

COUNTERFEIT DRUGS KILL!



IMPACT!

International Medical Products
Anti-Counterfeiting Taskforce



a WHO initiative
to combat
counterfeit
medical products

Dr V. Reggi
World Health Organization



A counterfeit medical product is
.....not a medical product!

Arbitrary and unpredictable composition

Manufactured evading regulatory control

Manufactured and sold hiding its real origin



Meant to deceive, unsafe



A counterfeit medical product

... jeopardizes the credibility of
health care delivery systems,
pharmaceutical supply systems,
... and governments!



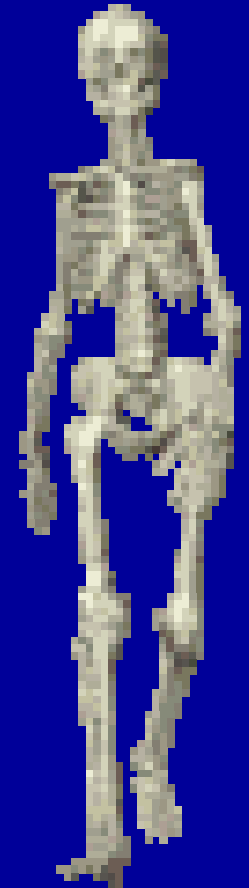
A counterfeit medical product

It is not primarily an IP issue!
It is mainly a personal and public health problem!

Medical products are not bags, CDs, watches or T-shirts!

2005: 3 women killed in Argentina by a counterfeit iron preparation

2006: 300+ people killed in Panama by mislabelled glycerine



Do we know the exact size of the problem?

...No, we don't

Data difficult to obtain or publish.

Sources: occasional reports from national authorities, NGOs, industry, and *ad hoc* surveys/snapshots.

SEARPharm
Forum
South East Asian FIP-WHO Forum of Pharmaceutical Associations

Regulatory category	Count and per cent in regulatory category of states	Status of Visual inspection of samples:		Total
		=Suspect N	=Ok Y	
Strong	Count	74	2196	2270
	% within Regulation of States	3.3%	96.7%	100.0%
Medium	Count	70	3018	3088
	% within Regulation of States	2.3%	97.7%	100.0%
Weak	Count	191	5194	5385
	% within Regulation of States	3.5%	96.5%	100.0%
Total	Count	335	10408	10743
	% within Regulation of States	3.1%	96.9%	100.0%



Do we need to know the exact figures?

No, we don't

A rough indication of different prevalence around the world can be enough.

Even one single case is not acceptable!



WHO, OECD, IFPMA, PSI estimates

- No single average figure! A single figure blurs the real picture and misleads the public.
- Range: from <1% of sales in developed countries (but growing), to >10% in developing countries, depending on the geographical area
- Internet sites that conceal their actual physical address sell counterfeits in over 50% of cases
- counterfeiting is greatest in those areas where regulatory and legal oversight are weakest



Are we serious about it?

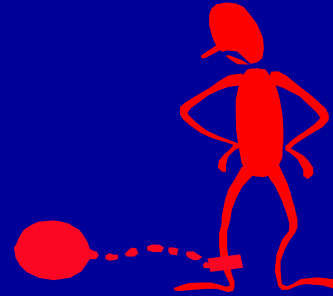
U.S. Federal Criminal Code

Trafficking in Counterfeit Goods or Services, 18 U.S.C. § 2320

1st offence: 10-year prison; \$2 million maximum fine



Fake T-shirt



Federal Food Drug and Cosmetic Act

Counterfeit Drugs, 21 U.S.C. § 331(i) -> **misdemeanor**

1st offence: 1-year & significant fines



Fake medicine



What makes counterfeiting possible?

- Inadequate legislation
- Weak regulatory oversight and enforcement
- Inadequate cooperation between drug regulators, police, customs, prosecutors, health professionals, manufacturers, wholesalers, retailers
- Unregulated trade, Internet-based sales, transit through "free zones"
- No access to reliable health care & medicines supply
- Corruption
- Inadequate control on contract manufacturing and outsourcing
- Unregulated parallel import
- Lack of control over medicines destined for export
- Weak control at ports & airports
- Trade through several intermediaries/wholesalers
- High prices or price differentials
- Illiteracy and poverty



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.



Who is in IMPACT ?

