**UNODC**

**DRAFT MODEL LEGISLATIVE PROVISIONS**

**ON**

**FRAUDULENT MEDICAL PRODUCTS**

**WORKING DOCUMENT**

Draft as of 17 November 2014

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**Introduction**

These model legislative provisions on fraudulent medical products follow from the mandate by the Commission on Crime Prevention and Criminal Justice (CCPCJ) in its Resolution 20/6[[1]](#footnote-1) on fraudulent medicines at its 20th session in 2011[[2]](#footnote-2) to the United Nations Office of Drugs and Crime (UNODC).

Vulnerabilities in the area of medicines legal and regulatory framework were recognised by the CCPCJ. Organized criminal groups were able to capitalize on capacity deficiencies in this framework of medicines regulation and enforcement. It recognized the attractiveness of this area of crime to criminals due to the comparatively low risk of detection and prosecution and the potential rewards without regard to human or public health or other detriment to victims. With this background, CCPCJ requested UNODC to assist Member States in building capacity to disrupt and dismantle the organized criminal networks responsible for the production, distribution and sale of and trafficking in fraudulent medicines. It further requested UNODC to better utilize the experiences, technical expertise and resources of other UN and international organizations, such as The World Health Organization (WHO), World Customs Organization (WCO), the International Criminal Police Organization (Interpol) and the European Police Office, as well as other parties to create synergies with interested partners.

CCPCJ expressed concern that the issue of fraudulent medicines has not been well addressed, with the exception of the Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health (Medicrime Convention). It recognised that the United Nations Convention against Transnational Organized Crime[[3]](#footnote-3) had a part to play in supporting combating the trafficking, including their manufacture and distribution, of fraudulent medicines through international cooperation, mutual legal assistance, extradition and the recovery of the proceeds of crime. This Convention against Transnational Organized Crime provided UNODC with a mandate to address the criminality of trafficking in fraudulent medicines. This includes the criminal justice system as well as the regulatory system.

UNODC has approached this matter using the term ‘fraudulent medicines’ as contained in Resolution 20/6. As the criminals’ fraudulent activity can exploit medical devices as well as medicines UNODC has sought to minimize this risk to public health by including within the scope of these model legislative provisions three components termed as medical products: medicines, including active substances and excipients; medical devices, including accessories intended to be used with the medical devices, and parts and materials designated for use in medical devices; and investigational medicines.

The term fraudulent medical product is not in universal use. Also used are the terms falsified medicines (Falsified Medicines Directive)[[4]](#footnote-4), counterfeit medical products (Medicrime Convention)[[5]](#footnote-5) and Substandard/spurious/falsely-labelled/falsified/counterfeit (WHO MSM)[[6]](#footnote-6). The term fraudulent medical product is similar in meaning to the Medicrime Convention meaning and the Falsified Medicines Directive meaning. WHO’s Member State Mechanism on SSFFC medical product does not apply any meaning, but utilizes actions, activities and behaviours to explain the characteristics of what SSFFC medical products are. The characteristics of the phenomenon are considered to approximate with the terms used in these model legislative provisions. The approach in these model legislative provisions, though using terms to provide context, is to allow for each Member State to insert its own term or meaning in place of fraudulent medical product. This is important in the context of encouraging Member States to build their capacities to combat fraudulent medical products, protect public health and to be compatible with the existing legislative framework within Member States.

The model legislative provisions on falsified medicines build on previous legislative instruments and draft principles for model legislation by international and regional organizations and bodies including the following:

 Untied Nations Convention against Transnational Organized Crime (2004)

The Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health and similar crimes (Medicrime Convention) (2011)

Directive 2011/62/EU of the Parliament and of the Council of 08 June 2008 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, regarding the prevention of the entry into the legal supply chain of falsified medicinal products (The Falsified Medicines Directive) (2011)

The World Health Organization’s International Medical Products Anti-Counterfeiting Task Force (IMPACT) Draft Principles and Elements for National Legislation against Counterfeit Medical Products (2007)[[7]](#footnote-7)

As noted by CCPCJ, there have been relatively few legislative initiatives in this field. It is therefore imperative that initiatives cooperate and collaborate to combat fraudulent medical products, in particular the organized criminal activity that facilitate these fraudulent medical products reaching vulnerable patients. While there is scope for experts and Member States to have divergent views on what on how to describe a fraudulent medical product, action to improve the ability of Member States to build capacity in this area is essential. The optimum use synergies between agencies will best protect and maximize the value gained from scarce resources in this area. It is hoped that these model legislative provisions will support Member States to introduce domestic legislation in this field to protect public health and combat organized crime in their States in the widest sense possible.

**UNODC**

**DRAFT MODEL LEGISLATIVE PROVISIONS**

**ON**

**FRAUDULENT MEDICAL PRODUCTS**

**Chapter I. General Provisions**

**Article 1: Objective of the model legislative provisions**

1. These model legislative provisions are intended to [support implementation] [complement] the United Nations Convention against Transnational Organized Crime
2. The purposes of these provisions are to:
	1. protect public health
	2. provide for the criminalization of certain acts
	3. prevent and combat fraudulent medical product crime
	4. support the integrity of the medical product supply system
	5. protect the right of victims of offences contained in these model legislative provisions
	6. Promote and facilitate national and international cooperation in order to meet these objectives consistent with [fundamental human rights and the rule of law] [international legal obligations, including human rights]

**Commentary**

The primary objective of these model legislative provisions is the protection of life and the prevention from harm. Give the known involvement of organised crime and the transnational nature of fraudulent medical product crime, it draws on the Convention against Transnational Organised Crime objectives and ensures that, with due regard to the existing domestic and international legislation and agreements, certain acts involving organized crime are criminalized. It provides for the criminalization of certain acts in articles 7-14 that create a risk to public health and threaten the integrity of the medical product supply chain. These model legislative provisions facilitate national and international cooperation to meet its objectives and be consistent with applicable human rights obligations

**Article 2. Scope of application**

These model legislative provisions shall apply to the protection public health and combating fraudulent medical product crime:

1. Where offences involve medical products, whether generic or not, including active substances and excipients, accessories designated to be used together with medical devices and parts and materials designated to be used in the production of medical devices

**Article3. Definitions and use of terms**

 In these provisions:

a. “Controlled Delivery” shall mean the technique of allowing illicit or suspect consignment of medical products, documentation or other ancillary equipment mentioned in Article 13 of these model legislative provisions, to pass within, out of, through or into the territory of [insert name of State] or other States, with the knowledge and under the supervision of [insert the name of the authorities designated for granting authorisation] with a view to the investigation of an offence and the identification of persons involved in offences that these model legislative provisions apply to.

**Commentary**

*Source:* *Organised Crime Convention, Article 2, paragraph (i)*

b. “Competent Authority” means the governmental authority designated to perform the designated functions for the regulation of medicines, medical devices and investigational medicines

**Commentary**

There is no standard definition for competent authority. A review of legislation defining this term refers to a governmental authority that is designated the particular functions under the particular legislation. There may be more than one competent authority involved with fraudulent medical products as in some States the functions are split between medicines and medical device competent authorities.

c. Documents include, whether physical or digital, any document that can travel with, in advance of or following the movement of the medical product for the purpose supporting the holding out of legitimacy of that product. For the purpose of this model legislation it shall also include packaging, patient information leaflets, invoices and delivery dockets, Customs related documents for importation and exportation, and sales documentation

d. Fraudulent medical product means any medical product with a false representation of:

(1) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;

(2) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or

(3) its history, including the records and documents relating to the distribution channels used.

**Commentary**

There is discrepancy over the use of the term counterfeit which WHO had used until 2011. The WHO Member State Mechanism uses the term Substandard/falsely-labelled/falsified/counterfeit (SSFFC)[[8]](#footnote-8), but does not have any definition for the term. Instead it concentrates on identifying the actions, activities and behaviours that result in SSFFC medical products. Different regions and countries have adopted various term, which are reflected in the WHO term, but none have adopted SSFFC as a term. Instead, a number have adopted similar definitions or ones encompassing the same meaning while using different terms. The Medicrime Convention[[9]](#footnote-9) has a similar definition to the above, except that ‘history’ in included in ‘source and the term ‘counterfeit’ is used rather than ‘fraudulent. The EU’s Falsified Medicines Directive[[10]](#footnote-10) uses the same meaning as included in these model legislative provisions. Whatever a State wishes to use as a term to describe this phenomenon, the meaning is likely to be similar to that used here. States may wish to insert their own term and meaning in place of those used in these model legislative provisions.

One of the issues arising regarding the manufacture of fraudulent medicines is whether to provide a separate definition and offence for an intentionally manufactured substandard medicine. This would capture intentional, and therefore fraudulent, manufacture by those manufacturers who are authorised/licensed/registered by their competent authority to manufacture medicines to a particular specification. The falsification of an authorised/licensed medicines at its production stage raises significant threats to patients and public health as it may not treat the disease or illness and may facilitate resistance to the medicine when administered in its correct dose. Those manufacturers commit a fraudulent act. However, as the deliberate manufacture of a medicine to falsified strength falls within the meaning of fraudulent medical products in that it is a false representation as to its identity. Therefore, it would be inappropriate to have two separate offences that have the same meaning in the one model legislative provisions. It should also be noted that a substandard medicine may not be a fraudulent one, but a fraudulent medicines will always be a substandard one.

e. Intention

**Commentary**

Source: *Organised Crime Convention, Article 5, paragraph 1 (a) (ii)*

This requires the Mens rea, or intent to defraud, which can be to make a gain or cause a loss to another, whether financial or otherwise. Intent is provided for in UNTOC Article 5(1) and inferred as provided for in 5(2) as the knowledge, intent, aim, purpose or agreement referred to in paragraph 1 (of Article 5- Criminalization of participation in an organized criminal group) that may be inferred from objective factual circumstances. An addition may be provided in domestic laws, where considered appropriate with the legal precedence, to allow for a rebuttal of this presumption

Example

Ireland’s, Criminal Justice (Theft and Fraud offences) Act 2001[[11]](#footnote-11), section 16(2), provides that “a person is reckless if he or she disregards a substantial risk that the property handled is stolen, and for those purposes “substantial risk” means a risk of such a nature and degree that, having regard to the circumstance in which the person acquired the property and the extent of the information then available to him or her, its disregard involves culpability of a high degree”.

Common Law jurisdictions consider gross negligence, criminal negligence and culpable negligence and reckless disregard as to the consequences of the action as evidence of intent. This is a matter for the domestic legal system to consider how it defines intent by reference to its existing statute laws or legal precedent, as appropriate

Consideration should be taken to ensure that offences do not require that the intent in committing the offence is for the purpose of causing harm. Objectively, causing harm is most likely to be a consequence of the manufacturing and trafficking a falsified medical product rather than its object. The offences in this model law are predicated upon fraudulent acts.

f. “Investigational medicinal product” means a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including a medicine that is already the subject of a marketing authorisation, but

 (1) is used, formulated or packaged in a way different from the form that is the subject of the authorisation,

(2) is used for an indication that is not included in the summary of product characteristics under the authorisation for the product, or

(3) is used to gain further information about the form of the product that is the subject of the authorisation

g. “Medical product” means medicines, medical devices and investigational medicines

h. “Medicines” means

 (1) any substance or combination of substances presented as having properties for treating or preventing disease in humans or animals

 (2) any substance or combination of substance which may be used in or administered to human being or animals either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis

 “Active substance” means any substance or mixture of substance that is designated to be used in the manufacture of a medicine, and that, when used in the production of a medicine, becomes an active ingredient of the medicine

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

**Commentary**

The terms investigational medicine and medicine are similar to the terms and meaning in the EU Directive[[12]](#footnote-12) on medicinal products. The additional reference to animals as well as to humans refers to the intention to include veterinary medicines in the scope of these model legislative provisions given the risk on human health as a consequent to animals in the food chain consuming fraudulent medicines.

Any alternative term and meaning for medicines may be inserted here to replace the above meaning in order to fit with the domestic legislative code

i. “Manufacture” means

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

(2)  as regards a medical device, any part of the process of producing the medical device, as well as parts or materials of such a device, including designing the device, the parts or materials, or of bringing the medical device, the parts or materials to their final state;

(3)  as regards an accessory, any part of the process of producing the accessory, including designing the accessory, or of bringing the accessory to its final state;

 j. “Medical Device” mean 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 beings for one or more of the specific medical purposes of:

1. diagnosis, prevention, monitoring, treatment or alleviation of disease,
2. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability, investigation, replacement or modification of the anatomy or of a physiological process or state,
3. control or support of conception,
4. disinfection or sterilisation of any of the above-mentioned products,

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

Accessories mean ‘accessory to a medical device’ means an article

which, whilst not being a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable or assist the device(s) to be used in accordance with its/their intended purpose(s);

Parts and Materials mean all parts and materials constructed and

designated to be used for medical devices and that are essential for the integrity thereof;

**Commentary**

The term medical device is similar in different States and may encompass the meanings provided in these model legislative provisions.

1. Medical Product shall mean a medicine, medical device and an

investigational medicinal product and be collectively described in these model legislative provisions as a medical product

1. Person means the natural or legal person

m. Serious offence means conduct constituting an offence punishable by a maximum deprivation of liberty of at least four years or a more serious penalty and includes the offence specified in Articles,7, 8, 9, 10, 12, 13, 16.

