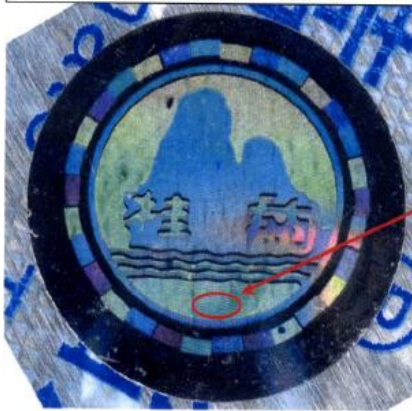


The Anti-Counterfeit Medicines programme of the World Health Organization

Counterfeit Artesunate – Type 4



Well crafted hologram – mountain outline similar to that on the genuine hologram, but lacks the 'Guilin Pharma' legend below the waves. The printing on the blisterpack is clear

No 'Guilin Pharma' legend

To date, all blister packs seen with this fake hologram are printed with:

Code = '000901' or '020305'
Date of 'manufacture' = '09/01' or '03/02'
Date of expiry date = '09/04' or '03/05'

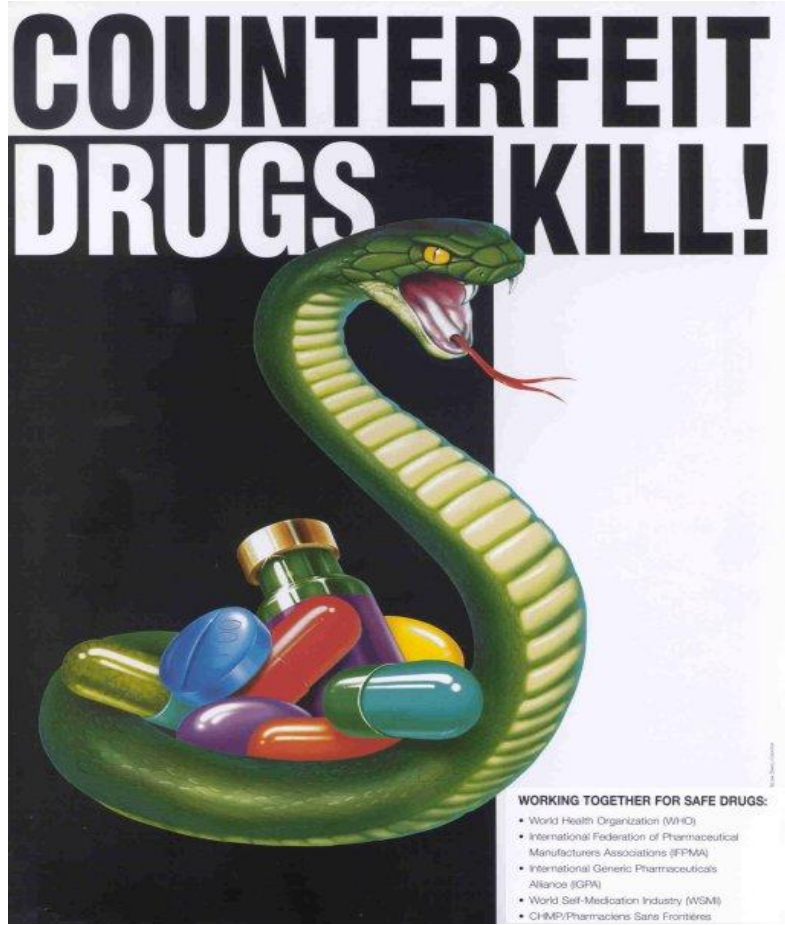


Text should be facing downwards as above

Hans V. Hogerzeil, MD, PhD, FRCP Edin
Director, Essential Medicines and Pharmaceutical Policies
World Health Organization



Problem: Counterfeiting medicines is a major public health concern



Definition of a counterfeit medicine

Different definitions are used in different countries

WHO definition (1992): A product that is:

- **deliberately and fraudulently mislabeled with respect to source and/or identity**
- **counterfeiting can apply to both generic and branded products**
- **counterfeit products may include: products with the correct ingredients, with the wrong ingredients, without ingredients, with incorrect quantities of active ingredients, with fake packaging**

WHO definition to be reviewed by Expert Committee



WHO receiving reports on cases of counterfeit medicines (1982)

- Majority of the reports did not distinguish between substandard and counterfeit medicines
- Most cases were not validated or confirmed
- Most sources of the counterfeit medicines were unknown



Is there a health risk?

