Unifying Efforts against Counterfeiting Medical Devices

Saudi Food and Drugs Authority Initiative

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Saudi Food and Drugs Authority

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MEDICAL DEVICES Definition

which doesn’t 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

- Diagnosis
- Prevention
- Monitoring
- Treatment
- Alleviation
- Compensation
- Investigation, replacement, modification, or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Control of conception
- Disinfection of medical devices

disease / injury
A variety of medical devices
Growth in Medical Devices Industry

Growth of Granted Patents over the years in US and Europe

- Data Source (USPTO, EPO) websites
- This is only in US and Europe
- Number of Applications is higher
- Not all inventors apply for patents

challenge
WHO Definitions for Counterfeit

- There is currently no universally agreed definition amongst Member States of what used to be widely known as ‘Counterfeit medicine’.
- WHO uses the term Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) Medical product until a new definition is agreed.
- The term ‘counterfeit’ is widely used to include falsified, unlicensed, falsely packaged, stolen and substandard medical products.
- WHO defines Counterfeit as:
  - A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient (inadequate quantities of ingredient(s) or with fake packaging.

Italian Agency Pharma- Impact

• WHO created the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) to raise awareness, mobilize nations, and draft international legislation.

• The task force published handbook at the end of 2010 demanding collaboration between nations to put legislations and regulations on manufacturers, importers, distributors, sale points and health facilities dealing with medical devices to combat counterfeit products.

• According to the World Health Organization (WHO), more than 8% of the medical devices in circulation are counterfeit.

"Impact- International Medical Products Anti-Counterfeiting Taskforce, Facts, activities", Developed by the working group, 2006-2010. Agenzia Italiana del Farmaco. [url]
Asia Pacific Economic Forum, Life sciences Innovation forum (APEC LSIF) Anti-counterfeit Action Plan

• APEC economies should work together to collect data on counterfeit medical products

• APEC economies should establish harmonized legislation and penalties for prosecuting medical product counterfeiters

• Many counterfeit elements enter into APEC economies through internet sales. Better internet prevention strategies and awareness is needed

• Track and trace technologies are important, but may are not the sole solution

• APEC cooperation on counterfeit medical product public awareness is also needed

FDA Project Pangea – Internet Sale

- Operation Pangea VIII was a project of massive scope, a lightning move by 115 countries that resulted in more than 2,400 websites being taken offline and the seizure of $81 million worth of potential dangerous illegal medicines and medical devices worldwide.

- Global Strategic Framework for counterfeit and substandard medical products (sometimes known by the acronym SSFFC, for Substandard, Spurious, Falsely-Labeled, Falsified, Counterfeit) to help protect consumers by reducing their exposure to counterfeit and substandard medical products. The framework is focused on three pillars: Prevention, Detection, and Response.

- Counterfeit Medical devices detected in the supply chain in variety of products ranging from bandages, contact lenses, spinal implants and aortic pumps.

European Union Impact Assessment on Counterfeiting devices

• Proposed Policy Action to tackle counterfeiting devices:
  1. Develop best practice guide to deal with counterfeiting
  2. Write a code of conduct for any company to report counterfeiting
  3. Enhance information collection and share databases with member states
  4. Increase Traceability and use UDI to track devices
  5. Take actions against sales on the internet
  6. Establish a code of conduct for procurement (private and public) to secure purchasing channels

"Impact Assessment of Policy Options for Combating Counterfeiting of Medical Devices and for Developing Safer Distribution Channels for Parallel Trade in Medical Devices", Europe Economics, URL http://europe-economics.com/, last visited May 2nd 2017
Substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products

- SSFFC medical products from all main therapeutic categories have been reported to WHO including medicines, vaccines and in vitro diagnostics.
- In 2013 WHO launched a global surveillance and monitoring system to encourage Member States to report SSFFC incidents in a structured and systematic format.
- Over 920 medical products have so far been reported representing all main therapeutic categories and representing both innovator and generic medicines.
- Unregulated websites supplying medicines, particularly those concealing their physical address or landline telephone number are frequently the source.
WHO Recommendations

• The opportunity of establishing one or more central databases within a region should be explored and implemented where appropriate.

