



National Institute
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Counterfeit medical devices

A risk indication

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“Medical devices are subject to counterfeit, according to a limited number of reported cases. Around the world authorities are preparing legislation to fight the counterfeiting of medical devices. Very few of the branch organisations and manufacturers in Europe appear to be actively working on counter measures to prevent the distribution of counterfeited products.”

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Summary and conclusion

Medical devices are counterfeited. Taking into account the thousands of different types of medical devices that are on the market and the small number of discovered counterfeited devices, the issue gives the impression of a series of incidents rather than a structural problem. Around the world authorities are preparing legislation to fight the counterfeiting of medical devices. The Council of Europe and the European Commission are working on several projects. Very few of the branch organisations and manufacturers in Europe appear to be actively working on counter measures to prevent the distribution of counterfeited products.

There is a great concern among authorities and industry about the prevalence of counterfeit medicinal products on the world market. The World Health Organisation estimates that up to 1% of the medicinal products available in the developed world are likely to be counterfeit. Information from public sources revealed relatively few discoveries of counterfeit medical devices. In the period from 2001 till June 2009 thirteen counterfeit medical devices were discovered; twelve of these in the last five years (see table 1). Fatal incidents as the result of the use of counterfeit devices have not been reported. A typical group of devices that is preferred by counterfeiters does not clearly stand out; there may be a slight preference for medical devices for personal use (see figure 1). The same is true for the distribution channel; no particular route stands out as counterfeited devices were sold via the internet but also in stores and pharmacies.

In the fight against counterfeit medicinal products and medical devices the Council of Europe focuses on measures that the member countries shall take to ensure that counterfeiting and related activities are properly criminalised. Although priority is given in the direction of medicinal products, medical devices are included in the activities. The WHO strives for world wide collaboration between all stakeholders to ensure that public health implications in relation to counterfeit medical products are appropriately addressed in national and regional legislation. In the fight against the counterfeiting of medical devices, a number of national authorities around the globe focus on raising public awareness and monitoring of the supply chain.

Of the 157 branch organisations and manufacturers in Europe, only 5 give a statement on their websites in which they explain their position on counterfeiting and the counter measures they develop (see table 2). The anti-counterfeiting strategies include certification of the supply chain, authentication of the product by advanced technical means, awareness raising, tracing of counterfeit devices and active cooperation between all stakeholders.

From the information given by the Dutch branch organisations it seems that the counterfeiting of devices is not a large concern to the Dutch manufactures and distributors (see table 3). Only one of the six organisations that were requested for information stated that counterfeiting is on the agenda.

The apparent general lack of concern amongst the stakeholders about counterfeiting may indicate that effort has to be put into education and awareness rising, not only of the general public but also of the trade partners. In this light, the campaign that the Dutch Ministry for Public Health intends to launch later this year, to inform the general public of the existence and dangers of counterfeit medical products, may be a step forward. The establishment of a 24 hour hotline where the public, health care workers and others dealing with medical devices can report possible counterfeits may prove to be helpful in obtaining information on counterfeited devices.

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Introduction

Counterfeit medicinal products and medical devices pose a risk for human health, because the quality and/or performance of these products are unknown. The supply of counterfeit medicinal products is a growing problem. The World Health Organisation (WHO) estimates that up to 1% of the medicinal products available in the developed world are likely to be counterfeit. This estimate grows to 50% for medicinal products available from websites which conceal their physical address. Counterfeit medicinal products originally focused on 'lifestyle' medicinal products, including erectile dysfunction and weight loss. Counterfeiters are now also focusing on lifesaving medicinal products, including indications like cancer and heart diseases. Counterfeit medicinal products also penetrate the regular distribution channels (MHRA 2007).

Whether this problem is of the same magnitude for medical devices is unclear. Reports of counterfeit products in the media mainly concern medicinal products. This not necessarily means that there are less counterfeit medical devices in circulation. It could also be that they have not yet been discovered. Possibly, the discovered counterfeit medical devices may only represent the proverbial 'top of the iceberg'. Mergent Industry claims that 5% of medical devices and diagnostics imported in the USA are counterfeit (Eucomed 2008).