**Commentary**

*Source:*  United Nations Convention against Transnational organized crime. Article 2

n. Service providers mean Service Providersinvolved in the supply by electronic and distance selling includes the electronic payment industry, banking and money transfer services, transport and logistical delivery services, internet service providers, including registrars and registry of internet service providers, and domain name registrees

**Commentary**

This is intended to include the sales platforms that advertise fraudulent and illicit medical products to the trade or to the consumer, the suppliers of domain names that facilitate the distance sales of fraudulent medical products, the express and postal carriers of personal and commercial mail packages, the supplier of and processing of finance facilities that enable the distance sales of fraudulent medical products

o. “Trafficking” means acts on own behalf or for another, for gain or for free, the storing, transporting, dispatching, dispatching in transit, distributing, brokering, offering, keeping for offer, selling, supplying a fraudulent medical product or an authentic medicinal product diverted from its intended market using fraudulent documentation

p. Victim means any natural person suffering adverse physical or psychological effects as a result of having used a fraudulent medical product or a medical product manufactured, supplied or placed on the market without authorisation or without being in compliance with the conformity requirements as described in Article 8 (2).

**Commentary**

*Source:* Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, Moscow, 28.x.2011

q. Witness includes any person in possession of information relevant to the investigation, prosecution or adjudication of an offence to which these model provisions apply

**Commentary**

*Source:*  United Nations Convention against Transnational organized crime. Article 2

Domestic legislation may already have a suitable and functional definition of the term “witness”. The UNODC Good Practices for the Protection of Witnesses in Criminal Proceeding Involved in Organized Crime[[13]](#footnote-13) lists the function of a witness as a person in possession of information important to the judicial or criminal proceedings that is relevant, rather than his or her status or the form of testimony. Witness may be informants and others who participated in the criminality; victim-witnesses and other innocent bystanders and expert witnesses. They may also be persons who assist an investigation with information even if they do not participate in judicial or criminal proceedings.

**Chapter II. Coordination and prevention of fraudulent medical products**

**Article 4. Measures for the Prevention of fraudulent medical products**

1. The [relevant Minister] shall establish a medical product regulatory authority tasked with the
	1. development of national standards for safety and quality requirements to prevent fraudulent medical products being introduced on to the market of [name of State];
	2. development of a safe and controlled distribution system for medical products
	3. arrangements for the provision of training and education of healthcare professionals, persons involved in the supply chain of medical products, the regulatory authority, law enforcement and customs services in the identification, prevention and investigation of fraudulent medical products
	4. arrangements for the development and provision of awareness raising campaigns to the public on fraudulent medical products
	5. establish technical coordination and cooperation agreements between the medical product regulatory authority, law enforcement, customs services and other relevant authorities to facilitate the exchange of information and intelligence to combat the manufacture and trafficking of fraudulent medical products
2. The [relevant Minister] may provide for
	1. Designation of specific ports of entry to and exit from the State for the import and or export of medical products
	2. The conduct of inspections at the ports of entry and exit in paragraph a, including bonded warehouses and Customs free zones
3. The [relevant Minister] [competent authority] may provide for
	1. Conditions to be adhered to by a person in the manufacture, storage, transportation, and keeping for supply so as to prevent the theft or other form of fraudulent diversion
	2. The requirement of a person holding or controlling medical products in transit not to permit the medical products in transit to be diverted to a destination or consignee different to that of the original manifest for the goods in transit.
	3. Any person, who permits, arranges, facilitates or controls or any cognate words shall apply, the diversion of medical products in transit to a consignee or destination other than the original consignee or destination on the original manifest shall be designated as the exporter of the diverted medical products.

**Commentary**

Preventive measures are necessary in order to prevent the occurrence of fraudulent medical products and when they occur to mitigate their impact. This can be approached through a number of measures, inter alia, the provision of technical standards for the control of quality and safety of medical products and their distribution from the manufacturer to the consumer. This is to enable the deployment of a set of standard decided by the regulatory authorities for medical products in the State that aims to oversee technical activities in the distribution chain and be able to look back over the life of the product to know its provenance. This will work best when supported by adequate training and educational measures for healthcare professionals, law enforcement, customs and regulatory authority staffs in the identification and reporting of fraudulent medical products. Awareness raising campaigns for the public will support the consumer involvement in ensuring their safety and preventing fraudulent medical products being consumed.

The competent authorities should be able to inspect bonded warehouses and Customs free zones to ensure that all medical products being stored there retain their integrity and do not leak into the distribution system in the internal market of the State without first being duly imported in accordance with the law of the State.

The theft and fraudulent diversion of medical products is a problem and result in medical products being placed on markets in States contrary to these model legislative provisions. Certain actions are considered necessary to prevent this, including the requirement for those responsible for the safe custody of the medical products at the different stages in the life of the medical products to safeguard them against theft and fraudulent diversion. Any person who engages in conduct permitting the unauthorised diversion of medical products in transit to a different consignee or State of destination, other than to the original consignee or State of destination, should be considered to be the original exporter and all relevant provisions of these model legislative provisions should apply to that person.

**Article 5. Research, data collection and analysis**

The [Relevant Minister] shall provide for:

 (1) the collection of statistical and other data and information on issues related to fraudulent medical products

(2) the facilitation of research into the

a. causes, prevalence and impact of fraudulent medical products

b. the circumstances in which fraudulent medical product incidents occur

**Commentary:** Model legislative provisions against organised crime, Chapter II, Article 5 provide for research into organised crime. The requirements of Article 5 of these model laws may be assisted by the implementation of the Model legislative provisions against organised crime or satisfied by existing national arrangements.

**Chapter III. Offences**

**Article 6. Jurisdiction**

1. [National Courts] shall have jurisdiction to determine proceedings for offences to which these model legislative provisions apply when:
2. Committed [wholly or partly] within the territory of [insert name of State]; or
3. Committed 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
4. Committed by a [insert the name of State] national present in [insert the name of State] territory whose extradition is refused on grounds of nationality; or
5. [National Courts] shall have jurisdiction to determine proceedings for offences to which these model legislative provisions apply when:
6. The [victim/object of the crime] is a national [or permanent resident] [or habitual resident] of [insert name of State];
7. The offence is committed by a [insert name of State] national [or permanent resident] [or habitual resident0; or
8. The offence is committed outside the territory of [ insert name of State] with a view to the commission of an [serious] crime within the territory of [insert name of State]

**Section A. General Offences**

**Article 7. Manufacture of a fraudulent medical product**

A person who intentionally manufactures, imports or exports a fraudulent

1. Medicine, active substance or excipients
2. Medical device, part or material, or accessory
3. Investigational medicine

Commits an offence punishable by [insert penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties]

Member States may decide within the provisions of its domestic laws not to apply 7 b or c where this model law would be inconsistent with the domestic law relating to those particular products. However, in coming to this conclusion it should be borne in mind that the offence relates to the fraudulent activity and not merely one of trading to those products

**Commentary**

This offence includes the deliberate manufacture of a substandard medicine or a medical device that does not conform to the essential requirements by a natural or legal person who has been authorised by the State (Competent Authority or other designated body by the State) to manufacture medicines (and their ingredients and excipients), medical devices (and their parts and materials, and accessories), or investigational medicines. A substandard medicine is one that fails to reach the best practice standards set by the State. A substandard medical device is one that does not conform to the essential requirements in that it fails to reach the standard of design, manufacture and use such that it may cause a risk to the consumer. Such standards, and their description, may vary over time and from one region to another. The offence in Article 7 relates to the act of fraudulent manufacture and not the failure to reach best practice standards or conformity assessments. It criminalizes situations where the manufacturer, including the person who has the legal right to manufacture and market the product, intentionally manufactures that product to a standard different to the standard laid down by the State, but fraudulently holds it out as being the product, including its manufacture, ingredients and levels thereof, as authorised by the State.

 Some Member States may opt to include a separate and distinct offence for the intentional manufacture of a substandard medicine for the purpose of avoiding the criminalization of non-intentional manufacture of poor quality medicines, which would be negligence act in the law of Torts. The experts, while appreciating the concerns involved, did not agree that a separate offence was needed here. Those concerns may better be addressed by the education and training of manufacturers in reaching a best practice standard and an appreciation of the difference between substandard manufacture and fraudulent manufacture.

Article 6 does not include the manufacture of medical products that are substandard by reason of a lack of good manufacturing practice, the standard decided by the State, that is not intentional or done by gross negligence or reckless disregard as to the consequences. All fraudulent medical products are considered to be substandard, but not all substandard medical products are fraudulent. The Good Manufacturing Practice is a regulatory standard that is not a criminal law standard.

The offence includes all aspects in the process of manufacture and includes the adulteration of the product with undeclared and unauthorised ingredients and excipients. It shall also include the tampering of a medical product as this results in a different medical product than that authorised by the State. Criminal liability shall attach to the natural or legal person who tampers with the product and not with any manufacturer who manufactured the medical product in accordance with its authorisation.

Some countries may have provisions relating to medical devices and investigational medicines that do not facilitate their inclusion in this model law and accordingly may not wish to apply the provisions of this article of the model law. However, in coming to this conclusion it should be borne in mind that the offence catered for is one of fraudulent activity and not merely one of trading to those products

**Article 8. Distribution of a fraudulent medical product**

1. A person who intentionally trafficks a fraudulent
2. Medicine, active substance or excipients
3. Medical device, part or material, or accessory
4. Investigational medicine

Commits an offence punishable by [insert the penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties]

Member States may decide within the provisions of its domestic laws not to apply 8 (1) (a) or (c) where this model law would be inconsistent with the domestic law relating to those particular products

**Commentary**

Some countries may have provisions relating to medical devices and investigational medicines that do not facilitate their inclusion in this model law and accordingly may not wish to apply those aspects of the model law. However, in coming to this conclusion it should be borne in mind that the offence catered for is one of fraudulent activity and not merely one of trading to those products

1. A person who intentionally trafficks
2. An [ unauthorised] [unlicensed][unregistered] medicine
3. A medical device that does not [conform to the essential requirements] of that medical device

Commits an offence punishable by [insert the penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties]

It shall be a defence to (2) (a) where the importation, storing, transiting, keeping for supply, and, or supply is permitted by [insert the exempting provision of the State] of an [unauthorised][unlicensed][unregistered] medicine to the order of a [registered] medical practitioner or dentist for the treatment of one of his patients

**Article 9. Possession of a fraudulent medical product**

(1)A person who possess a

1. Medicine, active substance or excipients
2. Medical device, part or material, or accessory
3. Investigational medicine

Where it is intended or likely that the fraudulent medical product will be used in a manufacturing process or placed in the distribution system for the supply of those medical products by wholesale or retail supply commits an offence punishable by [insert the penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties]

1. The onus shall be on the person in possession of the fraudulent medical product to show that the possession was not in contravention of any provision of these model legislative provisions
2. The possession of a fraudulent medical product shall not be an offence where it has been authorised by [the competent authority or other authority designated to authorize research using medical products] for use by research institutions, official medicines control laboratories for
	1. research purposes connected with the protection of public health ;
	2. analytical purposes connected to the investigation and prosecution of offences contained in these model legislative provisions
3. It shall be a defense where the person can show that
	1. he or she did not intentionally possess the fraudulent medical product in contravention of these model legislative provisions or know that it was a fraudulent medical product;
	2. He or she possessed the fraudulent medical products for personal use

Member States may decide within the provisions of its domestic laws not to apply 9 b or c where this model law would be inconsistent with the domestic law relating to those particular products

**Commentary**

Some countries may have provisions relating to medical devices and investigational medicines that do not facilitate their inclusion in this model law and accordingly may not wish to apply those aspects of the model law. However, in coming to this conclusion it should be borne in mind that the offence catered for is one of fraudulent activity and not merely one of the trading of those products.

 As the offence in this article relates to possession where it is intended or likely that the fraudulent medical product will be used in a manufacturing process or placed in the distribution system for supply by wholesale or retail supply, it cannot be an offence where the possession was not for the manufacturing process or re-supply, such as for investigative purposes by law enforcement officers or other competent investigative authority under the State. Therefore, exemptions relating to such activities are not considered necessary to place in the model legislative provisions. Possession for personal consumption of a fraudulent medical product may create situations where some action may be taken while no offence will arise. The fraudulent medical product may be seized or detained as it would be considered to be a health risk.

