

## **IMPACT**

**International Medical Products Anti-Counterfeiting Taskforce**

### **Principles and Elements for National Legislation against Counterfeit Medical Products**

**Text endorsed by IMPACT General Meeting  
Lisbon, 12 December 2007**

#### **INTRODUCTION**

The participants of the WHO International Conference 'Combating Counterfeit Drugs: Building Effective International Collaboration,' held in Rome on 18 February 2006, declared that<sup>1</sup>

“1. Counterfeiting medicines, including the entire range of activities from manufacturing to providing them to patients, is a vile and serious criminal offence that puts human lives at risk and undermines the credibility of health systems.

2. Because of its direct impact on health, counterfeiting medicines should be combated and punished accordingly.

3. Combating counterfeit medicines requires the coordinated effort of all the different affected stakeholders that are competent for addressing the various aspects of the problem.

4. Counterfeiting medicines is widespread and has escalated to such an extent that effective coordination and cooperation at the international level are necessary for regional and national strategies to be more effective.

5. National, regional<sup>2</sup> and international strategies aimed at combating counterfeit medicines should be based on:

- a) political will, adequate legal framework, and implementation commensurate to the impact of this type of counterfeiting on the health of individuals and on public health and providing the necessary tools for a coordinated and effective law enforcement,
- b) inter-sectoral coordination based on written procedures, clearly defined roles, adequate resources, and effective administrative and operational tools,
- c) creating an awareness about the severity of the problem among all stakeholders and providing information to all levels of the health system and the public,
- d) development of technical competence and skills in all required areas,
- e) appropriate mechanisms for ensuring vigilance and input from healthcare professionals and the public.“

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<sup>1</sup> The full text of the Declaration of Rome can be found at [www.who.int/impact](http://www.who.int/impact). The text presented here has been slightly revised for clarity and consistency with this document.

<sup>2</sup> Throughout this document, the term ‘regional’ refers to any regional or sub-regional group of countries (e.g. MERCOSUR, SADC, ASEAN, GCC, EU, etc.).

In addition, several international instruments, such as the International Covenant on Economic, Social and Cultural Rights, and the WHO Constitution recognize the “right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>3</sup>

It is on the basis of the above principles that WHO and other stakeholders established the International Medical Products Anti-Counterfeiting Taskforce, IMPACT, which aims at strengthening international collaboration among all involved stakeholders for the purpose of effectively combating counterfeit medical products.

IMPACT has established a secretariat within WHO and five working groups:

- Legislative and Regulatory Infrastructure;
- Regulatory Implementation;
- Technology;
- Enforcement;
- Communications.

The Legislative and Regulatory Infrastructure working group has coordinated the development of these guiding principles that national and regional institutions may use as a reference for developing ad hoc legislation aimed at effectively combating counterfeit medical products within their jurisdiction.

Given the sophistication and global reach of many counterfeiting operations, the potential dangers to consumers, and the fact that counterfeiters operate outside of the medical product regulatory system, it is imperative that regulatory authorities, administrative and criminal law enforcement agencies, legitimate manufacturers, and other concerned parties have at their disposal a comprehensive legal framework that:

- links medical product counterfeiting activities to appropriate criminal sanctions, and deterrent civil and administrative remedies and penalties;
- adequately regulates and controls each step in the supply and distribution chain;
- empowers, directs and provides adequate technical, financial and human resources to medical product regulatory authorities, law enforcement authorities, and customs to take effective and coordinated action involving all aspects (including export and internet activities);
- educates stakeholders about the inherent dangers of counterfeit medical products.

IMPACT stakeholders have surveyed currently available national and international legislative instruments. Further study is warranted; nonetheless some consistencies can be noted. Although this list may not be equally applicable to all WHO member states, a number of key issues have been identified:

- a definition for counterfeit medical products is absent or inadequate;
- counterfeiting medical products is not considered *per se* to be a serious crime or, in some cases, not even a crime;
- where counterfeiting medical products is considered a crime, sanctions are sometimes more lenient than for those crimes applicable to counterfeiters of products that have no implications for health, such as T-shirts;
- sanctions are not applicable unless it is proven that counterfeits have actually resulted in injuries or death;
- the responsibilities of those involved in the distribution system are not clearly defined,
- there are no provisions for effective coordination and information exchange among various authorities and other stakeholders at the national, regional and international level,

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<sup>3</sup> WHO Constitution.

