Country specific case studies – Best practices to combat counterfeit medicines and to protect public health

Luc Besançon
FIP Project Coordinator
Patient safety and pharmaceutical products
African situation

Products

WHAT

Source

WHERE

Illegal market
Possible actions

How big the problem is at national level (1)
Possible actions

Protect the pharmaceutical chain from counterfeit medicines (2)
Possible actions

Actions against illegal market (3)
Possible actions
Actions towards patients (4)

Legal Pharmaceutical Chain

Illegal market
1- Determining how big the problem is

• In several countries, evaluation of the incidence of counterfeit medicines as well as communication on this evaluation involve:
  – Drug Regulatory Agency (or Ministry of Health) with the (national) Laboratory for Quality control of medicines
  – And/or Local schools of pharmacies (Professors or Pharmacy Students).
  – And/or Association of pharmacists
• In many cases, such a detection can be helped by a North-South collaboration (and/or by WHO).
• Evaluation of the problem facilitates raising awareness on this issue

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1- Determining how big the problem is

• To determine the problem, several requirements:
  – Capacity in testing drugs:
    • Finances and technology available: chemical analysis, dissolution test, visual inspection (FIP guidelines)
    • At national level or at regional level, or through collaboration with the pharmaceutical industry
  – Methodology:
    • a pro-active method: with blind sampling of products (i.e. India)
    • a reactive one: based on the reports of the inspectorate … but the results of this reactive method is highly linked to the resources spent on the inspection and control of medicines.
    • Or based on the reports of pharmacists when facing a suspected case of counterfeit.
1- Determining how big the problem is

Examples of studies on counterfeit medicines in Africa

- 6 PharmD Thesis of Pharmacy students at the University of Conakry (Guinea) on counterfeit medicines sold in different markets of Conakry
- PharmD Thesis at the University of Bamako (Burkina Faso)
- Studies run in Senegal and in Côte-d’Ivoire with the collaboration of the local pharmacists associations and schools of pharmacy
- Limited number of published research articles but many grey literature that are of interest (PharmD thesis, reports…)

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2a - Information of all the members of the pharmaceutical chain

- Raising awareness of the members of the pharmaceutical chain and providing recommendations to protect patients from counterfeit medicines:
  - Actions within the pharmaceutical chain:
    - On their sources of medicines
    - On the stock management
  - Actions to relay the information to patients (see latter)
2a - Information of all the members of the pharmaceutical chain

• How?
  – Articles in professional journals
  – Edition of booklets on the issue. These booklets can be adapted from the French or English examples and from the EuroPharm Forum Framework under development.
  – National and international conferences on this issue, like the 8th Forum Pharmaceutique International (Togo, 6-8 June 2007).
2b - Avoid any entrance of the pharmaceutical chain

- Drug Regulatory Authority fight against counterfeit medicines:
  - Requires the support of the government (not only political support but also financial resources)
  - Can be facilitated by partners
  - Is a pre-requisite for any effective actions against counterfeit medicines
  - Activities: inspections, prosecution and banning manufacturers involved in counterfeiting...
  - Nigeria: a very clear example underlining that a tremendous change in the rate of counterfeit medicines in a market has been made under the leadership of Dr. Dora Nkem Akunyili and with the support of the government (rate from 41-80% down to 16%)
2b - Avoid any entrance of the pharmaceutical chain

- In many countries, pharmacists have to be registered at a Pharmacy Council (under the control of the Ministry of Health) or at a Pharmaceutical Society.
- Through the registration of pharmacists and wholesalers, competent authorities check whether they are allowed to buy from or to sell medicines to other pharmacists (based on national requirements).
- The competent authorities provide pharmacists with means enabling them to determine if a pharmacist / wholesaler/ industry is legally operating in the country for a specific activity (produce/buy/sell medicines).
2b - Avoid any entrance of the pharmaceutical chain

Pharmacist A working in a pharmaceutical wholesaler

Pharmacist B working in a community pharmacy

Check if the buyer is authorized to buy

Order

Registar or Drug Regulatory Authority

Check if the seller is authorized to sell

Deliver

The system enabling a clear identification of the buyers and sellers should be implemented in every country.