**Article 10. Supply by electronic and distance selling**

 A person who supplies, or facilitates the supply by electronic or distance selling a

1. Medicine, active substance or excipients
2. Medical device, part or material, or accessory
3. Investigational medicine

to any person in any Member State where the electronic or distance sale process, including payment processing, of the medical product does not comply with the laws of that Member State, or a Member State included in the process of the trafficking of that medical product during the electronic or distance sale commits an offence punishable by [insert the penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties]

Member States may decide within the provisions of its domestic laws not to apply this to a medical device or investigational medicine where this model law would be inconsistent with the domestic law relating to those particular products. However, in coming to this conclusion it should be borne in mind that the offence catered for is one of fraudulent activity and not merely one of trading to those products

**Commentary**

This requires the Mens rea, or intent to defraud, which can be to make a gain or cause a loss to another, whether financial or otherwise. Intent is provided for in UNTOC Article 5(1) and inferred as provided for in 5(2) as the knowledge, intent, aim, purpose or agreement referred to in paragraph 1 (of Article 5- Criminalization of participation in an organized criminal group) that may be inferred from objective factual circumstances. An addition may be provided in domestic laws, where considered appropriate with the legal precedence, to allow for a rebuttal of this presumption

**Article 11. Offences by Service Providers involved in the supply by electronic and distance selling**

A person who intentionally provides services to any person who is supplying for free or for gain a fraudulent medical product where

1. It has been brought to the attention of the service provider by any person, or
2. There are reasonable grounds for the service provider to suspect or believe

That such service is being exploited by a person involved in the supply by electronic or distance trafficking of fraudulent medical products commits an offence punishable by [insert the penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties]

# Commentary

# This provision criminalizes service providers, such as internet service providers, domain name registrars, electronic payment services, distance selling services, online auction services and logistical facilities (including, but not limited to Post Box and express delivery services), who become or ought to become aware that their services are being exploited from a criminal purpose. Service providers may already have internal contractual regulations and agreements with their clients that govern this issue. ICANN (International Corporation for Assigned Names and Numbers) Uniform Domain Name Dispute Resolution Policy provides that by registering a domain name the person registering the domain name will not knowingly use the domain name in violation of any applicable laws or regulations. It is the registrant’s” responsibility to determine whether your domain name registration infringes or violates someone else’s rights”[[14]](#footnote-14). ICANN’s Registrar Accreditation Agreement rule 3.18 provides that the Registrar shall establish an abuse contact to receive reports of abuse, including reports of illegal activity, and shall take reasonable and prompt steps to investigate and respond appropriately to such reports[[15]](#footnote-15). Illegal activity is defined in rule 1.13 as “conduct involving use of a Registered Name sponsored by Registrar that is prohibited by applicable law and/or exploitation of Registrar's domain name resolution or registration services in furtherance of conduct involving the use of a Registered Name sponsored by Registrar that is prohibited by applicable law”. However, not all service providers actively pursue abusers for criminal purposes of their services. The provision may be dispensed with where the domestic laws do not require the service provider to have an affirmative duty, without specific knowledge, to investigate for potential illegal activity regarding the service. (see Tiffany Inc. v. eBay, Inc., 600 F.3d 93 (2d Cir. N.Y. 2010[[16]](#footnote-16)) <http://www.lexisnexis.com/legalnewsroom/intellectual-property/b/copyright-trademark-law-blog/archive/2010/06/30/free-download-opinion-tiffany-inc-v-ebay-inc-600-f-3d-93-2d-cir-n-y-2010.aspx> ) . In other words, in such jurisdictions the illegality has to be reported to the service provider or it has to have actual knowledge regarding the specific sale offering before expecting action by the service provider.

**Offences of Falsification of Documents, Equipment, Implements and Materials**

**Article 12. The making and use of fraudulent documentation**

1. A person who intentionally tampers with an authentic document or make a fraudulent document relating to a medical product that is authentic or fraudulent, and, or
2. A person who intentionally possess or use a fraudulent or tampered document relating to a medical product that is authentic or fraudulent

Commits an offence punishable by [insert the penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties]

**Article 13. Equipment, implements and materials**

A person who possesses, designs, imports, exports, procures, produces, sells, donates, keeps for supply or otherwise 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 may be used for the purpose of facilitating the fraudulent manufacture, distribution or supply of

1. A medicine, an active substance or an excipient
2. A medical device, parts or materials to be designated for use in medical devices, or an accessory
3. An investigational medicine

commits an offence punishable by [insert the penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties]

It shall a defence where the person took all reasonable steps to prevent any act above from being trafficked or used to facilitate the fraudulent manufacture, distribution or supply.

**Commentary**

Fraudulent documentation may be used to accompany fraudulent medical product or authentic medical products with the consequence that those products enter the supply chain.

Some countries may have provisions relating to medical devices and investigational medicines that do not facilitate their inclusion in this model law and accordingly may not wish to apply those aspects of the model law. However, in coming to this conclusion it should be borne in mind that the offence catered for is one of fraudulent activity and not merely one of trading of those products

Member States are encouraged to align such offences within the context of pre-existing domestic criminal, customs, product regulatory or other laws against fraud/forgery/false claims.

**Article 14. Failure to report**

A person who fails to report without unreasonable delay to the competent authority for medical products [for medicines and, or medical devices], or to the police services or to the customs service where he has actual knowledge or reasonable suspicion that

1. a medical product that he has been offered, possesses or supplied is fraudulent
2. any act in Articles 12 or 13 has been, is being, or about to be conducted

commits an offence punishable by [insert the penalty sufficient to take into account the gravity of the offence]

**Section B. Offences related to participation in an organised criminal group**

**Article 15. Conspiracy or Criminal association**

 **(Option 1). Conspiracy**

1. A person who agrees with one or more other persons to commit a serious crime [involving an organized criminal group] in order to obtain directly or indirectly, a financial or other material benefit, commits an offence punishable by [insert penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties].
2. [Only include 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.]

 **(Option 2). Criminal association**

1. A person who intentionally takes an active part in criminal activities of an organized criminal group, knowing either the aim or general activity of the organized criminal group, or its intention to commit the offences in these model laws, commits an offence punishable by [insert penalty sufficient to take into account the gravity of the offence].

(2) A person who intentionally takes an active part in [any other] activities of an organized criminal group in relation to these model laws:

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

3. The acts or omissions engaged in for the purpose of [paragraph 2] need not otherwise be illegal.

**Commentary**

The Convention provides for either subparagraph 1(a) (i) or (ii) of article 5, or both, to be implemented.

*Source: Organized Crime Convention, article 5, paragraph 5(a)(i). The elements of the offence specified in article 5, paragraph 1 (a)(i) are based on a conspiracy offence.*

As noted in the Legislative Guides:

The requirements of this offence include the intentional agreement with one or more other persons to commit a serious crime for a purpose related directly or indirectly to obtaining a financial or other material benefit.

This requirement criminalizes the mere agreement to commit serious crimes for the purpose of obtaining a financial or other material benefit. The physical elements (sometimes called the “actus reus”) and the mental elements (sometimes called the “mens rea” or “fault element”). In some legal systems, the concept of intention (as a mental element) has its ordinary meaning, in the sense that a person only needs to intend to do the action for that action to have been intentional. In other legal systems, intention implies an awareness of the unlawfulness of the act (the relevant concept is dolus malus).This is an issue that must be resolved by reference to local legal traditions.

**Article 16. Aiding, abetting, attempts, organizing or directing the manufacture, trafficking and supply of fraudulent medical products**

1. A person who intentionally organizes, directs, aides, abets, facilitates, counsels, procures the commission of the manufacture, trafficking and supply of falsified medicines commits an offence punishable by [insert the penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties]
2. [only where attempts is considered part of the national criminal law system].

A person who intentionally attempts the commission of the manufacture, trafficking and supply of fraudulent medical products commits and offence punishable by [insert the penalty sufficient to take into account the gravity of the offence and the requirements for extradition treaties]

**Article 17. Proof of intention**

For offences under this chapter, the knowledge, intention, aim, purpose or agreement referred to in each offence may be inferred from objective factual circumstances.

**Commentary**

*Source: Organized Crime Convention, article 5, paragraph 2*

In some legal systems, it may already be clear from existing national laws on evidence (or criminal procedure) that circumstantial evidence can be drawn upon to prove mental elements such as intention (from P 41/42)

**Section C. Offences related to obstruction of justice**

**Article18. Obstruction of justice**

A person who, in a proceeding in relation to any offence covered by these model legislative provisions, uses force, threats or intimidation or promises, offers or gives any undue gift, concession or other advantage to:

1. Induce false testimony;
2. Interfere in the giving testimony or production of evidence;
3. Or otherwise interfere with duties of law enforcement, prosecution or judicial authorities in the course of justice;

Commits and offence punishable by [insert the penalty sufficient to take into account the gravity of the offence]

**Section D. Penalties and sentencing considerations**

**Article 19. Penalties and sentencing considerations**

 (1) In sentencing a person convicted for an offence in Articles 7, 8, 9, 12 and 15 to which these model legislative provisions apply, a court may take into account the following circumstances

a. and may increase the penalty proportionately where:

1. Any previous convictions for [an offence covered under these model legislative provisions][or a serious offence identical to one covered under these model legislative provisions] in another [State];
2. The offence was committed by a person in the framework of organised crime
3. The offence caused the death or harm to the physical or mental health of the victim
4. The offence involved fraudulent activity in relation to medical products used to treat life-threatening conditions [insert here the list of life-threatening conditions as decided by the State or in accordance with a list stipulated by another stated organisation/body, such as the World Health Organisation]
5. The offence involved a medical product that was intended to prevent, diagnose or treat a communicable or infectious disease
6. The health of a large number of persons was affected by the commission of the offence
7. The offence was committed by using large scale, manufacture, distribution, including online promotion, and supply
8. The offence was committed in the framework of holding
	1. An [Authorisation][Licence][Registration][Certification] granted by the [insert the name of the State or Competent Authority] relating to the manufacture, distribution, wholesale, brokering, advertising, sale or supply
	2. A [licence][registration][certification] granted to a person in relation to professional practice in the fields of healthcare, life sciences, law or accountancy [insert any other type of professional body licence considered relevant in relation to the commission of any offence within the scope of this model legislation in [insert the name of the State]]

b. and may decrease the penalty proportionately where the person voluntarily cooperated by providing information or otherwise assisted law enforcement authorities

* 1. to prevent harm to persons that otherwise results from the commission of an offence [and, or]
	2. to investigate and prosecute other offences

to which these model legislative provisions apply,

(2). Upon conviction for an offence to which these model legislative provisions apply, in addition to any other penalty provided in these model legislative provisions or other enactment, the court can make an order in relation to any of the measures listed below:

1. Prohibiting the exercise, directly or indirectly, of one or more social, vocational or professional activities [permanently] [for a maximum period of[…] years, including with regard to holding a public office;
2. Judicial winding-up order for legal person
3. Exclusion from public bidding [contracts][and/or] from entitlement to public benefits or aid
4. [Temporary][permanent] disqualification from participation in public procurement;
5. [Temporary][permanent] disqualification from acting as a director of legal persons incorporated in [insert name of State]
6. [Temporary][permanent] disqualification from practice of other commercial activities [and/ or being the holder of an [Authorisation][Licence][Registration][Certification] to manufacture, distribute, wholesale, broker, place on the market or dispense a medical product [insert name of State], or other [authorisation][licence][registration] [certificate] issued by the competent]
7. [Temporary][permanent] disqualification from practice as a [healthcare practitioner][medical practitioner, dentist, pharmaceutical chemist, veterinary surgeon, nurse, or other health care professional] [supervised][regulated] by [insert the name of the State], lawyer or accountant
8. Publicizing the decision;
9. Any other non-custodial measure as appropriate

**Commentary**

*Source: Organized Crime Convention articles 11,paragraph 1; 22; 26, paragraph 1 and 2; and 31, paragraph 2*

 *Medicrime Convention article 12, paragraph 1 and 2; 13; and 14*

Offences should be subject to penalties that take into account the grave nature of offences (Organized Crime Convention, art. 11, para.1; Medicrime Convention art. 12, para. 2). Sentences should be effective, proportionate and dissuasive. States may want to consider mitigating sentences or granting immunity from prosecution or leniency to those who cooperate with the authorities (Organized Crime Convention, art, 26, paras.2 and 3). This is optional and dependent on the State’s legal tradition[[17]](#footnote-17) .

 **Example**

 The Criminal Justice Act 2003 (United Kingdom), section 143 provides as follows:

1. In n 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 —
	1. The nature of the offence to which the conviction relates and its relevance to the current offence, and
	2. The time that has elapsed since the conviction.
2. Any reference in subsection (2) to a previous conviction is to be read as a reference to –
	1. a previous conviction in the United Kingdom;

(aa) a previous conviction by a court in another member State of the relevant offence under the law of that State

**Article 20. Measures imposed as an alternative to punishment**

Where a person has been has been convicted of an offence under articles 7, 8, 9, 12, 15 and where none of the circumstance in article 19 (2) a apply, or under any other article to which these model legislative provisions apply, a court may offer as an alternative a lesser custodial sentence and, or to non-custodial measures.

**Commentary**

Offences committed within the scope of these model legislative provisions may be committed under varying circumstances with varying risks being posed to public health. Where aggravating factors do not apply the punishment should be proportionate to the offence and the risk posed by the commission of that offence.

Guidance on alternatives to imprisonment are contained in the United Nations Standard Minimum Rules for Non-custodial Measures (the Tokyo Rules)[[18]](#footnote-18) 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),[[19]](#footnote-19) as well as in the UNODC handbooks on basic principles and promising practices on alternatives to imprisonmentand on strategies to reduce overcrowding in prisons.[[20]](#footnote-20)

While the Bangkok Rules specifically refer to substance abuse treatment programmes, they may be relevant to offenders under these model legislative provisions who may commit the offences within the scope of their substance abuse status. Some such substances have a controlled substances status while others are or of a non-controlled substance status in prescription medicines

In line with the Tokyo Rules, domestic law should provide for a wide range of non-custodial measures, from pre-trial to post-sentencing provisions.[[21]](#footnote-21) In particular, the authorities investigating or prosecuting criminal cases should be empowered to discharge the offender in appropriate circumstances and to impose non-custodial measures for minor cases.[[22]](#footnote-22) Non-custodial measures to be used by judicial authorities may include:[[23]](#footnote-23)

*(a)* Verbal sanctions, such as admonition, reprimand and warning;

*(b)* Conditional discharge;

*(c)* Status penalties;

*(d)* Economic sanctions and monetary penalties, such as fines and day fines;

*(e)* Confiscation or an expropriation order;

*(f)* Restitution to the victim or a compensation order;

*(g)* Suspended or deferred sentence;

*(h)* Probation and judicial supervision;

*(i)* A community service order;

*(j)* Referral to an attendance centre;

*(k)* House arrest;

*(l)* Any other mode of non-institutional treatment;

*(m*) Some combination of the measures listed above.

