecution for an offence against this Act, or for a contravention of a civil penalty provision, to have been engaged in also by the body corporate unless the body corporate establishes that the body corporate took reasonable precautions and exercised due diligence to avoid the conduct.

(3) Where, in proceedings for an offence against this Act, or for a contravention of a civil penalty provision, it is necessary to establish the state of mind of a person other than a body corporate in relation to particular conduct, it is sufficient to show that:

(a) The conduct was engaged in by a servant or agent of the person within the scope of his or her actual or apparent authority; and

(b) The servant or agent had the state of mind.

(4) Any conduct engaged in on behalf of a person other than a body corporate (in this subsection called the "employer") by a servant or agent of the employer within the scope of his or her actual or apparent authority is to be taken, for the purposes of a prosecution for an offence against this Act, or for a contravention of a civil penalty provision, to have been engaged in also by the employer unless the employer establishes that he or she took reasonable precautions and exercised due diligence to avoid the conduct.

[…]

(6) A reference in subsection 1 or 3 to the state of mind of a person includes a reference to:

(a) The knowledge, intention, opinion, belief or purpose of the person; and

(b) The person's reasons for the intention, opinion, belief or purpose.

(7) A reference in this section to a director of a body corporate includes a reference to a constituent member of a body corporate incorporated for a public purpose by a law of the Commonwealth, of a state or of a territory.

(8) A reference in this section to engaging in conduct includes a reference to failing or refusing to engage in conduct.

Chapter V.

INVESTIGATIONS

Penalties reflecting the seriousness of falsified medical product-related crimes cannot serve as effective deterrents if they are not enforced. In order to effectively achieve the goals of legislation on falsified medical product-related offences, it is critical that States establish an effective regime for investigating such offences, one that empowers investigative officers to carry out their functions in combating crime. The officials involved in investigating falsified medical product-related crimes may include law enforcement officials, officials responsible for forensic analysis and regulation of medical products, and officials of financial intelligence units and multi-agency task forces. The appropriate authority vested in such officials will necessarily differ, but may include the authority to do the following:

(a) Stop, arrest and search persons, vehicles, vessels or other conveyances;

(b) Enter and search premises;

(c) Seize any weapon, device or means suspected of being involved in the commission of an offence covered in this Guide;

(d) Seize items used in the commission of an offence covered in this Guide;

(e) Freeze and seize proceeds of crime;

(f) Initiate the recall and/or disposal of a falsified medical product;

(g) Question witnesses, suspected offenders and other persons of interest;

(h) Require the inspection or production of documents;

(i) Take photographs or make audiovisual recordings of a thing or place suspected of being involved in the commission of an offence covered by this Guide;

(j) Carry and, where necessary, use specified firearms and ammunition for the purposes of executing their duties;

(k) Manage crime scenes;

(l) Seize and analyse phones, computers and similar devices found in the possession of suspected offenders;

(m) Issue summons requiring attendance in court;

(n) Request forensic information from specialized laboratories;

(o) Where appropriate, compel persons to answer questions and/or produce documents relevant to the investigation of an offence covered by this Guide;

(p) Access bank and financial records;

(q) Access telecommunications records;

(r) Use special investigative techniques, such as wiretapping, controlled delivery and undercover investigations;[25]

(s) Conduct test purchases to obtain samples;

(t) Suspend, modify and revoke authorizations, permits or certificates held by suspected offenders;

(u) Disqualify suspected offenders from holding authorizations, permits or certificates;

(v) Exchange information with foreign law enforcement agencies;[26]

(w) Coordinate joint investigations;[27]

(x) Freeze assets.

The procedures for the exercise of such authority may vary among States. In some cases, it may be appropriate or necessary for States to restrict such authority to being exercised only under the supervision of a judge or magistrate or, in other cases, a prosecutor or a senior law enforcement official. For example, a warrant or other order of a judge or magistrate may be necessary to exercise certain types of authority to search, enter and seize, to freeze assets and to use special investigative techniques, such as wiretapping, controlled delivery and undercover investigations. States should also bear in mind the need to regulate the use of certain investigative techniques so as to ensure the admissibility of the evidence collected through the use of some techniques. In some jurisdictions, special regulations may be needed to make certain investigative techniques available to law enforcement authorities and to ensure that the evidence obtained through the use of such techniques is admissible in judicial proceedings.

In addition, the establishment of an appropriate framework to facilitate coordination at the national and international levels may be necessary for the effective implementation of the aforementioned powers, mandates and competencies, as they may be vested in a wide range of institutions.

Special investigative techniques

States may wish to include provisions regarding special investigative techniques in their legislation to combat falsified medical product-related crime. Special investigative techniques are covert techniques used for gathering information in such a way as not to alert the targeted person of interest; such techniques are used by law enforcement officials for the purpose of detecting and investigating crimes and suspects.[28] Article 20, paragraph 1, of the Organized Crime Convention requires States parties to take, if permitted by the basic principles of their domestic legal systems, the necessary measures to allow for the appropriate use of controlled delivery and, where appropriate, other special investigative techniques such as electronic or other forms of surveillance and undercover operations.

Where compatible with the basic principles of their legal systems, and to the extent possible, States should ensure that the provisions for special investigative techniques extend to investigations of serious cases of falsified medical product-related crime. Where special investigative techniques are not already available to law enforcement agencies investigating serious crimes under existing domestic laws, States should consider including such provisions in legislation addressing falsified medical product-related crime.

[25] See article 20 of the Organized Crime Convention. See also the discussion in the section on "Special investigative techniques" below.
[26] Law enforcement cooperation is discussed in chapter VII.
[27] Joint investigations are discussed in chapter VII.
[28] UNODC, *Model Legislative Provisions against Organized Crime* (2012), p. 59.

The term "special investigative techniques" refers to a number of discrete investigative techniques, each of which involves different levels of risk and potentially raises different issues. For example, it may be appropriate for controlled deliveries to be authorized by senior law enforcement officials, whereas electronic surveillance will usually require judicial authorization and supervision. Accordingly, domestic legislation should address each major type of special investigative technique separately, giving adequate consideration to the relevant issues arising from the use of specific techniques. Practices with regard to managing the risks and issues involved in the use of special investigative techniques may vary from jurisdiction to jurisdiction.

In general, provisions regulating the use of special investigative techniques should adequately address the need to prevent the abuse of such techniques and should provide appropriate protections for both the persons affected by the techniques and the law enforcement officials deploying such techniques. Special investigative techniques are powerful tools for law enforcement and it is important for them to be subjected to an adequate level of scrutiny to minimize the risk of their misuse, as well as of corruption and violations of human rights. To this end, it is recommended that a senior official, such as the head of the law enforcement agency or ministry of justice, or the equivalent, be required to report to the legislature on an annual basis on the number of requests made for authorization for use of special investigative techniques, the number of authorizations granted and the number of prosecutions in which evidence or information obtained through such authorizations was used. In addition, some States may wish to establish additional measures of scrutiny, for instance, a mechanism for review and reporting by an independent oversight body. Where this is the case, it will likely be necessary to provide for two levels of review. The first level would entail a full review, including access to sensitive operational information by an independent review body with a specific legislative mandate. The second level would entail a public review by, for example, the legislature, which does not disclose sensitive operational information such as methods and sources.[29]

A comprehensive examination of legislative issues relating to special investigative techniques is beyond the scope of this Guide. For further information on special investigative techniques, please refer to chapter IV (Investigations) of the *Model Legislative Provisions against Organized Crime*.