- there are no provisions allowing authorities to share information nationally, regionally or internationally or to use in legal proceedings the information obtained from others,
- there are no provisions addressing the problem of trade in packaging and labelling materials without the obvious involvement of the companies whose name appears on these materials,
- there are insufficient legal provisions concerning the confiscation and use of the assets, equipment and other materials used in conjunction with the manufacture, trade, transportation of counterfeit products.

Experts met in Brussels, 12 -13 July 2007, to prepare a preliminary draft of this document which was broadly circulated for comments. A revised version was discussed at a second, larger meeting of experts in Lisbon on 10-11 December 2007. As a result of that meeting, a draft was submitted to the 2007 IMPACT General Meeting for further vetting and finalization and was ultimately adopted by the Delegates present at the General Meeting on 12 December 2008.

Based on the above considerations, this document was prepared to assist Member States in establishing, complementing or updating national/regional legislation or regulation regarding counterfeit medical products.

## 1 - SCOPE

Counterfeit medical products need to be addressed through different bodies of legislation: on intellectual property protection and enforcement, on pharmaceutical and medical devices regulation and control, and criminal law. All these bodies of legislation should be in place.

The principles set forth in this document focus primarily on public and personal health implications relating to counterfeit medical products (as defined below) that should be appropriately addressed in legislation. As such, these principles should be viewed in the context of a broader regulatory framework. Specific national and/or regional bodies of criminal, pharmaceutical, administrative, intellectual property and civil legislation may need to be established or enhanced on the basis of the principles described in this document, which are intended to complement or strengthen other legislation and not to replace it.

On the basis of the above considerations, the principles set forth in this document do not specifically address:

- infringement of intellectual property rights (IPR), including trademark and patents,
- parallel importation of original goods from a third country where they have been sold by or with the consent of the right-holder;
- illegal activities such as diversion of supplies of authorized<sup>4</sup> medical products, or theft of authorized medical products.

It is recognized that these principles may need to be expanded and periodically updated in order to take into account other international instruments and to reflect current and emerging situations, such as the Internet and medical devices.

## 2 - DEFINITIONS

### **Medical product:**

For the purpose of this document, this includes medicines, medical devices (including diagnostics) and their accessories, active pharmaceutical ingredients and excipients which may be used in health care delivery, self-medication and/or clinical research, as defined in national legislation.

### **Counterfeit medical product:**

A medical product is counterfeit when there is a false representation in relation to its identity<sup>5</sup>, history or source<sup>6</sup>. This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components,<sup>7</sup> with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.

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<sup>4</sup> by the competent authority

<sup>5</sup> e.g. any misleading statement with respect to name, composition, strength, or other elements

<sup>6</sup> e.g. any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorisation holder

<sup>7</sup> this refers to ingredients or any other component of a medical product

Quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate, authorized medical products should not be confused with counterfeiting.

**Broker:** see “Operator of the distribution chain”

**Distributor:** see “Operator of the distribution chain”

**Exporter:** see “Operator of the distribution chain”

**Importer:** see “Operator of the distribution chain”

**Manufacturer:**

Any person who or legal entity that:

- 2.1. produces medical products; or
- 2.2. engages in any step of the process of producing medical products, including: purchasing of materials, processing, assembling, packaging, labelling, storing, sterilizing, as well as testing and releasing the medical product or any component or ingredient of the medical product as part of that process; or
- 2.3. has medical products designed or manufactured (as defined above) by a third party; or
- 2.4. re-packages or re-labels medical products (as defined above).