**Article 21. Liability of legal persons**

(1) Any legal person, other than the State, on whose behalf or for whose benefit an offence under these model legislative provisions has been committed by any natural person, acting either individually or as part of an organ of the legal person, who has a leading position within it, based on a power of representation of the legal person, an authority to take decisions on behalf of the legal person, or an authority to exercise control within the legal person, acting in such capacity, shall be punished by a fine of an amount equal to [indicate multiplier] times the fines specified for natural persons, irrespective of the conviction of those individuals as perpetrators of or accomplices to the offence.

(2) The following measures may be imposed on a legal person if there is criminal liability of directors, servants or agents acting within their authority:

1. If the activity of the legal person was entirely or predominantly used for the carrying out of criminal offences or if the legal person was created to commit an offence under these model legislative provisions, order that the legal person be dissolved;
2. Prohibit the exercise, whether directly or indirectly, of one or more social or professional activities [permanently] [for a maximum period of ...years]
3. Order the [temporary] [permanent] closure of the establishment, or one or more of the establishments, of the legal person that was used to commit the offences in question;
4. Make an order that the legal person be excluded from public bidding [and/or] from entitlement to public benefits or aid;
5. Order the disqualification of the legal person from participation in public procurement whether on a temporary or permanent basis;
6. [Temporary][permanent] disqualification from being the holder of an [Authorisation][Licence][Registration][Certification] to manufacture, distribute, wholesale, broker, place on the market or dispense a medical product [insert name of State], or other [authorisation][licence][registration] [certificate] issued by the competent], and, or the practice of other commercial activities
7. [Temporary][permanent] disqualification from conducting the practice of healthcare, law or accountancy
8. Disqualify the legal person from the creation of another legal person;
9. Order the legal person to publish the judgment by the court;
10. ([Make such further orders as it considers just].
11. The liability of any legal person does not preclude that of the natural person.

**Commentary**

*Source: United Nations Convention against Transnational Organized Crime and the Protocols Thereto, article 10*

Liability of legal persons may be covered through criminal, civil or administrative. Such liability needs to be without prejudice to the criminal liability of the natural persons who have committed the offences. It must be effective, proportionate and dissuasive criminal or non-criminal sanction, including monetary sanctions

Some offenders may seek to hide behind the veil of the legal person.

Complex corporate structures can effectively hide the true ownership, clients or particular transactions related to crimes ranging from smuggling to money-laundering and corrupt practices. Individual executives may reside outside the country where the offence was committed and responsibility for specific individuals may be difficult to prove. Thus, the view has been gaining ground that the only way to remove this instrument and shield of transnational organized crime is to introduce liability for legal entities. Criminal liability of a legal entity may also have a deterrent effect, partly because reputational damage can be very costly and partly because it may act as a catalyst for more effective management and supervisory structures to ensure compliance.[[24]](#footnote-24)

The Organized Crime Convention recognizes that States have different approaches to the issue of liability of legal persons and requires States to adopt measures as may be necessary, consistent with its legal principles, to ensure the liability of legal persons for participation in serious crimes involving organized criminal group.

**Example**

Under the French Penal Code, individuals are only criminally liable for their own conduct. However, there are also provisions on corporate liability:

Article 121-1

No one is criminally liable except for his 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 (Act no. 200-595 of 30 June 2000, article 2, Official Journal 1 July 2000)

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 to under 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**

The Swiss Criminal Code includes provisions on liability of corporations under criminal law:

Art. 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 organisation 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 260ter, 260quinquies, 305bis, 322ter,

322quinquies or 322septies paragraph 1 or is an offence under article 4a paragraph 1 letter a of the Federal Act of 19 Dec. 1986 on Unfair Competition, the undertaking shall be penalised irrespective of the criminal liability of any natural persons, provided the undertaking is responsible for failing to take all the reasonable organisational 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 organisational inadequacies and of the loss or damage caused, and based on the economic ability of the undertaking to pay the fine.

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[[25]](#footnote-25)

**Example**

German law imposes fines on legal entities and associations, in the following law:

The Administrative Offences Act(OwiG) of the Federal Republic of Germany

Section 30: Fine imposed on legal entities and associations

(1) If a person

1. acting in the capacity of an agency authorised to represent a legal entity, or as a member of such an agency,

2. as the board of an association not having legal capacity, or as a member of such a board,

3. as a partner of a commercial partnership authorised to representation, or

4. as the fully authorised representative or in a leading position as a procura holder, or as general agent of a legal entity or of an association as specified in Nos.2 or 3 has committed a criminal or administrative offence by means of which duties incumbent upon the

legal entity or the association have been violated, or the legal entity or the association has gained or was supposed to gain a profit, a fine may be imposed on the latter.

1. The fine shall be

1. up to one million Deutsche Mark in cases of a wilfully committed offence;

1. up to five hundred thousand Deutsche Mark in cases of a negligently committed offence.

In cases of an administrative offence the maximum amount of the fine shall be assessed in accordance with the maximum fine provided for the administrative offence in question.The second sentence shall also apply in cases of an offence which at the same time is both a criminal and an administrative offence if the maximum fine imposable for the administrative offence is in excess of the maximum fine in accordance with the first sentence

(3) Section 17 subsection 4 and section 18 shall apply, mutatis mutandis.

If criminal proceedings or administrative fine proceedings in respect of the criminal or administrative offence are not initiated, or if they are discontinued, or if no punishment is deemed appropriate, the fine may be assessed separately. It may be specified by means of a statute that the fine may also be assessed separately in further cases.

Separate assessment of a fine on the legal entity or association shall however be ruled out if the criminal or administrative offence cannot be prosecuted for legal reasons; section 33 subsection 1 second sentence shall remain unaffected.

(5) The assessment of a fine against the legal entity or association shall preclude forfeiture pursuant to sections 73 and 73a of the Criminal Code or Section 29a being ordered against it for the same act.

Section 130: Violation of obligatory supervision in firms and enterprises

(1) Whoever, as the owner of a firm or an enterprise, wilfully or negligently fails to take the supervisory measures required to prevent contravention of duties in the firm or the enterprise which concern the owner in this capacity, and the violation of which is punishable by a penalty or a fine, shall be deemed to have committed an administrative offence if such a contravention is committed which could have been prevented or made much more difficult by proper supervision. The required supervisory measures shall also comprise appointment, careful selection and surveillance of supervisory personnel.

(2) A firm or an enterprise in accordance with subsections 1 and 2 shall include a public enterprise.

(3) If the administrative offence is subject to punishment, it may be punished by a fine not exceeding one million Deutsche Mark. If the violation of duty is punishable by a fine, the maximum amount of the fine for a violation of obligatory supervision shall be dependent on the maximum amount of the fine provided for the violation of duty. The second sentence shall also apply in the event of a breach of duty which at the same time is punishable by a penalty and a fine if the maximum amount of the fine is in excess of the maximum amount in accordance with the first sentence.

**Example**

The Italian Law on liability of legal persons (Legislative Decree 231/2001 of 8 June 2001)[[26]](#footnote-26) provides as follows:

Art. 5 Liability of the agency

1. The agency is liable for crimes committed in its interest or to its advantage:

a) by persons having functions of representation, administration

or management of the agency or of an organizational unit thereof possessing financial and functional autonomy, and by

persons who exercise, also de facto, the management and control thereof

b)by persons subject to the management or supervision of one of the subjects as per letter a).

2. The agency is not answerable if the persons indicated in subsection 1 have acted in their own sole interest or that of third parties.

**Example**

The Israeli Penal Law 5737 - 1977 (6th Edition) provides as follows:

Article Four: Criminal Liability of Body Corporate Extent of Criminal Liability of a Body Corporate

23. (a) A body corporate shall bear criminal liability

(1) under section 22, if the offence was committed by a person in the course of the performance of his function in the body corporate;

(2) for an offence that requires proof of criminal intent or negligence, if – under the circumstances of the case and in the light of the position, authority and responsibility of the person in the management of the affairs of the body corporate – the act by which he committed the offence, his criminal intent or his negligence are to be deemed the act, the criminal intent or the negligence of the body corporate.

(b) If the offence was committed by way of omission, when the obligation to perform is directly imposed on the body corporate, then it is immaterial whether

 **Example**

 The Australian Therapeutic Goods Administration provides as follows:

 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 IV. Investigation**

 **Special Investigative Techniques**

The purpose of this chapter is to provide for special investigative techniques to permit law enforcement officers to gather information whilst not alerting the person being investigated of the fact. These provisions are intended to operate alongside and be compatible with other investigative techniques, laws in force and respect for privacy and human rights applicable in the jurisdiction of application. Where such special investigative techniques are already provided by legislation as part of existing framework to combat crime, it may not be necessary to provide for them in these model legislative provisions. However, the where the existing framework does not extend to the investigation to offences under these model legislative provisions, then they need to be considered for inclusion in a new framework to combat crime in the relevant State.

These special investigative techniques should be legislated for to prevent abuse, appropriate protection of both the person against whom they are targeted and the law enforcement officers deploying such techniques. They should be authorised by officials at an appropriate level, including judicial, prosecution and investigative person, depending on the level of personal intrusion involved for privacy and human rights. These authorities are confined to those involved in the decision, supervision and use of special investigative techniques[[27]](#footnote-27). The production in a prosecution of evidence obtained through the use of the special investigative techniques should be provided for.

These model legislative provisions do not mandate[[28]](#footnote-28) or recommend that such special investigative techniques be used in every instance. They should only be used where, as provided by the recommendations[[29]](#footnote-29):

* other less invasive measures cannot be used to guarantee the same level of evidence gathering
* The measure is proportionate to the seriousness of the offence being investigated and the object to be achieved. They should only be applied in relation to serious offences, as stipulated in these model legislative provisions
* Training in special investigative techniques and operational guidelines has been completed
* There has been prior authorisation, supervision during the investigation and ex post facto review.

The Model Legislative Provisions against Organized Crime[[30]](#footnote-30), list considerations in providing for national legislation the special investigative techniques. These include:

* Mechanism for approval of technique
* Threshold for grant of approval
* Conditions on use of technique
* Extent to which law enforcement officers using special investigative techniques are protected from civil and criminal liability
* Use of evidence obtained through a particular technique
* Extent to which that information can be disseminated
* Supervision, oversight and review mechanism
* Commentary:

Having regard to the global nature of crime involving medical products, there are a number of intermediaries between the manufacturer and the end supplier. It has been shown that this spans the entire globe. It is necessary to permit controlled deliveries to ensure that the persons supplying the fraudulent medical products into and within the legitimate supply chain and in the unregulated supply chain are identified to break the cycle without it being able to easily recover and continue in its activities. As much of these transactions take place over the internet the identities of suppliers is concealed. The use of assumed names by investigators is necessary to engage in communications and to uncover the true identities of the suppliers. The use of assumed identities is an invaluable technique for investigators to gather evidence without being detected so as to determine the extent and gravity of the fraudulent medical products being supplied, to stop the risks to human health and where possible, to build a prosecution case

**Article 22. Controlled delivery**

(1) For the purpose of this article, “controlled delivery” shall mean the technique of allowing illicit or suspect consignment of medical products falling within the provisions of Articles 7, 8 and 10, documentation falling within Article 12, or equipment, instruments and materials mentioned in Article 13 of these model legislative provisions, to pass within, out of, through or into the territory of [insert name of State] with the knowledge and under the supervision[insert the name of the authorities designated for granting authorisation] with a view to the investigation of an offence and the identification of persons involved in offences that these model legislative provisions apply to.

1. A controlled delivery is lawful if it has been authorised in accordance with this article
2. An official, or person assisting and official, who is engaged in conduct authorized in accordance with this article shall not be criminally or civilly liable for that conduct
3. A controlled deliver can be authorized by [insert the designated position holders, [such as the head of the law enforcement investigative body, prosecutor or investigative judge]
4. A law enforcement officer may apply to an authorizing officer for authority to conduct a controlled delivery on behalf of the law enforcement body, or a foreign law enforcement body
5. Foreign agents can undertake controlled deliveries only if authorization has been provided in accordance with paragraph 4 of this article
6. An application can be made by any means, but a written record should be made of every request and the subsequent decision, including refusals
7. The application must;
8. Provide sufficient information to allow the authorizing officer to decide whether or not to grant the application; and
9. State whether or not the matter has been the subject of a previous application
10. The authorizing officer can:
	1. Authorize the controlled delivery, unconditionally or subject to conditions, including the substitution or partial substitution of a consignment;
	2. Refuse the application
11. The authorizing officer must not approve the application unless satisfied on reasonable grounds, that:
	1. An offence to which these model legislative provision apply has been, is being or is likely to be committed;
	2. The nature and extent of the suspected criminal activity are such as to justify the conduct of a controlled operation;
	3. Any unlawful activity involved in conduct in the controlled delivery will be limited to the maximum extent possible consistent with conducting and effective controlled delivery;
	4. The operation will be conducted in a way that ensures that, to the maximum extent possible, any illicit goods involved in the controlled deliver will be under the control of a law enforcement officer at the end of the controlled delivery;
	5. The controlled delivery will not be conducted in such a way that a person is likely to be induced to commit an offence that the person would otherwise not have intended to commit; and
	6. Any conduct involved in the controlled delivery will not
		1. Seriously endanger the health or safety of any person
		2. Cause the death of, or serious injury to, any person
12. The [insert the name of the appropriate official/designate, such as the head of the investigative agency or authority] is to report annually to [Parliamentary Committee or other body designated by [insert name of State] about
	1. The number of authorizations sought for controlled deliveries
	2. The number that were granted; and
	3. The number of prosecutions where evidence or information obtained under an authorization provided by this article was used.

