WHO survey on terminology on "counterfeit" medicines or equivalent

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

Outcome: definition of 'counterfeit drug'
WHO Definition of a counterfeit medicine (1992)

A product that is:

- deliberately and fraudulently mislabelled with respect to source and/or identity.

Counterfeiting can apply to both

- generic and branded products.
WHO Definition of a counterfeit medicine

Counterfeit products may include:
- products with the correct ingredients or
- with the wrong ingredients,
- without active ingredients,
- with incorrect quantities of active ingredients or
- with fake packaging.
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
1994-2004: several ICDRAs request WHO to assist Member States to adopt measures to combat counterfeit medicines circulating.

Madrid 2004: ICDRA requested WHO to work at 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
Term and definition in WHO guidelines

- **Counterfeit** in *WHO Guidelines on import procedures for pharmaceutical products* (TRS 863, 1996)
- **Counterfeit** in *WHO Guidelines for inspection of drug distribution channels.* (TRS 885, 1999)
- **Counterfeit** in *WHO Good distribution practices for pharmaceutical products.* (TRS 863, 2006)
- *All TRS have passed through the Executive Board*
to invite Member States to provide information regarding their use of the term "counterfeit medicines" and/or equivalent in national legislation

to draw the attention of Member States to the IMPACT document: "Draft Principles and Elements for National Legislation against Counterfeit Medical Products" posted on the IMPACT web site for consultation; and to invite Member States to provide comments on the newly proposed IMPACT definition contained therein
Responses to C.L.25.2009

- 3 provided specific feedback on IMPACT document
- 57 are mixed responses on national legislation and terminology used, IMPACT document and other issues
- Evaluation work still in progress
Responses to C.L.25.2009 (in English)

- Australia
- Austria
- Bangladesh
- Belarus
- Botswana
- Brazil
- Cambodia
- China
- Croatia
- Czech
- Estonia
- Finland
- Germany
- Georgia
- Hungary
- Iraq
- Latvia
- Liberia
- Malaysia
- Maldives
- Malta
- New Zealand
- Oman
- Philippines
- Poland
- Saudi Arabia Suriname
- Sweden
- Switzerland
- Tanzania
- The Netherlands
- Thailand
- Turkey
- Ukraine
- United Kingdom
- USA
- EU
Responses to C.L.25.2009 (in Spanish)

- Argentina
- Chile
- Colombia
- Costa Rica
- Ecuador
- El Salvador
- Guatemala
- México
- Nicaragua
- Perú
- Venezuela
Responses to C.L.25.2009 (in French)

- Belgium
- Burundi
- Congo DR
- France
- Haiti
- Morocco
- Niger
- Senegal
# Responses to C.L.25.2009

**In Russian:**
- Moldova
- Russia
- Ukraine
- Uzbekistan

**In Arabic:**
- Egypt

**Other:**
- Serbia

- **Step 1:** Collation of comments
- **Step 2:** Translation of responses into English
- **Step 3:** Screening of answers to identify feedback on
  - national legislative issues,
  - comments to IMPACT document,
  - IMPACT definition,
  - additional points raised
- **Step 4:** Legal review and analysis of use of terms and related national legislations

- Step 5: Second independent review and analysis from health/medicines regulatory perspective
- Step 6: Consolidation of both reviews into a comprehensive analysis
- Step 7: Validation of information (final checks against original responses)
- Step 8: Finalisation of analysis as a report
- Step 9: Publication on the WHO web site
- Step 10: Feedback to WHO Expert Committee (Oct 2010)
Subject to verification, first preliminary results:

- Majority of Member States use "counterfeit" (34) in their national legislation

- Other terms used:
  - "falsified" (5, non English speaking MS)
  - "illicit", "illegal", "unregistered", "unauthorized", "adulterated", ....
Subject to verification, first preliminary results:

Types of national legislation in which "counterfeit" medicines are addressed:

- Medicines regulatory related (31)
- Intellectual property related (8)
- Crime related (6)
- None (12)
- Legislation in preparation (6)
Subject to verification, first preliminary results:

National context of use of term "counterfeit" medicines, or equivalent, vary a lot and include beside the aspects raised in the "WHO 1992 definition":

- Unauthorized medicines
- Substandard medicines (e.g. less than 80% of active)
- Intellectual property infringement
- ....
Next Steps

- Step 5: Second independent review and analysis from health/medicines regulatory perspective
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