Controlled delivery

The special investigative technique of controlled delivery is specifically mentioned in article 20, paragraph 1, of the Organized Crime Convention. In article 2, paragraph *(i)*, of the Convention, "controlled delivery" is defined as follows:

> 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.

States may wish to introduce special provisions on controlled delivery in legislation aimed at combating falsified medical product-related crime.

Assumed identities and infiltration

Assumed identities and infiltration comprise another type of special investigative technique that States may use in relation to falsified medical product-related crime, pursuant to article 20, paragraph 1, of the Organized Crime Convention, which makes specific reference to undercover operations and other forms of surveillance.

It is vital for drafters to consider the issue of whether evidence obtained through infiltration and/or undercover operations can be adduced in court and, if so, whether the undercover agent has to reveal his or her real identity to do so. In some States, this issue has been addressed by using an investigator other than the undercover agent as a proxy. The investigator remains in charge of the operation, drafts any relevant reports and can appear in court to testify, if necessary. The undercover agent may also testify by special means in order to protect his or her real identity. Another important issue for drafters to consider is the weight to be

[29] Ibid., p. 64.

given to evidence obtained through infiltration. In some States, a conviction cannot be grounded solely on evidence obtained through infiltration, for example. In addressing these and other issues concerning assumed identities and infiltration, it is important to balance the interests of justice, including the need to combat transnational organized crime, with the need to ensure a fair trial of the accused.[30]

Electronic surveillance

Electronic surveillance is another type of special investigative technique specifically referred to in article 20, paragraph 1, of the Organized Crime Convention. As in the case of other special investigative techniques, it is important that the use of electronic surveillance be subjected to an adequate level of scrutiny to minimize the risk of misuse or corruption. However, full public scrutiny of covert operations is not possible, as it would potentially jeopardize law enforcement operations, methods and sources, which need to be protected and may need to be reused. To balance these concerns, the use of two levels of scrutiny over the use of electronic surveillance is encouraged in this Guide. The first level would involve reporting to an independent oversight body that has a legislative mandate to scrutinize the use of electronic surveillance. Reports provided to such a body would be required to contain certain details about the use of electronic surveillance in law enforcement operations, and the oversight body would then be required to make its own assessment of whether proper processes were followed. The second level would involve a more general reporting function, through which the legislature would be informed about the number of warrants sought and granted, but sensitive information about methods and sources would not be disclosed.[31]

Seizure and confiscation

Article 12, paragraph 1, of the Organized Crime Convention requires States parties to adopt, to the greatest extent possible within their domestic legal systems, such measures as may be necessary to enable confiscation of both proceeds of crime derived from offences covered by the Convention and property, equipment or other instrumentalities used in or destined for use in offences covered by the Convention. Article 12, paragraph 2, requires States parties to adopt such measures as may be necessary to enable the identification, tracing, freezing or seizure of any such proceeds or items for the purpose of eventual confiscation.

Legislation to combat crime related to falsified medical products should provide for the seizure and confiscation of such products. Sample provision 24 below provides that where there are reasonable grounds to believe that a medical product, including its accompanying documentation and any ancillary equipment, is falsified, that medical product, as well as the equipment and the material used for the commission of an offence covered by this Guide, shall be seized without undue delay.

Sample provision 24: seizure

Where there are reasonable grounds to believe that a medical product, including its accompanying documentation and any ancillary equipment, is falsified, the medical product, its accompanying documentation and ancillary equipment, as well as any material used for the commission of an offence under this [*Act/Law/Chapter, etc.*], shall be seized without undue delay.

The purpose of such seizure is to preserve evidence and to protect health. The seizure must be carried out immediately following the discovery of a relevant medical product unless the medical product is currently subject to a controlled delivery operation in accordance with domestic laws.

States may require that the seizure and confiscation of medical products, including any accompanying documentation and ancillary equipment, be authorized by judicial order. Provision may also be made to facilitate the voluntary surrender of such items, taking into account the required capacities and procedures of the receiving institution for storing and, where appropriate, disposing of the items.

[30] Ibid., p. 70.
[31] Ibid., p. 84.

Disposal of confiscated or surrendered items is further discussed below. Additional information on seizure and confiscation can be found in chapter III of the UNODC and IMF publication entitled *Model Legislation on Money Laundering and Financing of Terrorism*.[32]

Collection and analysis of samples and certificates of result of tests, examinations or analyses

Legislation to combat falsified medical product-related crime should also provide for the collection and analysis of samples of suspected falsified medical products. The discovery and identification of such products can be a challenge for authorities, in particular as they may require forensic capabilities that are not available within the jurisdiction. The technical challenges associated with the identification and determination of falsified medical products should be addressed by States when drafting relevant legislative provisions. States may also wish to introduce provisions relating to the use of certificates of result of tests, examinations or analyses concerning suspected falsified medical products. For example, provisions could be introduced exempting expert witnesses from testifying when a certificate of result of a test, examination or analysis conforming to certain requirements is adduced.

States should also ensure that their legislation comprehensively regulates possible issues relating to the chain of custody of evidence obtained for use in cases concerning falsified medical product-related crime. If evidence, in particular in the form of medical products, is not properly collected or stored, there is a risk that it could be challenged in a court of law and found to be inadmissible, thereby posing a serious risk to the integrity of the investigation and the prosecution of offences. Investigations into falsified medical products often rely on scientific analyses of substances, or tests or examinations[33] of products, which are only possible if correct sampling and storage procedures are in place.[34]

Sample provision 25 outlines a recommended approach for the taking of samples to determine the nature or composition of a medical product through an expert test, examination or analysis; the approach is aimed at minimizing the risk of degradation of samples taken for that purpose.

Sample provision 25: collection and analysis of samples

Where an expert test, examination or analysis is considered necessary to determine the nature or composition of a medical product, such test, examination or analysis must be conducted in a manner prescribed by [*insert name of the competent authority, taking into account the class of hazardous waste applicable*] without delay, in order to minimize the risk of degradation of the sample of the medical product taken for such a purpose.

Sample provision 26 addresses the use of certificates to certify the results of such tests, examinations or analyses. It provides that such a certificate shall serve as evidence of the matters contained therein, thereby precluding the need for the person who conducted the test, examination or analysis to give oral testimony in court. Paragraphs *(a)* and *(b)* provide for the designation by the State of the laboratory or laboratories authorized to analyse, test or examine medical products and to produce a certificate of result. Paragraph *(c)* is intended to provide for the appointment by the State of an analyst in another laboratory, which may include a laboratory outside of the jurisdiction of the State. This may be relevant to States that do not have a suitable laboratory for conducting the necessary test, examination or analysis and therefore must engage the services of an analytical, test or examination facility outside of their jurisdiction.