**Commentary:**

*Source: Organized Crime Convention, Chapter IV, Investigations, Article 2(c), (Controlled delivery)*

 *Model Legislative Provisions against Organized Crime, Article 13*

Article 2 (c) of the Convention provides the definition of Controlled delivery.

Article 11 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988 [[31]](#footnote-31) recognise the place for controlled deliveries in the illicit trafficking of narcotic drugs. The same logic now applies to fraudulent medical products having regard to the risks posed by them and the participation in the crime by organised crime elements. Article 13 of the Model Legislative Provisions against Organized Crime provide the conditions under which controlled deliveries are conducted and proceduralized. This is considered an invaluable technique to enable investigations to identify persons implicated in the commission of offences contained within these model legislative provisions. The inclusion of provisions for oversight is to facilitate a balance between the authorizing of controlled deliveries at any stage during the 24 hours for rapid actions and ensuring against abuse of this power.

**Article 23. Assumed identities**

(1) The acquisition and use of an assumed identity is lawful if it has been authorized in accordance with this article.

(2) Officials and individuals assisting them are not subject to civil or criminal liability for conduct that has been authorized in accordance with this article.

(3) A law enforcement officer from [insert name of designated agencies or authority] may apply to acquire or use an assumed identity for the purpose of investigating an offence covered by these model legislative provisions [on behalf of the law enforcement agency, other designated authority, or a foreign law enforcement agency

(4) Use or acquisition of an assumed identity can be authorized by:[Insert designated position holders such as the head of the law enforcement investigative body, prosecutor or investigative judge]

(5) An application must be made in writing and must include:

* + - * 1. The name of the applicant
				2. Details of the proposed assumed identity;
				3. Reasons for the need to acquire or use and assumed identity; and
				4. Details of the investigation or intelligence-gathering exercise for which the identity will be used (to the extent known).
1. After considering the application, the authorizing officer can:
	* + - 1. Authorize the use or acquisition of an assumed identity, unconditionally or subject to conditions; or
				2. Refuse the application
2. The authorizing officer may not approve the application unless satisfied on reasonable grounds that the assumed identity is necessary for one or more of the following reasons:
	* + - 1. To investigate an offence covered by these model legislative provisions that has been, is being or is likely to be committed; and
				2. Any administrative function in support of subparagraph a.
3. A copy of each authorization must be provided to [insert name of relevant oversight body]
4. A person acting under an authorization may request assistance from a person to acquire evidence of an assumed identity that has been approved under this article. Notwithstanding any other laws, a person may create or provide evidence of an assumed identity in response to a request under this article.
5. The Chief Officer of the [insert names of relevant agencies] must periodically review each authority granted by the [insert details of relevant designated position holders, such as the head of the law enforcement investigative body]
6. If, having reviewed an authority, the Chief Officer is of the view that the authority is no longer necessary, he or she must cancel the authority under [ insert paragraph]
7. If, having reviewed an authority, The Chief Officer is of the view that the authority is still necessary, he or she must record his or her opinion, and the reasons for it, in writing
8. Every[insert relevant number of] months the Chief Officer of [designated agency/authority] must report to [insert oversight body] on:
	* + - 1. The number of assumed identities currently authorized; and
				2. How recently each has been reviewed and the outcome of that review
9. The [head of the designated investigative agency or authority] is to report annually to [a Parliament Committee or other designated body] on:
	* + - 1. The number of assumed identities that were granted;
				2. The number that were revoked; and
				3. The number of prosecution where evidence or information obtained through the use of an assumed identity was use [or played a role in the investigation or prosecution]

**Article 24. Infiltration**

1. For the purpose of this article. Infiltration consists of surveillance of persons suspected of committing offences covered by these model legislative provisions, carried out by [specialized] designated officers acting as participants to those offences. To that end, designated officers are authorized to use an assumed identity. They cannot act in a way that instigates the commission of offences.
2. Infiltration is lawful only if it has been authorized in accordance with this article
3. Designated officers are authorized, without being criminally responsible;
	1. To acquire, detain, transport, copy or deliver medical product, documents, ancillary items and information coming from the commission of offences covered by these model legislative provisions or used to commit those offences;
	2. To make available legal and financial means, transport, storage, housing and communications needed for the perpetration of those offences;
	3. This immunity is extended to all persons officially requested [by the designated officer or by the investigator] to assist in the infiltration.
4. Infiltration shall be carried out only by specially trained, designated officers
5. Infiltration shall be carried out only under the responsibility of an investigator who shall supervise the designated officers. This investigator will establish a report on the infiltration operation
6. Authority for infiltration shall be sought from [insert designated position holders, such as the head of the investigative body, prosecutor or investigative judge]
7. The authorization must be requested by specialized unit/agency/authority and shall mention the suspected offences, name of the investigator in charge, the duration of the infiltration which cannot exceed [insert the period] months and shall state the reason why the infiltration is needed.
8. Authorization shall be granted only if[insert relevant conditions]
9. This authorization may be revoked at any time by [head of the investigative body, prosecutor or investigative judge]. At the end of the infiltration operation, the designated officer shall be give the time necessary for a safe withdrawal, which cannot exceed [ insert the period] months, [time during which he will still be authorized to use his assumed identity and to commit offences as stated in paragraph 2]

**Article 25. Electronic Surveillance**

1. For the purpose of this article, electronic surveillance includes the monitoring, interception, copying or manipulation of messages or signals transmitted by electronic means.
2. Electronic surveillance is lawful if it has been authorized in accordance with this article
3. Officials, individuals and legal persons assisting them are not subject to the civil or criminal liability for conduct that has been authorized in accordance with this article.
4. A [insert designation of appropriate senior official] from [insert the name of the designated agency/authority] may apply to [insert the name of the relevant designated authority or judicial authority] for a warrant to undertake electronic surveillance. The application must specify:
	1. The type of surveillance that is proposed;
	2. The purpose for which the surveillance is to be undertaken;
	3. The nature of the information that it is expected will be collected;
	4. The individuals or devices that are the target of the surveillance; and
	5. The measures that are in place to ensure that the privacy or other human rights of individuals is protected as far as is possible.
5. The [ relevant designated authority or investigative judge] may, at its discretion, issue a warrant authorizing the use of electronic surveillance
6. The warrant may include any conditions attaching to the authority
7. The warrant must specify the time period of validity up to a maximum of [insert the time period]. Warrants may be renewed on application.
8. In exercising discretion under paragraph 2, the [insert name of relevant designated authority] or [judge] shall consider whether:
	1. The authority sought is reasonable and proportionate in all of the circumstances:
	2. It ensures the human rights of all persons concerned, including the right to privacy, are protected as far as is possible in the circumstances.
9. A copy of each warrant must be provided to [insert name of oversight body].
10. The Chief Officer of the agency or authority may authorize in writing officers of other individuals to carry out activities under the warrant
11. An official may seek assistance from a person, including a provider of electronic communication services, to effect surveillance authorized.
12. Information obtained through electronic surveillance cannot be disseminated outside the [relevant designated law enforcement agency or authority] without the approval of the [Chief Officer of the designated agency or authority, or designate, or head of investigative body or designate]. Such approval may be given only for the purpose of:
	1. Preventing or prosecuting [serious crime contained in these model legislative provisions]
	2. Enhancing international cooperation on the prevention or prosecution of [serious crime contained in these model legislative provisions]; or
	3. Ensuring proper oversight of the activities of the agency.
13. The [Chief Officer of the designated agency or authority] is to report annually to [Parliamentary Committee, or other designated body] on:
	1. The number of surveillance warrants sought;
	2. The number that were granted; and
	3. The number of prosecutions where evidence or information obtained under a surveillance warrant was used.

**Commentary**

*Source: Organized Crime Convention, Special Investigation Techniques; article 20 and 20 (1)*

*Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health[[32]](#footnote-32) (Medicrime Convention), Chapter III, Article 16 – Criminal Investigations*

The Organized Crime Convention provides for the possibility of special investigative techniques where this is permitted by the basic principles of its domestic legal system, to include electronic and other forms of surveillance, undercover operations by the State in its territory for the purpose of effectively combating organized crime.

The Medicrime Convention provides for the allowing, in conformity with the principles of its domestic law, or the conduct of covert operation and other special investigative techniques. These are intended to include surveillance and covert infiltration operations. The balance between the investigative requirements and the protection of privacy are considered to be adhered to in relation to Article 6 of the European Convention on Human Rights and that the principle of proportionality applies[[33]](#footnote-33)

**Chapter V National and international cooperation and Extradition**

**Article 26. National cooperation**

1. Notwithstanding any other law, the [insert the names of the designated investigative agencies and authorities] may cooperate and provide and exchange personal or other information or data among themselves, for the purpose of
	1. preventing, identifying and combating the offences to which these model legislative provisions apply to protect public health;
	2. providing items, medical products, substances, documents or records for analytical or investigative purposes;
2. The [insert the names of the designated investigative agencies and authorities] may cooperate with regard to:
	1. Seconding or exchanging personnel, including by making experts available and the posting of liaison officers
	2. Conducting joint investigations
	3. Other administrative assistance
3. Notwithstanding any other law, the [insert the names of the designated investigative agencies and authorities] may cooperate with the commercial and industrial sectors and civil society as regards
	1. risk management in relation to offences to which these model legislative provisions apply
	2. receiving and collecting information and data, including through contact points at national or local levels
4. The [insert the names of the designated investigative agencies and authorities] shall provide individual or inter-agency training to persons, units or services in charge of cooperation and information exchanged for this purpose

**Article 27. International cooperation**

1. The functions of [insert the names of the 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 to which these model legislative provision apply to protect and public health
2. Notwithstanding any other law, the [insert the names of the designated investigative agencies and authorities] may cooperate and provide and exchange personal or other information or data with another foreign law enforcement or other investigative agencies and authorities of another State and, where relevant, and competent international and regional organizations, for the purpose of
	1. preventing, identifying and combating the offences to which these model legislative provisions apply to protect public health;
	2. providing items, medical products, substances, documents or records for analytical or investigative purposes;
3. The [insert the names of the designated investigative agencies and authorities] may cooperate with a foreign law enforcement or other investigative agencies and authorities of another State, or international and regional organizations, with regard to:
	1. Seconding or exchanging personnel, including by making experts available and the posting of liaison officers;
	2. Conducting joint investigations;
	3. Witness protection, including relocation of the protected witness;
	4. Other administrative assistance
4. The [insert the names of the designated investigative agencies and authorities] may negotiate and conclude agreements with foreign law enforcement or other investigative agencies and authorities of another State, or international and regional organizations for the purpose of enhancing law enforcement cooperation to prevent, identify and combat the offences to which these model legislative provision apply to protect public health.

**Commentary**

*Source: Organized Crime Convention, Article 27 – Law enforcement co-operation*

*Article 1 (a)requires the establishing or enhancing channels of communications between the competent authorities, agencies and services to facilitate the fast and secure exchange of information*

*Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health[[34]](#footnote-34) (Medicrime Convention), Chapter IV, Article 17 – National measures of co-operation and information exchange; Chapter VII – International co-operation*

**Article 28 Joint Investigations**

1. Where appropriate, the [insert the names of the designated investigative agencies and authorities] may conclude arrangements with a foreign law enforcement or other investigative agencies and authorities of another State, or international and regional organizations regarding the establishment of a joint investigative body.
2. In addition to the provision in paragraph 1, the[insert the names of the designated investigative agencies and authorities] may enter into agreements or arrangements with foreign law enforcement authorities and relevant international and regional organizations in relation t the prevention, investigation and prosecution of judicial proceedings for offences to which these model legislative provisions apply in one or more States.
3. Where such an agreement or arrangement has been made [ or on a case-by-case basis even without agreement], the[insert the names of the designated investigative agencies and authorities] may engage in joint [operations/investigations] with the relevant State or international or regional organization.

**Commentary**

*Source: Organized Crime Convention, Article 19- Joint Investigations*

*Article 19 [provides for the conclusion of bilateral or multilateral agreements or arrangement in relation to the establishment of joint investigative bodies. The State parties involved are required to respect the sovereignty of the State party in whose territory the investigation is taking place. This should be read in tandem with Article 27 of the Convention*

**Article 29. Extradition**

**Commentary**

*Source: Organized Crime Convention, Article 16- Extradition*

*Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health[[35]](#footnote-35) (Medicrime Convention), Chapter VII, Article 21 –– International co-operation*

 Having regard to the transnational nature of trafficking of fraudulent medical products, the necessity for extradition is paramount in ensuring that the effective prosecution of offenders takes place. Article 16 of the Organized Crime Convention provides for extradition where the offence for which extradition is sought is punishable under the domestic law of both the requesting State Party and requested State Party.

