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WHO

- A counterfeit medication is one which is *deliberately and fraudulently mislabeled* with respect to its identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeited products may include products with the correct ingredients, or with the wrong ingredients, without active ingredients, with insufficient active ingredient or with fake packaging.
- A medical product is counterfeit when there is a *false representation* in relation to its identity, history, or source. This applies to the product, its container, packaging or other labeling information. This can apply to both branded and generic products and include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amount of active ingredients, or with fake packaging.

Proposed revision of “counterfeit drug”

May 2008 World Health Assembly – (WHO forum to discuss health issues)
Considered a draft resolution proposed by IMPACT (International Medical Products Anti-counterfeiting Taskforce)

- Supported by EU
- Supported by US: amendments to control transshipment of drugs, active pharmaceutical ingredients and excipients used in mfg of counterfeit drugs
- India and several other countries are concerned that it would include legally produced generic drugs
- To be considered at May 2009 World Health Assembly meeting

The Philippines

- Similar to WHO plus:
 - a drug product refilled in containers by unauthorized persons if the legitimate labels or marks are used
 - a drug which contains no amount of, or a different active ingredient, or **less than eighty percent (80%) of the active ingredient** it purports to possess, as distinguished from an adulterated drug including reduction or loss of efficacy due to expiration

- Will a report of a suspect counterfeit drug with “reduced amount of active ingredient” be classified as a counterfeit drug in the Philippines?

The Philippines

- Parties liable
 - the owner, proprietor, administrator of the drugstore, hospital pharmacy or dispensary, laboratory or other outlets or premises where the counterfeit drug is found who induces, causes or allows the commission of any act herein prohibited;
 - the registered pharmacist of the outlet where the counterfeit drug is sold or found who, sells or dispenses such drug to a third party and who has actual or constructive knowledge that said is counterfeit; and should the offense be committed by a juridical person, the president, general manager, the managing partner, chief operating officer or the person who directly induces, caused or knowingly allows the commission of the offense shall be penalized.

Other definitions

Viet Nam

- They do not have or have very little pharmaceutical ingredients
- They contain pharmaceutical ingredients that contradict to which stated on the label
- Label & package are identical or nearly identical to those of other products (to mean imitation/copy)

Thailand

- Any modern/traditional medicine which is faked
- An imitation of a drug which is produced, distributed and legally registered

Australia

- Goods containing false representation in any of the following:
 - any advertisement for the goods
 - any documentation of record relating the goods or their manufacture

Other definitions

Cambodia

- A drug which is deliberately produced with incorrect or wrong active ingredients
- A drug without active ingredients or which contains quantities of active ingredients outside the defined pharmacopoeial standards
- A drug which is deliberately and fraudulently mislabeled with respect to identity or source or with fake packaging
- A drug repacked or produced by unauthorized person

Lao

- A modern or a traditional medicine which is deliberately produced to be fake, or copied from another product that has been produced and distributed and registered officially

Counterfeit Drug Databases

WHO Database

- Not validated
- Underreporting also due to inconsistent national definitions of “counterfeit,” “illicit”, “fake”, “substandard”
 - glycerin contaminated with diethylene glycol (fake or contaminated?)
- 1982 to 1997: 770 reports from ~ 15% of 191 member countries
- 1999 to 2004: 85 reports

Pharmaceutical Security Institute (PSI): 21 international pharma companies

- 2003 to 2004: 620 reports from 63 countries (does PSI inform WHO?)

FDA MedWatch

- 2000 to 2007: 259 new cases opened
- 2004: FDA Form 3500 and instructions revised to report “suspected counterfeit products”

Top Ten in 2005
(Pharmaceutical Security Institute)

Country	# Counterfeit Drugs Discovered
Russia	93
China	87
South Korea	66
Peru	54
Columbia	50
United States	42
Ukraine	28
Germany	25
Israel	25

New cases opened by FDA

<u>Year</u>	<u>No. cases opened</u>
2000	6
2001	21
2002	27
2003	30
2004	58
2005	32*
2006	54
2007	31

* Some "new" cases related to existing cases

Hurdle

- how to evaluate effectiveness of international and national anti-counterfeiting efforts

Part of solution

- standardized definitions
 - similar approaches
 - standardized databases
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- Bottom line: proceed with fewer **apples** and **oranges**