**Operator of the distribution chain:**

Within this document, this term includes all professional or commercial activities concerned with purchasing, selling, procuring, storing, distributing, dispensing, importing, and exporting medical products, with the exception of dispensing/providing medical products to the end users<sup>8</sup> (see below definition for ‘retailer’). This refers to ownership, possession or control of medical products in both national and international trade, including products in transit, trans-shipment, bonded warehouses, and ‘free trade zones.’ Depending on national legislation, operators of the distribution chain may be referred to by different terms (e.g. distributor, wholesaler, full-line wholesaler, parallel trader, short-line wholesaler, broker, importer, exporter, sales representative, sales agent, etc.) reflecting specific activities and licensing or authorisation requirements. All of these activities should be subjected to the same requirements and accountability relating to counterfeit medical products.

**Other operators involved:**

Within this document, this term includes all other activities not stated in the other definitions of operators that are concerned with advertising, providing platforms for trade, providing Internet and other communications services, transportation, storage, providing assistance in commercial and financial transactions, providing forwarding and logistics services. This refers to ownership, possession or control of the medical products in both national and international trade, including products in transit, trans-shipment, bonded warehouses, and ‘free trade zones.’

**Retailer:** Within this document this term includes all activities concerned with procuring and storing medical products in order to sell or dispense to the end users. This includes, but is not limited to, pharmacies, clinics, hospitals, and healthcare practitioner premises. This refers, as applicable, to ownership or possession of medical products.

**Sales agent:** see “Operator of the distribution chain”

**Sales representative:** see “Operator of the distribution chain”

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<sup>8</sup> end users can be patients, consumers, or professionals who directly use the products on patients/consumers.

**Wholesaler:** see “Operator of the distribution chain”

### **3 - OBLIGATIONS OF GOVERNMENTAL INSTITUTIONS, MANUFACTURERS, OPERATORS OF THE DISTRIBUTION CHAIN, RETAILERS AND OTHER OPERATORS**

Combating counterfeit medical products is an obligation of all stakeholders, especially governments, and should be funded accordingly.

Sustained political will and strong commitment of governments are essential in order to develop and maintain a concerted effort to ensure the quality and safety of medical products and a decrease in the number of counterfeit medical products.

Establishment of, and ensuring compliance with, obligations of manufacturers, operators of the distribution chain, retailers, and other operators should be based on three main categories of approach:

- notification (by the regulated),
- authorisation/licence (by the regulator),
- supervision/inspection (directed by the regulator).

Manufacturers, operators of the distribution chain, and retailers are expected to establish a quality assurance or quality management system. In addition, all parties should work together to fulfil their obligations in the fight against counterfeit medical products.

**Government responsibilities** include, but are not limited to, the following:

- 3.1. establish an adequate legal basis (including criminal, administrative and civil frameworks) for imposing, ensuring compliance with, and enforcement of obligations of all concerned parties;
- 3.2. ensure that this legal basis can be applied to all medical products, including those that may be counterfeit medical products, and/or in transit/trans-shipment, bonded warehouses, free trade zones, and all situations of the international trade;
- 3.3. establish adequately resourced regulatory institutions with appropriate powers delineated in legislation. (Preferably, this should be a single national medical products regulatory authority with official control laboratories, if possible);
- 3.4. establish liability for Internet Service Providers and other operators who facilitate advertisement of, or trade in, counterfeit medical products;
- 3.5. regularly review and amend legislation as required;
- 3.6. regulate the manufacture, importation, exportation, distribution, supply, donation, offer for sale and sale of medical products, thereby ensuring that those who manufacture, import, export, distribute, supply, and perform any transaction related to medical products have a specific licence or are appropriately authorized to do so;<sup>9</sup>
- 3.7. establish regulations aimed at fostering a safe, transparent and secure distribution system, including the establishment of measures for traceability of medical products,

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<sup>9</sup> Note: Specific WHO documents and, where available, applicable national regulations provide more details on good manufacturing and good distribution practices.