 The Medicrime Convention, article 21, paragraph 2, provides for the respecting of the relevant applicable international, regional and bilateral treaties on extradition and mutual legal assistance in criminal matters concerning offences established in accordance with that Convention.

 As most States will already have international, regional or bilateral treaties on extradition and as there is a Model Law on Extradition (2004)[[36]](#footnote-36), it is not intended to provide model legislative provisions on extradition in these model legislative provisions.

**Chapter VI. Prosecution of offences**

**Introductory Commentary**

This chapter includes provisions that are intended to address some of the procedural matters that arise in the prosecution of offences in these model legislative provisions, including discretion to prosecute and the granting of immunity in certain circumstances.

**Article 30. Exercise of discretion to prosecute**

**Commentary**

States may have domestic arrangements, either by laws or by administrative procedures to exercise discretion on whether to prosecute having due regard to ensure the effectiveness of law enforcement measures and to deter the commission of offences. This may involve pleas bargaining arrangements, where they apply. Prosecutorial discretion may not be a feature of other States. Therefore, no proposals for the inclusion of the exercise of discretion to prosecute are being included in these model legislative provisions.

 For States that have the prosecutorial discretion there is a need to have measures to provide consistency in decision making relating to charges, when to or not charge and to whom these apply. This will depend on the specific circumstances in the case and public policy

The Legislative Guides for the Implementation of the United Nations Convention against Transnational Organized Crime and the Protocols thereto, require that

“These States must make an effort to encourage the application of the law to the maximum extent possible in order to deter the commission of … offences covered by the Convention…”[[37]](#footnote-37)

**Alternative**

The Model Legislative provision against Organized Crime, Article 21, contains wording on the provision on **Leniency and immunity from prosecution**

**Article 21. Leniency and immunity from prosecution**

(1) Subject to the provision in paragraph 5, the [competent authority] may, in its discretion, [grant immunity from prosecution to] [decision not to prosecute] a person who provides useful information and proves to be effectively cooperating in the investigation or prosecution of an offence to which these model legislative provisions apply, or other offences revealed as a consequence of that cooperation

(2) This article applies irrespective of whether the cooperation given was in relation to an investigation or prosecution in [insert name of State] or in any other State

(3) Where an agreement is in place between [insert name of State] and another State, substantial cooperation can include cooperation provided to the investigative or prosecuting authorities in that State. The agreement between States may be entered into before or after the relevant prosecution is commenced.

(4) Where a person has voluntarily cooperated, providing useful information and assisting law enforcement agencies to investigate and, or prosecute other offences to which these model legislative provisions apply, a judge may decide to apply leniency in sentencing if the cooperation proved to b effective to identify or prove the participation of other participants of organized criminal group, to locate the living victims of crime or to recover, totally or partially, the product and proceeds of crime.

(5) In any case, immunity from prosecution shall not be granted to those defendants who organized or directed the commission of a serious crime involving and organized criminal group or were the leaders of the organized criminal group

Commentary on Article 21

States may wish to consider adding to paragraph 1 wording relating to information that leads to the prevention of harm or death to persons and not just information generally

**Article 31 Statute of Limitations**

(1) Subject to paragraph 2, a criminal proceedings to which these model legislative provisions apply is [subject to [insert the domestic law provision relating to the institution of proceeding for an offence] [time-barred [insert number of years]] after the commission of the offence

(2) [Where a suspect has deliberately sought to evade the administration of justice for an offence to which these model legislative provisions apply, the limitation period in paragraph 1 is suspended.]

**Commentary**

Some States have a statue of limitations while others do not. The United Nations Convention against Organized Crime and the Protocols thereto, article 11, paragraph 5 provide that States should, where they so wish, introduce longer periods where the suspect has evaded the administration of justice

**Example**

Finland’s Criminal Code 39/1189, chapter 8 (Statute of limitations), section 1 (297/2003)), provides as follows:

(1) The right to bring charges for an offence for which the most severe sentence is life imprisonment does not become time-barred. (212/2008)

(2) The right to bring charges is time-barred if charges have not been brought

(1) within twenty years, if the most severe penalty provided for the offence is fixed-term imprisonment for over eight years,

(2) within ten years, if the most severe penalty is imprisonment for more than two years and at most eight years,

(3) within five years, if the most severe penalty is imprisonment for over a year and at most two years, and

(4) within two years, if the most severe penalty is imprisonment for at most a year, or a fine.

(3) The most severe penalty refers to the maximum penalty provided for the offence in the applicable provision.

(4) The minimum period during which the right to bring charges for offences in office becomes time-barred, however, is five years

Example

Germany’s Criminal Code, chapter 5, section 78 (Limitation period), provides as follows:

(1) The imposition of punishment and measures (section 11(1) No 8) shall be excluded on expiry of the limitation period. Section 76a(2) 1st sentence No 1 remains unaffected.

(2) Felonies under section 211 (murder under specific aggravating circumstances) are not subject to the statute of limitations.

(3) To the extent that prosecution is subject to the statute of limitations, the limitation period shall be

1. thirty years in the case of offences punishable by imprisonment for life;

2. twenty years in the case of offences punishable by a maximum term of imprisonment of more than ten years;

3. ten years in the case of offences punishable by a maximum term of imprisonment of more than five years but no more than ten years;

4. five years in the case of offences punishable by a maximum term of imprisonment of more than one year but no more than five years;

5. three years in the case of other offences.

**Article 32. Seizure [Detention]**

Subject to the provisions of article 22 (controlled deliveries), in the event of any offence under these model legislative provisions, the fraudulent

* 1. medical product;
	2. documentation;

and any ancillary equipment, as enumerated in article 13, vehicle, vessel, craft or premises used or intended to be used in the manufacture, trafficking or promotion of fraudulent medical products, shall be seized immediately upon discovery.

**Commentary:**

The purpose of the seizures provided for in this article of the model legislative provisions is to preserve evidence. They have to be carried out immediately following discovery of the substances unless a controlled delivery operation has been decided upon. Consideration must be given to the destruction of fraudulent medical products and ancillary equipment quickly, with the possibility to keep samples for evidentiary purpose. This is to prevent the leakage and diversion of this evidence back onto the market. However, this will depend on the courts in the particular State due to requirements to preserve part or all of the evidence seized

**Article 33. Preparation and safe keeping of sealed containers**

 (1) a. Seized medical products shall be immediately placed in sealed containers

b. The sealed containers shall be prepared in such a manner as to prevent any fraudulent removal. Each container shall be numbered and shall bear on its wrapping or on a label incorporated in the sealed container a description of the detained medical product that it contains.

c. The sealed container shall contain

(a) the date and time on which the seized medical products were seized and by whom.

(b) the place where the medical products were found and where seized

(b) a description and quantity [and any other relevant features] of the medical product

(c) the signature of the person seizing the medical products

(d) [the signature of any person who took custody of the seized medical product from the seizing person and the date, time and location where this took place

d. The sealed containers shall be stored in appropriate conditions to preserve the seized medical product from contamination or degradation and to prevent interference or theft

(2) A contemporaneous report, as appropriate to the timing of the actions below, shall be drawn up on

(a) the fact of and the circumstances of the seizure, including the date, place and reasons for the discovery and seizure, quantity or volume seized

(b) the transfer of custody of the sealed containers, to include who took possession, the date, time and location of transfer and the purpose of transfer.

(c) the fact of the secure storage [and the circumstances of that storage, such as being within the control of the person to whom it was transferred]

(d) the condition of the sealed containers [and any labeling attached] that they were

- intact and that the container numbers correspond to any record of seizure containing the container numbers, or

- tampered with and including the extent of tampering, or

- been removed without authority or lost

**Article 34. Taking of samples**

(1) Samples from the sealed container may be taken for test, examination or analysis

(2) The person removing samples shall, subject to subsection 4,

 a. take the samples and divide into three equal parts

 b. place each part into separate sealed containers, and

 c. forthwith seal and mark each such container in such a manner as to identify it as part of the samples seized

d. seal the remaining original container and the remaining seized medical product in a new container and record the circumstance of the opening of the original sealed container and the subsequent sealing in a new container containing the original container with the remaining medical product

(3) Subject to subsection 4, where the person has complied with subsection 2, he or she shall

a. offer one of the sealed containers to the person from whom seized

b. retain one of the sealed containers as a controlled sample, and

c. forward, or cause to be forwarded, one of the sealed containers for test, examination or analysis of the sample concerned by the person mentioned in article 32, paragraph 1.a.

(4) Where the seized medical product is contained in a container and its division into parts pursuant to subsection 2 is, for whatever reason, not practicable, the person, who wishes to take samples of such medical product for the purposes of any tests, examination or analysis shall take possession of three such containers [belonging to the same batch], and each such container shall be deemed to be part of a sample for the purposes of subsection 2, and the provisions of subsections 2 and 3 shall apply thereto accordingly.

**Article 35 Expert Examination**

Where an expert test, examination or analysis is considered necessary to determine the nature and composition of the seized medical products, such test, examination or analysis shall be ordered and conducted without delay following the seizure in order to minimize the risk of degradation of the sample

**Commentary:**

The laws of many countries may require the results of a test, examination or analysis by an expert prior to admission of the results in evidence. This article provides for the secure seizure of the medical product, the taking of samples and provision of the samples for a controlled sample, for independent test, examination or analysis by the offender, where this is not prohibited by law, and for official analysis to state the result of the test, examination or analysis

**Example**

Irish law provides for the taking of the medical product, referred to as the relevant thing, division into three parts and analysis. Section 32 C, Irish Medicines Board Acts 1995-2006[[38]](#footnote-38) is similar to the above provisions in article 31 A-C

**Article 36. Certificate of result of test, examination or analysis**

 (1) In any proceedings for an offence under these model legislative provisions, a certificate signed by

a. [insert the relevant designation of the analyst or duly qualified person] of [insert the designated laboratory by the State for conducting this analysis], or

b. another analyst or duly qualified designated person employed or engaged by the [insert the designated laboratory in a. above], or

c. any analyst or duly qualified designated person appointed by [insert the appointing authority for conducting test, examination or analysis of medical products]

stating the result of any test, examination or analysis of a sample of the medical product, shall be evidence of the matters stated in the certificated unless the contrary is proved

1. In any proceedings for an offence under these model legislative provisions, the medical product, or package containing the medical product, that purports to bear the name of the manufacturer or importer of that medical product, or the person who placed that medical product on the market, shall, unless the contrary is proved, be evidence that the medical product was manufactured, imported, or placed on the market, as the case may be, by the person so named
2. In proceedings for an offence under this model legislation, the medical product, or a package containing the medical product, that bears a trademark shall, unless the contrary is proved, be evidence that the medical product was manufactured by the person who at the time of the alleged commission of the offence owned that trademark.
3. In this section, ‘trademark’ has the same meaning as it has in the [insert the legislative provisions on trademarks]

**Commentary**

This part is intended to provide for the provision of a certificate of analysis, test or examination report such that it is evidence of itself without the analyst having to attend the proceedings in court unless the certificate is challenged. Paragraph 1 a and b also provides for the State to nominate the laboratory or laboratories that may analyse, test or examine medical products and to produce a certificate of analysis, test or examination. Paragraph 1.c is intended to provide for the appointment by the State of an analyst in another laboratory, which includes a laboratory not in the State. This may be relevant to States that do not have a suitable laboratory and have to engage the services of an analytical, test or examination facility outside the State.

The provision relating to trademarks in 4 and 5 does not refer in any way to intellectual property rights issues. The provisions are intended to fix responsibility to the person whose trade mark is exhibited on the medical product unless that person can show that the particular product is fraudulently made by a another person and not by the trademark owner.

**Article 37. Forfeiture and destruction**

(1) If the destruction or disposal of the seized medical products and any ancillary equipment referred to in article 13, is not essential to any prosecution, they shall be destroyed or disposed of by judicial order and subject to 3., as the [insert the name of the competent authority or prosecution body] thinks fit;

(2) On conviction for an offence to which these model legislative provisions apply, in addition to any other penalty, a court may

a. order the seized medical products and any ancillary equipment referred to in article 13 to be forfeited to [insert the name of the competent authority or prosecution body] for destruction or, and subject to 3., other disposal as the [insert the name of the competent authority or prosecution body] thinks fit;

(b) Upon application made to it or on behalf of the [insert the name of the competent authority or prosecution body], order the person convicted of the offence to pay to the relevant person all or part of such destruction or disposal subject to such conditions, if any, as are specified in the order

(3) All fraudulent medical products shall be totally destroyed in the manner prescribed by [insert the legal provision pertaining to the destruction of a class of hazardous waste applicable to medical products of the class in the State] and shall not be the subject of a donation, sale or other supply to any other body for consumption or use, other than samples for further research for the prevention of crime or protection of public health by test, examination or analysis

**Article 38. Confiscation of the Proceeds of Crime**

*Source: UN Convention against Transnational Organized Crime, Articles 12, 13 and 14*

*Model Provisions on Money-Laundering, and Financing of Terrorism prepared by the United Nations Office on Drugs and Crime and the International Monetary Fund (2005 for civil laws systems)*

*Model Provisions on Money-Laundering, Terrorist Financing, Preventive Measures and Proceeds of Crime (for common law legal systems), prepared by the United Nations Office on Drugs and Crime, the Commonwealth Secretariat and the International Monetary Fund (2009)*

**Commentary**

Many States may have existing laws relating to the confiscation and seizure of the proceeds of crime. The UN Convention against Transnational Organized Crime, Article 12 requires States to adopt to adopt within their domestic legal systems measure necessary to enable confiscation of the (a) proceeds of crime derived from offences covered by the Convention or property the value of which corresponds to that of such proceeds; (b) property, equipment or other instrumentalities used in or destined for use in offences covered by the Convention. Article 13 refers to the necessary cooperation at international level to facilitate the confiscation of the proceeds of crime. Article 14 refers to the disposal of confiscated proceeds of crime or property in accordance with the State’s domestic law and administrative procedures.