Due to the enormous variety of medical devices and the large amount of channels through which these products are placed on the market, it is impossible to estimate the number of counterfeit medical devices in the supply chain. Where the distribution of prescription drugs is legally restricted to pharmacies and drugstores, the legitimate supply chain for medical devices is much broader and includes supermarkets, department stores, and even vending machines in public areas (e.g. condoms). The internet is also becoming an important source for distributing medicinal products and medical devices. Unfortunately it is not easy to determine whether the companies behind the websites are trustworthy.

The WHO, that is drawing attention on the problem of counterfeit medicinal products for several years, recently changed their focus from 'counterfeit medicinal products' to 'counterfeit medical products'. The latter term implies that the WHO recognises that the scope of the problem is broader than just medicinal products and should also include medical devices (see box 1). For the purpose of this document this definition is adopted.

Three main questions are to be answered in this report:

- Which counterfeit medical devices are reported in Europe and other western countries?
- What measures are taken internationally, to prevent distribution of counterfeit medical devices?
- What activities are undertaken by branch organization and other stakeholders to prevent distribution of counterfeit medical devices?

The study was conducted in the period May until July 2009.

The term counterfeit medical product describes a product with a false representation^(a) of its identity^(b) and/or source^(c). 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^(d), with wrong ingredients/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.

Notes:

(a) Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behavior shall be considered during the legal procedures for the purposes of sanctions imposed.

(b) This includes any misleading statement with respect to name, composition, strength, or other elements.

(c) This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution.

(d) This refers to all components of a medical product.

(WHO 2008).

Box 1 WHO definition of counterfeit medical products

Reports on counterfeit medical devices

US FDA received a first report on a counterfeit device in October 1993. Several more cases including in Europe (France, UK, etc.) have been confirmed as counterfeited devices: e.g. condoms, contact lenses, diagnostic tests, dental resins, hernia mesh repair, wound care products, sutures, etc (Eucomed 2008).

The websites of competent authorities in Europe¹, the United States, Canada and Australia, the WHO website and the database of Health Devices Alerts of the ECRI Institute were screened for reports on counterfeit medical devices. In the period 2001 – June 2009, thirteen counterfeit medical devices were reported (see table 1).

2001	Medical device Problem	Intraocular lens The U.K. Medical Devices Agency (MDA) issued a Safety Notice informing users that counterfeit polymethyl methacrylate intraocular lenses (IOLs) have been made and sold in Pakistan. These IOLs carry a false CE marking.
	Risk	Not specified
	Reported country	UK
	Manufacturer/supplier	Unknown
	Distribution	Unknown
2004	Medical device Problem	Hi-Tec BARG TF Vaginal Tape tension Free used to surgically treat stress urinary incontinence Hi-Tec BARG TF vaginal tape may be available in the UK. This product is uncontrolled, carries a false CE marking. It imitates a product called Hi-Tec BARG P8 manufactured by Textile Hi-Tec.
	Risk	Unknown risk to patients
	Reported country	UK (MHRA 2004)
	Manufacturer/supplier	Unknown
	Distribution	Distributors
2004	Medical device Problem	Contact lenses CooperVision Proclear Contact Lenses may be counterfeit and not sterile if purchased through 1-800-CONTACTS, an unauthorized distributor
	Risk	Infection
	Reported country	USA (ECRI 2004)
	Manufacturer/supplier	1-800-CONTACTS
	Distribution	Telesales
2004	Medical device Problem	Contact lenses Forgeries of J&J SureVue contact lenses may have been distributed in France. These counterfeit items may pose an infection risk because they are not sterile and are not shaped properly.
	Risk	Infection
	Reported country	USA (ECRI 2004)
	Manufacturer/supplier	Unknown
	Distribution	Internet
2004	Medical device Problem	Contraceptive patches FDA and Johnson & Johnson issued a warning to the public stating that an overseas Internet site was selling counterfeit Ortho Evra transdermal contraceptive patches.
	Risk	Unwanted pregnancy
	Reported country	USA (ECRI 2004)
	Manufacturer/supplier	Unknown
	Distribution	Internet

¹ Only websites in the English, German or Dutch language were screened.