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2b - Avoid any entrance of the pharmaceutical chain

- To check if a pharmacist is registered, different solutions have been developed:
  - Website (constantly updated)
  - List displayed in journals (like in Kenya)
  - And always the possibility to phone or fax the competent authority to check
2b - Avoid any entrance of the pharmaceutical chain

- In addition, registration bodies have other major roles to play in the fight against counterfeiting:
  - Through the enforcement of their Codes of Ethics, these bodies are often able to exclude a pharmacist who is involved in counterfeiting.
  - As a representative body of the profession, they are allowed to ask for a prosecution of any person who fakes to be an authorized member of the distribution chain.
- Example: statement of the Conseil national de l’Ordre des pharmaciens of Côte d’Ivoire
2c - Discovery of a counterfeit medicine

- Counterfeit medicines can be discovered or suspected through:
  - Inspections from national DRA, Customs or police (or from neighboring countries)
  - Reports from pharmacists and healthcare professionals (to DRA or to pharmacovigilance centers)
- Patients can also report case of counterfeit medicines either directly or by complaining about a change in a medicine (or its efficacy) to their pharmacists or medical doctors
2c - Discovery of a counterfeit medicine

• Once the DRA is aware of the problem:
  – DRA should take a decision, based on the information available. Such a process is facilitated through a standard procedure.
  – DRA should inform healthcare professionals and patients on its decision. To increase the impact of its decision: reliable information system, guidelines for pharmacists already displayed to pharmacists…
  – In accordance to DRA decision, pharmacists may withdraw any suspected product and pay attention to their future deliveries.
  – Depending the danger, pharmacists may be requested to contact patients who received the counterfeit medicines (→ importance of patients records).
3 - Actions regarding the illegal market

- Pushing political leaders to act for the safety of patients, by
  - Raising awareness on:
    - The risks for patients (through ineffective medicines or intoxication) as well as for the whole society (antimicrobial resistance…)
    - Other consequences in terms of taxes, insecurity (attacks of pharmacies) and corruption.
  - Supporting and pushing for changes in regulation and for a better enforcement; WHO develops guidelines on these topics.
3 - Actions regarding the illegal market

- The fight against illegal market is successful only if the activities of the DRA, the customs and the police are coordinated.
- Healthcare professionals can be interesting partners to fight against illegal market.
- As most of the medicines are manufactured abroad, it is advised for Customs to be able to easily access to a pharmacist (e.g. from DRA) who could help to identify suspicious products (expertise sharing).
4 - Actions toward patients

- Educating / raising awareness of patients on the issue of counterfeit medicines:
  - Through communication campaign
  - Through interviews and messages on the radio (like in Madagascar)
  - Through strikes of pharmacists (like in Senegal in May 2008)
4 - Actions toward patients

Awareness campaigns

- Example of Ghana
- 31 minute film entitled ‘If symptoms persist’
- Gathering representatives of the pharmaceutical society, of the consumers Association as well as ordinary consumers
4 - Actions toward patients
Awareness campaigns

- Example of Côte d’Ivoire.
- A campaign based on key and strong messages to raise awareness on the risks of counterfeit medicines.
HELAS! IL FAISAIT CONFIANCE AUX MEDICAMENTS DE LA RUE
UNFORTUNATELY, HE TRUSTED MEDICINES BOUGHT IN THE STREET.
Message du Conseil National de l'Ordre des Pharmaciens en collaboration avec les Ordres Nationaux, les Syndicats de Santé et le Ministère de la Santé et de l'Hygiène Publique
4 - Actions toward patients
Awareness campaigns

Campaigns from ReMeD

Medicines bought in the street kill
Conclusion

- Cooperation is a key element for successful actions to combat counterfeit medicines
- Many of the presented activities do not require high financial resources but will and methodology. This methodology can be learned from country experiences and networking… like at the FIP Congress!
THANK YOU FOR YOUR ATTENTION

luc@fip.org