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Counterfeit medicines

Health reporter, November 2008

Feature: [Counterfeit medicines](#)

Recommended readings:

- [Combating counterfeit drugs: building effective international collaboration](#)
- [Medicines informal market in Congo, Burundi and Angola: counterfeit and sub-standard antimalarials](#)
- [The global threat of counterfeit drugs: why industry and governments must communicate the dangers](#)
- [Dangerous medicines: unproven AIDS cures and counterfeit antiretroviral drugs](#)
- [Faking it: counterfeit artesunate in South East Asia](#)

Latest additions:

- [Worldwide prevalence of anaemia 1993 to 2005](#)
- [Risk factors for stillbirth in developing countries: a systematic review of the literature](#)
- [The need and plan for global elimination of congenital syphilis](#)
- [State of the worlds mothers 2008: closing the survival gap for children under five](#)
- [Freeing up healthcare: a guide to removing user fees](#)

[Announcements](#)

Feature: Counterfeit medicines

The production of counterfeit drugs is a large but underreported global public health problem, which particularly affects developing countries where most counterfeits are of life-saving medicines. It is a significant cause of death, disability and injury, and loss of public confidence in medicines and health structures. Lower levels of an active ingredient can delay or prevent recovery, while toxic ingredients can be poisonous and possibly fatal. Counterfeit medicines also lead to drug resistance in infectious diseases and present

a significant economic burden for developing regions of the world.

The prevalence of counterfeit drugs appears to be rising, with estimates ranging from 1 to 50 percent. This rise suggests existing national measures and cooperation between pharmaceuticals and governments are failing to address the international nature and growing sophistication of the problem. Economic restrictions, weak drug regulation, insufficient controls on production; distribution, importation and labelling, as well as the inability of the poor to purchase branded high-cost medicines, all promote this rise.

The World Health Organization (WHO) has developed the following definition for a counterfeit drug: 'a medicine, which is deliberately and fraudulently mislabelled 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 or wrong ingredients, without or with insufficient active ingredients or with fake packaging'. Despite the consensus this appears to represent, differences in the definitions used in practice create problems when collecting and comparing data, and implementing measures to combat counterfeit drugs.

It is also possible that pharmaceutical companies and governments are reluctant to publicise the problem in the belief that it may reduce sales of brand-name drugs. However, the resulting lack of health warnings may harm patients and is not in the long term interests of the pharmaceutical industry. Some recommendations suggest that pharmaceuticals should carry out mandatory reporting to governments, who have a duty to investigate, issue public warnings and share information across borders. Although WHO has a reporting system used by national governments, there is currently little scientific or public enquiry relative to the scale of the problem, and no reliable databases accessible to health workers or the public exist.

In response to the problem, WHO have presented an international framework on counterfeit drugs to promote international cooperation and information exchange. This reflects the need for a multifaceted approach which should include: guidelines on national standards to combat counterfeit drugs; provision of effective, inexpensive drugs; enforcement of drug regulation; openness by governments and companies regarding the problem; more effective police action against the counterfeiters; better international cooperation between the industry, policy, customs, and drug regulators; and education of patients, drug sellers and health workers.

More information:

- International Journal of Drug Policy
<http://www.eldis.org/go/topics/resource-guides/health&id=8008&type=Organisation>
- WHO: Counterfeit medicines
<http://www.who.int/mediacentre/factsheets/fs275/en/>
- Counterfeit drugs: problem of developing and developed countries
<http://www.iisc.ernet.in/currsci/apr252006/1054.pdf>

- US Food and Drug administration: Counterfeit drugs questions and answers
<http://www.fda.gov/oc/initiatives/counterfeit/qa.html>
 - International Medical Products Anti-Counterfeiting Taskforce
<http://www.who.int/impact/en/>
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Recommended readings

1. Combating counterfeit drugs: building effective international collaboration

Authors: M. Forzley

Publisher: World Health Organization, 2006

This concept paper, prepared as a background document for a World Health Organization (WHO) conference held in February 2006, explores the problem of counterfeit drugs and considers steps needed to address the problem. The paper outlines how counterfeit drugs are a global health problem. Counterfeiting affects finished products as well as active pharmaceutical ingredients, medical devices, diagnostic kits and other types of health care related items. There is increasing evidence that measures taken at the national level are not enough to address the international nature and scope of counterfeit medicines. Evidence also highlights the growing expertise and sophistication of those that market and produce them.