- as applicable, throughout the distribution channels from the manufacturer/importer to the retailer;
- 3.8. regulate the manufacture of active substances and of certain excipients that may pose public health risks;
  - 3.9. establish specific import procedures; this may, especially in countries with limited human resources, include designating a limited number of entry points for imported medical products;
  - 3.10. ensure that all medical products in the national distribution channels are licensed/authorized, as required by national legislation;
  - 3.11. establish and enforce compliance with documented procedures for the appropriate destruction of counterfeit products; this includes the identification of operational and financial responsibilities;
  - 3.12. revoke licences/authorizations for poor or illegal performance according to established laws and regulations;
  - 3.13. issue and renew licences on the basis of documented satisfactory compliance with existing laws and regulations;
  - 3.14. require that medical products are suitably labelled and packaged according to their required specifications and licences/authorizations;
  - 3.15. ensure that the conditions for importation of medical products are clearly specified and importation is undertaken only with the appropriate import licences/authorizations issued by the national competent authority;
  - 3.16. ensure that imported medical products are licensed/authorized in the country of manufacture or, if not, that there are acceptable reasons for such non-authorisation;
  - 3.17. adequately fund medical product licensing and authorisation activities, including related assessments and inspections.
  - 3.18. provide adequate initial and in-service training for medical products control, customs and law enforcement personnel;
  - 3.19. establish legal mechanisms to allow/improve coordination and information exchange among health, regulatory, police, customs and other enforcement officers/authorities at a national, regional and international level, including the ability to use the information exchanged in legal/regulatory/investigative actions ;
  - 3.20. ensure that imported medical products are subjected to inspection at points of entry and that samples are collected and analysed as required by a national strategic plan;
  - 3.21. permit investigators, per appropriate guidelines, to conduct effective investigations, including undercover operations, in which samples can be obtained anonymously;
  - 3.22. perform effective controls and tests on medical products authorized for marketing in order to ascertain their quality and authenticity;
  - 3.23. ensure that non-compliance with anti-counterfeiting laws and regulations results in prosecution and severe penal sanctions including the confiscation, forfeiture and destruction of the counterfeit medical products, as well as equipment and other materials used in conjunction with their manufacture;
  - 3.24. foster international cooperation in the regulation of medical products by entering into bilateral and multilateral agreements with other governments and with regional and international organizations such as WHO, Interpol, World Customs Organisation, Council of Europe;
  - 3.25. ensure that policies/regulations concerning exported medical products address the following issues:
    - a) same standards for exported as for domestic products (e.g. WHO Certification Scheme for pharmaceuticals, other official certification as applicable, marketing authorisation, compliance with manufacturing practices requirements, appropriate product information, etc.);

- b) allowing importing countries to obtain products that satisfy their requirements in cases when such products might not have marketing authorisation in the exporting country;
  - c) exported products must have a remaining shelf-life allowing a reasonable timeframe for use (e.g. at least 2/3 of shelf-life at lot release or at least 6 months if 2/3 of shelf-life is shorter than 6 months);<sup>10</sup>
  - d) regulating international trade of labels and packaging materials for medical products.
- 3.26. communicate information on counterfeit medical products and product recalls to manufacturers, operators of the distribution chain, retailers, other operators and health professionals in a timely manner according to established policies, standards, and risk assessments;
- 3.27. conduct awareness initiatives and ensure that appropriate information is provided to the public on counterfeit medical products in order to minimize the risk of exposure to such products<sup>11</sup>;
- 3.28. establish contact mechanisms, such as phone number/web site, to allow health professionals and the general public to report suspected cases of counterfeit medical products.

**Responsibilities of manufacturers** include, but are not limited to, the following:

- 3.29. comply with applicable laws and regulations;
- 3.30. comply with official Good Practice Guidelines (e.g. Good Manufacturing Practices for medicinal products, Good Distribution Practices<sup>12</sup>)
- 3.31. comply with Quality Management Systems requirement for medical devices;<sup>13</sup>
- 3.32. ensure that suppliers of raw, starting and packaging materials are legitimate and finished medical products are delivered to legitimate operators of the distribution chain; this may include conducting audits or verifying the legitimacy of business partners;
- 3.33. establish policies and maintain records of transactions (including written contracts, where applicable) with suppliers, sub-contractors and operators of the distribution chain;
- 3.34. document the origin of all materials used in the manufacture of authorised products in accordance with applicable GMP requirements;
- 3.35. institute a process to ensure that each batch received and shipped is accompanied by control reports (e.g. a Certificate of Analysis), as required by applicable legislation;
- 3.36. establish a quality assurance system that addresses a) the manufacturer's response to reports of possible counterfeit medical products, b) mandatory reporting of information to competent authorities and c) handling of product recalls, all in compliance with applicable legislation;
- 3.37. document the appropriate disposal of expired or otherwise unusable products in manufacturer's possession to prevent such products from re-entering the distribution chain;

