The Real Impact of Counterfeit / Substandard Medications

SUBSTANDARD, SPURIOUS, FALSELY LABELED, FALSIFIED AND COUNTERFEIT (SSFFC) MEDICAL PRODUCTS

Presenter: Kenny Whyte – Drug Inspector – Standards and Regulation Division, Ministry of Health

2016
Objectives

✓ Definitions of key terms

✓ Discuss the potential dangers associated with counterfeit / substandard drugs - global perspective

✓ Outline the role of the national regulators and the pharmaceutical industry in preventing the distribution and use of counterfeit / substandard drugs

✓ Outline the benefits that can be achieved by mitigating the trade of substandard / counterfeit drugs by ensuring:
  ✓ Effective sharing of information between professional networks, national regulators and international organization

✓ Relate how a proper Drug Supply Management System can help to maintain supply chain integrity
Definition of Counterfeit Drug

A counterfeit medicine is one which is *deliberately* and *fraudulently* mislabeled with respect to its identity and/or its source.

World Health Organization - 2016

Counterfeit medicine is *fake medicine*. It may be *contaminated* or *contain the wrong active ingredient* or *no active ingredient*. They could have the right active ingredient but at the wrong dose.

Food and Drug Administration - 2016
Substandard, Spurious, Falsely Labeled, Falsified and Counterfeit (SSFFFC) Medical Products

There is currently no universally agreed definition amongst Member States.
Definition of Substandard Drug

Substandard / Out of Specification Product

- Genuine medicines produced by manufacturers authorized by the national medicines regulatory authority (NMRA) which do not meet quality specifications set for them by national standards.

WHO – 2009
Activity: Spot the fake in the picture.

WRONG!  RIGHT!
Definition of Spurious or Falsified Medical Products.

Are ones which deliberately misrepresent either their identity, and/or composition, and/or source.
Unregistered Medical Products

Are ones which are not authorized by the competent medicines regulatory authority for marketing and distribution, and have not undergone evaluation of their safety, efficacy and quality for the market in which they are distributed.

WHO – 2015

Hong Kong retailer raided for illegal medicines
Scope of the Problem

There are many estimates of the scope and scale of the market in SSFFC medical products with little validated evidence to underpin those estimates.

- WHO – 2013 Global surveillance and monitoring system

- Over 920 medical products have so far been reported representing all main therapeutic categories and representing both innovator and generic medicines.
Scope of the Problem

- Manufacturing of SSFFC medicines occur in many different countries and in all regions
- No country remain untouched by this issue
- Large scale manufacturing and small back street/basement operations
- Tableting machines, ovens, specialist equipment, ingredients and packaging materials
Scope of the Problem

Medicines mostly affected:

- Anti-Infectives
- Anti-Malarials
- Genito urinary/Sex Hormones
- Expensive cardio vascular and oncology products
- Low priced pain suppressants
- Drugs for Non-Communicable Disease
- Male sexual enhancers
Scope of the Problem

- Pakistan – 45% – 50% fake drugs
- 10,000 registered pharmacies vs. 100,000 illegal merchants
  Former Pakistani Interior Minister – 2010

Estimated Annual deaths worldwide – 1,000,000
(WHO 2015)

The British think-tank, International Policy Network, estimates that globally, 700,000 deaths a year are caused by fake malaria and tuberculosis drugs—comparing the death toll to the equivalent of “four fully laden jumbo jets crashing everyday.”
Scope of the Problem

Caribbean is vulnerable
- Weaker laws
- Transshipment
- Porous borders
- Lack of capacity
  - Human
  - Capital

2008 - Caribbean Poison Information Network estimated the value of the counterfeit drug trade in Latin America and the Caribbean to be around USD 30.5 billion.2
Scope of the Problem

USD 75 billion/year - The Economist - 2010

USD 431 billion/year – WHO - 2012
Scope of the Problem

1,153 imported drug products examined
- majority, 1,019 (88%)…contained unapproved ingredients.
- Many of these imported drugs could pose clear safety problems.

Drugs arrive from many countries
- For example, 15.8% entered the U.S. from Canada
- 14.3% from India
- 13.8% from Thailand
- 8.0% from the Philippines. The remaining entries came from other countries.