It is not intended to create separate provisions in these model legislative provisions as the State may use existing provisions for this purpose or enact similar provisions having regard to the UN Convention against Transnational Organized Crime and the Model Provisions on Money Laundering, as referred to above. It is, however, important to ensure that the confiscation of the proceeds of crime, as they relate to offences committed in articles 7, 8, 9, 12, 15 in these model legislative provisions, be provided for.

**Article 39. Money Laundering**

**Commentary**

These model legislative provisions do not propose any model provision on money-laundering as model laws for money-laundering already exist: The UNODC/IMF Model Legislation on Money Laundering and Financing of Terrorism (2005, for civil law systems)[[39]](#footnote-39) and the UNODC/Commonwealth Secretariat/International Monetary Fund — Model Provisions on Money Laundering, Terrorist Financing, Preventive Measures and Proceeds of Crime (2009, for common law systems)[[40]](#footnote-40) contain detailed model legislation on laundering, confiscation and international cooperation in relation to the proceeds of crime, which may be usefully consulted at the time of drafting provisions on laundering.

The United Nations Convention against Transnational Organized Crime of 2004, article 7, also contains key provisions concerning the laundering of proceeds of crime. To ensure the effective suppression of money-laundering, and in particular to prevent problems concerning proof of the origin of unlawfully acquired property, it is most useful not to restrict their scope to proceeds of drug trafficking but to extend it to proceeds of crime in general.

In this context, it is not considered that separate provisions on money laundering of proceeds of crimes relating to these model legislative provisions should be included.

**Chapter VII. Protection of and assistance to victims and witnesses**

**Introductory Commentary**

Both victims and witnesses may require protection from intimidation and, or retaliation relating to the evidence they are due to give or have given in criminal proceedings. Victims may also be the witnesses. Therefore, the same provisions may be made to both parties, if they are different, relating to their protection in this regard

 Victims also require care relating the effects of the fraudulent medical products that they have consumed and, or been exposed to. They may require assistance in their standing as victims in the criminal investigation and in criminal proceedings against offenders. They may also be entitled to reparation for their injuries. ‘Victims’ has been defined as

‘“victims” means persons who, individually or collectively, have suffered harm, including physical or mental injury, emotional suffering, economic loss or substantial impairment of their fundamental rights, through acts or omissions that are in violation of criminal laws operative in Member States, including those laws proscribing the criminal abuse of power.[[41]](#footnote-41)

Victims in this context should be considered to be the natural person suffering harm to their physical or psychological wellbeing as a result of the commission of an offence to which these model legislative provisions apply.

 The Convention against Transnational Organized Crime, article 24, provides for two situations where witnesses may be provided with protection while being proportionate and with due regard to the rights of the accused as being innocent until proven guilty; the right to confront his or her accusers and the right to due process under domestic law and international conventions. The two situations provided by article 24 are

1. Establishing procedures for the physical protection of such persons, such as, to the extent necessary and feasible, relocating them and permitting, where appropriate, non-disclosure or limitations on the disclosure of information concerning the identity and whereabouts of such persons;
2. Providing evidentiary rules to permit witness testimony to be given in a manner that ensures the safety of the witness, such as permitting testimony to be given through the use of communications technology such as video links or other adequate means

More extreme measures may be necessary and are outlined in the Good Practices for the Protection of Witnesses in Criminal Proceedings involving Organized Crime (2008), p.1. This includes the resettlement of the witness under a new identity in a new, undisclosed place of residence in the same country or even abroad[[42]](#footnote-42). A model law on witness protection is currently under review by UNODC. Some States may have witness protection programmes and may utilize these in respect of these model legislative provisions.

**Article 40. Safety of Victims and Witnesses**

1. The [competent authority] shall take all appropriate measures to ensure that a victim or witness of an offence to whom these model legislative provisions apply, and his or her family, is provided adequate protection [before, during and after] proceedings if his or her safety is at risk, including measures to protect him or her from intimidation and retaliation by suspects, offenders and their associates.
2. The measures to which paragraph (1) applies may include
	1. Closing the court;
	2. Giving evidence from behind a screen or other barrier;
	3. Giving evidence via video link or other remote means;
	4. [Suppression/non-publication] of identity;
	5. Sealing records of the trial; and
	6. Any other matters the court considers necessary as appropriate.
3. Victims and witnesses of offences to whom these model legislative provisions apply shall have access to any existing witness protection measures or programmes

**Commentary:**

The safety of victims and witnesses in giving evidence to the court is essential in the prosecution of offenders for offences to which these model legislative provisions apply. Otherwise, it may be impossible to secure a conviction.

**Example**

The Criminal Procedure Code of the Russian Federation, in its articles 376 and 389 as well as Federal Law No. # 39-FZ of 2011, allows for the use of videoconferences. As a procedural guarantee, the federal law envisages the presence of a judge on both sides of the video transmission.

In the Federal Law No. # 119-FZ (“On State Protection of Victims, Witnesses and Other Participants of Criminal Proceedings”) of 2004, the following security measures are envisaged:

(a) Providing for personal security and security for the dwelling and property;

(b) Granting special measures of individual protection, communications and danger warning;

(c) Providing for confidentiality of information about the protected person;

(d) Moving to another place of residence;

(e) Changing of documents;

(f ) Changing of appearance;

(g) Changing the place of work (service) and education;

(h) Temporarily placing in a safe location;

(i) Applying additional security measures in respect of the protected person who is kept in custody or is in the place of serving his sentence, including transfer from one place of custody or a place of serving punishment to another one

**Article 41. Provision of care to victims**

1. The [competent authority] shall take appropriate measures to ensure that a victim of an offence to whom these model legislative provisions apply
	1. Have access to information relevant to their injury and the medical product causing the injury and which is necessary for their health
	2. Have assistance in their physical, psychological and social recovery

**Article 42. Restitution and compensation for victims**

1. Where a person is convicted of an offence to which these model legislative provision apply, the court may order the offender to pay compensation or restitution to the victim, in addition to or in place of any other punishment ordered by the court
2. When imposing an order for compensation or restitution, the court shall take the offender’s means and ability to pay compensation or restitution into account and [shall give priority to a compensation or restitution order over a fine].
3. The aim of an order for restitution shall be to give back t the victim the value of wrongful gain taken by the offender.
4. The aim of compensation shall be to compensate the victim for any loss suffered. An order for compensation may include payment for or towards;
	1. The cost of medical, physical, psychological or psychiatric treatment required by the victim;
	2. The cost of physical or occupational therapy or rehabilitation required by the victim;
	3. The cost of necessary transportation, temporary childcare, temporary housing or the movement of the victim to a place of temporary safe residence;
	4. Lost income and due wages according to national law and regulations regarding wages;
	5. Legal fees and other costs or expenses incurred, including costs incurred related to the participation of the victim in the criminal investigation and prosecution process;
	6. Payment for non-material damages, resulting from moral, physical or psychological injury, emotional distress, pain and suffering suffered by the victim as a result of the crime committed against him or her; and
	7. Any other costs or losses incurred by the victim as a direct result of the conduct of the offender and reasonably assessed by the court.
5. The immigration status or the return of the victim to his or her home country or other absence of the victim from the jurisdiction shall not prevent the payment of compensation and/or restitution under this article.
6. [Where not payable by the offender, the victim shall be eligible for compensation from[insert name of public fund]]
7. Where the offender is a public official whose actions constituting an offence under these model legislative provisions were carried out under actual or apparent State authority, the court may order the State to pay compensation to the victim [in accordance with national legislation]. An order for State compensation under this article may include payment for or towards all or any of the items under paragraph (a) to (g).

**Commentary:**

The Explanatory report to the Medicrime Convention, Article 10- Protection of victims, outlines that where there is no national victim funds in existence, there is no obligation on States to establish such a fund.

**Article 43. The standing of victims in criminal investigations and proceedings**

1. The [competent authority/investigative agency or other investigative authority/prosecutor] shall take all reasonable measures to ensure the rights and interests of victims at all stages of the criminal investigation and proceedings, [in so far as permitted by domestic legislation/procedural/administrative arrangements] by
	1. Bringing to their attention their rights under the legislation of [insert name of State] and service at their disposal
	2. Providing information on the actions taken subsequent to their complaint, to include the general progress of the investigation, whether a criminal prosecution will take place, the charges involved and the outcome of the proceedings
	3. Enabling them, in the manner consistent with procedural rules of [insert name of State] to be heard, to provide evidence and to choose the means of having their views, needs and concerns presented directly or through an intermediary
	4. Providing them with appropriate support services so that their rights and interests are duly presented and taken into account
2. The [competent authority/investigative agency or other investigative authority/prosecutor] shall ensure that victims have access,
	1. as from their first contact with the competent authorities, to information on relevant judicial and administrative proceedings
	2. [and provided free of change where warranted, to legal aid according to [state the rules for legal aid] ]

**Commentary:**

In some States, victims have rights to be heard or represented in the criminal proceedings, where other cases this is not provided for by legislation, but may be permitted by the prosecutor in the selection of witnesses for the prosecution case against the offender. The Medicrime Convention and the Explanatory report provides that where the victim is entitled to be heard that it will be in accordance with domestic legislation or national rules. In such case, the victim may choose the option to provide this directly or indirectly. Indirectly may be by governmental or non-governmental organizations, associations or other party where so permitted by domestic legislation. The provision of information on the investigation 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 proceedings, as in some situations the proper handling of the case may be adversely affected by the disclosure of information.

**Chapter VIII. Miscellaneous Provisions**

**Introductory Commentary:**

Protective disclosures by an employee, commonly referred to as whistleblowing, is a mechanism whereby wrongdoing by an employer can be disclosed in the public interest without the employee suffering any adverse action being taken against them in retaliation by the employer.

 Some States have laws enacted to permit the disclosure of relevant information such that the person reporting is protected from victimisation as a result of the disclosure. The relevant information relates to the reasonable belief of the worker that an offence has been, is being or likely to be committed; that the person reported has failed, is failing or likely to fail to comply with legal obligations; that a miscarriage of justice has occurred; and that information tending to show any matter falling within any of these matters has been, is being or likely to be concealed or destroyed. This is particularly relevant to the disclosure of wrongdoing relating to the manufacturing of fraudulent medical products. Such disclosure is necessary for the protection of public health. The ‘whistleblower’ is guaranteed that his/her identity will not be disclosed where he/she does not consent, except for certain circumstances, including the necessity to prevent serious risk to public health; the prevention of crime or where required by law. The whistleblower must believe that the wrongdoing reported is so and that the allegations are substantially true. Otherwise, the whistleblower may lose some or all of the protections otherwise provided.

 Some States may have laws that limit protection to person who otherwise make makes a protective disclosure and may even criminalise such disclosures in relation to sensitive matters, such as State security. For this reason, any provisions made to deal protective disclosures regarding fraudulent medical products should be confined to matters within these model legislative provisions.

 States should utilise their domestic protective disclosure laws where they exist and apply them to these model legislative provisions. Where they do not exist the following may be regarded as a minimum provision within these model legislative provisions.

**Article 44. Protective disclosures**

(1) where an employee has knowledge of a wrongdoing, committed under these model legislative provisions and reports it confidentially to his employer or to [competent authority or law enforcement or other relevant investigative authority or any official designated for such purpose by [insert name of the State]], no information that might identity the person by whom the protective disclosure was made shall be disclosed unless:

a. The person by whom the protective disclosure was made consents or does not object to the disclosure;

 b. Necessary for the prevention of risk to public health

 c. The prevention of crime or prosecution of a criminal offence under these model legislative provisions

 d. The effective investigation of the wrongdoing committed within the framework of these model legislative provisions

 e. The disclosure is otherwise necessary in the public interest or is required by law.

1. A wrongdoing under paragraph (1) shall be a disclosure concerning:
	1. An offence has been, is being or likely to be committed
	2. A person has failed, is failing or is likely to fail to comply with any legal obligation under these model legislative provisions;
	3. The health or safety of any person has been, is being or is likely to be at risk as a result of the wrongdoing committed against these model legislative provisions
	4. The environment has been, is being or is likely to be damaged as a result of the wrongdoing committed against these model legislative provisions
	5. The act or omission by [competent authority, law enforcement or other investigative agency] is oppressive, discriminatory or grossly negligent or constitutes gross mismanagement in relation to the provision of these model legislative provisions, or
	6. The information tending to show any matter falling within any or the preceding paragraphs has been, is being or is likely to be concealed or destroyed.
2. It shall not be a criminal offence where a person makes a protective disclosure and the protective disclosure is
	1. A wrongdoing under paragraph 2, and
	2. The allegations are substantially true.

The motivation of the person by whom the protective disclosure was made shall be irrelevant

1. A court may award damages against an employer in relation to retaliation or detrimental action taken against the person who makes a protective disclosure

**Commentary**

 **Example**

 Ireland’s Protected Disclosures Act 2014[[43]](#footnote-43), provides the protections for the protections to be applied to the person by whom the protective disclosure was made and circumstances where this protection may cease.

