

COUNTERFEIT DRUGS KILL!



IMPACT!
International Medical Products
Anti-Counterfeiting Taskforce

a WHO
initiative
to combat
counterfeit
medical products



Dr V. Reggi
World Health Organization



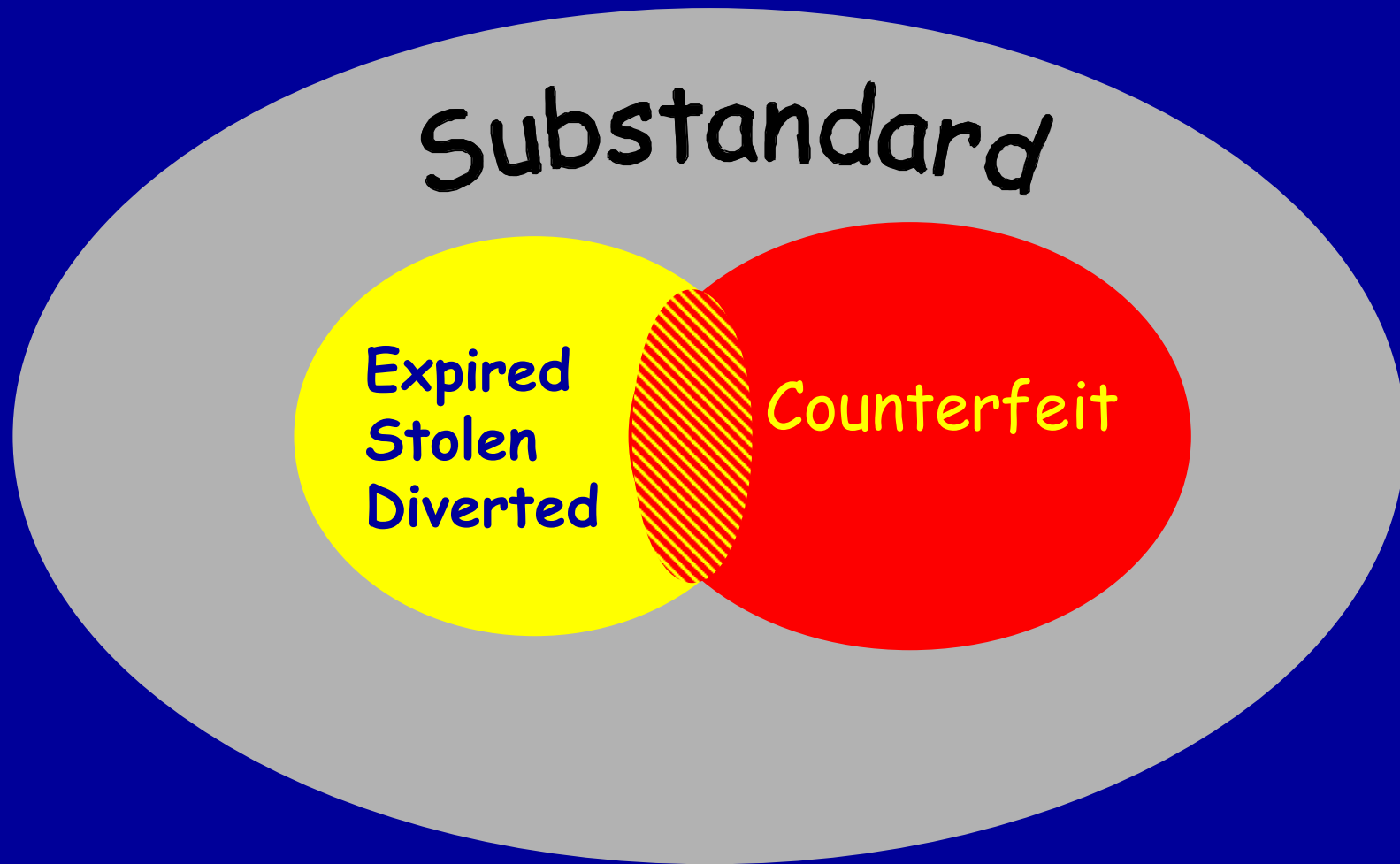
WHO definition - 1992

“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”



All counterfeits are substandard

Not all substandard are counterfeit



It affects products of all kinds



**Expensive,
prescription**



Inexpensive, OTC



Inexpensive, generic



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.