2005	Medical device Problem	Dental filling material As a result of recently reported complaints, it has come to the attention of Dentsply, that counterfeit "Spectrum® TPH" products are being distributed throughout Europe. Counterfeit Spectrum TPH compules (container/dispenser of the filling material) have been illegally placed on the UK market under the legitimate manufacturer's brand name "Dentsply". Use of the product has led to premature curing of the composite filling material and fracture of the compule.
	Risk	The housing of the compule may fracture, thus leading to possible injury to the user and/or patient.
	Reported country	UK (MHRA 2005)
	Manufacturer/supplier	Unknown
	Distribution	Unknown
2005	Medical device Problem	Condom Non-Durex condoms in fake Durex packaging condoms. Initial testing of the counterfeit product indicates that the product may not provide an effective barrier and therefore cannot be guaranteed to prevent transmission of sexually transmitted diseases or work as an effective means of contraception
	Risk	Sexually transmitted infection or pregnancy
	Reported country	Ireland (IMB 2005)
	Manufacturer/supplier	Unknown
	Distribution	Retail outlet and pharmacies
2005	Medical device Problem	Polypropylene mesh used in the repair of hernias and other fascial deficiencies. Counterfeit Prolene® polypropylene mesh are not sterile
	Risk	Infection
	Reported country	USA (FDA 2005)
	Manufacturer/supplier	Unknown
	Distribution	Unknown
2006	Medical device Problem	One Touch Glucose strips Fake test strips, show erratic test results. LifeScan, Inc. has discovered incidents of counterfeit OneTouch® Test Strips in various countries around the world. This counterfeit product is a fake product not made by LifeScan.
	Risk	Inaccurate test result and improper treatment of diabetes.
	Reported country	Several countries, e.g. USA (2006), Greece (2006), China (2007), India (2007), Pakistan (2007), Philippines (2007), Saudi Arabia (2007), Turkey (2007), United Arab Emirates(2007). (LifeScan 2006)
	Manufacturer/supplier	China
	Distribution	Wholesalers, distributors and pharmacies
2006	Medical device Problem	Diagnostic kits for self-testing (HIV and Chlamydia) Defective test kits: kit contain components of other kits, which are also past their expiry date.
	Risk	Inappropriate/inaccurate results leading to misdiagnosis/undetected illness, lack of appropriate medical therapy and potential for transmission to others of undetected infectious disease.
	Reported country	Ireland (IMB 2006)
	Manufacturer/supplier	Celtic Integrated Network, www.testkitsdirect.com
	Distribution	Pharmacy or internet
2008	Medical device Problem	Thermoskin Ice-Pack Contains toxic chemical; diethyleenglycol which can leak out of the ice-pack
	Risk	Poisoning
	Reported country	Australia (TGA 2008)
	Manufacturer/supplier	China, Taiwan, Eastland Medical
	Distribution	Store

2009	Medical device Problem	Littmann® Stethoscope Counterfeit stethoscopes are being sold using the Littmann® brand. While available at a lower cost than the genuine products, these scopes deliver correspondingly poor performance.
	Risk	Inaccurate diagnosis
	Reported country	USA (3MHealthcare 2009)
	Manufacturer/supplier	Unknown
	Distribution	Websites and other unauthorized outlets.
2009	Medical device Problem	NovoFine insulin pen needles There is no assurance that these needles are manufactured to the appropriate quality standard.
	Risk	Adverse reactions; pain and discomfort; infection and difficulty in attaching the needle to the pen injection device.
	Reported country	UK (MHRA 2009), NL (IGZ 2009)
	Manufacturer/supplier	Unknown
	Distribution	Wholesaler, Pharmacy

Table 1 Reports on counterfeit medical devices

The information presented in table 1 is taken directly from the reports on counterfeit medical devices. The reports are not always complete and in some cases important information is not available. For instance manufacturers and or suppliers of counterfeit devices are rarely known and the supply chain (e.g. import, wholesalers, distribution, internet) is not always clear. Without this information it is difficult to prevent the introduction of the counterfeit product on the market.

