

# COUNTERFEIT DRUGS KILL!



# IMPACT!

International Medical Products  
Anti-Counterfeiting Taskforce



a WHO  
initiative  
to combat  
counterfeit  
medical products

Dr V. Reggi  
World Health Organization



# What is IMPACT ?

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

2) **IMPACT** is led by **WHO** to keep focus on the public health implications of counterfeiting rather than on IPR-related aspects.



# Why do we need strengthened international collaboration?

Criminals are not stopped by borders, regulation and enforcement must be able to effectively act internationally

Globalization of economies is helping to 'globalize' the problem

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



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



# Who is/should be in IMPACT ?

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



# 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>

Currently being updated



# REGULATORY IMPLEMENTATION

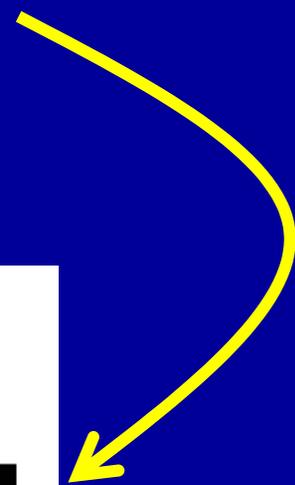
- Recommendations for revision of GDP with emphasis on counterfeit medical products;
- Check lists and decision trees on action upon cases/signals;
- Amendments/Improvements to 1999 WHO guidelines on measures to combat CMP;
- Data Collection Tool on assessment of national situations
- Sampling strategy
- 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

INTERPOL officer based in WHO-Geneva

### Result:

- launched the establishment of a SPOC-based network;
- new coordinated operation in 2008 in the Mekong sub-region and in Uganda and Tanzania: sources of counterfeits, seizures and prosecutions



# 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**



# TECHNOLOGY

## *Supply system security*

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

## *Mobile testing technologies*

- Laboratory testing is too expensive and complex for many developing countries: need to further develop cheaper screening/testing technologies and deploy them to field level



Asia Pacific Economic Cooperation,  
Life Sciences Innovation Forum  
2 Asia Anti-Counterfeiting Medical Products SeminarS  
*"Building International Cooperation to Protect Patients"*  
January & March/April 2008  
Singapore

**COUNTERFEIT COUNTERFEIT COUNTERFEIT**  
**DRUGS KILL! DRUGS KILL! DRUGS KILL!**



1. APEC members should consider a harmonized definition of "counterfeit medical products," based on the WHO IMPACT definition, in order to improve collaboration and cooperation on anti-counterfeiting efforts.
2. APEC members should take all necessary measures to effectively deter counterfeiting by ensuring that there is a strong legal framework, severe penalties, and active enforcement of applicable laws and regulations.



3. APEC members should cooperate in combating the growing problem of illegal internet sales of medical products to consumers and businesses, including educating consumers and health professionals.
4. APEC members should involve health professionals in educating consumers on detecting, avoiding, and reporting counterfeit medical products.
5. APEC members should educate health professionals to consider counterfeit medical products as a possible cause of adverse reactions and therapeutic failure and report suspected incidences to authorities and the manufacturer, as appropriate.



6. APEC members should perform a self-assessment of its counterfeit medical products landscape and apply outcomes towards improving policy
7. Each APEC member should identify a single point of contact (SPOC) for international communications concerning counterfeit medical products.



8. APEC members should increase internal communication and collaboration among various authorities that have competence for combating counterfeit medical products and establish mechanisms for government and industry to work together to rapidly respond to reports of suspect counterfeit medical products.
9. APEC LSIF should work with other APEC Fora on anti-counterfeiting efforts for medical products to improve public health and safety, such as the "Intellectual Property Experts Group", "Law Enforcement Group", and "Customs Working Group".



1. .... harmonized definition of “counterfeit medical product”...