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

Counterfeit	Number of Incidents CY 2006 – CY 2007		
	2006	2006 update	2007
	(as of 12/31/2006)	(as of 12/31/2007)	(as of 12/31/2007)
	1,184	1,216	1,513



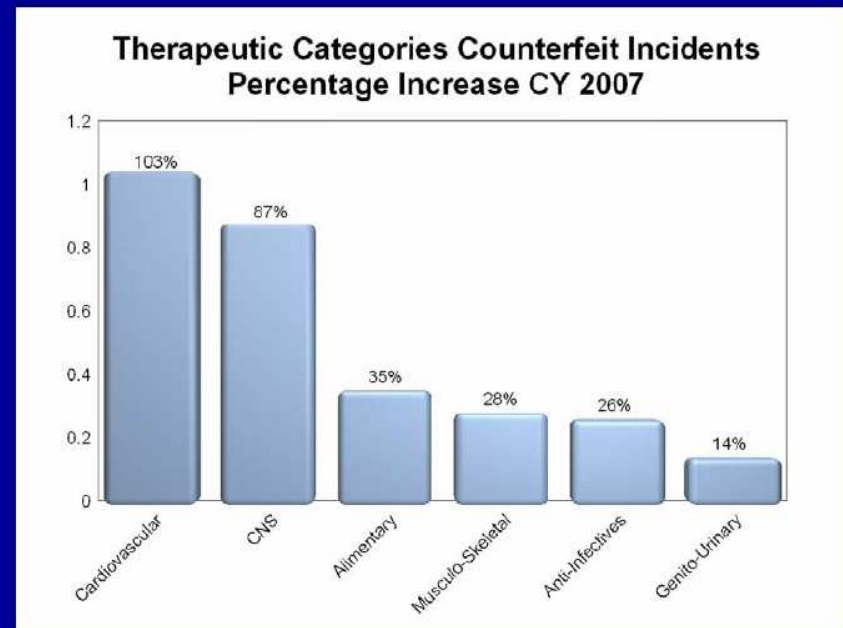
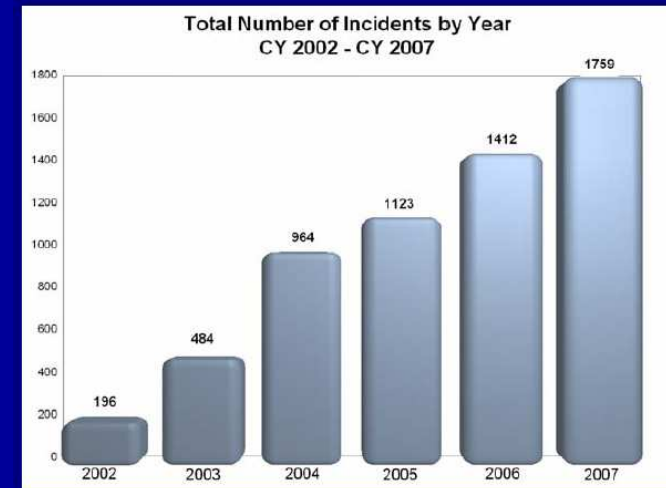
Do we need to know the exact figures?

No, we don't

Even one single case is not acceptable!

It is there and growing!

If we don't act, it will continue to grow!



It affects many different countries

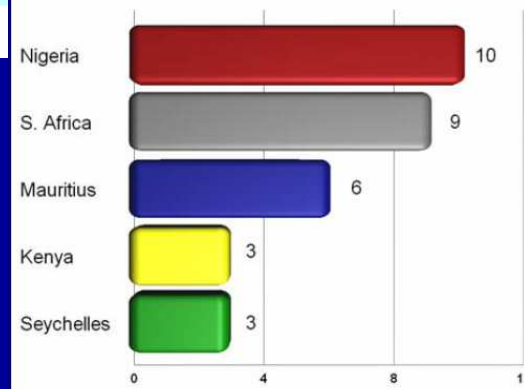
2007

Top Ten Ranked Reported Incidents

	Country	Counterfeiting
1	China	395
2	India	130
3	United States	63
4	Peru	107
5	Russia	101
6	Brazil	60
7	Uzbekistan	86
8	Colombia	60
9	Japan	79
10	South Korea	68

But, where is the data for Africa?

Incidents - Countries in Africa



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 some 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



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", unregulated parallel import
- No access to reliable health care & medicines supply
- Corruption
- Inadequate control on contract manufacturing and outsourcing
- 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



Milestones in WHO's work in the anti-counterfeiting area

First reports from member states: early 80's

1988: Resolution WHA 41.16 requesting WHO to initiate programmes for the prevention and detection of the exportation, importation and smuggling of counterfeit pharmaceutical products.