[32] See also articles 12–14 of the Organized Crime Convention.

[33] Medical devices not containing medicines are subject to technical testing and examination. Such examination might simply involve examining the packaging materials and print.

[34] For further information, see WHO, *WHO Expert Committee on Specifications for Pharmaceutical Preparations: Fifty-second Report*, WHO Technical Report Series, No. 1010 (Geneva, 2018), annex 5 and *Guidelines on Representative Drug Sampling* (United Nations publication, Sales No. E.09.XI.13).

Sample provision 26: certificate of result of tests, examinations or analyses

In any proceeding for an offence covered by this [*Act/Law/Chapter, etc.*], a certificate signed by:

(a) [*Insert relevant designation of the analyst or duly qualified person*] of [*insert name of the laboratory designated by the State to conduct the analysis*]; or

(b) Another designated analyst or duly qualified person employed or engaged by [*insert name of the designated laboratory in paragraph (a) above*]; or

(c) Any designated analyst or duly qualified person appointed by [*insert name of the appointing authority for conducting tests, examinations or analyses of medical products*];

stating the result of any test, examination or analysis of a sample of the medical product shall serve as evidence of the matters stated on the certificate.

Disposal

Article 14, paragraph 1, of the Organized Crime Convention provides that proceeds of crime or property confiscated by a State party pursuant to articles 12 or 13, paragraph 1, of the Convention (concerning confiscations made at the request of another State party) shall be disposed of by that State party in accordance with its domestic law and administrative procedures. In this regard, States should provide for the destruction of falsified medical products and ancillary equipment, subject to the keeping of samples for evidentiary purposes, where appropriate. Falsified medical products often constitute a hazard to public health and may require specific procedures for their disposal. Such items must be destroyed without undue delay to prevent contamination resulting from potential leakages and to prevent them from being diverted back onto the market. The destruction of such items will necessarily be subject to domestic legal requirements for the preservation of seized evidence.

Sample provision 27, paragraph 1, provides that a court or other competent authority, as relevant, may order the destruction or disposal of falsified medical products and the disposal of ancillary equipment. Sample provision 27, paragraph 2, provides for the prohibition of the donation, sale or supply of any medical product subject to such an order, except in limited circumstances. The prohibition is aimed at reducing the risk of falsified medical products being reintroduced on the market. In particular, donations of falsified medical products destined for remarketing on other markets risk being re-imported into the country of origin.

Sample provision 27: disposal

(1) [*Insert name of the court or other competent authority*] may order that any falsified medical product be destroyed or otherwise disposed of in a manner prescribed by [*insert name of the competent authority, taking into account the class of hazardous waste applicable*] and that ancillary equipment shall be disposed of in a manner prescribed [*insert name of competent authority, taking into account the class of hazardous waste applicable*].

(2) A falsified medical product subject to an order under paragraph 1 shall not be donated, sold or otherwise supplied for any use other than the taking of samples for tests, examinations or analyses undertaken in support of efforts to prevent crime and protect public health.

States may need to consider issuing additional guidelines on disposal procedures. In particular, they may wish to consider making a distinction between the procedures applicable to medicines and those applicable to medical devices. In the case of falsified medicines, destruction should be the only form of disposal allowed, whereas alternative procedures could be used in relation to falsified medical devices. Procedures regulating the disposal of hazardous materials may also be required if they are not already provided for in the existing legal framework.

Sample provision 27 addresses falsified medical products and ancillary equipment differently. This is because various disposal procedures may be appropriate for ancillary equipment and, unlike in the case of falsified medical products themselves, the donation or reuse of ancillary equipment may be appropriate in some circumstances.

Chapter VI.

PROSECUTION OF OFFENCES

Combating falsified medical product-related crime requires not only the establishment of substantive criminal offences but also effective criminal procedures. In the prosecution of such offences, prosecutors and judges should keep in mind the potential consequences of falsified medical product-related crime to public health, which may include loss of confidence in the public health system or the medical product supply chain, increases in the number of victims and negative financial impacts on victims, hospitals and industries. Where falsified medical products have entered the supply chain, there will inevitably be a need for close coordination between regulatory authorities, investigators, the affected industry and any identified victims. Prosecutors should expect that cases concerning falsified medical product-related crime will involve long investigations to identify networks and offenders and may garner attention from the media. Prosecutors should be prepared to deal with the media in a way that does not jeopardize any ongoing investigation or prosecution. Even if no victims are identified, prosecutors should give such crimes high priority, seek penalties commensurate with not only their actual consequences but also with the harm they could have caused or the impact they could have made, and aggressively seek to trace and confiscate illicit proceeds derived from them.

In this chapter, some of the key procedural issues that may arise in the prosecution of offences covered by this Guide are briefly addressed. These include detention pending trial, prosecutorial discretion, alternatives to trial and issues relating to statutes of limitations.

Detention pending trial

Offenders cannot be brought to justice if they evade the jurisdiction of prosecuting and judicial authorities. Falsified medical product-related crime is sometimes committed by foreign nationals or persons who may otherwise be at risk of absconding. It is imperative that States take steps to prevent offenders from fleeing the country prior to trial or sentencing, within their constitutional and human rights frameworks. In some cases, an offender's level of flight risk may require that he or she be detained pending trial. In other cases, measures such as confiscation of an offender's passport may be sufficient to mitigate the flight risk.

Prosecutorial discretion

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. Plea bargaining can be a useful tool for prosecutors and can allow them to bring cases against high-level offenders by securing testimony from lower-level offenders. In other States, however, prosecutors do not exercise such discretion. Given the differences in legal traditions with respect to prosecutorial discretion, this Guide does not contain any recommended sample provisions relating to the subject. In States that do afford prosecutors discretion as to whether to initiate and continue prosecutions, there is a need to ensure consistency in prosecutorial decision-making regarding when to initiate, maintain or drop prosecutions and when to accept plea bargains. Where applicable, States should adopt appropriate measures to this effect.

There are a number of considerations that drafters should bear in mind when considering the issue of immunity from prosecution. In most countries where immunity from prosecution is granted to a person, the immunity is conditional or confined in some way. For example, there may be a requirement that the cooperation given should reflect honestly the views held by the person cooperating (even if the information supplied turns out to be incorrect) or a requirement that a link be identified between the crime for which the immunity is granted and the crime for which the suspect testifies. Different responses may be needed depending on the value of the suspect's evidence and its actual impact (for example, where the evidence prevents or stops a crime from occurring). Some countries allow for transactional immunity, on the condition that truthful and complete testimony is given. This should be regarded as distinct from mitigation of sentencing. Furthermore, States should not take measures such as granting or endorsing amnesties that would prevent accountability for international crimes or gross violations of human rights.