## WHO's 1992 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”*



## 2. .... strong legal framework ...

# 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>

- Obligations for governments, manufacturers, operators of distribution chain, other operators
- Illegal acts
- Sanctions



### 3. .... illegal internet sales ...

- Comprehensive strategy being addressed by **IMPACT**: legislation, regulatory, enforcement, technology and communication aspects
- **TRIPS**: no obligation to control exportation and small quantities of goods
- Postal/customs regulations: parcel belong to sender until addressee gets it, what's 'counterfeit'?, 'personal use'
- Pop-up when payment takes place: needs cooperation from ISP and ...banks!
- **IPR= Inward-Processing-Release**



## 4. .... involve health professionals in educating consumers ...

- Need to educate health professionals first!
- WHPA already very active
- Need more local initiatives
- Requires improved reporting/case stories

International Council of Nurses

### Counterfeits kill®

Nurses target counterfeit medicines

Counterfeits make up more than 10% of the global medicines available in the market and are available in both developed and developing countries.

International Nurses Day  
12 MAY 2005



Tool for Visual Inspection of Medicines

## BE AWARE

Helping to fight counterfeit medicines, keeping patients safer

- BACKGROUND FOR HEALTH PROFESSIONALS
- INFORMATION FOR PATIENTS
- SAMPLE REPORTING FORM
- VISUAL INSPECTION FORM
- INFORMATION FOR HEALTH PROFESSIONALS
- POSTER



5. .... health professionals should also consider counterfeit medical products as a possible cause of adverse reactions or therapeutic failure ...

- Need to strengthen adverse reaction reporting systems first
- 2007: WHO's International Drug Monitoring Programme included counterfeit issue in training course for national officers
- Need to gather cases into comprehensive set to be used for training and advocacy



## 6. .... perform a self-assessment of counterfeit medical products landscape ...

- **Methodology for assessment of situation**
- **Purpose is identifying weaknesses, quantification is impossible**
- **IMPACT Data Collection Tool being field-tested in Uganda-Kenya-Tanzania**



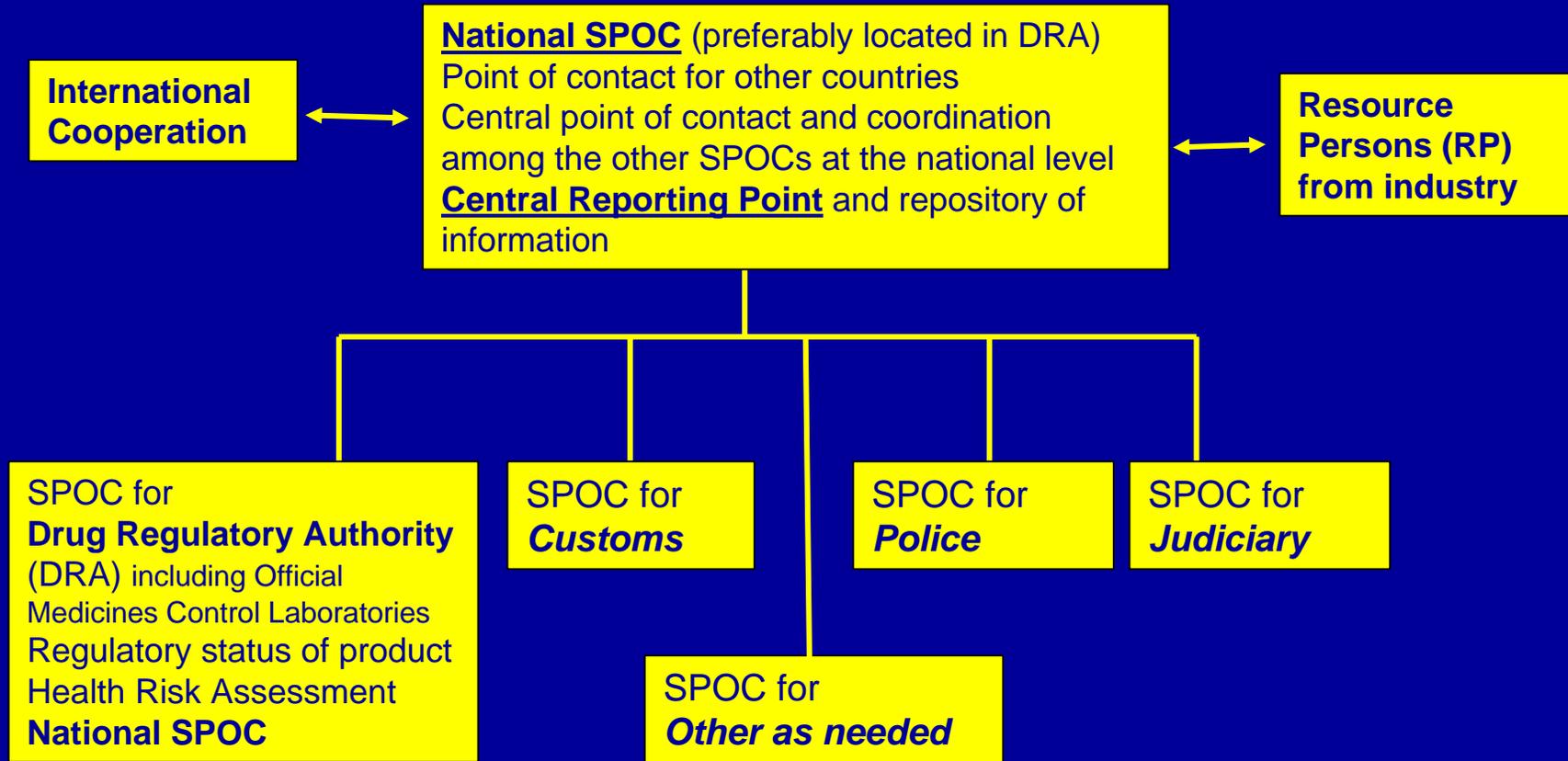
7. and 8. .... a single point of contact (SPOC) for national and international communications ...