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<sup>10</sup> WHO guidelines for drug donations,

<http://www.who.int/medicinedocs/collect/edmweb/pdf/whozip52e/whozip52e.pdf>

<sup>11</sup> Specific model materials and advice are developed by IMPACT's Communications working group

<sup>12</sup> Quality Assurance of Pharmaceuticals - A Compendium of Guidelines and Related Materials - Volume 2 Updated and Revised Edition - Good Manufacturing Practices and Inspection - WHO, Geneva, 2003

<http://www.who.int/medicinedocs/collect/edmweb/pdf/s4900e/s4900e.pdf>

<sup>13</sup> e.g. ISO Standard 13485

- 3.38. cooperate with health, customs, police, other enforcement authorities and other stakeholders in the detection of counterfeit medical products, investigation of cases and the prosecution of those responsible for their manufacture or distribution (see also 3.25, 3.26, 3.27).

Depending on product and circumstances, manufacturers should perform appropriate risk assessment to determine anti-counterfeit measures that should be taken to minimize product vulnerability to counterfeiting.

Manufacturers that use the Internet to sell and/or provide medical products should be subject to the same requirements applicable to operators of the distribution chain (see also sessions 3.57 to 3.61).

**Responsibilities of operators of the distribution chain** include, but are not limited to, the following:

- 3.39 comply with applicable laws and regulations;
- 3.40 comply with official Good Practice Guidelines (e.g. GDP<sup>14</sup>);
- 3.41 comply with appropriate quality management systems for medical devices;
- 3.42 ensure suppliers of products are legitimate manufacturers or operators of the distribution chain and ensure delivery to legitimate operators of the distribution chain or retailers; this may include performing audits or verifying the legitimacy of business partners;
- 3.43 establish and maintain copies of records of transactions (including written contracts) with suppliers, sub-contractors and operators of the distribution chain;
- 3.44 accurately document the purchase and supply of all medical products, including returns from retailers;
- 3.45 ensure that each batch received and shipped is accompanied by appropriate documentation, as required by national legislation;
- 3.46 establish a quality assurance system that addresses a) the operator's response to suspected or confirmed counterfeit medical products, b) mandatory reporting of information to competent authorities and c) handling of product recalls, all in compliance with applicable legislation;
- 3.47 cooperate with health, customs, police, other enforcement authorities and other stakeholders in the detection of counterfeit medical products, investigation of cases, and the prosecution of those responsible for their manufacture or distribution (see also 3.25, 3.26, 3.27);
- 3.48 document the appropriate disposal of expired or otherwise unusable products in operator's possession to prevent such products from re-entering the distribution chain.

Operators should perform appropriate risk assessments to determine anti-counterfeit measures that should be taken to minimize risks of acquiring or selling counterfeit medical products.

Internet site and mail order operators that offer for sale and/or provide medical products should be subject to the same requirements as operators of the distribution chain or retailers, as applicable (see also sessions 3.57 to 3.61).

