



## IMPACT

International Medical Products Anti-Counterfeiting Taskforce

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

*Draft as discussed at the Interregional Meeting of an ad-hoc Working Group on Medical Devices  
Bonn, Germany, 25-26 November 2008*

*and at the third IMPACT General Meeting in Hammamet, Tunisia, 3-5 December 2008*

Please address comments on this proposal by 15 November 2009 to Dr S. Kopp, Secretary ad interim IMPACT  
fax: (+41 22) 791 4730 or e-mail: [kopps@who.int](mailto:kopps@who.int)  
with a copy to Professor Dr Konstantin Keller, Chair, IMPACT Legislative and Regulatory Infrastructure Working Group, e-mail: [Konstantin.Keller@bmg.bund.de](mailto:Konstantin.Keller@bmg.bund.de).

## INTRODUCTION

The participants of the WHO international conference "Combating counterfeit drugs: building effective international collaboration", gathered 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 stakeholders that are affected and are competent for addressing the different aspects of the problem.

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<sup>1</sup> The full text of the Declaration of Rome can be found at <http://www.who.int/medicines/services/counterfeit/RomeDeclaration.pdf>; the text presented here has been slightly updated for the purposes of clarity and consistency with the text of this document. Although the original text of the Declaration refers to medicines, the subsequent establishment of IMPACT expanded the scope to include all medical products.

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) intersectoral 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."

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 the different stakeholders for the purpose of effectively combating counterfeit medical products.

IMPACT has established a secretariat within WHO and five working groups addressing these five areas: legislative and regulatory infrastructure; regulatory implementation; technology; enforcement; and communications.

Among the activities of the legislative and regulatory infrastructure working group, a project is being undertaken with the aim of developing guiding principles that national and regional institutions may use as 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: (i) subjects medical product counterfeiting activities to effective criminal sanctions, and deterrent civil and administrative remedies and penalties; (ii) adequately regulates and controls each link in the supply and distribution chain; (iii) 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, encompassing all aspects (including exports and online Internet activity); and (iv) educates stakeholders about the inherent dangers of counterfeit medical products.

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<sup>2</sup> Throughout this document, the term "regional" refers to any regional or subregional gathering of countries (e.g. MERCOSUR, SADC, ASEAN, GCC, EU, etc.).

<sup>3</sup> WHO Constitution.

IMPACT stakeholders have gathered experience and information on current national and international legislative instruments in different parts of the world. Although additional study is necessary to further improve our understanding, some lessons have been learned. Even if the situation appears to differ considerably (and, therefore, this list is not equally applicable to all WHO Member States), a number of key problems (others may exist) 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 even just a crime;
- where counterfeiting medical products is considered a crime, sanctions are sometimes much lighter than those applicable to counterfeiters of products that have no implications for health, such as T-shirts;
- sanctions are not linked to counterfeiting medical products per se, but to the proven fact 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 enabling effective coordination and exchange of information among different authorities and other stakeholders at the national, regional and international level;
- there are no provisions enabling different authorities to provide information to others (nationally, regionally and internationally) or to make legal use of the information obtained from others (nationally, regionally and internationally);
- there are no provisions addressing the problem of trade in packaging materials, especially labels, without the obvious involvement of the companies whose name appears on these materials;
- insufficient provisions concerning the confiscation and use of the assets, equipment and other materials used in conjunction with the manufacture, trade, transportation of counterfeit products.

A meeting of experts<sup>4</sup> took place in Brussels on 12-13 July 2007 and prepared a preliminary document which was broadly circulated for comments. The revised version was discussed at a second, larger meeting of experts which took place in Lisbon on 10-11 December 2007. The result of this second meeting was discussed and finalized at the 2007 IMPACT General Meeting.

As suggested by the second general meeting an ad hoc expert group on medical devices was convened in December 2008 in order to clarify terms and requirements specific to medical devices. The ad hoc group proposed changes that were supported and clarified further by the third IMPACT General Meeting. The draft modifications specific to medical devices are presented here for comments and further improvement.

