

## **IMPACT**

**International Medical Products Anti-Counterfeiting Taskforce**

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

#### **Background document for a meeting of experts Lisbon, 10-11 December 2007**

## **INTRODUCTION**

The participants of the WHO International Conference 'Combating Counterfeit Drugs: Building Effective International Collaboration', gathered in Rome on 18 February 2006, declared that

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 public and private stakeholders that are affected and are competent for addressing the different 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 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 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.

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

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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.

IMPACT stakeholders have gathered experience and information on current national and international legislative instruments in different parts of the world. Although further 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 responsibility 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>1</sup> has taken place in Brussels on 12 and 13 July 2007 and has prepared the present document which describes principles for legislation that could be recommended by IMPACT to all WHO member states.<sup>2</sup>

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<sup>1</sup> See annex 1 for a list of participants

<sup>2</sup> This draft is meant for wide circulation after August 2007 and will be the basis for an international conference to be held in Lisbon, Portugal, on 10 and 11 December 2007. The outcome of this conference will be submitted to the IMPACT annual General Meeting, which will take place in Lisbon, Portugal, on 12-14 December 2007.

## 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 out in this document focus on public and personal health implications in relation to counterfeit medical products (as defined below) that need to be appropriately addressed in legislation. Specific national and/or regional bodies of criminal, pharmaceutical, administrative and civil legislation may need to be enriched by 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 specifically 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. other illegal activities such as a) diversion of supplies of authorized<sup>3</sup> medical products, or b) theft of authorized medical products.

## 2 - DEFINITIONS

### **Medical product:**

For the purpose of this document, this includes, at least, medicines, medical devices 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 (name, composition, strength, or any other element that may influence the judgement of health professionals, patients or consumers about the identity of the product) or source (manufacturer, country of manufacturing, country of origin, marketing authorisation holder, or any other element that may influence the judgement of health professionals, patients or consumers about the source of the product). 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>4</sup> or with the wrong components, without active ingredients, with insufficient active ingredients or with fake packaging.

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

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

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<sup>3</sup> by the competent authority

<sup>4</sup> this refers to ingredients or any other component of a medical product

**Exporter: see Operator of the distribution chain.** Depending on national legislation, exporting medical products may be considered the activity of either a distributor or a manufacturer.

**Importer: see Operator of the distribution chain.** Depending on national legislation, importing medical products may be considered the activity of either a distributor or a manufacturer.

### **Manufacturer**

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. re-packages or re-labels medical products (as defined above).

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

For the purpose of this document this term encompasses **all** the different professional or commercial activities concerned with purchasing, selling, procuring, storing, distributing, dispensing, importing, exporting medical products, with the exception of dispensing/providing medical products to the end users<sup>5</sup>. This refers, as applicable, to ownership or possession of the medical products. 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 authorisation 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 **all** the different activities 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, as applicable, to ownership or possession of the medical products.

**Retailer:** For the purpose of this document this term encompasses **all** the different activities concerned with procuring and storing medical products in order to sell or dispense them to the end users. This refers, as applicable, to ownership or possession of the medical products

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

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

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

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<sup>5</sup> end users can be patients, consumers, or professionals who directly use the products on patients/consumers.

### **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.

Political will and the continuous strong commitment of governments are essential if there is to be 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 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),
- authorisation/licence (by the regulator),
- supervision/ inspection (directed by the regulator).

It should be noted that manufacturers, operators of the distribution chain and retailers are expected to establish a quality assurance or management system. In addition, all parties should work together in order 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 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/trans-shipment, bonded warehouses, free-zones and all situations of the international trade;
- 3.3. establish adequately resourced regulatory institutions (preferably a single national medical products regulatory authority including, if possible, official control laboratories) with appropriate powers enshrined in legislation;
- 3.4. establish liability for Internet Service Providers and other operators who facilitate advertisement or trade of counterfeit medical products;
- 3.5. regularly scrutinize and amend legislation as required;
- 3.6. regulate the manufacture, importation, distribution, supply, donation, offer for sale and sale of medical products, thereby ensuring that those who manufacture, import, distribute, supply, and perform any transaction related to medicinal products and medical devices are in the possession of a specific licence or are authorized to do so in defined premises under the responsibility of suitably qualified persons;<sup>6</sup>
- 3.7. regulate the manufacture of active substances and of certain excipients entailing possible public health risks;

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<sup>6</sup> Note: Specific WHO documents and, where available, applicable national regulations provide more details on good manufacturing and good distribution practices.