Drugs different from those approved by FDA
- requiring careful dosing
- Quality concerns
- inadequate labeling
- inappropriately packaged
Why are Medicines a Target?

◦ Counterfeit drugs can be made relatively cheaply
◦ Even in the industrialized countries, the risk of prosecution and penalties for counterfeiting are inadequate
◦ The way in which medicines reach the consumer is also different from other goods: the end-user has little knowledge of the product – a ‘credence’ good.
◦ Freer trade – relaxed border controls
◦ Long distribution chains; parallel trade; trading of pharmaceuticals by brokers as commodities
Why are Medicines a Target?

- Economic motive – poverty, and looking for “bargain” products
- Many countries, especially in the developing world are without adequate regulation and enforcement and border security
  - New element -- the Internet
- Weak intellectual property protection
- Not recognized as an international threat
SSFFC Medical Products and the Internet

- Spam email advertising medicines – Fake Viagra
- Lack of authenticity; no verification logo or certificate
- Spelling mistakes and poor grammar on the packaging
- Websites that do not display a physical address or landline
- Websites offering prescription only medicines without a prescription
- Prescription medications improperly labeled
- Suspiciously low priced products.
Dangers of SSFFC Medicines – Recipe For a Fake

Contents of SSFFC medicines

◦ No active ingredient,
  ◦ corn starch, potato starch or chalk.

◦ Wrong active ingredient

◦ Wrong amount of the correct active ingredient

◦ Other toxic chemicals
  ◦ Brick dust
  ◦ Lead paint
  ◦ Rat poison – not Warfarin
  ◦ Boric acid
  ◦ Sheet rock dust
  ◦ Floor wax
Dangers of SSFFC Medicines

Poor Manufacturing practices
- Poor condition / unhygienic
- Unqualified personnel
- Lack of written and authorized Standard Operating Procedures, Records for activities carried out
- Lack of validation
  - Assay
  - Freedom from contaminants
  - Product stability
Dangers of SSFFC Medicines

Unauthorized manufacturing sites

- Manufacturing unauthorized products
- Non compliance with National regulatory requirements
- Unauthorized modification of product or packaging
- Substitution of contents of medical product in authorized packaging
- Unauthorized replication of registered medical products
- Using false authorizations or unauthorized use of another's authorization
- Sourcing medical products from unauthorized or unknown origins
- Manufacturing medical products that violate the approved formulae
This counterfeit drug manufacturing site in China produced fake Viagra and other drugs that were sold to customers in the Europe and the U.S. This machine was used to make counterfeit labels. Pfizer - 2013.
A makeshift factory in China found to be manufacturing counterfeit Pfizer medicines
Dangers of SSFFC Medicines

Perfect example of poor storage conditions for “Medicines”
WHO Member State Mechanism – Est. 2012

The Member State Mechanism is the global forum at which countries can convene, coordinate, decide and organize activities to address SSFFC medical products.

It was established in order to protect public health and promote access to affordable, safe, efficacious and quality medical products, through effective collaboration among Member States and WHO to prevent and control SSFFC medical products and associated activities.

- Establishment of Member State (MS) Workplan
WHO Member States Work Plan

- Strengthen capacity of Regulatory Authorities and Quality Control Labs.
- Provide guidance
  - Regulatory affairs
  - GMP / GDP inspection tools
- Encourages collaboration amongst regulatory authorities and WHO
- Communicate, Educate and raise awareness
- Transparent collaboration with relevant stakeholders
- Identify actions, activities and behaviors associated with SSFFC medical products
WHO Global Surveillance and Monitoring System

The Global Surveillance and Monitoring System for SSFFC medical products was launched in 2013.

- Open to all Member States, currently 113 countries and 18 of the largest procurement agencies have been trained to use the system.

Provide technical support in emergencies, link incidents between countries and regions, and issue WHO medical product alerts.