Further guidance on drafting provisions relating to leniency and immunity from prosecution can be found in the UNODC publication *Model Legislative Provisions against Organized Crime* (pages 98–100).

Alternatives to trial

In some jurisdictions, prosecutors may exercise discretion with regard to resolving cases through alternatives to trial, such as by means of deferred prosecution agreements, diversion programmes and other alternative forms of dispute resolution. In relation to falsified medical product-related crime, deferred prosecution agreements may be offered to defendants who agree to fulfil certain conditions such as paying compensation for or repairing damage caused.

Giving full consideration to the variety of legal traditions of States, no position is adopted in this Guide on prosecutorial discretion to conclude cases through alternatives to trial such as deferred prosecution agreements. For jurisdictions in which such alternatives to trial do exist, laws or guidelines regulating their use should prohibit or discourage agreements to close cases that solely involve monetary payments, in whatever form. Monetary payments from members of organized criminal groups or legal persons involved in falsified medical product-related crimes are at high risk of having an illicit origin. There is also a danger that such payments made under deferred prosecution agreements and other alternatives to trial will be simply absorbed by organized criminal groups as an operating cost of involvement in criminal activities, without having any deterrent effect on their criminal conduct.

Statute of limitations

In some jurisdictions, the commencement of a prosecution is limited by periods of time known as "limitation periods" under laws known as "statutes of limitations". States handle limitation periods in a number of different ways. In some jurisdictions, limitation periods do not apply to criminal offences. Article 11, paragraph 5, of the Organized Crime Convention requires States parties that do impose limitation periods on the prosecution of criminal offences to ensure that the limitation periods applying to offences covered by the Convention are sufficiently long, particularly where the alleged offender has deliberately sought to evade the administration of justice.[35] States should ensure that the legislative provisions implementing this obligation pursuant to the Organized Crime Convention also extend to the offences covered by this Guide. In some States, the counting of time elapsed within a limitation period can be suspended while evidence is gathered

[35] UNODC, *Legislative Guide for the Implementation of the United Nations Convention against Transnational Organized Crime and the Protocols Thereto*, p. 135.

from abroad. States should consider whether such a provision would be desirable in their legal system, taking into account the length of any limitation periods applicable to the offences covered by this Guide and the potential difficulties in gathering evidence from abroad. Sample provisions on limitation periods are available in the publication *Model Legislative Provisions against Organized Crime* (pages 101–103). Regardless of the approach it takes to limitation periods, each State should ensure that its prosecutorial process is sufficiently streamlined to bring prosecutions to trial in a timely fashion.

Photo credits: iStock/FotografiaBasica

Chapter VII.

NATIONAL AND INTERNATIONAL COOPERATION

Because the manufacture and distribution of and trade in falsified medical products is a global phenomenon, effectively combating falsified medical product-related crime requires efficient cooperation among competent authorities, at both the national and the international levels.

National cooperation

National cooperation among all relevant stakeholders, including those in industrial and commercial sectors, is crucial in any legal framework aiming to comprehensively address falsified medical product-related crime.

At the national level, cooperation should be based on a multidisciplinary and multisectoral approach. States are encouraged to provide for cooperation and the exchange of information among their competent authorities in order to effectively combat such crimes and prevent them from threatening public health. In this context, it should be noted that the involvement of health authorities in strategies to prevent and combat falsified medical product-related crime is essential for the effective protection of public health. Given the vast expertise of the commercial and industrial sectors that deal with medical products, facilitating the provision of assistance to competent authorities by those sectors should be considered as part of a comprehensive risk management strategy.[36]

In addition, the investigation of the offences described in this Guide may involve a number of different agencies within a single State, each with different roles, designations and investigatory powers. Investigations may also involve interactions with scientific authorities, accredited and specialized laboratories, industry stakeholders and civil society and private-sector organizations. The involvement of prosecutors or judicial authorities may also be required at the investigation stage, depending on the legal system and legislation of the particular State.

Given the potentially large number of government authorities that could be involved in carrying out prevention and disruption efforts, it is crucial that relevant legislation contain provisions establishing procedures and responsibilities for inter-agency cooperation. The Council of Europe's Single Points of Contact (SPOC)[37] network model can serve as inspiration for States on how to proceed in this regard. The SPOC model is already in use in several European countries.

[36] "Explanatory report to the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health".

[37] Developed by the Committee of Experts on Minimizing Public Health Risks posed by Falsification of Medical Products and Related Crimes. More information is available at www.edqm.eu/en/single-points-contact-spoc-network.

At the national level, countries may choose to assign responsibility for efficient cooperation and information exchange to any of the principal competent authorities, such as those concerned with health, law enforcement and customs, or to a group of such authorities or a separate body established at a high level.

In order to prevent and effectively combat crimes involving the falsification of medical products, States should take the necessary legislative and other measures to ensure the following:

(a) Cooperation and the exchange of information among the competent health, customs, police and other authorities (as well as, where appropriate, industry groups and private-sector organizations);

(b) That mechanisms for receiving and collecting information and data, at both the national and local levels and in collaboration with the private sector and civil society, are established or strengthened, in accordance with data-protection requirements, and that information and data obtained by competent health, customs, police and other authorities is made available for use in cooperation efforts among authorities;

(c) That persons, units or services in charge of cooperation and information exchange are trained for that purpose and are provided with adequate resources to fulfil their functions;

(d) The development and implementation of a national strategy to prevent and combat falsified medical product-related crime;[38]

(e) The establishment of educational and awareness-raising programmes concerning falsified medical products.

Example: Bulgaria—Drugs and Precursors Control Act

Article 11

The National Drug Council shall:

(1) Define and coordinate the national policy in the field of drugs and precursors through the adoption of a national strategy to combat the drug abuse and illicit traffic in drugs and precursors for a three-year period;

(2) Adopt national programmes to fight against drug abuse and illicit traffic in drugs and precursors;

(3) Submit to the Minister for Finance a draft budget for the enforcement of national policy in the said area;

(4) Submit to the Council of Ministers draft legislation relating to drugs and precursors;

(5) Give its opinion on draft instruments for conclusion of or accession to international treaties;

(6) Give its statement on the participation of the Republic of Bulgaria in international programmes aimed at combating the distribution, abuse of and illicit traffic in drugs and precursors, and shall control their enforcement;