1992: first international meeting on counterfeit drugs - organized by WHO, CIOMS* and IFPMA



definition of 'counterfeit drug' and called all parties involved in manufacturing and distribution as well consumers to collaborate with governmental institutions in combating counterfeit drugs

* Council for International Organizations of Medical Sciences



Spread of counterfeit drugs continues

1994: of resolution WHA 47.13 requesting WHO to assist Member States in their efforts aimed at combating counterfeit drugs.

1996: WHO Project on Counterfeit Drugs

1999: *Guidelines for the Development of Measures to Combat Counterfeit Drugs, guidance that is far from being achieved in the majority of WHO Member States.*



2000: WHO, IFPMA, EGA, Pharmaciens Sans Frontières established a working group on combating counterfeit medicines

2001: Technical Briefing during WHA

1994-2004: several ICDRA request WHO to assist member states to adopt measures to combat counterfeit medicines

Madrid 2004: Pre-ICDRA meeting requested WHO to work at a draft international convention on counterfeit drugs



No consensus among Member States on an international convention on counterfeit drugs

February 2006: Rome conference recommended establishment of an international taskforce

July 2006: ToR and name (IMPACT) endorsed at meeting in Rome

September 2006: Circular Letter announcing the establishment of IMPACT to Member States



November 2006: First IMPACT General Meeting, Bonn, Germany - nomination of IMPACT Chair and Vice-Chairs, nomination of Chairs of IMPACT five Working Groups, and establishment of a work plan for 2007.

December 2007: Second IMPACT General Meeting, Lisbon, Portugal - endorsement of "Principles and Elements for National Legislation against Counterfeit Medical Products"



IMPACT's conceptual framework

1) **IMPACT** is a voluntary coalition of stakeholders that has the purpose of coordinating international activities aimed at combating counterfeit medical products;

2) **IMPACT** current stakeholders reflect the fact that combating counterfeiting of medical products cannot be successfully achieved by the health sector alone but requires coordinated effort and effective collaboration among health sector, enforcement, border control, justice (all at different administrative levels), as well as the private sector (manufacturers, importers, distributors, health professionals, media, patients/consumers);



Who is/should be in IMPACT ?

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



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



How does IMPACT work?

Secretariat: WHO

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

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



LEGISLATIVE & REGULATORY INFRASTRUCTURE

IMPACT

International Medical Products Anti-Counterfeiting Taskforce

Principles and Elements for National Legislation against Counterfeit Medical Products

Text endorsed by IMPACT General Meeting
Lisbon, 12 December 2007

<http://www.who.int/entity/impact/events/FinalPrinciplesforLegislation.pdf>



REGULATORY IMPLEMENTATION

- Recommendations for revision of GDP 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
- Sampling strategy
- Initiative to address trade of counterfeit medical products though the Internet



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
ASEAN Secretariat, 10 ASEAN Member Countries+China

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

Result:

- launched the establishment of a SPOC-based network;
- new coordinated operation (in the wake of Jupiter South-East Asia operation that lead to identifying source of counterfeit antimalarials)



TECHNOLOGY

Priority: *supply system security*

- IMPACT role: foster dialogue and exchange of information among technology developers, regulators, manufacturers, wholesalers, retailers



COMMUNICATION

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



IPR approach is inadequate to address counterfeiting of medical products

- IPR have broad scope and no focus on public health
- No consumer demand, stealthy sales to patients
- Counterfeiting medical products does not always entail violating IPR (e.g. heparin, 'Brainy')
- IPR approach requires right-holder to trigger/sustain enforcement action
- The complexity and sophistication of the regulation of manufacture, trade and use of medical products has no equivalent in other types of goods and cannot be adequately taken into account by an IPR approach.



The 'perfect copy' myth:

if a manufacturer makes a perfect copy of a medicine there is no public health concern

- How do we know that it is a 'perfect copy'?
- What role for drug regulatory systems?
- Laboratory testing is worthless without precise knowledge of starting and packaging materials, manufacturing process, etc.
- Laboratory testing can only find what is being sought
- A 'perfect copy' of heparin has caused 80+ deaths in the first 4 months of 2008



The 'source country' myth: *all counterfeits come from*

- Responsibility should be appropriately shared between exporting and importing countries
- National definitions calling 'counterfeit' all products that have no marketing authorisation in the country where they are seized are not helpful and discourage international collaboration



PROTECT YOUR REPUTATION



The New York Times June 8, 2003

The Toxic Pharmacist

Robert Courtney, Kansas City, Mo.,

dilute chemotherapy medications for profit
he will inhabit a prison cell for the next 30 years,

- 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 take care of it
- Join IMPACT working groups through FIP