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- 3.8. establish specific import procedures; this may include designation of a limited number of points of entry for imported medical products, a measure which is particularly desirable in countries with limited human resources;
- 3.9. take measures to ensure that all medical products in the national distribution channels are licensed/authorized, as required by national legislation;
- 3.10. 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;
- 3.11. ensure that licences/authorizations are revoked for poor or illegal performance as judged against established laws and regulations;
- 3.12. issue and renew licences on the basis of documented satisfactory compliance with existing laws and regulations;
- 3.13. require that medical products are suitably labelled and packaged according to their required specifications and licences/authorizations;
- 3.14. ensure that the conditions for importation of medical products are clearly specified and importation is undertaken only with the necessary import licences/authorizations issued by the national competent authority;
- 3.15. ensure that either imported medical products are licensed/authorized in the country of manufacture or, where not, there are acceptable reasons for such non-authorisation;
- 3.16. provide adequate resources for licensing and authorisation activities concerning medical products as well as for related assessments and inspections.
- 3.17. provide adequate initial and in-service training for medical products control, customs and law enforcement personnel;
- 3.18. 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);
- 3.19. ensure that imported medical products can be and are inspected at points of entry and samples are collected and analysed as required by a national strategic plan;
- 3.20. permit investigators, under appropriate guidelines, to conduct effective investigations, e.g. under-cover operations, in which samples can be obtained anonymously;
- 3.21. perform effective controls and tests on medical products approved for marketing in order to ascertain their quality and authenticity;
- 3.22. ensure that non-compliance with laws and regulations attracts prosecution and severe penal sanctions and results in the confiscation, forfeiture and destruction of counterfeit medical products.
- 3.23. foster international cooperation in the control of medical products and 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;
- 3.24. ensure that controls/regulations concerning exported medical products take into account the following aspects:
  - a) same standards (e.g. WHO Certification Scheme for pharmaceuticals, other type of official certification if applicable for other types of products; as applicable: marketing authorisation, 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 they do not have marketing authorisation in the exporting country;

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- c) where applicable, clause mentioning remaining shelf-life to allow exportation and a reasonable timeframe for use (e.g. at least 2/3 of shelf-life at lot release or 6 months if 2/3 of shelf-life is shorter than 6 months)<sup>7</sup>;
  - d) clause to regulate international trade of labels and packaging materials for medical products.
- 3.25. ensure that appropriate information on counterfeit medical products is provided to manufacturers, operators of the distribution chain, other operators and health professionals;
- 3.26. ensure that appropriate information and awareness is provided to the public on counterfeit medical products<sup>8</sup>;
- 3.27. 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:

- 3.28. obligation to comply with applicable laws and regulations;
- 3.29. obligation to comply with official Good Practice Guidelines (e.g. GMP requirements for medicinal products, GDP<sup>9</sup>)
- 3.30. obligation to comply with Quality Management Systems requirement for medical devices;<sup>10</sup>
- 3.31. obligation to ensure supply from and further distribution to legitimate business partners, including, where appropriate, audits or appropriate certificates on the basis of risk assessment;
- 3.32. obligation to establish and keep copies of written contracts with suppliers, sub-contractors and business partners;
- 3.33. obligation to document the origin of all materials used in the manufacture;
- 3.34. obligation to ensure that each batch received and shipped is accompanied by control reports (e.g. a Certificate of Analysis);
- 3.35. obligation to establish a Quality Assurance System which addresses the response to counterfeit medical products, a responsible person, mandatory reporting to competent authorities and recalls;
- 3.36. obligation to document the appropriate disposal of expired or otherwise unusable products to prevent them from entering into the distribution chain;
- 3.37. obligation of manufacturers to cooperate with health, customs, police and other enforcement authorities in the detection and prosecution of counterfeit medical products.

In addition to what is stated above, and depending on product and circumstances (e.g. regions), manufacturers should consider an appropriate risk assessment for a decision on anti-counterfeit measures and technologies.

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.

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<sup>7</sup> WHO guidelines for drug donations,

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

<sup>8</sup> Specific model materials and advice are developed by IMPACT's working group on Communications

<sup>9</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>10</sup> e.g. ISO Standard 13485

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

- 3.38 obligation to comply with applicable laws and regulations;
- 3.39 obligation to comply with official Good Practice Guidelines (e.g. GDP<sup>11</sup>);
- 3.40 obligation to comply with appropriate Quality Management Systems for medical devices;
- 3.41 obligation to ensure supply from and further distribution to legitimate business partners, including, where applicable, audits or appropriate certificates on the basis of a risk assessment
- 3.42 obligation to establish and keep copies of written contracts with suppliers, sub-contractors and business partners
- 3.43 obligation to accurately document the purchase and supply of all medical products, including returns from retailers;
- 3.44 obligation to ensure that each batch received and shipped is accompanied by appropriate documentation as required by national legislation;
- 3.45 obligation to establish a Quality Assurance System which addresses the response to counterfeit medical products, a responsible person, mandatory reporting to competent authorities and recalls;
- 3.46 obligation to cooperate with health, customs and police enforcement authorities in the detection and prosecution of counterfeit medical products;
- 3.47 obligation to document the appropriate disposal of expired or otherwise unusable products to prevent them from entering into the distribution chain.