The paper considers the idea of an International Framework Convention as a response to the inadequacy of national measures to meet the challenges presented by counterfeit drugs. Such a framework could establish norms for national measures and their implementation, and regulate transactions in the global trade in medicines. As an immediate response to the need for internationally coordinated action, the paper reports that WHO is proposing to establish an International Medical Products Anti-Counterfeiting Taskforce (IMPACT), which would explore the possible development of a framework convention. The nature of this taskforce and the national measures needed to support it are discussed.

Available online at: <http://www.eldis.org/go/topics/resource-guides/health&id=22595&type=Document>

2. Medicines informal market in Congo, Burundi and Angola: counterfeit and sub-standard antimalarials

Author: M.C. Gaudiano, A. Di Maggio, E. Cocchieri

Publisher: Malaria Journal, BioMed Central, 2007

This article, published in the Malaria Journal, reports on the quality of antimalarial tablet samples from the informal market in Congo, Burundi and Angola. In many developing countries, the medicines market consists of illegal vendors due to weak drug regulatory

systems; insufficient controls on production, distribution and importation; and high costs of branded medicines. The presence of counterfeits and sub-standards in African medicines market is a serious problem that causes many deaths each year.

The results obtained from thirty antimalarial tablet samples showed the presence of different kinds of problems: in more than 50 percent of cases, medicines were sold without the original primary packaging; in 25 percent of the samples the expiry date was not available; and storage conditions reported in the study were inadequate. The most common quality problem is the low dissolution profile; the presence of the right active substance in the right quantity is not a sufficient condition for a good quality drug. The authors conclude that counterfeits and sub-standards are an economic and health problem mainly owing to lower strength ingredients, absence of active substance or presence of a different active ingredient.

Available online at: <http://www.eldis.org/go/topics/resource-guides/health&id=31340&type=Document>

3. The global threat of counterfeit drugs: why industry and governments must communicate the dangers

Authors: R. Cockburn; P. Newton; E. Kyeremateng Agyarko; D. Akunyili; N. White
Publisher: Public Library of Science Medicine, 2005

This article from PLoS Medicine reviews the problem of counterfeit drugs and the public regulations which govern the fight against them. The article outlines how pharmaceutical companies and government are reluctant to publicise problems to health staff and the public. Publicly, this secrecy is justified as an attempt to avoid alarm which would prevent patients from taking their genuine medicines. However, the authors argue that the fiercely competitive market is the real reason for lack of public notification. The authors argue that this secrecy, and the subsequent lack of public health warnings, harms patients and is not in the long-term interests of the legitimate pharmaceutical industry.

The authors call for mandatory reporting to governmental authorities, which should have a legal duty to investigate, issue appropriate public warnings, and share information across borders. The pharmaceutical industry needs to work with pharmacists, health workers and government to make the behind the scenes fight against 'fakes' a public collaborative approach. Individuals who report information should remain anonymous and be protected from the criminal counterfeiting underworld. Moreover, international agreements between companies should avoid taking advantage of competitors' misfortunes and facilitate enhanced cooperation within the pharmaceutical industry.
[adapted from author]

Available online at: <http://www.eldis.org/go/topics/resource-guides/health&id=19182&type=Document>

4. Dangerous medicines: unproven AIDS cures and counterfeit antiretroviral drugs

Authors: J. J. Amon

Publisher: Globalization and Health, 2008

This paper published in the journal Globalization and Health looks at anecdotal evidence that unproven AIDS 'cures' are widely used, and promoted by some countries' governments, instead of evidence based antiretroviral therapy (ART).

The article focuses on reasons why these 'cures' are used, including the high cost of conventional medicine and stigma associated with accessing healthcare systems. The authors discuss case studies from Gambia, South Africa and Iran where governments have promoted unproven treatment creating confusion over the legitimacy of AIDS medicines. Governments appear reluctant to dismiss these 'cures' for fear of being seen to criticise traditional medicine. The authors conclude that the full extent of the availability and use of unproven 'cures' and counterfeit antiretrovirals (ARVs) has not been fully documented, and that more research, as well as scaling up of ARV programmes is needed.

Available online at: <http://www.eldis.org/go/topics/resource-guides/health&id=38991&type=Document>

5. Faking it: counterfeit artesunate in South East Asia

Author: Paul Newton; Nicholas White

Publisher: id21 Development Research Reporting Service, 2002

Artesunate is the recommended treatment for life-threatening malaria in much of south-east Asia, particularly where there is widespread resistance to other anti-malarial drugs. The recent appearance of counterfeit artesunate in this region has caused many unnecessary deaths. How widespread is the distribution of fake tablets? How can national malaria programmes verify the authenticity of the drug?