Personal risk: Under treatment or non-treatment

Public health risk:

- Ineffective medicines
- Intoxication: harmful ingredients
- No quality assurance, no regulatory oversight
- Adverse reactions not monitored; product recall not possible
- Erosion of public confidence in medical care and health systems
- Waste of money

In numbers, counterfeit medicines are less common than substandard medicines; but the health risks are much greater, and increasing



Main factors encouraging counterfeiting of medicines (I)

- **Social value of medicines is not given priority when defining national medicine policies**
- **Manufacturing medicines without Good Manufacturing Practices compliance; poor storage and distribution condition**
- **Lack of government commitment to create strong medicines regulation**
- **Presence of unregulated markets, manufacturing & distribution outlets**
- **High prices and price differentials, health care providers and patients looking for cheaper sources**
- **In developing countries: scarcity or erratic supply of medicines**
- **Lack of respect for trademark and other international agreements**
- **Corruption**



Main factors encouraging counterfeiting of medicines (2)

- "Denial" of existence of problem by governments, industries, regulators
- International aspect of manufacture and supply of pharmaceuticals - > difficult to control → multi-jurisdictional
- New trade arrangements
 - *opening of borders for trade*
 - *trade through free ports*
 - *trade through several intermediaries*
 - *promotion and trade through Internet*



WHO's work in combating counterfeit medicines:

Three strategies

- 1. Providing tools, international norms, standards and guidelines to assist that medicines circulating in national and international commerce are safe, efficacious and of good quality**
- 2. Providing support to Member States to build national regulatory capacity**
- 3. Developing global activities to combat counterfeit medicines, in collaboration with all relevant stakeholders**



Milestones in WHO's work in anti-counterfeiting (1)

1988:

Resolution WHA 41.16 requests WHO to initiate programmes for prevention and detection of exportation, importation and smuggling of counterfeit medicines

1992:

First international meeting on counterfeit drugs organized by WHO, CIOMS and IFPMA gives first definition of 'counterfeit drug'

→ called all parties involved in manufacturing and distribution as well consumers to collaborate with governmental institutions in combating counterfeit drugs

→ called all parties involved in manufacturing and distribution as well consumers to collaborate with governmental institutions in combating counterfeit drugs



Milestones in WHO's work in anti-counterfeiting (2)

1994:

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.

2000-2005: WHO, IFPMA, EGA, PSF **Working group** on counterfeits

2001: WHA Technical Briefing



Milestones in WHO's work in anti-counterfeiting (3)

1994-2004:

Several ICDRA* requests to WHO to assist Member States to adopt measures to combat counterfeit medicines

* International Conference of Drug Regulatory Authorities

2004:

ICDRA requests WHO to work towards international convention on CF medicines

2005-2006:

No consensus among Member States on international convention on CF medicines

February – July 2006:

Rome conference recommends establishment of an international taskforce. Terms of Reference and name (IMPACT) endorsed at second meeting in Rome



Milestones in WHO's work in anti-counterfeiting (4)

September 2006:

Circular Letter announcing the establishment of IMPACT to Member States

November 2006:

First IMPACT General Meeting, Bonn - nominating IMPACT Chair and Vice-Chairs, Chairs of Working Groups, and establishment of a Work Plan for 2007

December 2007:

Second IMPACT General Meeting, Lisbon – endorsement of "Principles and Elements for National Legislation"

May 2008:

Discussion of WHO report and draft resolution in WHA; much disagreement

December 2008:

Third IMPACT General Meeting, Hammamet/Tunisia; "IMPACT definition" approved



Milestones in WHO's work in anti-counterfeiting (5)