Section 5 – Relevant Information

(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. |

Protection of identity of maker of protected disclosures

|  |  |  |
| --- | --- | --- |
|  |  | **16.** (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**

The United Kingdom’s Public Interest Disclosure Act 1998, Section 43B is similar in content to that of Ireland’s Protective Disclosure Act 2014, Section 5.

Right not to suffer detriment

### 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**

Malta’s Protection of the Whistleblower Act 2013

Section 4 – Protected disclosures

4. (1) Notwithstanding the provisions of the Criminal Code or of any other law, a whistleblower who makes a protected disclosure is not liable to any civil or criminal proceedings or to a disciplinary proceeding for having made such a disclosure.

(2) The protection afforded to a whistleblower shall not be prejudiced on the basis only that the whistleblower making the disclosure was, in good faith, mistaken about its import or that any perceived threat to the public interest on which the disclosure was based has not materialised or that the person making the disclosure has not fully respected the procedural requirements of this Act or of any regulations or guidelines made under this Act.

Prohibition of disclosure of information to identify the whistleblower.

6. (1) Every whistleblowing reporting officer or whistleblowing reports unit to whom a protected disclosure is made or referred must not disclose information that identifies or may lead to the identification of the whistleblower unless the whistleblower expressly consents in writing to the disclosure of that information. (2) The whistleblowing reports unit shall not communicate the contents of the disclosure to other departments within the authority of which it forms part until it has duly investigated the disclosure and it has established that it is necessary or appropriate in the public interest for further investigation to be carried out by such other departments or with the police in relation to an improper practice which constitutes a crime or contravention under any law. Notwithstanding any other law, the authority shall not be restricted in any manner in sharing information with the whistleblowing reports unit about its investigations from time to time for the whistleblowing reports unit to determine whether it has any relevant information on the subject matter under investigation.

Protected disclosure

9. (1) A disclosure is a protected disclosure if -

(a) it is made in good faith; and

(b) the whistleblower reasonably believes, at the time of making the disclosure based on the information he has at that moment, that:

(i) the information disclosed, and any allegation contained in it, are substantially true;

(ii) the information disclosed tends to show an improper practice being committed by his employer, another employee of his employer or by persons acting in the employer’s name and interests; and

(c) the disclosure is not made for purposes of personal gain.

(2) The protections conferred by this article do not apply to an employee who knowingly discloses information which he knows or ought to reasonably know is false and any person or organisation, other than the employer or officers or shareholders of the same when an organisation, which is prejudiced by the disclosure of such false information given in a disclosure made under this Act shall not by virtue of this Act be hindered in the exercise of any legal action or in the enforcement of any legal remedy available to that person or organisation under any other law in respect of the said prejudice:

Provided that such remedy shall only be available if the identity of the whistleblower has been obtained or otherwise disclosed in accordance with the provisions of this Act.

 (3) It shall be an offence punishable in accordance with article 101 of the Criminal Code to knowingly provide false information in terms of this Act.

 OFFENCES AND PENALTIES

Threatens to use violence.

19. Any person who, for the purpose of compelling any other person to abstain from doing or to do any act which such other person has a legal right to do or to abstain from doing under the provisions of this Act, wrongfully or without legal authority –

(a) uses or threatens to use violence against such person, or the wife, husband or child of such person, or a member of his household, or causes or threatens to cause damage to his property;

(b) persistently follows such other person from place to place;

(c) watches or besets the house or other place where such other person resides or the approaches to such house or place;

(d) deprives such person, or in any matter hinders him in the use of, any tools, clothing or other property owned or used by such other person,

shall be guilty of any offence …

 **Example**

 India’s Ministry of Health & family Welfare Reward Scheme for whistleblowers in the fight against

 the menace of spurious or fake drugs, cosmetics and medical devices[[44]](#footnote-44)

8. The salient features of the aforesaid reward scheme are as

follows:-

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

(ii) Reward is to be given to the whistleblowers 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 sub-zonal 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 sub-zonal 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 is the Central Drug Standards and Control Organization

1. UNODC (2011). Resolution 20/6. Countering fraudulent medicines, in particular their trafficking. UNODC. At <https://www.unodc.org/documents/organized-crime/FM/Resolution_20_EN.pdf> [↑](#footnote-ref-1)
2. The Commission on Crime Prevention and Criminal Justice recommends to the Economic and Social Council the approval of the following draft resolution for adoption by the General Assembly: Curbing trafficking in fraudulent medicines. E/CN.15/2011/L.12 at <http://daccess-dds-ny.un.org/doc/UNDOC/LTD/V11/820/84/PDF/V1182084.pdf?OpenElement> [↑](#footnote-ref-2)
3. UNODC (2004). United Nations Convetnion against Transnational Organized Crime and the Protocols Thereto. At <http://www.unodc.org/documents/treaties/UNTOC/Publications/TOC%20Convention/TOCebook-e.pdf> [↑](#footnote-ref-3)
4. Directive 2011/62/EU of the Parliament and of the Council of 08 June 2008 amending Directive 2011/83/EC on the Community code relating to medicinal products for human use, regarding the prevention of the entry into the legal supply chain of falsified medicinal products (The Falsified Medicines Directive). Official Journal of the European Union, at <http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf> [↑](#footnote-ref-4)
5. Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health and similar crimes. Moscow, 28.x.2011, at Conventions.coe.int/treaty/EN/Treaties/Html/211.htm  [↑](#footnote-ref-5)
6. World Health Organisation (2014). Substandard/spurious/falsely-labelled/falsified/counterfeit medical products, at <http://apps.who.int/gb/ssffc/> [↑](#footnote-ref-6)
7. The World Health Organization International Medical Products Anti-Counterfeiting Task Force (IMPACT) Draft Principles and Elements for National Legislation against Counterfeit Medical Products (2007), at <http://www.who.int/impact/events/PrinciplesElementsforNationalLegislation.pdf> [↑](#footnote-ref-7)
8. World Health Organisation (2014). Substandard/spurious/falsely-labelled/falsified/counterfeit medical products, at http://apps.who.int/gb/ssffc/ [↑](#footnote-ref-8)
9. Council of Europe (2011). Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, Moscow, 28.x.2011, at Conventions.coe.int/treaty/EN/Treaties/Html/211.htm [↑](#footnote-ref-9)
10. European Commission (2011). Directive 2011/62/EU of the Parliament and of the Council of 08 June 2008 amending Directive 2011/83/EC on the Community code relating to medicinal products for human use, regarding the prevention of the entry into the legal supply chain of falsified medicinal products (The Falsified Medicines Directive). Official Journal of the European Union, at <http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf> [↑](#footnote-ref-10)
11. Criminal Justice (Theft and fraud offences) Act, 2001, no. 50 of 2001. Irish Statute Book, at <http://www.irishstatutebook.ie/2001/en/act/pub/0050/print.html> [↑](#footnote-ref-11)
12. European Commission (2004). Directive 2004/27/EC of the European Parliament and the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use. Official Journal of the European Union, LL136/34, at <http://ec.europa.eu/health/files/eudralex/vol-1/dir_2004_27/dir_2004_27_en.pdf> [↑](#footnote-ref-12)
13. UNOC (2008). Good Practices for the Protection of Witnesses in Criminal Proceedings involving Organized Crime, p.1, at <http://www.unodc.org/documents/organized-crime/Witness-protection-manual-Feb08.pdf> [↑](#footnote-ref-13)
14. ICANN (1999). Uniform Domain Name Dispute Resolution Policy. At <https://www.icann.org/resources/pages/policy-2012-02-25-en> [↑](#footnote-ref-14)
15. ICANN (2013). Registrar Accreditation Agreement. at <https://www.icann.org/resources/pages/approved-with-specs-2013-09-17-en#whois> [↑](#footnote-ref-15)
16. Tiffany Inc. v. eBay, Inc., 600 F.3d 93 (2d Cir. N.Y. 2010, at <http://www.lexisnexis.com/legalnewsroom/intellectual-property/b/copyright-trademark-law-blog/archive/2010/06/30/free-download-opinion-tiffany-inc-v-ebay-inc-600-f-3d-93-2d-cir-n-y-2010.aspx> [↑](#footnote-ref-16)
17. *Legislative Guides for the Implementation of the United Nations Convention against Transnational Organized crime and the Protocols Thereto, pp. 93-94* [↑](#footnote-ref-17)
18. General Assembly resolution 45/110, annex. [↑](#footnote-ref-18)
19. General Assembly resolution 65/229, annex. [↑](#footnote-ref-19)
20. Available at http://www.unodc.org/unodc/en/justice-and-prison-reform/tools.html. [↑](#footnote-ref-20)
21. Rules 2.3 and 3.1 of the Tokyo Rules. [↑](#footnote-ref-21)
22. Rule 5.1 of the Tokyo Rules. [↑](#footnote-ref-22)
23. Rule 8.2 of the Tokyo Rules. [↑](#footnote-ref-23)
24. Legislative Guides for the Implementation of the United Nations Convention against Transnational Organized Crime and the protocols Thereto, p.116 [↑](#footnote-ref-24)
25. See www.admin.ch/ch/e/rs/311\_0/a102.html [↑](#footnote-ref-25)
26. Italy imposed a system of administrative liability of corporations through the Decree-Law No. 300 of 29

September 2000 and the Decree-Law No. 231 of 8 May 2001, entitled “Discipline of the administrative liability of legal persons, of companies and of associations even without a legal status, pursuant to Article 11 of Law no. 300 of 29 September 2000” published in the Gazzetta Ufficiale no. 140 of 19 June 2000. Further information available from www.oecd.org/dataoecd/61/31/45508054.pdf. [↑](#footnote-ref-26)
27. Council of Europe Committee of Ministers Recommendation Rec(2005)10 of the Committee of Ministers to member states on “special investigative techniques in relation to serious crimes including acts of terrorism, adopted on 20 April 2005 at <https://wcd.coe.int/ViewDoc.jsp?id=849269&Site=CM> [↑](#footnote-ref-27)
28. Travaux Preparatoires of the Negotiations for the Elaboration of the United Nations Convention against Transnational Organized Crime and the Protocols thereto, p.206 [↑](#footnote-ref-28)
29. ibid [↑](#footnote-ref-29)
30. Model Provisions against Organized Crime, Chapter 4, Investigations, UNODC, p 61 <http://www.unodc.org/documents/organized-crime/Publications/Model_Legislative_Provisions_UNTOC_Ebook.pdf> [↑](#footnote-ref-30)
31. United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988, at <http://www.unodc.org/pdf/convention_1988_en.pdf> [↑](#footnote-ref-31)
32. *Council of Europe (2011). Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, Moscow, 28.x.2011, at Conventions.coe.int/treaty/EN/Treaties/Html/211.htm*  [↑](#footnote-ref-32)
33. Explanatory report to the *Council of Europe (2011). Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, Moscow, 28.x.2011,* at <http://conventions.coe.int/Treaty/EN/Reports/Html/211.htm> [↑](#footnote-ref-33)
34. *Council of Europe (2011). Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, Moscow, 28.x.2011, at Conventions.coe.int/treaty/EN/Treaties/Html/211.htm*  [↑](#footnote-ref-34)
35. *Council of Europe (2011). Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health, Moscow, 28.x.2011, at Conventions.coe.int/treaty/EN/Treaties/Html/211.htm*  [↑](#footnote-ref-35)
36. UNODC (2004). Model Law on Extradition. Model Law and Treaties at <https://www.unodc.org/tldb/en/model_laws_treaties.html> [↑](#footnote-ref-36)
37. Legislative Guides for the Implementation of the United Nations Convention against Transnational Organized Crime and the Protocols thereto, p.133 [↑](#footnote-ref-37)
38. Irish Medicines Board (Miscellaneous Provisions) Act 2006, at <http://www.irishstatutebook.ie/2006/en/act/pub/0003/sec0017.html#sec17> [↑](#footnote-ref-38)
39. available at http://www.unodc.org/documents/legal-tools/AML\_MLawEnglish.pdf. [↑](#footnote-ref-39)
40. available at http://www.unodc.org/documents/legal-tools/AML\_Model\_Provisions\_Common\_Law.pdf. [↑](#footnote-ref-40)
41. UNODC (2008). Good Practices for the Protection of Witnesses in Criminal Proceedings involving Organized Crime: Key elements, p.21. at <http://www.unodc.org/documents/organized-crime/Witness-protection-manual-Feb08.pdf> [↑](#footnote-ref-41)
42. UNODC (2008). Good Practices for the Protection of Witnesses in Criminal Proceedings involving Organized Crime, p.1, at <http://www.unodc.org/documents/organized-crime/Witness-protection-manual-Feb08.pdf> [↑](#footnote-ref-42)
43. Protected Disclosures Act 2014, at <http://www.irishstatutebook.ie/2014/en/act/pub/0014/print.html> [↑](#footnote-ref-43)
44. Ministry of Health & family Welfare. (2009). Reward Scheme for Whistleblowers in the fight against the meance of spurious or fake drugs, cosmetics and medical devices, at [http://www.cdsco.nic.in/writereaddata/Whistle%20Blowe%20(3).pdf](http://www.cdsco.nic.in/writereaddata/Whistle%20Blowe%20%283%29.pdf) [↑](#footnote-ref-44)