Based on the above considerations, this document is aimed at Member States that intend to establish, complement or update national/regional legislation or regulation against 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 on criminal law. All these bodies of legislation should be in place.

The principles set out in this document focus primarily on public and personal health implications in relation to counterfeit medical products (as defined below) that need to be appropriately addressed in

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<sup>4</sup> See Annex 1 for a list of participants.

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 enriched by or established on the basis of the principles illustrated 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 out in this document do not address:

- 1.1 infringement of aspects of intellectual property rights (IPR), including patent rights;
- 1.2 parallel importation of original goods from a third country where they have been sold by or with the consent of the right-holder;
- 1.3 illegal activities such as diversion or theft of medical products first placed on the market in compliance with the applicable regulatory requirements.

It is recognized that these principles may need to be further developed and constantly updated in order to take into account other international instruments and in order to better address emerging and specific issues, e.g. the complexity of Internet trade and medical devices. As medical devices are, in many countries, regulated differently from medicinal products and as in those countries the legal marketing of medical devices may not depend on an authorization, the term "authorization" or "authorized" is to be understood as "legally marketed" medical devices.

## 2. TERMS USED IN THIS DOCUMENT

A common glossary of terms used by IMPACT needs to be established; no "special glossaries".

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

### **Counterfeit medical product**

A medical product is counterfeit when there is a false representation<sup>5</sup> in relation to its identity<sup>6</sup> and/or source.<sup>7</sup> This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct components<sup>8</sup> or with the wrong components, without active ingredients, with incorrect amounts of active ingredients or with fake packaging.

Violations or disputes concerning patents must not be confused with counterfeiting of medical products.

Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit.

Substandard batches of or quality defects or non-compliance with good manufacturing practices/ good distribution practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting.

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

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<sup>5</sup> Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behavior shall be considered during the legal procedures for the purpose of sanctions imposed.

<sup>6</sup> This includes any misleading statement with respect to name, composition, strength, or other elements.

<sup>7</sup> This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution.

<sup>8</sup> This refers to all components of a medical product.

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

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

**Manufacturer of medical devices**

“Manufacturer” means any natural or legal person who designs and/or manufactures a medical device with the intention of making the finished medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by a third party(ies).

**Manufacturer of medical products other than medical devices**

Any natural or legal person who:

- 2.1 produces the medical products;
- 2.2 engages in any part of the process of producing the medical products or of bringing the medical products to their final state. This includes any of the following: purchase of materials, processing, assembling, packaging, labelling, storage, sterilizing, testing and releasing for supply of the medical products or of any component or ingredient of the medical products as part of that process;
- 2.3 has the medical products designed or manufactured (as defined above) by a third party;
- 2.4 repackages or relabels medical products (as defined above).

**Medical device**

Medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

- a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
  - diagnosis, prevention, monitoring, treatment or alleviation of disease,
  - diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
  - investigation, replacement, modification or support of the anatomy or of a physiological process,
  - supporting or sustaining life,
  - control of conception,
  - disinfection of medical devices,
  - providing information for medical or diagnostic purposes by in vitro means
  - examination of specimens derived from the human body;and
- b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

**Note 1:** The definition of a device for in vitro examination includes, for example, reagents, calibrators, sample collection and storage devices, control materials and related instruments or apparatus. The information provided by such an in vitro diagnostic device may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions some in vitro diagnostic devices, including reagents and the like, may be covered by separate regulations.

**Note 2:** Products which may be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are:

- aids for disabled/handicapped people,
- devices for the treatment/diagnosis of diseases and injuries in animals,

- accessories for medical devices (see Note 3),
- disinfection substances,
- devices incorporating animal and human tissues which may meet the requirements of the above definition but are subject to different controls.

**Note 3:** Accessories intended specifically by manufacturers to be used together with a "parent" medical device to enable that medical device to achieve its intended purpose should be subject to the same Global Harmonization Task Force (GHTF) procedures as apply to the medical device itself. For example, an accessory will be classified as though it is a medical device in its own right. This may result in the accessory having a different classification to the "parent" device.

**Note 4:** Components to medical devices are generally controlled through the manufacturer's quality management system and the conformity assessment procedures for the device. In some jurisdictions, components are included in the definition of a "medical device".

