

COUNTERFEIT DRUGS KILL!



WORKING TOGETHER FOR SAFE DRUGS:

- World Health Organization (WHO)
- International Federation of Pharmaceutical Manufacturers Associations (IFPMA)
- International Generic Pharmaceutical Alliance (IGPA)
- World Self-Medication Industry (WSMI)
- O-MPI/Pharmaceuticals Sans Frontières

IMPACT

International Medical Products
Anti-Counterfeiting Taskforce

a WHO initiative to
combat counterfeit
medicines

FIP CONGRESS 2006
SALVADOR, BRASIL
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Combating counterfeit medicines

➔ What is "counterfeiting medicines"?



What is 'counterfeiting medicines'? (1)

To manufacture and give unaware patients 'medicines' that . . . are not medicines

Arbitrary and unpredictable composition:
no active ingredient, another active ingredient, wrong amount, bad quality



What is 'counterfeiting medicines'? (2)

A vile and serious crime threatening everybody's health, including that of law makers, health ministers, directors of health services, inspectors, policemen, customs officers, corrupt civil servants, as well as their families and friends!



What is 'counterfeiting medicines'? (3)

It is not an intellectual property problem!

It is a public health problem!

It threatens everybody's life and undermines the credibility of our health care delivery and pharmaceutical supply systems!



What is 'counterfeiting medicines'? (4)

It is a problem that has consequences becoming evident at the national levelbut with international dimensions, transactions and ramifications



What is 'counterfeiting medicines'? (5)

It is a “murderous attack on the sick”!

It is therefore a direct challenge to all health professionals, who have made caring for sick their mission



What is 'counterfeiting medicines'? (6)

WHO definition

“a medicine, 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 active ingredients or with fake packaging”



Combating counterfeit medicines

*What is
counterfeiting
medicines?*



**Why should we talk
about it?**



Why should we talk about it?

Because it is there!

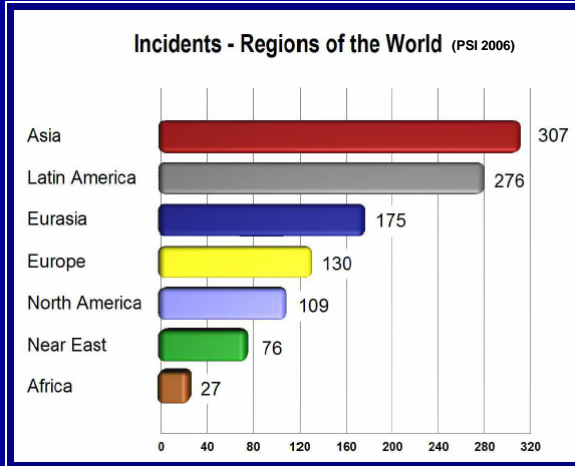
Because it is not dwindling, on the contrary, it is growing!

Because if we don't do anything, it will continue to grow!

	Number of incidents (PSI 2006)		
	2004 (as of 31/12/2004)	2004 update (as of 31/12/2005)	2005 (as of 31/12/2005)
Counterfeit	390	557	781
Diversion	113	151	124
Theft	50	57	68
Total	553	765	973



Why should we talk about it?



Continuing Increase in the Detection of Counterfeit Medicines (PSI, 2006)

Top Ten Ranked by Counterfeits Seized/Discovered

	Country	Seizures/Discoveries
1	Russian Federation	93
2	China	87
3	Korea	66
4	Peru	54
5	Colombia	50
6	USA	42
7	UK	39
8	Ukraine	28
9	Germany	25
10	Israel	25



...e no Brasil?

FOLHAONLINE
www.folha.com.br

27/08/2006 - 09h02

Explode falsificação de remédios no Brasil

FOLHAONLINE
www.folha.com.br

27/08/2006 - 09h25

Combate às fraudes de remédios não é organizado

FOLHAONLINE
www.folha.com.br

27/08/2006 - 10h28

Quadrilhas falsificam até contrabando de medicamentos

At least 14 lots of fake medicines in 2006

"Quanto mais a gente aperfeiçoa os mecanismos de fiscalização, mas os falsários se aperfeiçoam. É uma brincadeira de gato e rato."



Combating counterfeit medicines

*What is
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What should we do?



What should we do?



**International Conference:
16-18 February 2006 - Rome**

160 participants: 57 national authorities, 7 international organisations, 12 international associations representing patients, health professionals, manufacturers, wholesalers

**IMPACT: International Medical Products
Anti-Counterfeiting Taskforce**



What is IMPACT ?