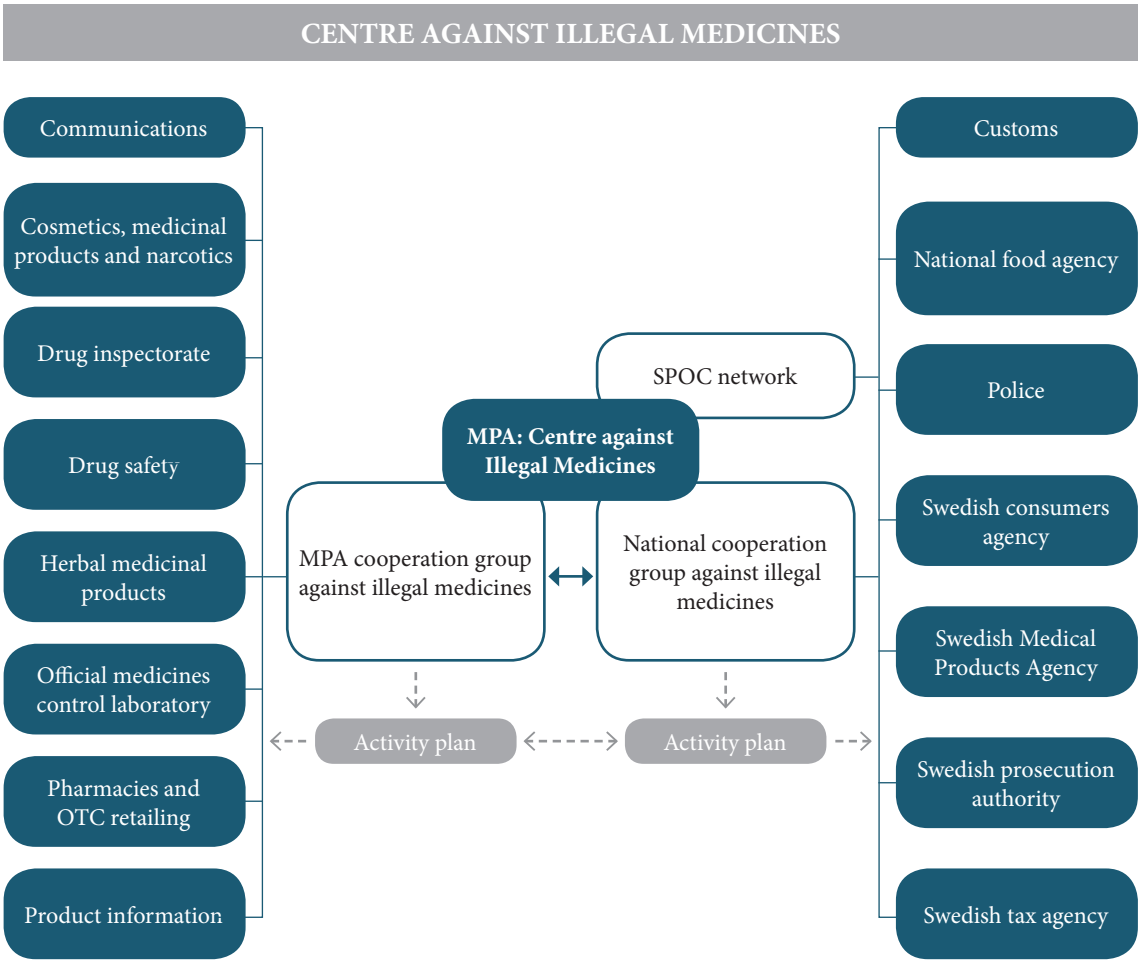
(7) Nominate and endorse the national coordinators on international programmes and projects in the field of drugs.

For another relevant example, see the Decision establishing the Committee for Eliminating Counterfeit Medicines and Illegal Health Services for Poverty Reduction of Cambodia, presented in chapter II.

A useful example of a cooperation network at the national level is the Swedish cooperation system, summarized in figure 2.

[38] See WHO, "A framework for national health policies, strategies and plans" (June 2010).

Figure 2. Organigram of the cooperation system of Sweden



Note: The boxes on the left represent departments of the Swedish Medical Products Agency (MPA) involved in work related to illegal medicines. The boxes on the right represent the relevant Swedish national authorities.

The MPA Centre against Illegal Medicines consists of a group of five experts working at MPA and is responsible for the administration of the two cooperation groups and the Single Points of Contact network, and also for other activities to counter illegal medicines, for example, supervision and communication. International cooperation and cooperation with other stakeholders are not included in the organigram.

International cooperation

Falsified medical product-related crime is a transnational phenomenon. Supply chains of illicitly acquired medical products extend around the globe. Effective international cooperation among agencies of different States is essential to preventing and combating this form of crime. International cooperation refers to the sharing of information, resources and personnel, and the provision of assistance to achieve common goals. Cooperation between States may be carried out formally or informally. Formal cooperation may be carried out within the framework of the Organized Crime Convention or other multilateral or bilateral treaties.

The Organized Crime Convention requires States to take, or consider taking, steps to implement a number of measures to enable and facilitate international cooperation. The measures include extradition (article 16), mutual legal assistance (article 18), joint investigations (article 19), law enforcement cooperation (article 27), transfer of sentenced persons (article 17) and transfer of criminal proceedings (article 21).

As part of their approach to international cooperation, States should designate a national contact point responsible for transmitting and receiving requests for information and/or cooperation in connection with the fight against falsified medical product-related crime.

Mutual legal assistance

Mutual legal assistance in criminal matters is a process by which States seek and provide assistance in gathering evidence for use in criminal cases.[39] For example, through mutual legal assistance, witnesses can be summoned, persons can be located, evidence can be produced and warrants can be issued in foreign jurisdictions.[40] Article 18 of the Organized Crime Convention establishes a framework for mutual legal assistance between States parties in relation to serious crimes and offences established under the Convention and its Protocols. Mutual legal assistance in relation to falsified medical product-related crime is also dealt with by the MEDICRIME Convention.[41]

States should ensure that domestic mutual legal assistance regimes established under bilateral and multilateral treaties apply to investigations, prosecutions and judicial proceedings in relation to the offences provided for in this Guide. Sample provision 28 provides an example of a provision that a State could include in legislation introduced pursuant to this Guide to this effect.

Sample provision 28: mutual legal assistance

The provisions on mutual legal assistance in [*insert name of national legislation on mutual legal assistance*] and in any bilateral or multilateral treaty to which [*insert name of the State*] is a party shall apply to investigations, prosecutions and judicial proceedings in relation to the offences established under this [*Act/Law/Chapter, etc.*].

An extensive examination of the Organized Crime Convention's framework for mutual legal assistance is beyond the scope of this Guide. Further information on this framework can be found in previous publications by UNODC.[42]

Extradition

Extradition refers to the formal process by which persons charged with offences in a foreign jurisdiction may be returned or transferred to that jurisdiction to stand trial for such charges or by which convicted persons may be returned or transferred to serve imposed sentences. Extradition is generally dealt with under bilateral or multilateral treaties. Arrangements for extradition are critical for the effective prosecution of offenders involved in falsified medical product-related crime, given its often transnational nature. Extradition is addressed in article 16 of the Organized Crime Convention. Article 16 of the Organized Crime Convention applies to cases where the offence for which extradition is sought is punishable under the domestic law of both the requesting and requested States. Extradition for falsified medical product-related crime is also dealt with in the MEDICRIME Convention.[43]

Extradition is a necessarily complex area of law. Most States have existing frameworks for extradition that rely on multilateral or bilateral treaties with other States. It would be neither possible nor desirable for this Guide to provide a comprehensive examination of legal issues relating to extradition or to sample provisions for establishing a complete legal framework for extradition. This Guide does, however, address some of the basic legal issues relating to extradition that a State will have to consider when introducing legislation to combat falsified medical product-related crime.