### **Medical product**

For the purpose of this document, medical products means medicines (including vaccines and other biologicals), 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.

### **Operator of the distribution chain**

For the purpose of this document, this term encompasses any person or legal entity engaged in purchasing, selling, procuring, storing, distributing, dispensing, importing or exporting medical products, with the exception of dispensing/providing medical products to the end-users (see definition below for "retailer").<sup>9</sup> This refers, as applicable, to ownership, possession or control of the medical products in both national and international trade, including products in transit, transshipment, bonded warehouses, and "free trade zones". Depending on national legislation, operators of the distribution chain will 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 authorization requirements. For the purpose of this document all these activities are grouped under one definition because they should all be submitted to the same requirements and accountability in relation to counterfeit medical products.

### **Other operators involved**

For the purpose of this document this term encompasses any person or legal entity engaged in advertising, providing platforms for trade, providing Internet services that facilitate trade and supply of medical products, and other communications services, transportation, storage, providing assistance in commercial and financial transactions, providing forwarding and logistics services. This refers, as applicable, to ownership, possession or control of the medical products in both national and international trade, including products in transit, transshipment, bonded warehouses, and "free trade zones".

### **Retailer**

For the purpose of this document this term encompasses any person or legal entity engaged in procuring and storing medical products in order to sell or dispense them to the end-users. This includes, but is not limited to, pharmacies, clinics, hospitals, doctors' premises and retail outlets. This refers, as applicable, to ownership or possession of the medical products.

### **Sales agent: see Operator of the distribution chain**

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<sup>9</sup> End-users can be patients, consumers or professionals who directly use the products on patients/consumers.

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

**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 and supervision of 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),
- authorization/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, among others, all the following:

- 3.1 establish an adequate legal basis (comprising criminal, administrative and civil frameworks), for imposing and supervising compliance with and enforcement of obligations by all concerned parties;
- 3.2 ensure that this legal basis can be applied to all medical products, including counterfeit medical products, in transit/transshipment, bonded warehouses, free zones and all situations of the international trade;
- 3.3 establish adequately resourced authorities charged with combating counterfeiting of medical products with appropriate investigative and enforcement powers enshrined in legislation;
- 3.4 in case a third-party assessment body is established, it should be made sure that the body is adequately designated and regular oversight established;
- 3.5 establish liability for Internet service providers and other operators who facilitate advertisement of or trade in counterfeit medical products;
- 3.6 regularly scrutinize and amend legislation as required;
- 3.7 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, are in the possession of a specific licence,<sup>10</sup> as applicable;

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<sup>10</sup> Note: Specific WHO documents and, where available, applicable national regulations provide more details on good manufacturing and good distribution practices.

