

**Eucomed contribution to the public consultation of the European Commission in the context of the Study on distribution channels for medical devices: combating counterfeit medical devices and safe medical devices in the distribution chain.**

**General comments:**

- **Counterfeiting of healthcare products can put human lives at risk**, undermines customer confidence and trust in brands and has obvious negative impact on the ethical business players; consequently it should be considered a criminal offence throughout the world, and punished accordingly.
- **Counterfeiting is a global issue** that needs to be addressed by multiple stakeholders including trade organizations, business partners, legislators, regulators and enforcement agencies.
- **Diversion and other related activities encourage counterfeiting**  
Diversion (including parallel trade and repackaging) can facilitate the entry of counterfeit products into the legitimate supply chain. In particular, the safety of healthcare products can be undermined due to these activities. Certain segments of the Medical Technology sector are particularly vulnerable in Europe.
- **Consumers and patients trust in medical devices may be reduced** by counterfeit product. Due to poor consumer experience, the consumer may not be able to differentiate the genuine from the counterfeit. Hence, brands may become tarnished with serious economic consequences..

**Background:**

- The International Chamber of Commerce identified in 2006 human medicines and Medical devices & diagnostics as the 3<sup>rd</sup> most counterfeited items in the world.
- A Mergent Industry report states that 5% of medical devices and diagnostics imported in the USA are counterfeit
- 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: HIV test kits, blood glucose monitoring test strips, dental resins, hernia mesh repair, wound care products, sutures, etc. None of the products identified and tested were found to be sterile.

**The Medical Devices Industry:**

- **A very diverse sector** but with a major impact on patient and consumer health and safety:
  - There are over 500.000 medical devices
  - 10.000 different categories

- Simple to highly sophisticated; Electro-medical equipment, consumer products, professional use products, including implants; high volume, very limited target population; high margin – very low margin.
  - Finished goods, spare parts, accessories, raw materials and components are all of concern when talking about counterfeiting and diversion of medical devices and diagnostics
  - End-user: Healthcare professional, consumers and patients.
  - Mainly SME players relying a lot on intermediaries for distribution
  - Purchasing methods range from direct sale, tenders to internet sale, etc.
- As a result of the above, the **supply chain models are very complex and totally unregulated**, with the exception, to a limited extent, in Belgium:
    - Supply chain models of MD&D are very complex: Direct distribution, agents with or without warehousing; distribution with exclusive territory with or without inventory; wholesalers; ‘consumer’ products via pharmacies or retail distribution, Internet sales, etc.
    - No national requirements imposed on intermediaries in MD&D supply chain;
    - Lack of legal clarity re. Re-packaging and over(re)labeling with no focus on product integrity and patient safety.
    - Many SME’s in MD&D; no internal resources put against counterfeiting; parallel trade size does not seem to be a problem yet in general for the industry sector today, but you don’t know what you do not know and there is also a reluctance in industry to report about findings of counterfeit products because of the highly competitive nature of this sector. In addition, the focus on implementing measures to better protect pharmaceutical products could drive those acting in the counterfeit “business” to review opportunities in the medical devices and diagnostic sector.
  - The **specific issues the industry is faced with** are:
    - No proactive market sweeps/surveillance are being performed; approach to incidents reporting system in companies is generally not addressing specifically ‘counterfeiting’.
    - Occurrence of infections after use of device and/or re-intervention on patient because of infections or inappropriate performance do happen in clinical settings and can happen with genuine products too, but the extent of which we see it today could be partly due to inappropriate practices such as non-authorized reprocessing, counterfeiting and diversion.
    - Cases of tampering products, e.g. change expiration date; change of IFU; ...
    - Cases of Trade Mark infringements
    - The complexity of supply chain generates a certain vulnerability of ‘legitimate’ supply chain in identifying counterfeited and tampered products . The issues can hardly be dissociated for medical devices and diagnostics.
    - Little experience exist in the MD&D sector to work in partnership with customs authorities in this field
  - **Patient Safety; brand integrity and potential liability do concern the MD&D sector considerably.**

## **Our Contribution**

- With what we know today, we believe that the degree of vulnerability of the sector sub-groups varies. Electro-medical and Professional diagnostic equipment might be less vulnerable than those products than self-test diagnostic products, devices used by consumers and/or patients. Direct distribution and supplies as agreed in public tenders are not or less vulnerable than those supplied via internet, wholesalers, etc.
- We 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 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.
- 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.

To that end, we see the need for all stakeholders to specifically focus on the following areas related to measures to combat counterfeiting.

### **Product Protection**

- Support the protection of intellectual property rights around the world and actively support Governments to strengthen and standardize these rights.
- We encourage our members to incorporate features in products and packaging to distinguish genuine from counterfeit products.

### **Supply Chain Security**

- The development of global standards for serialization, tracking and tracing products through the supply chain.
- Establishing and enforcing law that permits the use and audit of authorized distributors to ensure that they are buying and distributing authentic product from the original manufacturers.
- Establishing a surveillance program of both internet and supply chain activities to find and monitor potential counterfeiting operations
- Address issues around legislation to manage healthcare products being offered for sale on the internet
- Procedures for controlling the sale and disposal of products, manufacturing equipment, packaging and other materials to ensure that these cannot be used for the production of counterfeits. Where customs regulations exist ensure that these prohibit seized counterfeit product from being re-introduced into the supply chain.
- Explore the benefits of the creation of an internationally recognised confidential reporting system that enables wholesalers to confidentially report any offers to supply suspected counterfeit devices.
- The creation of industry and law enforcement databases that would identify companies known to deal in counterfeit products and make this information available to authorized industry persons.

### **Market Monitoring**

- We are committed to working in partnership with broader international and national stakeholders around the world, including patient advocacy groups, healthcare providers, regulatory authorities, legislators, customs and law enforcement authorities, and other stakeholders, to prevent counterfeit healthcare products from reaching patients and consumers. We advocate creating an environment that fosters increased cooperation, collaboration, and sharing of information among these entities.

### **Anti-Counterfeiting Law, response to counterfeiting cases and Enforcement**

- We promote proactive, zero-tolerance public policy that helps eliminate counterfeiting by encouraging:
  - Laws that make it easier to prosecute counterfeiters
  - Stiffer penalties for counterfeiters
  - Increased resources for law enforcement and Customs activities
  - Increased collaboration among governments and national and international law enforcement agencies
- Where we become aware of counterfeit products, we:
  - Encourage our members to obtain samples and conduct a health hazard assessment to determine the potential impact to consumers.
  - Encourage authorities to help our members to conduct an investigation to identify the source of the counterfeit product and work with enforcement agencies to bring an end to the counterfeiting, including seizing counterfeit stock and prosecuting individuals responsible for their production and distribution
  - Strongly believe our members should make vigorous use of civil litigation to complement criminal litigation.

### **Education and Awareness**

- We support and will contribute to increased awareness and education for patients, business partners, healthcare professionals and consumers about counterfeit products and their roles in protecting individuals' health and in identifying, and reporting counterfeits. We encourage increasing governmental resources to this end.