# World Health Professions Alliance (WHPA) workshop on combating falsified medical products

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# Outline

- Brief history
- WHO definition of counterfeit medicines
- MediCrime
- OEWG

# When did it start?

## Terms used in WHO and WHA documentation

**Reports from WHO Member States: early 80's**

- **May 1988: Resolution WHA 41.16 requesting WHO**

***"to initiate programmes for the prevention and detection of export, import and smuggling of falsely labelled, spurious, counterfeited or substandard pharmaceutical preparations, and to cooperate with the Secretary-General of the UN in case provisions of the international drug treaties are violated"***

**first international meeting : 1992**
**"counterfeit drugs" – organized in WHO**

**Outcome: definition of 'counterfeit drug'**

- **May 1994: resolution WHA 47.13 requesting WHO..**

***"to assist Member States in their efforts ..in combating the use of counterfeit drugs".***

- **1996: WHO Project on Counterfeit Drugs**

**→outcome 1999:**

***WHO Guidelines for the Development of Measures to Combat Counterfeit Drugs***

- 2000-2005: WHO, IFPMA, IGPA/EGA, Pharmaciens Sans Frontières, WSMI Round table meetings on counterfeit drugs

- 2001: WHA Technical Briefing on Counterfeit drugs

# International Conferences of Drug Regulatory authorities (ICDRA)

1994-2004: many ICDRAs request WHO to assist Member States to adopt measures to combat counterfeit medicines circulating

Madrid 2004: ICDRA requested WHO to work on a draft international convention on counterfeit medicines

# Follow-up to ICDRA recommendations

**2005-06: No consensus among Member States on an international convention on counterfeit medicines**

**February 2006: Rome conference recommended *establishment of an international taskforce***

**July 2006: ToR and name International Medical Products Anti-Counterfeiting Taskforce (IMPACT) endorsed at meeting in Rome**

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

# WHO Definition of "counterfeit" medicine

"A counterfeit medicine is one which is deliberately and fraudulently mislabeled 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 ingredient or with fake packaging."

1992

# WHO Definition of “counterfeit” medicine

- “Counterfeit” products may include:
  - products with the correct ingredients
  - with the wrong ingredients
  - without ingredients
  - with incorrect quantities of active ingredients
  - with fake packaging

# IMPACT definition of "counterfeit medical product"

The term counterfeit medical product describes a product with a false representation (a) of its identity (b) and/or source (c). This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components (d), with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging.

Violations or disputes concerning patents must not be confused with counterfeiting of medical products. Medical products (whether generic or branded) that are not authorized for marketing in a given country but authorized elsewhere are not considered counterfeit. Substandard batches of, or quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate medical products must not be confused with counterfeiting.

# IMPACT definition of "counterfeit medical product"

**Notes:**

**(a) Counterfeiting is done fraudulently and deliberately. The criminal intent and/or careless behaviour shall be considered during the legal procedures for the purposes of sanctions imposed.**

**(b) This includes any misleading statement with respect to name, composition, strength, or other elements**

**(c) This includes any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder or steps of distribution**

**(d) This refers to all components of a medical product**

# Issues arising during past months

- Concerns that fight against “counterfeit medicines” may have negative impact on access to generics
- Use of counterfeit argument for limiting free trade / competition / parallel trade
- Terminology “counterfeit”/”falsified”? – Use of term “counterfeit medicinal product” in patent disputes
- Concerns from some parties that technical measures would be too costly, e. g. for OTC and Generics
- Discussion about WHO's role in IMPACT

# 63rd WHA 2010 – “SSFFC”

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## Draft discussions of the Working Group

2. REQUESTS the Director-General to convene and facilitate the work of the working group;

3. DECIDES that the working group will examine, from a public health prospective, excluding trade and intellectual property considerations, the following:

a) WHO's role in measures to ensure availability of quality, safe, efficaous and affordable medicinal products;

b) WHO's relationship with the International Medical Products Anti-Counterfeiting Taskforce;

c) WHO's role in prevention and control of medical products of compromised quality, safety, efficacy such as as substandard/spurious/falsely-labeled/falsified/counterfeit medical products from a public health perspective, excluding trade and intellectual property considerations

# What is "SSFFC"?

**Terminology since World Health Assembly held in May 2010 to cover:**

**Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit**

# WHO's work in combating SSFFC medicines: Three strategies

1. Providing tools, international norms, standards and guidelines to assist that drugs 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, including networking + exchange of information

# Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health Moscow, 28 October 2011

Austria
Israel
Iceland
Italy
Cyprus
Germany

Portugal
Russian Federation
Ukraine
Finland
France
Switzerland

**Lichtenstein as 13th state on 4 November**

http://www.coe.int/t/DGHL/StandardSetting/MediCrime/Default_en.asp

# WHO open-ended working group (OEWG) 25 – 28 October 2011

**3. WHO's role in measures to ensure the availability of good-quality, safe, efficacious and affordable medical products**

**4. WHO's role in the prevention and control of medical products of compromised quality, safety and efficacy such as substandard/spurious/falsely-labelled/falsified/counterfeit medical products**

**5. WHO's relationship with the International Medical Products Anti-Counterfeiting Taskforce**

# The “Agreed Elements of the MS mechanism” contained in an Annex to the draft resolution agreed at the OEWG

**General goal: “In order to protect public health and promote access to affordable, safe, efficacious and quality medical products, promote, through effective collaboration among Member States and WHO, the prevention and control of SSFFC medical products and associated activities”**

# The key elements of the draft resolution

- reaffirms “the fundamental role of WHO in ensuring the availability of safe, quality and efficacious medical products”;

- recognizes “the need to promote access to affordable, safe, efficacious and quality medicines including through the full implementation of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property”;

- recognizes “the importance of ensuring that combating SSFFC medical products does not result in hindering the availability of legitimate generic medicines”;

# The key elements of the draft resolution (2)

- acknowledges “the need for improving access to affordable, quality, safe and efficacious medicines as an important element in the effort to prevent and control medicines with compromised quality, safety and efficacy and in the decrease of SSFFC medical products”;

- takes “note of resolution 20/6 of the United Nations Commission on Crime Prevention and Criminal Justice entitled ‘Countering fraudulent medicines, in particular their trafficking'”;

- expresses “concern regarding the lack of sufficient financing of WHO's work in the area of quality, safety and efficacy of medicines”;

- recognizes “the need to enhance support to national and regional regulatory authorities to promote the availability of quality, safe and efficacious medical products”

# Safe quality medicines

# THANK YOU

# for your kind attention