- 3.8 establish regulations aimed at fostering a safe, transparent and secure distribution system by establishing measures to ensure that medical products, as applicable, have a form of documentation that can be used to permit traceability of the products throughout the distribution channels from the manufacturer/importer to the retailer;
- 3.9 regulate the manufacture of active substances and of certain excipients entailing possible public health risks;
- 3.10 establish specific import (and export) procedures; this may include designation of a limited number of points of entry for imported medical products, as applicable, a measure which is particularly desirable in countries with limited human resources;
- 3.11 take measures to ensure that all medical products in the national distribution channels are licensed/authorized as required by national legislation;
- 3.12 take measures to enforce effective compliance with documented procedures to ensure the appropriate destruction of counterfeit products; this includes the identification of operational and financial responsibilities;
- 3.13 ensure that licences/authorizations are revoked for poor or illegal performance as judged against established laws and regulations;
- 3.14 issue and renew licences on the basis of documented satisfactory compliance with existing laws and regulations;
- 3.15 require that medical products are suitably labelled and packaged according to their required specifications and licences/authorizations;
- 3.16 ensure that the conditions for importation of medical products, as applicable, are clearly specified and importation is undertaken only with the necessary import licences/authorizations issued by the national competent authority;
- 3.17 ensure that imported medical products, as applicable, are licensed/authorized in the country of manufacture or, where not, there are acceptable reasons for such non-authorization;
- 3.18 provide adequate resources for licensing and authorization activities concerning medical products as well as for related assessments and inspections;
- 3.19 provide adequate initial and in-service training for medical products control, customs and law enforcement personnel;
- 3.20 establish legal mechanisms to improve coordination and exchange of information among health, regulatory, police, customs and other enforcement officers/authorities at a national, regional and international level (especially the ability to provide and use the information exchanged in legal /regulatory action in each Member State);
- 3.21 ensure that imported medical products can be and are inspected at points of entry and that samples are collected and analysed as required by a national strategic plan;
- 3.22 permit investigators, under appropriate guidelines, to conduct effective investigations, e.g. under-cover operations, in which samples can be obtained anonymously;
- 3.23 perform effective controls and tests on medical products, as applicable, authorized for marketing in order to ascertain their quality and authenticity;
- 3.24 ensure that non-compliance with anti-counterfeiting laws and regulations attracts prosecution and severe penal sanctions and results in the confiscation, forfeiture and destruction of counterfeit medical products as well as equipment and other materials used in conjunction with their manufacture;
- 3.25 foster international cooperation in the control of medical products and enter into bilateral and multilateral agreements with other governments and with regional and international organizations such as WHO, Interpol, World Customs Organization, Council of Europe;
- 3.26 ensure that export controls/regulations take into account the following aspects:
  - a) same safety and performance standards (e.g. WHO Certification Scheme for pharmaceuticals, other type of official certification if applicable for other types of products; as applicable: marketing authorization, compliance with manufacturing

- practices requirements, appropriate product information, etc.) for exported as for domestic products,
  - b) clause for allowing importing countries to obtain products that satisfy their requirements although such products might not have marketing authorization in the exporting country,
  - c) where applicable, clause mentioning remaining shelf-life to allow exportation providing a reasonable timeframe for use (e.g. residual shelf life should be at least 2/3 of shelf-life at lot release or six months if 2/3 of shelf-life is shorter than 6 months),<sup>11</sup>
  - d) clause to regulate international trade of labels and packaging materials for medical products;
- 3.27 ensure that appropriate information on counterfeit medical products is provided to manufacturers, operators of the distribution chain, retailers, other operators and health professionals; information and related actions such as compliance and enforcement actions should be based on appropriate standards and permit a timely and appropriate risk assessment;
- 3.28 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>12</sup>
- 3.29 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**, among others:

- 3.30 obligation to comply with applicable laws and regulations;
- 3.31 obligation to comply with official good practice guidelines (e.g. good manufacturing practices for medicinal products, good distribution practices<sup>13</sup>)
- 3.32 obligation to comply with applicable quality management systems requirement for medical devices;<sup>14</sup>
- 3.33 obligation to ensure supply of raw, starting and packaging materials from legitimate suppliers to manufacturers and ensure delivery of finished medical products from manufacturers to legitimate operators of the distribution chain, in accordance with applicable legislation, including, where appropriate, audits or appropriate certificates on the basis of risk assessment;
- 3.34 obligation to establish and maintain copies of records of transactions (including written contracts, where applicable) with suppliers, subcontractors and operators of the distribution chain;
- 3.35 obligation to document the origin of all materials used in the manufacture of authorized products in accordance with applicable GMP requirements;
- 3.36 obligation to have a process in place that would contribute to ensure that each batch received and shipped is accompanied by control reports (e.g. a certificate of analysis), as required by applicable legislation;
- 3.37 obligation to establish a quality assurance system which addresses (a) the manufacturer's response to reports of possible counterfeit medical products, (b) mandatory reporting of information to competent authorities and (c) work with competent authorities to trace, seize and destroy counterfeit product in compliance with applicable legislation;
- 3.38 obligation to document the appropriate disposal of expired or otherwise unusable products in a manufacturer's possession to prevent such products from re-entering the distribution chain;
- 3.39 obligation of manufacturers to cooperate with health, customs, police, other enforcement authorities and other stakeholders in the detection of counterfeit medical products, investigation

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<sup>11</sup> WHO guidelines for drug donations: <http://www.who.int/medicinedocs/collect/edmweb/pdf/whozip52e/whozip52e.pdf>.