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<sup>14</sup> Reference to WHO GMP, GDP, GPP guidelines

### **Responsibilities of retailers:**

- 3.49. comply with applicable laws and regulations;
- 3.50. comply with official Good Practice Guidelines (e.g. GDP, GPP<sup>15</sup>);
- 3.51. ensure products are sourced from legitimate operators of the distribution chain;
- 3.52. establish policies and maintain records of written contracts with suppliers, sub-contractors and operators of the distribution chain;
- 3.53. document the purchase and return of all medical products;
- 3.54. establish a quality assurance system that addresses a) the retailer's response to suspected or confirmed counterfeit medical products, b) mandatory reporting of information to competent authorities and c) handling of product recalls, all in compliance with applicable legislation;
- 3.55. cooperate with health, customs, police, other enforcement authorities and other stakeholders in the detection of counterfeit medical products, investigation of cases, and the prosecution of those responsible for their manufacture or distribution (see also 3.25, 3.26, 3.27);
- 3.56. document the disposal of expired or otherwise unusable products to prevent them from entering into the distribution chain.

Depending on the national situation, retailers may consider auditing distributors and request relevant certificates. Retailers should perform risk assessments to determine other anti-counterfeit measures that should be taken to minimize risks of acquiring counterfeit medical products.

Internet site and mail order operators that offer for sale and/or provide medical products should be subject to the same requirements as operators of the distribution chain or retailers, as applicable (see also sessions 3.57 to 3.61).

### **Responsibilities of other operators:**

- 3.57. maintain awareness of legal requirements regarding medical products and comply with applicable legislation;
- 3.58. exert due diligence for ensuring business with legitimate business partners;
- 3.59. cooperate with health, customs, police, other enforcement authorities and other stakeholders in the detection of counterfeit medical products, investigation of cases, and the prosecution of those responsible for their manufacture or distribution (see also 3.25, 3.26, 3.27);
- 3.60. document any activity related to medical products;
- 3.61. take necessary actions if there are reasons to suspect or if the appropriate authorities have cited that the services are being exploited for the trade/advertisement of counterfeit medical products.

## **REGIONAL/ INTERNATIONAL OBLIGATIONS**

Medical product counterfeiting is a global public health problem. Therefore, all governments are encouraged to engage in international regulatory and enforcement cooperation, to the fullest extent possible, to combat this public health threat.

**Governments**, in accordance with existing international obligations, should employ or establish legal mechanisms to permit:

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<sup>15</sup> Reference to WHO current GDP and GPP guidelines, [www.who.int/medicines](http://www.who.int/medicines)

- 3.62. regional/international information exchange among health, regulatory, police, customs and other enforcement officers/authorities, including the ability to provide and use the information exchanged in legal/regulatory actions; this includes all areas within member states as well as free-trade zones;
- 3.63. cross-border joint/coordinated activities among health, regulatory, police, customs and other enforcement officers/authorities; this includes all areas within member states as well as free-trade zones;
- 3.64. effective regional/international cooperation in criminal matters for the purpose of investigating, collecting evidence, or proceedings concerning criminal offences related to counterfeit medical products;
- 3.65. criminal offences directly related to counterfeit medical products to be considered extraditable offences;
- 3.66. the ability to prosecute criminal offences directly related to counterfeit medical products by a country affected by such criminal offences, even if committed abroad by, or against, a citizen of that country<sup>16</sup>;

## 4 - ILLEGAL ACTS

It is prohibited to:

- 4.1. manufacture (i.e. perform any of the activities described under 2.1 – 2.4 ‘**manufacturer**’) a counterfeit product,
- 4.2. own, possess or control counterfeit medical products in transit, trans-shipment, free-trade zones, bonded-warehouses and other situations of international commerce,
- 4.3. introduce into the distribution chain any counterfeit medical product by any means, including but not limited to, selling, delivering, distributing, importing, exporting, donating, storing or otherwise supplying others with a counterfeit medical product;
- 4.4. own, possess or control counterfeit medical products that are likely to enter the distribution chain;
- 4.5. design, produce, print, sell, deliver, distribute, import, export, donate or otherwise supply others with any packaging material or labels, intended for a counterfeit medical product;
- 4.6. manufacture, transport, or distribute any equipment, materials, components (including genuine articles) or documentation used in the production of, or to accompany the distribution of, counterfeit medical products with the knowledge or being reckless to the fact that they be used for such purposes;
- 4.7. provide services such as on-line services, electronic-sale platforms, electronic payments, or transportation when providers have reasonable grounds to believe or notice has been given to them by the appropriate authorities of such services being exploited by persons engaged in any of the offences described above;

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<sup>16</sup> In proceedings involving the infringement of (registered) intellectual property rights, these considerations may be complemented by relevant principles on exclusive jurisdiction, especially over validity matters.

