**WHO initiative to combat counterfeit medical products**

**Combating counterfeit medical products**

### Define the problem

**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”

### All counterfeits are substandard

- Expired
- Stolen
- Diverted
- Counterfeit

Not all substandard are counterfeit

### 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

It affects products of all kinds

Expensive, prescription

Inexpensive, OTC

Inexpensive, generic

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!

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.

We know is there and growing!

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

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 areas of some developing countries
- 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”
- 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?

What is IMPACT?

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

IMPACT aims at coordinating global action in order to promote and protect public health.

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

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 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**

**IMPACT**

International Medical Products Anti-Counterfeiting Taskforce

Draft Principles and Elements for National Legislation against Counterfeit Medical Products

Draft endorsed by IMPACT General Meeting

Lisbon, 12 December 2007

- Basis for IMPACT advocacy work in 2008

**ENFORCEMENT**

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

**REGULATORY IMPLEMENTATION**

- Recommendations for revision of GDP with emphasis on counterfeit medical products: DONE
- 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
- Action to be taken by NRA, health professionals
- Initiative to address trade of counterfeit medical products though the Internet

**ENFORCEMENT**

Strengthened Interpol-WHO collaboration

“ASEAN+” 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;
- preparatory work for new coordinated operation (in the wake of Jupiter South-East Asia operation that lead to identifying source of counterfeit antimalarials)
COMMUNICATION

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

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.

What next steps?

IMPACT will start making use of the documents endorsed by the Lisbon meeting. This means:

- Advocacy initiatives aimed at decision-makers,
- Training of concerned officers in the regulatory and enforcement areas,
- Awareness campaigns aimed at health professionals and patients
- Assisting member states to establish national coordination mechanisms based on the SPOC (Single Points of Contact) principle
- Assess national situations to identify weaknesses and needs and assist member states to improve their capacity to combat counterfeiters
- Ad hoc initiatives in sub-Saharan Africa

All this requires resources and calls for a concerted fund-raising effort by all IMPACT stakeholders

IMPACT needs YOU!!

- Report and help investigating cases
- Increase security and transparency of distribution systems (nationally and internationally)
- Join IMPACT working groups
- Help us raise funds

Thank you