In addition it is important to get a picture of the scale of the problems caused by counterfeit medical devices. Therefore information is needed on the number and nature of risks and incidents. In almost all reports, risks are identified and described. This is however not the case for the incidents that have occurred with the counterfeit devices. In only one report an incident and the follow up action by the authorities is described in detail (box 2). For another product (OneTouch® Test Strips) incidents are registered, but information on the number and nature of the incidents is not provided. The remaining reports contain no information on incidents after use.

A Recall of toxic ice packs after the near death of a toddler who ingested some of a pack's contents last month has been widened after more than 20 products - including one targeted at children - were found to be contaminated. However, authorities and manufacturers have been slow to alert the public to the potentially dangerous ice packs, which include one designed to ease pain from breastfeeding. The second national recall of ice packs in less than a month was announced on Friday after the Therapeutic Goods Administration found that almost one in three products it tested contained highly toxic ethylene glycol, a substance commonly used in antifreeze and as an air-conditioning coolant. In all, 21 additional products from seven manufacturers were recalled. Most of the products were manufactured in China, while two were manufactured in Taiwan. Others were sourced to British manufacturers. Among them was the Frosty Bear REDI Hot and Cold Pack, produced by Eastland Medical and marketed specifically for use by toddlers (Dart 2008). A product sold by the Australian company Smartchoices was also recalled. It is designed to be applied around a woman's chest during breastfeeding to ease pain. A warning by the Therapeutic Goods Administration said all banned products should be kept away from children. A list of recalled products can be viewed at www.tga.gov.au (TGA 2008).

Box 2 Incident with toxic ice packs

Possible explanation for the relative small number of reports on counterfeit medical devices is that counterfeits are difficult to identify. They may be good imitations of bona fide products and may give an acceptable performance in the eye of unknowing user. A universal and effective solution for this problem has not yet been introduced. Technical solutions are available to authenticate products, but these are either easy to falsify (e.g. packaging materials, type face, holograms) or the authentication marks are laborious to verify (e.g.

unique product code that should be verified on the internet by the costumer). An international standard for the performance requirements of such authentications is in preparation by the International Organization for Standardization (ISO/PC246).

