Problem of Counterfeit Medicines: Causes of Existence and Possible Ways of Solving

Valeryia Stukina

Department of Chemical Drugs, Faculty of Pharmacy,
University of Veterinary and Pharmaceutical Sciences,
Brno

Ostrava ,22-23th of November 2012

Introduction

- Aim of the presentation - an overall picture of the problem of counterfeit medicines.
- Tasks - possible ways of its solving in the spheres of:

1. law
2. management.

The main points of the presentation

- The problem in progress: from history to this day
- The definition of “counterfeit medicine”
- Four main types of counterfeit medicines
- Principal stakeholders of the problem
- Causes of problem existence
- Legal ways of solving the problem
- Management ways of solving the problem
- Conclusions and recommendations

The problem in progress from history to this day

Pedanius Dioscorides (1st century AD) the first record of the problem

- Connection with the notion of medicine dose
- The more scientific - the more problematic (side effects, purity and etc.)
- Complication production technology
- Complication of the legal aspects (patents, due…)
- Complication of the supply chain
- Increase of the counterfeit drug sales to over $70 billion globally in 2010. This is an increase of more than 90 percent from 2005.

The notion (definition) of “counterfeit” medicine

- Spurious/falsely-labelled/falsified/ counterfeit medical products (SFFC) medicines are defined differently in different countries. The definitions used in the various WHO Member States show that the nature of the problem of SFFC medicines varies from country to country.

- **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) active ingredient(s) or with fake packaging.

- "Substandard medicines are pharmaceutical products that fail to meet either their quality standards and specifications, or both.

Four main types of counterfeit medicines

Active substances' presence in counterfeit medicines:

- Placebo, is a useless treatment (an inactive substance or other sham form of therapy) which looks like medicine by its exterior view.

- Analogue, where the active substance is replaced by cheaper or less effective substance.

- Imitation, when the amount of the active substance is not the same as in the original.

- Medicine, where the pharmaceutical formulation is the same as in the original, but the origin of it is unknown, and there is no any quality control, so administration of it is dangerous.

Principal stakeholders (subjects) of the problem

1. Patients
2. The World Health Organization (WHO),
3. The European Federation of Pharmaceutical Industries and Associations (EPFIA) and etc.
4. Governments
5. National pharmaceutical associations
6. Pharmaceutical Industry (manufacturers)
7. Clinical trials
8. Researchers
9. Last but not least: the widening involvement of organized transnational criminals and even international terrorist groups

Problem of Counterfeit Medicines: Causes of Existence

- Medicines are attractive for counterfeiting
- Lack of political will and commitment to establish strong national medicines regulatory authorities (NMRA)
- Lack of appropriate medicine legislation
- Absence of or weak national medicines regulatory authorities (NMRA)
- Weak enforcement
- Corruption and conflict of interest
- Shortage or erratic supply of medicines
- Inappropriate use of medicines
- High prices of medicines
- Price differentials
- Inefficient co-operation between stakeholders
- Lack of control over export medicines
- Trade through several intermediaries
- Trade through free-trade zones/free ports

Internet Sales and Access to Safe Medicines

The Internet has opened the door to thousands of illegal internet sites posing as legitimate pharmacies and selling potentially unsafe medicines to unknowing consumers.

- According to a 2012 report and data collected 2008-2012 by the U.S.-based National Association of Boards of Pharmacy (NABP), 96 percent of approximately 9,000 websites reviewed are not in compliance with state and federal laws and/or pharmacy practice and patient safety standards and pose a significant risk to consumers (1).
-
- According to the WHO, purchase of medicines via the Internet has a high chance of exposing patients/consumers to spurious, falsely labeled, falsified, or counterfeit medicines and in over 50% of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit.
-
- Based on data collected by University of California San Diego (UCSD) researchers, the largest illegal online drug sellers may generate between $1 million and $2.5 million in sales every month (2).
-
- According to the January 2012 report of the U.S. Customs and Border Protection (CBP) on FY2011 seizures, seizures of counterfeit pharmaceuticals increased by 200 percent and seizures occurring at express consignment and mail facilities have risen by 84% since 2007 due to the continued growth of websites selling counterfeit products and a marked shift towards using international mail and express courier services to transport the illegal merchandise (3).

- According to the July 2011 European Commission's annual report on European Union Customs enforcement, the number of shipments stopped by EU Customs has doubled compared to 2010, with an 82% increase in detentions of postal traffic largely due to the increase in online purchases. That report states that 69 percent of articles detained in postal traffic are medicines

- Ect

Management of Internet Sales

As far as more and more patients (because of the lack of time and money for doctor visiting) look to the Internet for the supply of medicines:

- **The International Federation of Pharmaceutical Manufacturers & Associations**
- **Pharmaceutical Research and Manufacturers of America**
- **European Federation of Pharmaceutical Industries and Associations** and
- **The Japan Pharmaceutical Manufacturers Association**

are united in the effort to protect their and our safety and finance.