The key legal issue with respect to extradition for the purposes of this Guide is the designation of falsified medical product-related offences as extraditable offences. Some of the offences contained in this Guide may not be deemed by a State to be sufficiently serious to warrant extradition. The offence of possession of a falsified medical product set out in sample provision 8 may be one such offence. Whether an offence is considered sufficiently serious to potentially warrant extradition is a matter for each State to determine in accordance with its legal system and values. States should take care to ensure that offences potentially warranting extradition are considered as such under both their domestic law and bilateral and multilateral

[39] UNODC, *Manual on Mutual Legal Assistance and Extradition* (Vienna, 2012), p. 19.

[40] See also UNODC, *Legislative Guide for the Implementation of the United Nations Convention against Transnational Organized Crime*, chap. V, sect. B.

[41] Article 23, paragraph 3, of the MEDICRIME Convention; and its explanatory report, para. 133.

[42] See UNODC, *Manual on Mutual Legal Assistance and Extradition*; and *Legislative Guide for the Implementation of the United Nations Convention against Transnational Organized Crime*, chap. V, sect. B.

[43] Article 23, paragraph 3, of the MEDICRIME Convention; and its explanatory report, para. 133.

extradition treaties to which they are party. How this can be implemented will depend on the approach to designating extraditable offences taken by the individual State.

Two approaches have historically been used for designating offences as extraditable offences: the "list approach" and the "minimum penalty approach". Under the list approach, whether or not an offence is extraditable is determined by reference to a list of extraditable offences contained in the extradition treaty and implementing legislation. Under the minimum penalty approach, whether or not an offence is extraditable is determined by reference to the maximum penalty applicable to the offence. Any offence with a maximum penalty at or above the minimum threshold in the requested and requesting States (that is, the minimum penalty) is liable to be an extraditable offence.

States using the minimum penalty approach should ensure that falsified medical product-related offences covered in this Guide meet the minimum requirements for extradition under their bilateral and multilateral extradition treaties. States using the list approach should take steps to ensure that offences covered in this Guide are included in lists of extraditable offences in relevant bilateral and multilateral extradition treaties and in any relevant implementing legislation.[44]

States should also ensure that extradition-related legislation that applies to perpetrators of falsified medical product-related offences is consistent with the "extradite or prosecute" principle outlined in article 16, paragraph 10, of the Organized Crime Convention, which provides that, in relation to an offence covered by the Convention, a State party, where it refuses to extradite the alleged offender solely on the ground that he or she is one of its nationals, shall, at the request of a State party seeking extradition of an alleged offender, submit the case to its competent authorities for the purpose of prosecution.

Law enforcement cooperation

International cooperation among law enforcement agencies is addressed in article 27 of the Organized Crime Convention. Article 27, paragraph 1, requires States parties to closely cooperate with one another, consistent with their respective domestic legal and administrative systems, to enhance the effectiveness of law enforcement action to combat serious crime involving organized criminal groups and other offences covered by the Convention. In that regard, the particular measures required under article 27 include the establishment of channels of communication between competent authorities, agencies and services to facilitate the secure and rapid exchange of information relating to organized crime; the exchange of such information; cooperation with other States parties in investigating persons involved in, and property and proceeds derived from, organized crime; the provision of items and substances for analytical and investigative purposes; and the posting of liaison officers.

Sample provision 29 serves as a model for a legislative provision regarding such forms of international law enforcement cooperation; it is primarily relevant to those States in which a legal mandate is required for investigative agencies to cooperate with international counterparts. In other States, such a provision may not be necessary, but could be desirable for clarifying and enhancing existing mechanisms for law enforcement cooperation.

[44] It is worth noting that article 16, paragraph 4, of the Organized Crime Convention provides that, in the absence of a treaty and if a State normally insists on a treaty for extradition, the State may consider the Convention as the legal basis for extradition in respect of any offence to which article 16 applies. The negotiation and drafting of individual treaties can be a costly and time-consuming exercise that may not be within the financial means of all States. Thus, bilateral treaties, although very common and effective, may not be possible, even if the participating States desire to have them.

Sample provision 29: law enforcement cooperation

(1) The functions of [*insert names of designated investigative agencies and authorities*] include assisting and cooperating, consistent with domestic legal and administrative systems, with foreign law enforcement or other investigative agencies and authorities and competent international and regional organizations to prevent, identify and combat offences criminalized by this [*Act/Law/Chapter, etc.*].

(2) In accordance with [*insert relevant legislation on privacy, etc.*], the [*insert names of designated investigative agencies and authorities*] may cooperate with, and exchange personal or other information or data with, law enforcement or other investigative agencies and authorities of another State and, where relevant, competent international and regional organizations, for the purpose of:

(a) Preventing, identifying and combating offences under this [*Act/Law/Chapter, etc.*]; and

(b) Providing specimens, documents or records for analytical or investigative purposes.

(3) The [*insert names of designated investigative agencies and authorities*] may cooperate with law enforcement or other investigative agencies and authorities of another State, and competent international and regional organizations, with regard to:

(a) Seconding or exchanging personnel, including by making experts available, and the posting of liaison officers;

(b) Conducting joint investigations;

(c) Witness protection, including the relocation of protected witnesses; and

(d) Other administrative assistance.

(4) The [*insert names of designated investigative agencies and authorities*] may negotiate and conclude agreements with law enforcement or other investigative agencies and authorities of another State, and competent international and regional organizations, for the purpose of enhancing law enforcement cooperation to prevent, identify and combat the offences criminalized by this [*Act/Law/Chapter, etc.*].

Care also should be taken to ensure that the State's law relating to evidence is adequately adapted to deal with evidential issues that may arise from international cooperation in cases of falsified medical product-related crime. Among the possible issues are the admissibility of evidence obtained from foreign law enforcement agencies through mutual legal assistance and international cooperation and the transmission of evidence to forensic services located in foreign jurisdictions.

Joint investigations

Because falsified medical product-related crime often involves offences of a transnational nature, joint investigations carried out by law enforcement agencies of two or more States can sometimes prove to be more effective in dismantling organized criminal groups, especially in complex cases. Joint investigations are a form of law enforcement cooperation but involve a greater degree of cooperation than the law enforcement cooperation outlined above. Article 19 of the Organized Crime Convention requires that States parties consider concluding agreements or arrangements with other States to establish frameworks for conducting joint investigations. The article provides that, in the absence of such frameworks, joint investigations may be undertaken on a case-by-case basis, although this will depend on whether, in the absence of such a framework agreement, joint investigations are possible under the laws of individual States.