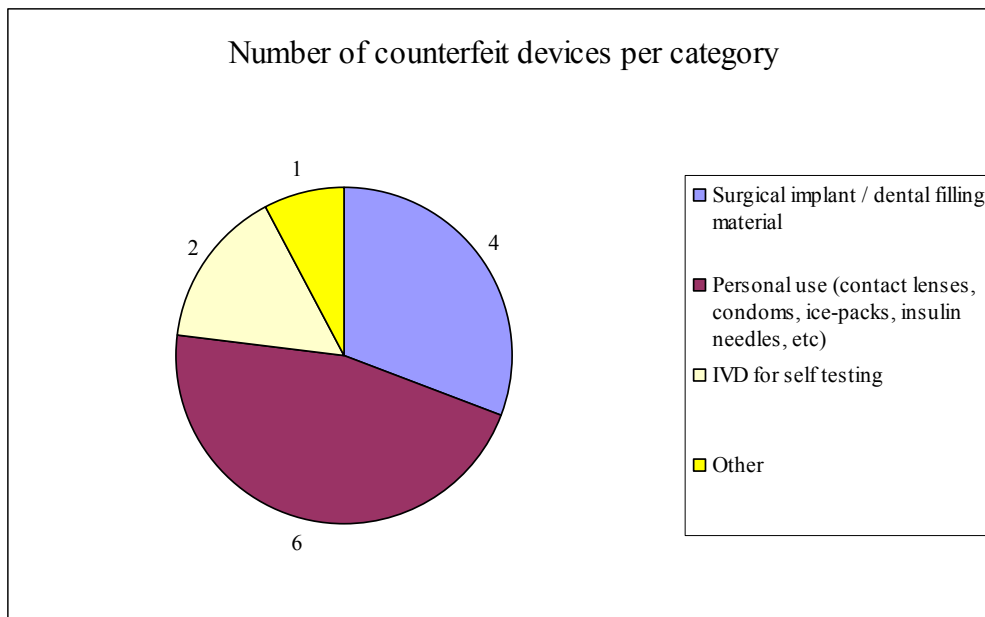


Figure 1. Number of counterfeit devices per category

Actions to prevent distribution of counterfeit medical devices

In the public consultation on the revision of the European medical devices directives, counterfeiting of medical devices was regarded as a limited problem. However the majority of the respondents were in favour of preventive measures to ensure the traceability of devices. Strategies are developed by several organisations in Europe and other western countries to prevent the distribution of counterfeit medical devices. These anti-counterfeit strategies vary from legal instruments to raising public awareness and are described in the next sections.

Authorities in Europe and other western countries

Council of Europe; development of an international legally binding instrument to fight crime concerning counterfeit medical products

A Group of Specialists on Counterfeit Pharmaceutical Products (PC-S-CP) is set up by decision of the European Committee on Crime Problems (CDCP). The first task of this group was to prepare a report focusing on the key elements, which could be included in a international legally binding instrument (Convention) to fight crime concerning counterfeit medical products (including medical devices), focusing in the first place on the criminal law aspects of the problem and on strengthening of international co-operation in preventing this crime. The draft Convention contains the legal measures that each of the member countries shall enforce within their territory in order to create the legal base for the fight against counterfeiting and similar crimes involving threats to public health. In short, all member states that ratify the convention shall take the necessary legislative or other measures to ensure that the manufacturing, the supplying, the promotion, the illicit trafficking of counterfeit medical products, ingredients or components as well as the falsifying of any document related to a medical product, ingredient or component are criminalised. (COE 2009)

European Commission; European Observatory on Counterfeiting and Piracy

On 2 April 2009 an European Observatory on Counterfeiting and Piracy was launched. By enhancing cooperation across the EU, the Observatory will be at the forefront in the fight against fake goods in general. The launch of the Observatory answers the urgent need for a better targeted and more focused enforcement of intellectual property rights. It will be a platform to collect data, raise awareness, facilitate dialogue, exchange views and share best practices in enforcing intellectual property rights between business and national authorities. (EuropeanCommission2 2009)

European Commission; amendment of Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of counterfeit medicinal products

The European Commission has proposed amendments to Directive 2001/83/EC (on the Community code relating to medicinal products for human use), to protect the legal distribution chain from the infiltration of fake medicinal products. This will help to ensure confidence of distributors, health care professionals and patients in the medicinal products they trade, prescribe and purchase in the legal supply chain. At the moment the medical devices are not included in this regulation. (EuropeanCommission 2008)

European Commission; National Competent Authority questionnaire on the distribution channels of medical devices

At the Council of Europe meeting of June 2009, the European Commission announced that they will send a questionnaire to the member countries to assess the impacts of possible actions related to the distribution channels for medical devices. One aspect of the study concerns actions in relation to counterfeiting of medical devices. The questionnaire was distributed on June 30, 2009. (EuropeanCommission3 2009)

The World Health Organisation (WHO); National Legislation against Counterfeit Medical Products

The International Medical Products Anti-Counterfeiting Taskforce (IMPACT), has been established by the WHO. Goal of IMPACT is to promote and strengthen international collaboration to combat counterfeit medical products. IMPACT is a voluntary grouping of governments, organisations, institutions, agencies and associations from developing and developed countries aimed at sharing expertise, identifying problems, seeking solutions, coordinating activities and working towards the common goal of fighting counterfeit medical products. In the report 'Principles and Elements for National Legislation against Counterfeit Medical Products' by IMPACT, the focus lays primarily on public health implications in relation to counterfeit medical products that need to be appropriately addressed in legislation. The principles are intended to complement or strengthen national and/ or regional legislation not to replace it. In the report definitions (e.g. medical product) are formulated. Also the obligations of governmental institutions, manufacturers, operators of the distribution chain, retailer, and other operators are described. Furthermore, regional and international obligations, illegal acts, sanctions and nature of sanctions are defined. (WHO 2008)