19-27 January 2009

WHO Executive Board requests WHO to prepare two background documents for WHA in May 2009: (1) WHO's activities in substandard and counterfeit medicines; (2) IMPACT and potential conflict of interest

18-23 May 2009

World Health Assembly - discussion postponed to WHA 2010



IMPACT conceptual approach

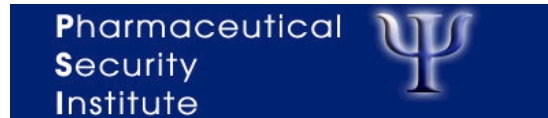
- 1) IMPACT is a voluntary coalition of partners, with the purpose of coordinating international activities aimed at combating counterfeit medical products**
- 2) IMPACT partners reflect the fact that combating counterfeiting of medical products cannot be successfully achieved by the health sector alone but requires a coordinated effort and effective collaboration among health sector, enforcement, border control, justice (all at different administrative levels), as well as health professionals, manufacturers, importers, distributors, media, and patients/consumers**
- 3) IMPACT is led by WHO (Chair, Secretariat) with a focus on the public health implications of counterfeiting rather than on IPR-related aspects**
- 4) IMPACT outputs include recommendations, policy advice and training materials that reflect consensus reached among IMPACT partners**



All 193 WHO Member States and major international partners are members of IMPACT



European Commission



COUNCIL OF EUROPE
CONSEIL DE L'EUROPE



How does IMPACT work?

Secretariat:

**WHO (in the Department of Essential Medicines and Pharmaceutical Policies,
WHO, Geneva)**

Executive Secretary *a.i.*: Dr Sabine Kopp

Five IMPACT working groups:

**Technical areas where weaknesses were identified and action is required at
national and international level:**

- 1) legislative and regulatory infrastructure**
- 2) regulatory implementation**
- 3) enforcement**
- 4) technology**
- 5) communication**



Political issues arising during the past 12 months

- **Concerns by many developing countries that the fight against counterfeit medicines may have a negative impact on free trade in generic products**
- **Use by some countries and companies of the counterfeit argument for limiting free trade / competition / parallel trade**
- **Use of the term "counterfeit medicinal product" in patent disputes; suggesting that the term counterfeit medicines should exclusively be used for IPR disputes and not for public health**
- **Concerns from some parties that certain technical measures would be too costly, e.g. for OTC and generic medicines**
- **Major divisions in the WHO / EB and WHA, especially between USA/EU/Africa and L.America (Brazil)/Asia (India).**



Future ... until WHA 2010 and beyond

WHO:

- **New programme in WHO/EMP: Anti-Counterfeit Medicines (ACM)**
- **Fund-raising and staffing for ACM and IMPACT related activities**
- **Close collaboration of ACM with regulatory and quality assurance programmes and WHO Expert Committee (IMPACT documents on distribution chain and model legislative text)**
- **Communication with Member States to prepare for WHA 2010**

IMPACT:

- **Continuation of WHO involvement in IMPACT (chair, secretariat)**
- **Communication with IMPACT partners and working groups, IMPACT web site clearly separated from WHO/EMP**
- **Regional and 4th General IMPACT meetings organized**
- **Enforcement activities with Interpol and national authorities**

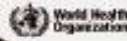


Work on the definition of counterfeit medicines: final review by WHO Expert Committee

- **All Member States have been asked for information on use of term "counterfeit medicines" and related definitions**
- **WHO Expert Committee on Specifications for Pharmaceutical Preparations will closely follow the comments from Member States regarding the definitions**
- **Circulation of a new draft definition for "substandard medicines" as recommended by WHO Expert Committee (normal consultative procedure)**
- **IMPACT Model Legislation (with draft definition) on IMPACT web site for consultation; Member States invited to submit comments**
- **When IMPACT consultation is concluded, submission of the draft Model Legislation document to WHO for Expert Committee review and possible adoption; includes the recommended definition.**



30 Years of Essential Medicines



Where is my essential medicine?

¿Dónde está mi medicamento esencial?

Et moi?

www.who.int/medicines

Thank you!

**The Essential
Medicines family**