Sample provision 30 empowers the relevant law enforcement agency of a State to conclude arrangements with foreign law enforcement agencies and relevant international and regional organizations regarding the establishment of joint investigative bodies for the prevention, investigation and prosecution of offences to which this Guide applies in one or more States.

Sample provision 30: joint investigations

(1) This [*Provision/Article/Paragraph, etc.*] applies to the investigation of offences established under this [*Act/Law/Chapter, etc.*].

(2) The [*insert the name of the law enforcement authority*] may, in relation to matters that are the subject of investigations, prosecutions or judicial proceedings in one or more States, conclude agreements or arrangements with one or more foreign law enforcement agencies and/or relevant international and regional organizations regarding either or both of the following:

(a) The establishment of a joint investigative body; and

(b) The undertaking of joint investigations on a case-by-case basis.

(3) The [*insert name of the law enforcement authority*] may engage in a joint investigation that is the subject of an agreement or arrangement under [*paragraph 2*].

Member States may also elect to authorize, by legislation, the undertaking of joint investigations on a case-by-case basis, even in the absence of an agreement with a relevant foreign law enforcement agency or international or regional organization.

In its previous work, UNODC has identified several legal impediments relating to the establishment of joint investigations. These include a lack of a clear framework or specific legislation dealing with the establishment of joint investigations and a lack of clarity regarding both operational control and liability for the costs of joint investigations. Legislation providing for joint investigations in the context of falsified medical product-related crime must ensure that each of these issues is clearly addressed so that joint investigations can be carried out effectively.[45]

[45] See UNODC, *Model Legislative Provisions against Organized Crime*, pp. 87–93.

Photo credits: iStock/HRAUN

Chapter VIII.

PROTECTION OF AND ASSISTANCE TO WITNESSES AND VICTIMS

Both witnesses and victims, including victims who testify as witnesses, may require protection from intimidation and/or retaliation relating to the evidence they have given, might give or are due to give in criminal proceedings. Victims also require care relating to the effects of the falsified medical products that they have consumed or been exposed to. They may also be entitled to reparation for their injuries. These matters are further discussed below.

Safety of victims and witnesses

Ensuring the safety of victims and witnesses in giving evidence to the court is essential in the prosecution of offenders for offences to which this Guide applies. Without such assurance, it may be impossible to secure a conviction. Article 24 of the Organized Crime Convention deals with the protection of witnesses. Article 24, paragraph 1, provides that each State party shall take appropriate measures within its means to provide effective protection from potential retaliation or intimidation for witnesses in criminal proceedings who give testimony concerning offences covered by the Convention and, as appropriate, for their relatives and other persons close to them. Some specific measures that may be taken in accordance with article 24, paragraph 1, are set out in article 24, paragraph 2. Furthermore, article 25, paragraph 1, of the Convention provides that each State party shall take appropriate measures within its means to provide assistance and protection to victims of offences covered by the Convention, in particular in cases of threat of retaliation or intimidation. In order to ensure that, in cases involving falsified medical product-related crime, witnesses and victims are not dissuaded from testifying owing to the threat of intimidation or retaliation, provisions should be made for their protection.

It is important to also consider whether appropriate protections exist for other persons such as court staff members, interpreters, transcribers, court reporters, judges and jurors. In most countries, it is only in exceptional circumstances that judges, prosecutors, undercover agents, expert witnesses and interpreters are included in witness protection programmes. Intimidation or threats against their lives are sometimes considered to be an unavoidable pitfall in the performance of their duties. Although they may qualify for special police protection, job transfers or early retirement, measures for their protection nevertheless differ in nature from those intended for at-risk witnesses. States should ensure that adequate protection is available for such persons.

Further information on the protection of witnesses can be found in the UNODC publication entitled *Good Practices for the Protection of Witnesses in Criminal Proceedings Involving Organized Crime*.[46]

[46] UNODC, Vienna, 2008.

Provision of care to victims

As mentioned above, article 25, paragraph 1, of the Organized Crime Convention provides that each State party shall take appropriate measures within its means to provide assistance and protection to victims of offences covered by the Convention, in particular in cases of threat of retaliation or intimidation. Pursuant to article 25, paragraph 3, of the Convention, States parties shall, subject to their domestic laws, enable views and concerns of victims to be presented and considered at appropriate stages of criminal proceedings against offenders in a manner not prejudicial to the rights of the defence.

Sample provision 31 below establishes a number of measures for the protection of victims in the context of falsified medical product-related crime.

Sample provision 31: protection of victims

(1) The [*insert name of competent authority*] shall take appropriate measures to ensure that victims of offences to which this [*Act/Law/Chapter, etc.*] applies:

(a) Have access to information relevant to their injury and the medical product causing the injury as is necessary for their health;

(b) Are provided with assistance to facilitate their physical, psychological and social recovery;

(c) Receive information on their rights and the services at their disposal under [*insert name of legislation*]; and

(d) Receive information on the actions taken in consequence of their complaint.

(2) Victims of an offence to which this [*Act/Law/Chapter, etc.*] applies shall be given the opportunity to present their views and concerns, provide evidence and choose the means by which their views, needs and concerns are presented, whether directly or through an intermediary, in a manner consistent with [*insert applicable criminal procedural rules*] and without prejudice to the rights of the defence.

In some States, victims have the legal right to be heard or represented in criminal proceedings. In States where this is not the case, victims may still be able to be heard in court if they are called as a witness by the prosecutor.

Article 20 of the MEDICRIME Convention provides that, where a victim is entitled to be heard, such entitlement must be consistent with the procedural rules of domestic law. In such a case, the victim may choose to be heard either directly or indirectly. Being heard indirectly may involve the victim being spoken for by a governmental or non-governmental organization, an association or other party, where permitted by domestic law.

As referred to in paragraph 1 *(d)* of sample provision 31, the right to receive information on actions taken in consequence of a victim's complaint relates to the general progress of the investigation. It may not always be possible to provide victims with detailed information about aspects of the investigation or the legal proceedings against a defendant, as, in some situations, the proper handling of the case would be adversely affected by the disclosure of such information.

Compensation and restitution for victims

Article 25, paragraph 2, of the Organized Crime Convention provides that each State party shall establish appropriate procedures to provide access to compensation and restitution for victims of offences covered by the Convention. States may elect to introduce provisions establishing a system of compensation for victims of offences covered by this Guide. The term "compensation" is used in this Guide to refer to a legal mechanism by which persons suffering harm or injury as a result of a falsified medical product-related crime can receive recompense from offenders (or, in some circumstances, from the State) for such harm or injury. In some legal systems, other terms, such as "restitution" or "damages", may be used to refer to such a mechanism. In other legal systems, the terms "compensation" and "restitution" may refer to different mechanisms of redress for victims of crime. In some legal systems, payments of compensation may depend upon the conviction of the relevant offender. In others, compensation may be paid by the State and may be

independent of any conviction. Both mechanisms may exist in other States, such as where compensation from the State is available to victims in circumstances where, for example, the offender is not known or does not have the resources to compensate the victim.