<sup>12</sup> Specific model materials and advice are developed by IMPACT's Working Group on Communications.

<sup>13</sup> Quality assurance of pharmaceuticals. A compendium of guidelines and related materials. Volume ,2 Second updated edition. Good manufacturing practices and inspection. Geneva, World Health Organization, 2007  
<http://www.who.int/medicinedocs/collect/edmweb/pdf/s4900e/s4900e.pdf>.

<sup>14</sup> For example, ISO Standard 13485.

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 undertake 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 submitted to the same requirements as both manufacturers and operators of the distribution chain (see also sections 3.59 to 3.63).

**Responsibilities of operators of the distribution chain** include, among others:

- 3.40 obligation to comply with applicable laws and regulations;
- 3.41 obligation to comply with official good practice guidelines (e.g. GDP<sup>15</sup>) for medicinal products and applicable guidelines for active pharmaceutical ingredients (APIs) and excipients;
- 3.42 obligation to consider implementation of appropriate quality management systems for medical devices;
- 3.43 obligation to ensure supply of products from legitimate suppliers (manufacturers or operators of the distribution chain) and ensure delivery to legitimate operators of the distribution chain or retailers, in accordance with applicable legislation, including, where applicable, audits or appropriate certificates on the basis of a risk assessment;
- 3.44 obligation to establish and maintain copies of records of transactions (including written contracts) with suppliers, subcontractors and operators of the distribution chain;
- 3.45 obligation to accurately document the purchase and supply of all medical products, including returns from retailers;
- 3.46 obligation to ensure that each batch received and shipped is accompanied by appropriate documentation as required by national legislation;
- 3.47 obligation to establish a quality assurance system which addresses (a) the operator's response to suspicion or reports of possible counterfeit medical products, (b) mandatory reporting of information to competent authorities and (c) work with competent authorities to trace, seize and destroy counterfeit products in compliance with applicable legislation;
- 3.48 obligation of operators to 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);
- 3.49 obligation to document the appropriate disposal of expired or otherwise unusable products in the operator's possession to prevent such products from re-entering the distribution chain.

Operators should undertake appropriate risk assessment 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 submitted to the same requirements as operators of the distribution chain or retailers, as applicable (see also sections 3.59 to 3.63).

**Responsibilities of retailers**

- 3.50 Obligation to comply with applicable laws and regulations.
- 3.51 Obligation to comply with official good practice guidelines (e.g. GDP, GPP<sup>16</sup>).

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<sup>15</sup> Reference to WHO GMP, GDP and GPP guidelines.

<sup>16</sup> Reference to WHO GDP and GPP guidelines.

- 3.52 Obligation to establish and maintain records that allow for tracing medical devices beyond retailer level if and as required by applicable legislation.
- 3.53 Obligation to ensure supply from legitimate operators of the distribution chain.
- 3.54 Obligation to establish and keep copies of written contracts with suppliers, subcontractors and operators of the distribution chain.
- 3.55 Obligation to document the purchase and return of all medical products.
- 3.56 Obligation to establish an appropriate quality assurance system which addresses (a) the retailer's response to suspicion or reports of possible counterfeit medical products, (b) mandatory reporting of information to competent authorities and (c), work with competent authorities to trace, seize and destroy counterfeit product in compliance with applicable legislation.
- 3.57 Obligation of the retailer to 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).
- 3.58 Obligation to document the appropriate 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 requesting appropriate certificates. Retailers should undertake appropriate risk assessment 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 submitted to the same requirements as operators of the distribution chain or retailers, as applicable (see also sections 3.59 to 3.63).

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

- 3.59 Obligation to be aware of legal requirements regarding medical products and comply with applicable legislation.
- 3.60 Obligation to exert due diligence for ensuring business with legitimate business partners.
- 3.61 Obligation of operator to 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).
- 3.62 Obligation to document any activity related to medical products.
- 3.63 Obligation to take the necessary actions in case operators have reasonable grounds to believe or notice has been given to them by the appropriate authorities of the fact that their services are being exploited for the trade/advertisement of counterfeit medical products.

