a WHO initiative to combat counterfeit medical products

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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.
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

Federal Food Drug and Cosmetic Act
Counterfeit Drugs, 21 U.S.C. § 331(i) -> misdemeanor
1st offence: 1-year & significant fines

You know, I’m not that bad...
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:
“IMPACT approach”: collaboration among all those concerned is essential

BORDER CONTROL AUTHORITIES
PERIPHERAL PUBLIC SECTOR INSTITUTIONS
OTHER PUBLIC SECTOR INSTITUTIONS
MEDIA
MANUFACTURERS
DISTRIBUTION SYSTEM
FAKE MEDICAL PRODUCTS
JUDICIARY
POLICE & OTHER ENFORCEMENT AUTHORITIES
DRUG REGULATORY AUTHORITIES
PATIENTS
HEALTH PROFESSIONALS

IMPACT: International Medical Product Anti-Counterfeiting Taskforce
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
AIM: agreed set of principles underpinning national legislation

• Meeting of jurists from different legal systems: draft principles July 2007 Brussels
• 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
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.
Thank you