IMPACT is a taskforce launched by WHO to gather all the most important international actors in the fight against counterfeiting

IMPACT aims at coordinating global action against the counterfeiting of medical products in order to promote and protect public health.



Why do we need IMPACT ?

Counterfeits have harmful effects on patients' health, including death.

Counterfeits frustrate efforts to deal with high burdens of disease.

Counterfeits undermine the credibility of health care delivery systems.

Globalization of economies is helping to 'globalize' the problem.

Increased commercial use of the Internet also contributes to the expansion of the problem.



Who can participate in IMPACT ?

All 192 WHO Member States and all major international stakeholders, such as:



How does/will IMPACT work?

IMPACT shall function on the basis of existing structures/institutions and will in the long term explore further mechanisms for strengthening international action against counterfeit medicines

5 working groups:

- ➔ legislative and regulatory infrastructure
- ➔ regulatory implementation
- ➔ enforcement
- ➔ technology
- ➔ communication



LEGISLATIVE & REGULATORY INFRASTRUCTURE

- survey existing national and international legislation & requirements;
- assess gaps in existing national and international legislation & requirements on manufacturing, distribution, exportation, and importation;
- develop guiding principles for legislation;
- develop initiatives aimed at law-makers in order to promote adoption of new legislation;
- requirements for the distribution system;
- assess existing national best practices and develop model best practices.



REGULATORY IMPLEMENTATION

- promote implementation of Good Manufacturing, Good Distribution and Good Pharmacy Practice guidelines and quality assurance systems to ensure supply chain integrity;
- develop model training materials aimed at improving quality assurance within and supervision of distribution chain;
- develop guidance on the role of quality control laboratories in combating counterfeit drugs;
- develop data collection tools and methodologies to assess national regulatory and enforcement systems in order to identify gaps and measures needed;
- at the request of national authorities develop ad hoc projects to improve capacity to combat counterfeit medicines;
- promote secure exchange of information and alerts among regulatory and/or enforcement officials as appropriate;
- promote networking and collaboration among national drug regulatory authorities;
- develop guidance for pharmacovigilance systems to include reporting and investigating suspected cases of counterfeit medicines.



ENFORCEMENT

- develop advocacy materials to increase resources available for enforcement;
- promote multi-country initiatives to improve coordination and information exchange among enforcement institutions and officers;
- develop projects aimed at improving communication and collaboration between regulatory and enforcement officers;
- develop training materials and manuals to improve skills of enforcement officers;
- identify gaps in existing legislation, need for resources and propose solutions.



TECHNOLOGY

- assess (including piloting when feasible and necessary) technologies to prevent, deter, or help to detect counterfeit products taking into account: a) cost, b) scalability, c) specific country needs and situations, d) feasibility, e) regulatory implications;
- facilitate exchange of information on technologies and their implementation
- disseminate information and recommendations on the merits and limitations of technologies



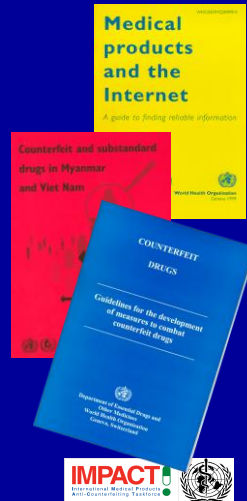
COMMUNICATION

- develop agreed messages and ensure IMPACT presence, as appropriate, at important national and international events;
- develop advocacy, risk communication and education strategies and materials taking into account the need to address specific target groups such as patients and health professionals;
- develop more effective collection and analysis of information on suspected and confirmed cases of counterfeit medical products and dissemination of confirmed cases as appropriate;
- develop initiatives to communicate risks of purchasing medicines from unknown sources (e.g. Internet);
- assist national authorities to develop risk communication and advocacy materials.



IMPACT toolkit

- Experience from different countries;
- Model legislation & regulations;
- Training materials and methodologies;
- Tools and manuals to assist national authorities in implementing activities;
- Tools and methodologies for the assessment of national/regional situations.



"IMPACT approach":
collaboration among all those concerned is essential





IMPACT NEEDS YOU!



PROFESSION'S REPUTATION NEEDS YOU!



- Report and help investigating cases
- Increase security and transparency of distribution systems
- In many countries pharmacists' monopoly is an illusion: if you do not organize informal networks others will do it
- FIP in IMPACT working groups (e.g. training materials, risk communication, regulation of distribution chain, exchange information...)