Accumulate a validated body of evidence to more accurately demonstrate the scope, scale, harm caused by SSFFC medical products and identify the vulnerabilities, weaknesses and trends.
Role of the Regulator - (National Medicine Regulatory Authority (NRMA))

1. Improve the dynamism of strategies stop SSFFC medicine to match market trends
   ◦ Control of supply channels – prevent illegal importation
   ◦ Monitoring of supply and demand
   ◦ Participation in international forums and conventions

2. Provision of clear, firm and equitable legislation that address important issues with appropriate sanctions for violators
   ◦ Enforcement of legislation
   ◦ Provide financial support
   ◦ Provide information to all stake holders
     ◦ Websites, briefs, alerts, training etc.
Role of the Regulator (National Medicine Regulatory Authority (NRMA))

3. Collaborate with other agencies
   ◦ Customs, Police, Immigration

4. Product registration and assessment

5. Licensing of premises and persons

6. Ensure compliance with preset standards for high quality medicine
   ◦ Post-marketing Surveillance
   ◦ GMP / GDP Inspections
   ◦ Predisposal Inspections
Pharmacists’ Role in the Prevention of SSFFC medical Products

○ Report all suspected cases of SSCCs
  ◦ Familiarize oneself with medicines
  ◦ Take note of client complaints

○ Beware of Fraudulent Distributors

○ Plan for shortages

○ Monitor counterfeit product alerts

○ Education – raising awareness among coworkers and patients

○ Implement recommendations to ensure the integrity of the supply chain

○ Determine whether distributor purchased from the registered source
Identifying an SSFFC Medical Product

Examine packaging for condition
- Spelling mistakes / Grammatical errors
- Dispensing system (blister etc.)
- Compare the packaging to other batches – e.g. labels and seals
- Check monograph – correct language
- Manufacturing and expiry dates / batch numbers
- Ensure consistency between outer package and inner package (dates language and batch number)
- Check Appearance
  - Color / discolored, degradation, unusual smell/ taste
Identifying an SSFFC Medical Product

Scratch and text

Radio Frequency Identification (RFID) tags

Near-Infrared spectrometers
Identifying an SSFFC Medical Product

Energy Dispersive X-Ray Diffraction

Medicines Quality Databases
Benefits of preventing SSFFC Medical Products

- Removal of public health risk
- Reduce the strain on health care facilities
- Conservation of consumer income
- Restoration of trust in medication therapy
- Less corruption in the pharmaceutical industry
Why No Collective Priority Global Action???

- Ignorance about the scope of the problem and its
- Problem is not recognized as more than a “commercial issue”: association with “branded” products
- Confusion of counterfeiting issue with IP issues
- Confusion of counterfeiting with issues facing jeans and watches
- Priority in global monitoring and control by police authorities given over to illegal drugs
- Refusal of some regulatory agencies to admit problem
- WHO’s disease focus; relatively low priority given to quality until recently
Components of the Drug Supply Chain

Primary Manufacturer (production of active ingredients)
Secondary Manufacturer (production of final product)
Market warehouses / distribution centers
Wholesalers
Retailers/hospitals

Flow of goods and flow of information (Abstraction)
Drug Supply Management System – Protection of Supply Chain Integrity

- Strengthen legislation to protect medicine supply chain
  - Drug Quality and Security Act (DQSA) was signed into law by President Obama on November 27, 2013.
  - Enable easier tracing of medicines
  - Safety and Innovation Act (FDASIA), which was signed into law on July 9, 2012.
  - Give increased powers to the national authority

- Harmonization – International GMP requirements
Drug Supply Management System – Protection of Supply Chain Integrity

- Demand management – forward forecasts e.g. 3 – 24 months based on historical data, market intelligence etc.
- Inventory management and distribution requirements planning
- Visibility of supply chain
  - Where
  - When
  - Why
- Use of technology
Summary Points

SSFFC medical products may cause harm to patients and fail to treat the diseases for which they were intended.

They lead to loss of confidence in medicines, healthcare providers and health systems.

SSFFC medical products from all main therapeutic categories have been reported to WHO including medicines, vaccines and in vitro diagnostics.

Anti-malarials and antibiotics are amongst the most commonly reported SSFFC medical products.

Both Generic and Innovator medicines are falsified including very expensive products for cancer to very inexpensive products for treatment of pain.

They can be found in illegal street markets, via unregulated websites through to pharmacies, clinics and hospitals.
Summary Points

Drug shortages, a long and convoluted supply chain, and Internet pharmacies are contributing factors.

Controlling the availability of counterfeit drugs is not simple, but necessary, given the serious public health issues they pose.

Substandard, Spurious, Falsified, Falsely Labelled, Counterfeit medicines constitute a crime against humanity…

… Let us help in the fight.
THANK YOU

Very Much!