In addition to what is stated above, and depending on product and circumstances (e.g. regions), operators of the distribution chain should consider an appropriate risk assessment for a decision on anti-counterfeit measures and technologies.

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).

**Responsibilities of retailers:**

- 3.49. obligation to comply with applicable laws and regulations;
- 3.50. obligation to comply with official Good Practice Guidelines (e.g. GDP, GPP<sup>12</sup>);
- 3.51. obligation to ensure supply from legitimate business partners;
- 3.52. obligation to establish and keep copies of written contracts with suppliers, sub-contractors and business partners;
- 3.53. obligation to document the purchase and return of all medical products;
- 3.54. obligation to establish an appropriate Quality Assurance System which addresses the response to counterfeit medical products, a responsible person, mandatory reporting to competent authorities and recalls, where applicable;
- 3.55. obligation to cooperate with health, customs and police enforcement authorities in the detection and prosecution of counterfeit medical products;
- 3.56. obligation to document the appropriate disposal of expired or otherwise unusable products to prevent them from entering into the distribution chain.

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<sup>11</sup> Reference to WHO GMP, GDP, GPP guidelines

<sup>12</sup> Reference to WHO GDP and GPP guidelines

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Depending on the national situation, retailers may consider auditing distributors or requesting appropriate certificates.

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).

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

- 3.57. obligation to be aware of legal requirements regarding medical products and comply with applicable legislation;
- 3.58. obligation to exert due diligence for ensuring business with legitimate business partners;
- 3.59. obligation to cooperate with health, customs and police enforcement authorities in the detection and prosecution of counterfeit medical products;
- 3.60. obligation to document any activity related to medical products;
- 3.61. 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:

- 3.62. 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;
- 3.63. 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;
- 3.64. make use, to the widest extent possible, of relevant regional/international instruments on international co-operation in criminal matters for the purposes of investigations, collection of evidence, or proceedings concerning criminal offences related to counterfeit medical products;
- 3.65. that criminal offences related to counterfeit medical products be included as extraditable offences in any extradition treaty established or to be concluded;
- 3.66. that criminal offences related to counterfeit medical products should also be prosecuted by a country if committed abroad by a citizen of that country<sup>13</sup>;
- 3.67. that, in the absence of prosecution in the country of citizenship of the offender or the country where the offence took place, criminal offences related to counterfeit medical products may also be prosecuted by any country regardless of the nationality of the offenders and place where offences took place under established principles of universal jurisdiction<sup>13,14</sup>.

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<sup>13</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.

<sup>14</sup> e.g. Convention for the Suppression of Unlawful Seizure of Aircraft (Hijacking Convention).

860 U.N.T.S. 105 - The Hague, 16 December 1970 - , entered into force 14 October 1971

## 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 or possess counterfeit medical products in transit, trans-shipment, free-trade zones, bonded-warehouses and other situations of the 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 or possess counterfeit medical products that are likely or intended 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 or intent that they be used for such purposes;
- 4.7. to provide services such as on-line services, electronic-sale-platforms, electronic payments, or transport 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;
- 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.

## 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 the necessary measures to effectively deter it, including introducing **severe criminal sanctions against its perpetrators regardless of evidence of actual harm caused to others.**

These **sanctions should be equivalent to those provided by national legislation for other serious crimes, and adequate to the gravity of the offences mentioned above, including<sup>15</sup> mandatory jail sentences where mitigating circumstances are not present.** In addition, offences related to counterfeit medical products may also be pursued and penalised, with cumulative effect, under other applicable criminal, civil or administrative legislation.

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<sup>15</sup> if locally applicable constitutions or other instruments permit

Quality defects or GMP/GDP incompliance 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.

Legislation should also address the following aggravating conditions:

- 5.1. death or serious injury to persons affected,
- 5.2. affecting the health of a large number of persons,
- 5.3. risk for 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 authorised operator (manufacturer, retailer, other)
- 5.7. perpetrator is a health professional
- 5.8. repeated offence
- 5.9. organized crime

## 6 - NATURE OF SANCTIONS

In order to effectively combat counterfeiting of medical products all 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>16</sup>:

- 6.1. custodial sentences;
- 6.2. fines;
- 6.3. confiscation of assets;
- 6.4. confiscation of instruments 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 ban to engage in medical-product-related activities;
- 6.7. destruction of the goods involved in the offences;
- 6.8. ban on the access to public assistance or subsidies;
- 6.9. placing under judicial supervision;
- 6.10. judicial winding-up;
- 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 organisations and to national competent authorities of other countries);
- 6.13. withdrawal of licences.

Without prejudice to other compensation mechanisms, money derived from confiscation of assets should be placed in a public fund for the purpose of compensating the victims and financing anti-counterfeit medical product operations.

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<sup>16</sup> This list is not exhaustive

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