Australian Government - Department of Health and Ageing - Therapeutic Goods Administration; Monitor supply chain

The TGA closely monitors the supply chain in Australia to prevent counterfeit medicinal products or medical devices from entering the market. Appropriate safeguards and penalties are also in place to discourage this activity and, when it is detected, the TGA will initiate action aimed at bringing the matter before the court. (TGA 2009)

Canadian Government - Health Canada; Raising public awareness

Health Canada is the Federal department responsible for helping Canadians maintain and improve their health, while respecting individual choices and circumstances. They provide an information leaflet on their website explaining the risks of buying medical devices over the internet and how people can minimize the risks when doing so. Health Canada specifically warns for the risk of receiving a device that does not meet the requirements, or that has been recalled for safety reasons, or that is second hand so there may be safety issues related to cleanliness, or that is counterfeit, or that has not been stored properly. A clear advice is given to the public to consult their health care provider on forehand and to buy only from reliable parties. (HealthCanada 2006)

Dutch Government - Ministry of Health, Welfare and Sport; Raising public awareness

The of the Ministry of Public Health launched a pilot campaign on the internet to make people aware of the dangers of purchasing medicinal products on the internet. Before and after this campaign (November 2008 and February 2009) a survey was performed to measure the public's awareness. About half of the respondents indicated that as a result of seeing the campaign their awareness about the risks of buying medicinal products and herbal remedies on the internet was increased. Based on the encouraging results of this small scale pilot campaign the ministry decided to launch a broad campaign to raise public awareness about counterfeit medicinal products and in vitro diagnostics. The campaign is planned for spring 2010.

UK Government - Medicines and Healthcare products Regulatory Agency (MHRA); Anti-counterfeiting strategy

The MHRA made an extensive document on anti-counterfeiting strategy. This strategy is based on the following items:

- Communication (e.g. public awareness)
- Collaboration (e.g. with IMPACT)
- Regulation (e.g. market surveillance)

The MHRA have formed an intelligence unit concerning counterfeit medicinal products and devices. To obtain information on counterfeit products, they have launched a 24 hour hotline to enable the public, health care professionals, those engaged in the supply chain and industry to report directly, and where necessary confidentially to the MHRA, any suspicions that they may have concerning counterfeit medicinal products or medical devices. Furthermore, there is close collaboration with the device industry to share information, raise awareness and monitor the threat from counterfeit devices. When it comes to internet investigations, the organisation makes use of automated search tools and locates websites selling ‘at risk’ devices. It carries out test purchases and expert analyses of materials. (MHRA 2007)

US Government - U.S. Food and Drug Administration (FDA); Unique Identification for Medical Devices

In 2004, the FDA announced a regulation to require bar code identification on pharmaceutical labelling. In the course of its deliberations, FDA chose not to include medical devices in the bar code rule, noting that such devices lack a standard and unique identifying system comparable to the National Drug Code system for pharmaceuticals. FDA is reconsidering whether some form of unique device identification (UDI) is warranted for medical devices, given the potential of UDI to help reduce medical errors, facilitate recalls, identify incompatibility with devices or potential allergic reactions, improve inventory control, improve reimbursement, and reduce product counterfeiting. Although the report concerning the promotion for an unique identification for medical devices is prepared in 2006, still no final decision is made whether this system is going to be implemented. (FDA 2006)

Manufacturers, branch organization and other stakeholders

The medical devices industry has an important role in identifying false products at an early stage. This is, because manufacturers have all the information about their product at hand and are familiar with the supply chain of their products. Two major reasons can be identified for the participation of the industry in anti-counterfeiting strategies. First, to prevent distribution of false products on the market that might harm the users of these products. Second, the availability of cheaper counterfeit products may impede legitimate businesses and undermine the economical position of the company.