#### **Regional/international obligations**

Due to the international nature of counterfeit medical products all governments are encouraged to establish a close and efficient cooperation in this area.

**Governments**, in line with existing international obligations, should make use of or establish legal mechanisms to permit:

- 3.64 regional/international exchange of information among health, regulatory, police, customs and other enforcement officers/authorities (especially the ability to provide and use the information exchanged in legal/regulatory action in each Member State); this includes all areas within Member States as well as free trade zones;

- 3.65 to facilitate cross-border joint operations among health, regulatory, police, customs and other enforcement officers/authorities; this includes all areas within Member States as well as free trade zones;
- 3.66 to use, to the widest extent possible, relevant regional/international instruments on international cooperation in criminal matters for the purposes of investigations, collection of evidence or proceedings concerning criminal offences related to counterfeit medical products;
- 3.67 to include criminal offences directly related to counterfeit medical products as extraditable offences;
- 3.68 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>17</sup>

## 4. ILLEGAL ACTS

It is prohibited to:

- 4.1 manufacture, including performing any of the activities described above under "manufacturer", a counterfeit medical product;
- 4.2 own, possess or control counterfeit medical products in transit, transshipment, free trade zones, bonded warehouses and other situations of international commerce;
- 4.3 introduce into the distribution chain any counterfeit medical product through any means including but not limited to selling, delivering, distributing, importing, exporting, donating or otherwise supplying others with a counterfeit medical product, or storing it;
- 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, including labels, intended for a counterfeit medical product;
- 4.6 manufacture, transport, or distribute any equipment, materials, components (including genuine ones) or documentation used in the production or to accompany the distribution of counterfeit medical products with the knowledge of or being reckless to the fact that they be used for such purposes;
- 4.7 to provide services such as online services, electronic sale platforms, electronic payments or transport to persons or legal entities when such service providers have reasonable grounds to believe or notice has been given to them by the appropriate authorities that such persons or legal entities are using such services to engage in any of the offences described above;
- 4.8 conspire to commit, attempt to commit, aid and abet, counsel or facilitate or incite to commit any of the offences set forth in these provisions.

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

## 5. SANCTIONS

Given that counterfeiting of medical products per se 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), including introducing **severe criminal sanctions against its perpetrators regardless of evidence of actual harm caused to others.**

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<sup>17</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.

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

These sanctions should:

- reflect the gravity of the respective offences, especially according to the presence and level of guilt,
- be equivalent to those provided by national legislation for other serious crimes, such as the manufacture 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. The specific circumstances and facts (e.g. previous record of persons involved, availability of proper documentation regarding manufacture or trade, etc.) will permit to identify 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 per se regardless of evidence of harm actually caused:

- 5.1 death or serious injury to persons affected;
- 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 to persons affected;
- 5.5 acquisition of considerable pecuniary gain;
- 5.6 perpetrator is an authorized operator (manufacturer, retailer, other);
- 5.7 perpetrator is misusing a position of trust, e.g. a health professional;
- 5.8 repeated offence;
- 5.9 organized crime;
- 5.10 exposure of a large number of persons to ineffective diagnostics.

In addition, other offences that present themselves in conjunction with counterfeit medical products may also be pursued and penalized 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 available without prejudice to those additional remedies and/or sanctions which are available under relevant criminal, civil or administrative legislation:<sup>18</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 a temporary or permanent basis, of the establishment(s) involved in

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<sup>18</sup> This list is not exhaustive.

- 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 wind up the operation and related activities;
- 6.11 indemnification of affected/damaged parties (including inter alia affected patients, affected operators and manufacturers of genuine products);
- 6.12 publication of judicial decisions (including dissemination of information to international organizations and to national competent authorities of other countries);
- 6.13 withdrawal of licences.

Without prejudice to other compensation mechanisms and to 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, money derived from confiscation of assets should contribute to compensating the victims and supplement the financing of anti-counterfeit medical product operations by the appropriate authorities.

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