Provisions on ensuring access to compensation need only be included in legislation to combat falsified medical product-related crime if general provisions for adequate compensation do not already exist under domestic law.

Further information on compensation of victims can be found in *Model Legislative Provisions against Organized Crime* (pages 115–117).[47]

Protected disclosure (whistle-blower protection)

Protected disclosure, commonly referred to as "whistle-blower protection", is a legal mechanism whereby an employee can disclose wrongdoing committed by an employer where there is a public interest in such disclosure, without being subjected to retaliation by the employer for making the disclosure.

Protected disclosures concern information disclosed by an employee in circumstances where the employee has a reasonable belief that an offence has been, is being or is likely to be committed, that a person has failed, is failing or is likely to fail to comply with his or her legal obligations or that a miscarriage of justice has occurred, or where the employee has information suggesting that any of these matters has been, is being or is likely to be concealed or destroyed.

Protective disclosure is particularly relevant to the disclosure of wrongdoing relating to the manufacture of falsified medical products. Such disclosure is necessary for the protection of public health. Protections afforded in relation to protected disclosures typically provide that the identity of the whistle-blower will not be disclosed without his or her consent, except in certain limited circumstances, such as where the disclosure is necessary to prevent serious risk to public health or the commission of a crime, or where it is required by law. Generally, in order to benefit from protective disclosure, a whistle-blower must honestly believe that the substance of the information or wrongdoing he or she is reporting is true.

Some States have laws that limit protections for, or indeed criminalize, the disclosure of certain types of sensitive information, such as information relating to matters of State security. Specific provisions intended to provide for protected disclosure in relation to falsified medical products should be drafted carefully to ensure that they are harmonized with other such laws. However, such specific provisions may be unnecessary where general provisions for protected disclosure already exist under domestic law.

The following national legislative provisions serve as examples of protected disclosure schemes; some of them apply generally, while others are specific to falsified medical products. Additional legislative guidance on protected disclosure can be found in the *Resource Guide on Good Practices in the Protection of Reporting Persons*.[48]

[47] See also the model legal provisions contained in the annex to the United Nations document entitled "Assistance, good practices and the comparison of national legislation in the areas of identifying and protecting victims of and witnesses to organized crime" (CTOC/COP/WG.2/2013/2).

[48] UNODC, Vienna, 2015.

Example: Ireland – Protected Disclosures Act (2014)

Section 5. Protected disclosures

(2) For the purposes of this Act, information is "relevant information" if:

(a) In the reasonable belief of the worker, it tends to show one or more relevant wrongdoings; and

(b) It came to the attention of the worker in connection with the worker's employment.

(3) The following matters are relevant wrongdoings for the purposes of this Act:

(a) That an offence has been, is being or is likely to be committed;

(b) That a person has failed, is failing or is likely to fail to comply with any legal obligation, other than one arising under the worker's contract of employment or other contract whereby the worker undertakes to do or perform personally any work or services;

[…]

(d) That the health or safety of any individual has been, is being or is likely to be endangered;

(e) That the environment has been, is being or is likely to be damaged,

[…]

(g) That an act or omission by or on behalf of a public body is oppressive, discriminatory or grossly negligent or constitutes gross mismanagement; or

(h) That information tending to show any matter falling within any of the preceding paragraphs has been, is being or is likely to be concealed or destroyed.

(4) For the purposes of subsection 3 it is immaterial whether a relevant wrongdoing occurred, occurs or would occur in the State or elsewhere and whether the law applying to it is that of the State or that of any other country or territory.

(5) A matter is not a relevant wrongdoing if it is a matter which it is the function of the worker or the worker's employer to detect, investigate or prosecute and does not consist of or involve an act or omission on the part of the employer.

[…]

(7) The motivation for making a disclosure is irrelevant to whether or not it is a protected disclosure.

(8) In proceedings involving an issue as to whether a disclosure is a protected disclosure, it shall be presumed, until the contrary is proved, that it is.

Section 16. Protection of identity of maker of protected disclosures

(1) A person to whom a protected disclosure is made, and any person to whom a protected disclosure is referred in the performance of that person's duties, shall not disclose to another person any information that might identify the person by whom the protected disclosure was made.

(2) Subsection 1 does not apply if:

(a) The person to whom the protected disclosure was made or referred shows that he or she took all reasonable steps to avoid so disclosing any such information;

(b) The person to whom the protected disclosure was made or referred reasonably believes that the person by whom the protected disclosure was made does not object to the disclosure of any such information;

(c) The person to whom the protected disclosure was made or referred reasonably believes that disclosing any such information is necessary for:

(i) The effective investigation of the relevant wrongdoing concerned;

(ii) The prevention of serious risk to the security of the State, public health, public safety or the environment; or

(iii) The prevention of crime or prosecution of a criminal offence; or

(d) The disclosure is otherwise necessary in the public interest or is required by law.

(3) A failure to comply with subsection 1 is actionable by the person by whom the protected disclosure was made if that person suffers any loss by reason of the failure to comply.

Example: United Kingdom of Great Britain and Northern Ireland – Employment Rights Act 1996

Section 47B. Protected disclosures

(1) A worker has the right not to be subjected to any detriment by any act, or any deliberate failure to act, by his employer done on the ground that the worker has made a protected disclosure.

Example: India – Reward scheme for whistle-blowers in the fight against the menace of spurious or fake drugs, cosmetics and medical devices of the Ministry of Health and Family Welfare

(8) The salient features of the aforesaid reward scheme are as follows:

(i) The reward scheme shall be applicable for whistle-blowers in the area of drugs, cosmetics and medical devices.

(ii) Reward is to be given to the whistle-blowers, i.e., the informers/officials only when there is a confirmation of the seizure of spurious, adulterated and misbranded drugs, cosmetics and medical devices by the designated officers of the CDSCO.

[…]

(xiii) Drug Controller General (India) along with other officials will be the nodal authority who will, inter alia, oversee the functioning of the reward scheme as proposed herein above.

(xiv) The zonal and subzonal officers of the CDSCO will act as the nodal officer to whom the whistle-blower/informer can provide the information about the manufacture/movement of spurious/adulterated drugs.

(xv) The identity of the whistle-blower/informer will be kept secret and will be known only to the concerned zonal and subzonal officers of the CDSCO, the DCG(I) and the Director General Health Services. It will be the responsibility of the concerned officials to keep the details of the whistle-blower/informer secret.

(xvi) The identity of the whistle-blower/informer will not be disclosed to the committee.

Note: "CDSCO" stands for the Central Drug Standards and Control Organization.

UNODC
United Nations Office on Drugs and Crime

Vienna International Centre, P.O. Box 500, 1400 Vienna, Austria
Tel.: (+43-1) 26060-0, Fax: (+43-1) 263-3389, www.unodc.org

V.19-00741