Stakeholders were found through the member lists of the branch organisations Eucomed (34 National Association members and 61 corporate members) and EDMA (23 National Association members and 39 corporate members). Also information out of the personal network of the authors was used. The websites of these stakeholders were visited and where a search option was available, the website was searched for the word “counterfeit”. The list below only mentions those stakeholders that offer statements on their websites about counterfeiting of medical devices (table 2).

Stakeholders Action	<p>Manufacturer; Roche</p> <p>Roche participates in national and international industry and governmental efforts to develop stronger laws and improve enforcement, educate the public and train local officials. Roche has implemented technical anti-counterfeiting measures for some products. However, such measures cannot prevent counterfeits; sophisticated counterfeiters can detect and replicate them. Roche will not make these measures public, as they would immediately lose their protective impact. Roche will incorporate requirements from authorities. The company will also pursue and coordinate anti-counterfeiting measures relating to the design, including packaging and labelling, of products that are subject to counterfeiting or that may have a high probability to become subject to counterfeiting. (Roche 2009)</p>
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Stakeholders Action	<p>Manufacturer; 3M-ESPE Partnership of Trust; Certification of the logistic process. Before distributors may use the seal of approval as a certified channel partner, they have to undergo 3M-ESPE's authorisation process – a process that is based on mutual protection. For any infringements of the rules, the channel partner in question will be removed from the list of certified channel partners and barred for 12 months. Dentists are advised to buy 3M-ESPE dental products only from certified channel partners. All it takes is a quick glance at the logo, and they can be sure that they are purchasing the genuine article. (3M-ESPE 2009)</p>
Stakeholders Action	<p>Manufacturer; Hospira Inc. As part of Hospira's vision, the company is committed to ensuring that its customers and their patients are provided only quality, authentic Hospira product. As such, the company's trading partners play a vital role in maintaining this integrity, and Hospira-authorized distributors share the company's commitment to patient safety and the prevention of counterfeit products entering the distribution channel. (Hospira 2009)</p>
Stakeholders Action	<p>Manufacturer; LifeScan Inc. Our first responsibility is to the patients, healthcare professionals and all those who use our products. Regrettably, counterfeit medical devices and pharmaceutical products have become more prevalent in recent years, posing a very real and serious threat to public health. To help safeguard our products and patient safety we are continually developing and applying anti-counterfeiting measures throughout the process of product development, distribution, prevention measures and enforcement. Working with regulatory agencies, distributors, retailers and healthcare professionals, we are making great strides toward our goal of eliminating counterfeit medical devices. (LifeScan 2009)</p>
Stakeholders Action	<p>Branch organisation; Eucomed Eucomed will encourage its member companies to protect its products, secure the supply chain, monitor markets and assertively enforce its legal rights to prevent and remove counterfeit products in the marketplace. They will work with business partners, legislators, regulators and enforcement agencies to create an adequate regulatory and operational environment that identifies and eliminates counterfeit products from the marketplace and health care community. Eucomed will contribute to educate and raise the awareness of all key stakeholders about the dangers of counterfeit products and their roles and responsibilities in eliminating counterfeiting. Eucomed sees the need for all stakeholders to specifically focus on the following areas related to measures to combat counterfeiting; product protection, supply chain security, market monitoring, anti-counterfeiting law, response to counterfeiting cases and enforcement, education and awareness raising. (Eucomed 2008)</p>

Table 2 Stakeholders and actions to prevent distribution of counterfeit medical devices

The European Diagnostic Manufacturers Associations (EDMA) convened a workshop on the recast of the medical devices directive in June 2008. Although a proposal from a Labelling & Counterfeiting ad-hoc group (Measures regarding counterfeit IVDs) was on the agenda, the final position paper does not mention counterfeit. None of the 23 National Association Members of EDMA mentions anything about counterfeit on their websites. Of the 36 Corporate Associate Members, four present their position on counterfeit products and their activities to prevent the distribution of counterfeit products. Two of these are however manufacturers of medicinal products; their statements are only valid for medicinal products. Ironically, one of the device manufacturers with information on counterfeit devices on their website was LifeScan; the manufacturer that suffered from the appearance of counterfeit glucose test strips on the market in 2004.