- 4.8. conspire to commit, attempt to commit, aid, abet, counsel, facilitate, or incite any of the offences set forth in these provisions.

These acts should be considered illegal acts regardless of the monetary value or volume involved.

## 5 - SANCTIONS

Given that counterfeiting of medical products represents a serious threat to individual health and jeopardizes health care systems, governments should take all necessary measures to effectively deter the illegal acts described above (section 4). This includes introducing severe criminal sanctions against perpetrators, regardless of whether evidence exists of actual harm caused to others.

The illegal acts described above (section 4) should be considered criminal offences even if committed by negligence.

Sanctions should:

- reflect the gravity of the respective offences and take into consideration the presence and level of guilt, and
- be equivalent to sanctions for other serious crimes, such as manufacturing or commercialization of dangerous substances or substances harmful to human health, or drug trafficking, and
- include, where applicable constitutions or other instruments permit, mandatory prison sentences.

Quality defects or GMP/GDP failures in authorized medical products should not be confused with counterfeiting. Specific circumstances and facts (e.g. previous record of persons involved, availability of proper documentation regarding manufacture or trade, etc.) will assist in identifying cases where offences are the result of a manufacturing or trade accident.

When sentencing, the following aggravating circumstances should also be taken into consideration, with the understanding that counterfeiting medical products is a serious crime regardless of evidence of harm actually caused:

- 5.1. whether death or serious injury occurred,
- 5.2. effect upon the health of a large number of persons,
- 5.3. risk of endangering the health of a large number of persons,
- 5.4. risk of death or serious injury,
- 5.5. acquisition of considerable pecuniary gain,
- 5.6. if perpetrator is an authorised operator (manufacturer, retailer, other)
- 5.7. if perpetrator is a health professional
- 5.8. repeated offence
- 5.9. organized crime involved

In addition, other offences that may have been committed in conjunction with the counterfeiting of medical products may also be pursued and penalised under other applicable criminal, civil and/or administrative legislation.

In order to effectively combat counterfeiting and ensure enforcement of anti-counterfeiting laws, certain procedural rules and provisions might need to be established or enhanced, including provisions to ensure transparency of processes and decisions, while maintaining confidentiality as necessary.

## 6 - NATURE OF SANCTIONS

In order to effectively combat counterfeiting of medical products, the sanctions described below should be established and pursued regardless of those additional remedies and/or sanctions that may be available under other relevant criminal, civil or administrative legislation<sup>17</sup>:

- 6.1. custodial sentences;
- 6.2. fines;
- 6.3. confiscation of assets including forfeiture of illegal proceeds;
- 6.4. confiscation of instruments, equipment and materials used to commit the crime;
- 6.5. total or partial closure, on temporary or permanent basis, of the establishment(s) involved in the commission of the offence;
- 6.6. permanent or temporary prohibition to engage in medical-product-related activities;
- 6.7. destruction of the counterfeit goods involved in the offences and recovery of the related costs;
- 6.8. ban on the access to public assistance or subsidies;
- 6.9. placing the operation under judicial supervision;
- 6.10. judicial order to close or halt the operation and related activities;
- 6.11. indemnification of affected/damaged parties (including affected patients, affected operators, and manufacturers of genuine products);
- 6.12. publication of judicial decisions (including dissemination of information to international organisations and to national competent authorities of other countries);
- 6.13. withdrawal of licences.

Money derived from confiscation of assets should contribute to compensating any victims of medical product counterfeiting crimes, and to supplement the financing of anti-counterfeit medical product operations by the appropriate authorities. This should occur regardless of other compensation mechanisms and of the ability of concerned parties to seek redress of injuries or damages that may have been suffered by patients, health professionals, manufacturers or operators of the distribution chain and their licensees.

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<sup>17</sup> This list is not exhaustive