Counterfeiting of Medical Products And Similar Crimes

A threat for public health, public security and economic development affecting all regions of the world

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GLOBAL SITUATION

- Worldwide problem affecting both developed & developing countries
- No reliable data on the extent of the problem
- Situation most severe in developing countries
- Counterfeit business is one of the world’s fastest growing industry!
### Threats & Risks

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<th>ECONOMIC DEVELOPMENT</th>
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| 1. Drug resistance  
2. Treatment failure  
3. Serious injury  
4. Death | 1. Profits are increasingly used to fund organised crime & terrorist activities | 1. Loss of public confidence in medicine and healthcare structures  
2. Diminished respect for regulatory and enforcement systems  
3. Loss of foreign investments  
4. Healthcare costs spent in the treatment of casualties |
Factors Facilitating the Increase

Weak drug laws

Limitation in resource & technical expertise
Weak regulatory & enforcement systems
Other pressing health & enforcement problems competing for priority

Confusion & lack of global consensus on the legal definition for counterfeit medicines

IPR issues leading to impediment in access to legitimate and lower cost generic drugs

POSSIBLE SOLUTIONS?
Small Country
- Land Area: 715.8 Sq Km, 5.3 million people
- Global trading and business hub
- Porous borders – millions of goods and people pass through our borders each day

Singapore’s Statistics
(Based on Ministry of Trade & Industry 2012 Data)

- Total sea cargo handled: 538 million tons
- Total air cargo handled: 1.8 million tons
- Total sea passengers handled: 6.4 million
- Total air passengers handled: 49.9 million
- Total postal articles handled: 2030 million
- Total broadband internet subscriptions: 10.2 million
Singapore’s Counterfeit Situation

- General overview of cases in Singapore
  - occurrence
    - largely confined to ‘fringe’ or black market
    - no penetration into mainstream healthcare system and formal sources (e.g. hospitals)
  - type of medicines involved
    - mostly ‘lifestyle’ drugs, particularly those for erectile dysfunction (e.g. Viagra, Cialis)
    - essential drugs (e.g. antibiotic) not affected
  - Mostly detained at the borders - container imports, personal imports and parcel imports

Singapore’s Anti-Counterfeiting Strategies

- Multi-Prong Approach
  - Addressing counterfeit medicines as top priority
  - Strong national drug regulation
  - Clear definition for counterfeit medicines
  - Effective Enforcement
  - Well-developed drug laws
  - Strong collaborative network with local, regional & global stakeholders
Singapore’s Anti-Counterfeiting Strategies

Counterfeit medicines – Top health priority
- Singapore views counterfeit medicines as top safety concern
- All counterfeit cases reported are investigated immediately
- Existing resources may be diverted to manage the concern

Safeguarding the ‘known environment’
- Stringent drug approval process & dealers’ licensing
- Proactive sampling of marketed products to check for their quality

Enforcing the ‘known + unknown environment’
- Other than managing technical regulatory violations in the known legal environment, a huge part of Singapore's resources is channelled to investigate criminal offences arising from the ‘unknown illegal environment’ eg. illegal import/manufacture/ supply of counterfeit medicines

Singapore’s Drug Laws on Counterfeit Medicines

Well developed drug laws & Clear definition
- Definition, offence and penalty clause for unlawful dealings in counterfeit medicines are clearly defined in Singapore’s drug laws to facilitate enforcement
Singapore’s Drug Laws on Counterfeit Medicines

**Definition**
A health product is counterfeit if it is presented in such a manner as to resemble or pass off as a registered health product when in fact it is not or it is presented with any false information as to its manufacturer or origin.

**Offence**
Specific sections in the law to prohibit the manufacture, import, wholesale and supply of counterfeits.

**Penalty**
Fine not exceeding SGD $100,000 or imprisonment for a term not exceeding 3 years or to both.

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**Strong Collaborative Network - Local**

External Regulatory Partners
- Singapore’s Ministry of Health
- Professional Bodies

External Enforcement Partners
- Police, Narcotics Bureau, Immigration, Customs, Environment Agency

Legal Market - known entities
- Pharmaceutical Industry
- Medical Device Industry
- Medical Clinics
- Hospitals
- Pharmacies
- Medical Halls
- Optical Shops

Health Products
- (a) Pharmaceuticals
- (b) Complementary Health Products
- (c) Cosmetics
- (d) Medical Devices

Illegal Market - Unknown entities, difficult, time consuming
- Black Market
  - ED drugs
  - Midazolam
  - Dextromethorphan
  - Codeine
  - Cybercrimes
  - Counterfeits

Internal Partners: Product and Licensing Units within the organisation
Strong Collaborative Network - Regional

- ASEAN Economic Community (AEC)
- Pharmaceutical Products Harmonisation Efforts includes:
  - Eg. Pharmaceutical Product Working Group (PPWG)
- Complementary Health Products Harmonisation Efforts includes:
  - Eg. Traditional Medicines & Health Supplements Product Working Group (TMHSPWG)

Strong Collaborative Network - Global
Progression of Global Anti-Counterfeiting Initiatives with active participation by Singapore

- **2006**: Rome Declaration
- **2007 to 2010**: Establishment of WHO IMPACT
- **Nov 2010**: Initiation of STORM Projects & Establishment of STORM Network under ambit of IMPACT led by INTERPOL
- **Oct 2011**: Establishment of INTERPOL MPCPC
- **2011 to 2013**: MEDICRIME Convention
- **WHO SSFFC Initiative**

### Abbreviations
- WHO SSFFC: Substandard/Spoofed/False-Labeled/Falsified/Counterfeit medical products
- WHO IMPACT: International Medical Products Anti-Counterfeiting Task Force
- INTERPOL MPCPC: Medical Product Counterfeiting and Pharmaceutical Crime

Rome Declaration

- **Feb 2006**: Rome Declaration
- **2007 to 2010**: Rome Declaration
- **Nov 2010**: Rome Declaration
- **Oct 2011**: Rome Declaration
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Establishment of WHO Impact

- Nov 2006
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STORM Projects & STORM Network

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Council of Europe
The Medicrime Convention
Combating counterfeiting of medical products and similar crimes
The Council of Europe established the first international treaty against counterfeit medicines and similar crimes involving threats to public health.

MEDICRIME Convention was set up to offer a legal framework for world-wide co-operation to combat the counterfeiting of medicines.

Aims to tackle illegal activities relating to:
- manufacture of counterfeit medicines
- supply and trafficking of counterfeit medicines
- falsification of documents.
- unauthorised manufacture or supply of medicines
- marketing of medical devices that do not comply with conformity requirements.

MEDICRIME Convention (Apr 2013, Singapore)
Conclusion

- Counterfeit medicines is a global problem and no country can be immune of it
- Safeguarding public health and safety remains top priority
- Within the constraints of resources, regulatory & enforcement agencies worldwide would need to leverage on local, regional and global partnership programs as well as regulatory networks such as the Medicrime Convention in order to achieve anti-counterfeiting initiatives
- Collaboration and cooperation amongst all relevant stakeholders are vital and necessary