Collaboration can be *ad hoc* for isolated cases, but for effective and sustained action, collaboration should be structured within a network of members with defined roles and procedures.

Within networks, single points of contact (SPOCs) are the basis to achieve effective collaboration and results.



# ..... a single point of contact (SPOC) for national and international communications ...



## Lesson learnt: IPR approach is inadequate to address counterfeiting of medical products

1. IPR have broad scope and no focus on public health: fake T-shirt considered as serious as fake medicine;

Trademark laws define counterfeiting broadly and impose a wide range of potentially harsh civil and criminal penalties, regardless of the type of good being copied or the possible impact of counterfeiting on consumers.

*Who sells a \$20 "Rolex" to a bargain-hunting consumer should not be in the same category with a counterfeiter who sells a sugar pill to a sick and unsuspecting AIDS patient. The respective levels of moral culpability and economic harm are not remotely comparable.*



**Lesson learnt:** IPR approach is inadequate to address counterfeiting of medical products

2. IPR approach identifies right-holder as the victim and requires right-holder to trigger/sustain enforcement action and prosecution

in the case of medical products, the real victim of counterfeiting is the patient and legislation should enable patients and health authorities to undertake appropriate procedures regardless of IPR holders' action.



# Lesson learnt: IPR approach is inadequate to address counterfeiting of medical products

3. Counterfeiting medical products does not always entail violating IPR (e.g. heparin, 'Brainy', 'Artrin');



- 4. Complex pharmaceutical regulations warrant more specific approach than one based on IPR;
- 5. Some WHO MS fear that addressing counterfeit medicines through IPR could result in hindering trade in legitimate generics.



# Conclusions

Counterfeiting medical products:

- is a serious crime that puts human lives at risk
- jeopardizes progress achieved in public health and challenges the effectiveness of major initiatives aimed at priority diseases
- challenges people's confidence in the entire health system, affecting the reputation of manufacturers, wholesalers, pharmacists, doctors, private organizations and government institutions alike.



# Conclusions

Broad collaboration among many stakeholders is essential to combat counterfeit medical products

Vulnerabilities that make counterfeiting possible to be identified and addressed in each setting

Act simultaneously on legislation, regulations, enforcement, technology and communication

IPR approach is insufficient because it does not empower patients and health authorities

IMPACT needs to be strengthened