Problem of Counterfeit Medicines: Legal ways of solving

- International level

First of all the WHO's initiatives and documents

- European level

Were adopted:

Directive 2001/83/EC of the European Parliament of the 6th of November 2001; on the 10th of December 2008 the Commission adopted three legislative proposals to revise Directive 2001/83/EC;

In progress:

New Directive of the European Parliament 2011/62/EU (''Falsified Medicines Directive'') of 08 June 2011 amending Directive 2001/83/EC describes requirements for excipients.

- National level

Criminalization of counterfeit medicines production and etc as far as it is dangerous for the public health and security

Problem of Counterfeit Medicines: Management ways of solving

At international level:

Counterfeiting of medicines is now a global issue affecting all countries. Therefore in order to combat the problem effectively: there should be

- timely exchange of information on counterfeit medicines between main stakeholders
- more cooperation between all interested parties
- a global mechanism similar to the one used to control narcotic drugs should be created

At national level governments must:

- improve the availability and affordability of medicines;
- enact deterrent legislation prohibiting the manufacture, importation, exportation, distribution and sale of counterfeit medicines;
- establish or strengthen (National medicine regulatory authorities) NMRA by clearly setting out its power, duties and responsibilities;
- ensure that personnel working in national medicine regulation and those involved in the detection and investigation of counterfeit medicines sign conflict of interest forms;
- ensure that the medicine legislation is enforced;
- ensure that courts speedily dispose of cases involving counterfeit medicines and that sentences passed by the judiciary reflect the seriousness of the problem and the offence;

National medicine regulatory authorities NMRA must:

- ensure that all medicine manufacturing, importation, exportation and distribution activities are carried out in premises approved by the NMRA, and that individuals and

companies engaged have license to operate such activities;

- inspect medicine establishments regularly to ensure that they comply with national medicine regulatory requirements;
- ensure that all medicines are assessed and authorized before they are introduced to the market;
- inspect the informal market to prevent any illegal trade in medicines;
- foster bilateral and multilateral agreements with other countries, in particular with countries sharing common borders to prevent cross boarder trade and smuggling;

Problem of Counterfeit Medicines: Management ways of solving

- **Manufacturers** have to produce medicines in accordance with good manufacturing practice (GMP) requirements and distributors have to store and distribute medicines in accordance with good storage and good distribution practices as provided in the WHO guidelines
- **NGO's approach** being taken at least in India, and Kenya (The technology was developed by mPedigree, an agency that works with telecoms to fight counterfeits in Africa.) is to have unique PIN numbers on packets of drugs. A unique identifier number is revealed on a scratch-off card.

When consumers buy a product made by a manufacturer participating in the scheme, they are able to query the pedigree information stored in the registry by means of a free SMS message. An automatic response from the registry certifies whether the particular product is truly "from source" or not. The proponents of the scheme believe the system will be effective in the fight against counterfeit medicines in the region.[1]

Consumers should:

- buy medicines only from licensed pharmacies and medicine outlets;
- be suspicious of heavily discounted medicines;
- do not buy from peddlers or market places;
- insist to get receipts when buying medicines;
- check packaging carefully if it is properly sealed;
- check if the packaging indicates the batch number, manufacturing date, expiry date, and the manufacturer's name
- report to your health worker or doctors any lack of improvement after taking a medicine.

Conclusions

Counterfeiting affects all medical products, from medicines and pharmaceutical ingredients to medical devices and diagnostics.

Possible ways of solving this complicated problem:

1. law (criminal law, medicine law and intellectual property rights protection)
2. management.

There are negative moments: the most acute are increasing of counterfeit medicine production and Internet selling

There should be broad legislative controlled cooperation of all stakeholders on all levels

Recommendation. The only one.

BE CAREFUL!

Thank you

for your attention and consideration!

CHEMISTRY
Approaches to detect counterfeiting

- Colorimetric assays were used to identify artesunate, which turned yellow, from the fakes, which were colourless. But then the counterfeit drug was modified to contain trace amounts of artesunate in order to trick colorimetric assays. That was a successful ploy.
- Holograms were developed for packaging of artesunate.
- Radio-frequency identification (RFID) tracking system, somewhat akin to bar coding on packages. It shows great promise for detecting fakes more quickly, including in low resource settings.
- Paper analytical device or PAD to detect Panadol, an overseas brand of acetaminophen (Tylenol), often used to adulterate other medications because it provides some symptomatic relief of pain and fever, thereby fooling patients into believing the drug is effective. Their technique relies on a color change when the paper, swiped over the pill in question, is dipped in water—rather like a litmus test.
- Mass spectrometry technique. This works by breaking down the compound into individual components, and the mass of the molecules is used to identify individual chemicals. Although more complex, this technique has the advantage of having both qualitative and quantitative detection modes, as well as identifying specific adulterants.
- Ion mobility spectrometry application for screening samples in the field.