Of the 95 Eucomed members only one company gives a statement on counterfeit products. None of the corporate members whose products were actually counterfeited (see table 1) gave a statement on counterfeiting on their websites.

Dutch branch organisations

Six Dutch branch organisations for manufacturers and distributors of medical devices and in vitro diagnostics have been contacted by email and telephone. The spokespersons of the branch organisation were asked whether they consider counterfeit devices to be a problem and which actions the branch organisations and their members take to prevent the distribution of counterfeit devices. Three organisations gave a statement (see table 3).

Stakeholder	Branch organization A (personal communication)
Action	Until recent the subject of counterfeit medical devices was not an issue within the organisation. There was more concern about the inferior quality of non-original spare parts that are used in the maintenance and repair of medical devices, e.g. battery packs for infusion pumps. However, now that counterfeit devices actually surface in the market, concerns are growing. Especially since the diversity of medical devices is enormous, it is very difficult to get a complete overview. The organisation started a working group to prepare a set of measures to minimise the changes of counterfeit devices being sold. An European database in which every encountered counterfeit device is registered may be helpful to swiftly warn all stakeholders. <u>The authorities should facilitate the founding of such a database.</u>
Stakeholder	Branch organization B (personal communication)
Action	This organisation stated that they do not encounter any problems concerning counterfeit medical devices. At the moment it is not an issue for the members. They do however question the validity of the CE-marking procedure followed by some manufacturers.
Stakeholder	Branch organization C (personal communication)
Action	The organisation raised the question at the last annual members meeting. None of the members had observed counterfeited devices in the market. It is noted that this is no guarantee that counterfeit devices do not exist. As for branch organisation A, there is a growing concern about the use of spare parts and accessories from other sources than the original equipment manufacturer. Although these are not counterfeit materials, they are generally cheaper, but may be of lesser quality.

Table 3 Position of Dutch branch organisations

Judging from the poor response and the reactions given by three branch organisations it appears that the counterfeiting of medical devices is not a large concern to the Dutch manufactures and distributors. Only one organisation stated that counterfeiting is on the agenda.

The Royal Dutch Association for the Advancement of Pharmacy (KNMP) provides clear guidelines to pharmacists to ensure that the medicinal products that are provided to the public are of the prescribed quality and that counterfeited products are discovered before they are delivered. The Guideline on policy and organization states; The pharmacy takes adequate measures when purchased or delivered medicinal products or delivered care services are of insufficient quality. This includes that the pharmacist is aware of the risks of drug counterfeiting and is aware of the authenticity of its resources. If the pharmacist is in doubt about the authenticity of a product, than he must consult the register holder and the Health Care Inspectorate. (KNMP 2007)

Although pharmacists mainly deal with medicinal products, they are also an important provider of (prescription) medical devices. The Guideline is clear and the described measures may be equally effective to prevent the distribution of counterfeit medical devices.

Service providers to fight counterfeiting

Although outside of the scope of this risk indication, it is worth mentioning that a number of specialised companies offer services that may assist manufacturers in their fight against counterfeiters. The list given in table 4 gives examples of the services offered².

Stakeholders Action	Solution provider; Schalke & Partners Bedrijfsrecherche Fight counterfeit products. Schalke & Partners can be hired to purchase products from various distributors and / or sales offices. The authenticity of products can be tested. (Schalke&Partners)
Stakeholders Action	Solution provider; Validus Technologies Validus Technologies is a security solution provider for both the document security and brand protection market. They develop new and innovative authentication and verification solutions which give our customers a head start in authenticating their products and documents. (Validus-Technologies)
Stakeholder Action	Solution provider; SNB-REACT, The European Anti-Counterfeiting Network Overall objective of SNB-REACT is to provide the members an economic operational service enabling a consistent anti counterfeiting strategy, through convening information meetings for police and customs, providing expert advice regarding counterfeit issues, filing law suits, etc., etc. (SNB-REACT)

Table 4 Services offered to fight counterfeiting; examples

² The list is not intended to present an all inclusive list of all service providers.

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