Media centre

Medicines: spurious/falsely-labelled/falsified/counterfeit (SFFC) medicines

Fact sheet N°275
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Key facts

- Spurious/falsely-labelled/falsified/counterfeit (SFFC) medicines are medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source.
- Use of SFFC medicines can result in treatment failure or even death.
- Public confidence in health systems may be eroded following use and/or detection of SFFC medicines.
- Both branded and generic products are subject to counterfeiting.
- All kinds of medicines have been counterfeited, from medicines for the treatment of life-threatening conditions to inexpensive generic versions of painkillers and antihistamines.
- SFFC medicines may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging.

SFFC medicines are found everywhere in the world. They range from random mixtures of harmful toxic substances to inactive, ineffective preparations. Some contain a declared, active ingredient and look so similar to the genuine product that they deceive health professionals as well as patients. But in every case, the source of a SFFC medicine is unknown and its content unreliable. SFFC medicines are always illegal. They can result in treatment failure or even death. Eliminating them is a considerable public health challenge.

Extent of the problem

Defining the extent of counterfeiting is difficult for a number of reasons.

The variety of information sources makes compiling statistics a difficult task. Sources of information include reports from national medicines regulatory authorities, enforcement agencies, pharmaceutical companies and nongovernmental organizations, as well as ad hoc studies on specific geographical areas or therapeutic groups.

The different methods used to produce reports and studies also make compiling and comparing statistics difficult.
Studies can only give snapshots of the immediate situation. Counterfeiters are extremely flexible in the methods they use to mimic products and prevent their detection. They can change these methods from day to day, so when the results of a study are released, they may already be outdated.

Finally, information about a case under legal investigation is sometimes only made public after the investigation has been concluded.

Counterfeiting is greatest in regions where regulatory and enforcement systems for medicines are weakest. In most industrialized countries with effective regulatory systems and market control (i.e. Australia, Canada, Japan, New Zealand, the United States of America, and most of the European Union), incidence of SFFC medicines is extremely low – less than 1% of market value according to the estimates of the countries concerned. But in many African countries, and in parts of Asia, Latin America, and countries in transition, a much higher percentage of the medicines on sale may be SFFC.

Not only is there a huge variation between geographic regions in terms of incidence of SFFC medicines, variation can also be significant within countries: for example, between urban and rural areas, and between cities.

All kinds of medicines have been counterfeited – branded and generic – ranging from medicines for the treatment of life-threatening conditions to inexpensive generic versions of painkillers and antihistamines (see table).

### Table: Examples of SFFC medicines

<table>
<thead>
<tr>
<th>SFFC medicine</th>
<th>Country/Year</th>
<th>Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Avastin (for cancer treatment)</td>
<td>United States of America, 2012</td>
<td>Affected 19 medical practices in the USA. The drug lacked active ingredient ¹</td>
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<tr>
<td>2. Viagra and Cialis (for erectile dysfunction)</td>
<td>United Kingdom, 2012</td>
<td>Smuggled into the UK. Contained undeclared active ingredients with possible serious health risks to the consumer ²</td>
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<tr>
<td>3. Truvada and Viread (for HIV/AIDS)</td>
<td>United Kingdom, 2011</td>
<td>Seized before reaching patients. Diverted authentic product in falsified packaging ³</td>
</tr>
<tr>
<td>4. Zidolam-N (for HIV/AIDS)</td>
<td>Kenya, 2011</td>
<td>Nearly 3 000 patients affected by falsified batch of their antiretroviral therapy ⁴</td>
</tr>
<tr>
<td>5. Alli (weight-loss medicines)</td>
<td>United States of America,</td>
<td>Smuggled into the USA. Contained undeclared active ingredients with</td>
</tr>
</tbody>
</table>
6. Anti-diabetic traditional medicine (used to lower blood sugar) China, 2009 Contained six times the normal dose of glibenclamide. Two people died, nine people were hospitalized.


Internet sales
In over 50% of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit.

Public health risks
SFFC medicines pose a public health risk because their content can be dangerous or they can lack active ingredients. Their use can result in treatment failure and contribute to increased resistance (eg. in the case of antimalarials that contain insufficient active ingredient) or even death. Unlike substandard medicines where there are problems with the manufacturing process by a known manufacturer, SFFC medicines are made by people with the intent to mislead.

The extreme difficulty in tracing the manufacturing and distribution channels of SFFC medicines makes their circulation on markets difficult to stop. Even a single case of a SFFC medicine is unacceptable since it indicates that the pharmaceutical supply system in which it was detected is vulnerable. It undermines the credibility of national health and enforcement authorities.

Contributory factors
Several factors contribute to the SFFC medicine problem.

Paying for medicines can consume a significant proportion of individual or family income. Some people seek medicines that are sold more cheaply. These are often available from non-regulated outlets, where the incidence of SFFC medicines is likely to be higher.

People might also purchase medicines from non-regulated outlets if, as is often the case in rural areas of developing countries, supplies of medicines at regular health facilities do not meet demand.

Counterfeiting medicines can be very lucrative. Since many countries have not yet enacted deterrent legislation, counterfeiters often do not fear prosecution.
The growth in international trade of pharmaceutical ingredients and medicines adds a further dimension of complexity to this issue. For example, trade through brokers and free trade zones where regulation is lax or absent (and medicines are repackaged and relabelled to conceal the country of origin) is increasing.

**WHO response**

Stringent regulatory control of medicines and enforcement by national medicines regulatory authorities contributes significantly to the prevention and detection of SFFC medicines. WHO provides direct country and regional support for strengthening medicines regulation. In 2010, the World Health Assembly established a Working Group of Member States to review WHO’s role in ensuring the availability of quality, safe, efficacious and affordable medical products and in the prevention and control of medical products of compromised quality, safety and efficacy such as substandard/spurious/falsely-labelled/falsified/counterfeit medical products from a public health perspective, excluding trade and intellectual property considerations.

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1. Food and Drug Administration, United States of America  
2. The Medicines and Healthcare Products Regulatory Agency, United Kingdom  
3. The Medicines and Healthcare Products Regulatory Agency, United Kingdom  
4. Pharmacy Board, Kenya  
5. Food and Drug Administration, United States of America  
6. State Food and Drug Administration, People’s Republic of China  
7. Tanzania Food and Drugs Authority, United Republic of Tanzania  
8. Some Internet pharmacies are legal operations, established to offer clients convenience and savings. They deliver medications from government-licensed facilities and sell only on the basis of a prescription.

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**For more information contact:**

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**Related links**

WHO Counterfeit medicines programme

http://www.who.int/mediacentre/factsheets/fs275/en/