All 193 WHO Member States and all major international stakeholders, such as:



INTERNATIONAL FEDERATION OF PHARMACEUTICAL WHOLESALERS



Pharmaceutical Security Institute



USP United States Pharmacopeia



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



How does IMPACT work?

Secretariat: WHO

5 working groups, focusing on the areas where weaknesses have been identified and action needs to be taken at national and international level:

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



LEGISLATIVE & REGULATORY INFRASTRUCTURE

FINAL DRAFT - 31 August 2007



IMPACT

International Medical Products Anti-Counterfeiting Taskforce

Draft Principles and Elements for National Legislation against Counterfeit Medical Products

- Meeting of jurists and MPs to finalise endorse principles **10-11 December 2007 Lisbon**
- One parliament debates and pass national legislation based on agreed principles **TBD 2008**



REGULATORY IMPLEMENTATION

April 2007 - Washington DC, final drafts of:

- Revised GDP and GPP with emphasis on counterfeit medical products;
- Check lists and decision trees on action upon cases/signals;
- Amendments/Improvements to 1999 WHO guidelines on measures to combat CMP;
- Data Collection Tool on assessment of national situations
- Role of pharmacovigilance systems

Finalised drafts to be discussed/finalized at coming
IMPACT General Meeting - 12-14 December 2007



ENFORCEMENT

- Coordination of operations among participating countries
- Internet monitoring and purchases
- Training materials and manuals to improve skills of enforcement officers
- Data/reports on issues/gaps hindering action at national level

PHARMACEUTICAL CRIME INVESTIGATION GUIDE





ENFORCEMENT

Strengthened Interpol-WHO collaboration

“ASEAN+China” Conference - November 2007, Jakarta
10 ASEAN Member Countries + China

Invited: NRAs, police and other enforcement bodies, associations representing health professionals, manufacturers, wholesalers, NGOs.

Expected result: improved coordination among authorities, specific operations launched (e.g. Jupiter), analysis of situation in ASEAN with recommendations for action to be taken at level of Member Countries, ASEAN Secretariat and beyond



COMMUNICATION

- IMPACT communication strategy
- Agreed 'IMPACT messages'
- IMPACT web site
- Event organization/participation strategy
- Model materials addressing different audiences (health professionals, distribution system, patients, enforcement officials, media, etc.)
- Short films



TECHNOLOGY

Prague Meeting Statement – 13 MARCH 2007

- There is no “worldwide” applicable technology
 - No one global “solution” exists
 - Developing countries should prioritize GMP, GDP and GPP
 - RFID implementation will take many more years
 - Technologies already available (cheaper) are preferred (e.g., bar codes)
 - Any technology needs to be sustainable and locally appropriate
- WHO/IMPACT establishing ongoing dialogue between drug regulatory authorities, manufacturers, distributors and technology providers in order to permit to assess recent trends in anti-counterfeiting technologies:
- International Conference, Feb. 2008 (Singapore)
 - <http://www.who.int/impact>



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.





www.who.int/impact
www.impactglobalforum.org

World Health Organization

Only get your medicines from known and reliable sources

IMPACT!

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IMPACT
The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) is a voluntary grouping of governments, organizations, institutions, agencies and associations from developing and developed countries, aimed at sharing expertise, identifying problems, seeking solutions, coordinating activities and working towards the common goal of fighting counterfeit medical products. IMPACT aims at ensuring appropriate regional representation, in particular from developing countries.

The mission of IMPACT is to promote and strengthen international collaboration to combat counterfeit medical products.

This website serves as the resource centre for all IMPACT Global Forums and related meetings. The latest information on meeting registrations and programmes will also be found here. Should you be interested in finding out more about a particular IMPACT related meeting, please contact counterfeitconf@who.int

For more information regarding IMPACT's initiatives, please visit the WHO website at <http://www.who.int/impact/en>.

[:: learn more about IMPACT >>](#)

FEATURE EVENTS:

**1st IMPACT GLOBAL FORUM:
USING TECHNOLOGY TO
COMBAT COUNTERFEIT
MEDICAL PRODUCTS**

Technology developers meet manufacturers, wholesalers and regulators
Singapore
13 to 15 February 2008

[MORE EVENTS >](#)

LATEST INFO

Registration:
Download booking forms for the below meetings:
• Lisbon, 10-13 Dec 2007
• Singapore, 13-15 Feb 2008

[MORE INFO >](#)

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