• The feasibility of developing a database for notification and surveillance of counterfeit medical products should also be explored.
Action is needed!

- We have a commitment of ensuring safety and efficacy of devices to protect patients around the globe
- Multiple authorities around the globe are noticing the problem
- Current efforts are mostly focusing on drugs
- Medical device community needs to step forward
  - Form a taskforce of MEDICAL DEVICES Experts to tackle this problem
- SFDA re-state the request to WHO to form a workgroup dedicated for Medical devices
SFDA Experience

Inspection, Surveillance teams
Medical Device Establishment License (MDEL)

All establishments (supplier, distributor, manufacturer) are not entitled of handling any medical devices in the Saudi market only when obtaining a license for their establishment (MDEL).
Medical Device Market Authorization (MDMA)

Handling of medical devices in the Saudi market is not eligible, only when obtaining a permission to market the (MDMA)

<table>
<thead>
<tr>
<th>سنة تقديم الطلب</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>المجموع</th>
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<tr>
<td>مسودات لم تقدم</td>
<td>474</td>
<td>1110</td>
<td>2258</td>
<td>2969</td>
<td>5212</td>
<td>3812</td>
<td>5033</td>
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Total Applications

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<tr>
<th>ApplicationSubmissionYear</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
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MDMA Statistics
If the device is not pre-authorized in Saudi, SFDA will block it at the ports of entry

Ports of Entry Statistics

(2009- Quarter3 2016)
Cleared shipments
(2009- Quarter3 2016)

<table>
<thead>
<tr>
<th></th>
<th>MD</th>
<th>IVD</th>
<th>Non-Medical IVD</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cleared Shipments</td>
<td>61,702</td>
<td>32,877</td>
<td>427</td>
<td>95,106</td>
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<tr>
<td>Number of cleared Items</td>
<td>138,660</td>
<td>46,302</td>
<td>620</td>
<td>185,580</td>
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<tr>
<td>Quantity of cleared items</td>
<td>7,697,067,476</td>
<td>715,754,876.80</td>
<td>534,272</td>
<td>8,711,997,486</td>
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<tr>
<td>Value of cleared items</td>
<td>25,504,242,260</td>
<td>11,201,656,874</td>
<td>65,734,676</td>
<td>36,771,633,809</td>
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</tbody>
</table>
## Rejected shipments

**(2009- Quarter3 2016)**

<table>
<thead>
<tr>
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<th>MD</th>
<th>IVD</th>
<th>Non-Medical IVD</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of rejected Shipments</strong></td>
<td>2,456</td>
<td>1,951</td>
<td>40</td>
<td>4,447</td>
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<td><strong>Number of rejected Items</strong></td>
<td>16,207</td>
<td>15,632</td>
<td>199</td>
<td>30,914</td>
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<tr>
<td><strong>Quantity of rejected items</strong></td>
<td>64,129,677</td>
<td>8,227,712</td>
<td>281,070</td>
<td>72,663,461</td>
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<tr>
<td><strong>Value of rejected items</strong></td>
<td>366,702,654.40</td>
<td>103,736,580</td>
<td>1,653,150</td>
<td><strong>472,092,386.40</strong></td>
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</tbody>
</table>
Forged Documents Detected by SFDA

• Trends in Forging Documents:
  • MHRA Free sale certificates (multiple cases)
  • Label Related:
    • Editing/Change Manufacturer name
  • Certificate Related
    • Adding additional products into certificates (ISO 13485, Free sale, CE certificates)
    • Editing SFDA Market authorization
  • Instruction for Use (IFU)
    • Removing/adding comments
  • Attestations:
    • Authorized Representative forging attestations on behalf of manufactures
• SFDA Champions: Omar Aljarallah, Abdulaziz Alkhalifa, Mohammed Muhanna, Abdullah Alsobai, Marwan Alduhami, Tuki Alturki, Mohammed Zakour, Abdullah Aljaser, Abdullah Alshammari, Ahmed Aljaser, UL, TUV, BSI
Sell an Authorized, deliver an Un-Authorized

- Distributors obtain market authorization for products using proper documentation and claim to have FDA approval with health facility.
- Products shipped to facility come from another factory (i.e. not FDA approved, submitted documents don’t apply to that factory)
- Products picked at ports of entry after inspection and shipment was rejected
- Hospital escalated the issue against SFDA
- Once situation explained to hospital, the distributor was black listed with the hospital
- Now Hospital refuses to purchase equipment not authorized by SFDA.
CE Certificate valid, ISO13485 and audit report expired

- These two certificates are valid.

The audit report provided was more than 1 year old (02-Oct-2015) and therefore not acceptable.
Trademark Counterfeiting

Aerochamber counterfeit product. Reported by authorized representative, detected by Saud Aldossary from SDFA.

Contact lenses reported by manufacturer, Saud Aldossary tracked the product, compared bills and concluded that it is counterfeit.
Trademark Counterfeiting

Dental file marketed in KSA at Newmat French company, reported by a patient because it broke. Investigation lead to discovering that it is a counterfeit product.

Dents Ply reported by authorized representative, investigation resulted in identifying as counterfeit.
Trademark Counterfeiting

• Counterfeit Contact lenses; odel: FASHION LOOK.

• Discovery Method:

  • Adverse event reported by an end user claiming that he could not remove the lense from his eyes. SFDA inspected and tested the products and discovered that the product has a fake CE mark and conformity body number.
Trademark Counterfeiting

“Sugar style” sugar stripes, suppose to be distributed free by Ministry of health, box is changed and sold separately

Authorized representative reported counterfeit product in the market, inspection team investigated, requested receipts, samples from original and counterfeit, manufacturer was contacted and product was proved to be counterfeit

Waleed Alsubaihi
Trademark Counterfeiting

Pregnancy tests by HCG counterfeited

Inspection visits lead to suspecting the products. Receipts were compares, samples were tested and identified as counterfeit.
Trademark Counterfeiting

Litman Stethoscope Counterfeited

Reported by the authorized representative, inspected and after communicating with the manufacturer we determined that it is a counterfeited product.

Walled Alsubahi
Trademark Counterfeiting

Mani Root canal files Counterfeited
Reported by the authorized representative, inspected and after communicating with the manufacturer we determined that it is a counterfeited product
Abdulrahman Alkhulaifi
Counterfeited natura silner Medical socks

Reported by the authorized representative, inspected and after communicating with the manufacturer we determined that it is a counterfeited product by Ahmad Alamoud.
Trademark Counterfeiting

Dental Glue by PRIME & BOND NT

An Alert was sent by the manufacturer to warn against counterfeited product being marketed globally

Saud Aldossary
Trademark Counterfeiting

Lenses cleaner “Retreshing”, tampering label to change expiration date

Consumer Protection requested product verification, after inspection, SFDA discovered that the label was edited to change the expiration date

Waleed Alsubahi
Trademark Counterfeiting

Counterfeit laryngoscope sold as a genuine “Riester”.

Captured by port inspectors, when compared with original product, they discovered that it is a counterfeit product.

Inspector: Waleed Alsubahi
Trademark Counterfeiting

Another counterfeited product sold as genuine “Riester”
Captured by port inspectors, when compared with original product, they discovered that it is a counterfeit product
Inspector: Waleed Alsubahi
Trademark Counterfeiting

Counterfeited Needles for glucose meter sold as genuine “Accu-Chek”

Field inspection team suspected the product and when verified it, it turned out to be counterfeit
SFDA Initiative

United Against Counterfeit Devices and Equipment
Data Sharing Platform for Regulators

• SFDA launched an online portal for regulators to upload information on counterfeited products detected in their area

• www.sfda.gov.sa/

• We urge you to visit the website, submit a request to join the initiative and we will contact you with instructions to proceed.