Available online at: <http://www.eldis.org/go/topics/resource-guides/health&id=10307&type=Document>

Latest additions from the Health resource guide

1. Worldwide prevalence of anaemia 1993-2005

Authors: B. de Benoist; E. McLean; I. Egli

Publisher: World Health Organization, 2008

Anaemia is a public health problem that affects populations in both rich and poor countries. Its primary cause is iron deficiency, but a number of other conditions, such as malaria, parasitic infection, other nutritional deficiencies, and haemoglobinopathies are also responsible, often in combination. This report on the World Health Organisation (WHO) Global Database on Anaemia provides estimates of the prevalence of anaemia at country, regional and global levels for all population groups (preschool-age children, school-age children, pregnant and non-pregnant women, men, and the elderly).

The WHO Global Database on Anaemia can be used to describe the nutritional status of populations and to identify the needs for interventions to prevent and control anaemia. It also tracks trends over the years and shows progress toward the goal of anaemia reduction adopted by the World Summit for Children. The indicator used in this report is haemoglobin concentration. A chapter of the report is dedicated to the criteria used to identify, revise, and select the surveys, and the methodology developed to generate national, regional, and global estimates. The authors argue that in order for the database to reach its full potential, data should be collected on other vulnerable population groups such as the elderly and school-age children, and surveys should be more inclusive and collect information on iron status and other causes of anaemia. The report also finds that there are almost no countries where anaemia is not at least a mild public health problem. The statistics show that globally, anaemia affects 1.62 billion people, approximately 24 percent of the world's population.

Available online at: <http://www.eldis.org/go/topics/resource-guides/health&id=40700&type=Document>

2. Risk factors for stillbirth in developing countries: a systematic review of the literature

Authors: S.D. Mario; L. Say; O. Lincetto. 2007

Even though stillbirths represent a large proportion of perinatal deaths, direct and indirect causes of stillbirths are poorly understood, particularly in developing countries. This article in the Journal of Sexually Transmitted Diseases identifies the risk factors for stillbirth in developing countries and measures their impact by calculating the population attributable fraction (PAF) for each risk factor. PAF is the proportion of cases occurring in the total population that would be avoided if the exposure was removed. The authors provide a systematic review of published studies on risk factors for stillbirth within three broadly defined categories: infections, other clinical conditions, and context-dependent conditions such as socioeconomic status, maternal literacy, and receipt of antenatal care.

A total of 33 studies, conducted in 31 developing countries, were included in the review. The definition of stillbirth varied widely in these studies. Risk factors for stillbirth having a PAF higher than 50 percent were maternal syphilis, chorioamnionitis, maternal malnutrition, lack of antenatal care, and maternal socioeconomic disadvantage. The authors conclude that maternal syphilis prevention, screening and treatment together with other interventions targeting universal use of antenatal care could effectively contribute towards reducing the unacceptably high burden due to stillbirth in developing countries.

Available online at: <http://www.eldis.org/go/topics/resource-guides/health&id=40664&type=Document>

3. The need and plan for global elimination of congenital syphilis

Authors: G.P. Schmid; B.P. Stoner; S. Hawkes, 2007

In every society, congenital syphilis (CS) has significant medical, economic, societal and emotional burdens. Inexplicably, the elimination of CS has failed to attract international attention. Yet, the cornerstones of programs to do this universally are in place. The recent development of new diagnostic tools offers the now-practical possibility of testing every pregnant woman, testing is cost-effective, and programs for the elimination of CS can be joined with other programs to enhance efficiency. This short review in the American Sexually Transmitted Disease Journal argues that the magnitude of the CS burden, globally, rivals that of HIV infection yet receives little attention. The authors then examine the proposed World Health Organization Strategy for the Global Elimination of Congenital Syphilis which aims to mobilise resources and provide a plan to address this underrecognised health problem.

No reliable global estimates of the numbers of cases of CS exist. To determine the magnitude of the problem of CS, the authors of this review have estimated the numbers of cases of CS occurring annually and present preliminary results. Data is presented from 31 countries. CS rates were at their highest in the American region (3.9 percent), followed by the African region. The authors argue that the number of cases of CS and their clinical morbidity have important economic and social implications. The review concludes that countries do not face insurmountable obstacles in attempts to achieve CS elimination. It says that what they often lack are political commitment evidence-based priority setting, and advocacy at all levels; there is little reason why the elimination of CS is not a priority, and many reasons why it should be.

Available online at: <http://www.eldis.org/go/topics/resource-guides/health&id=40643&type=Document>

4. State of the worlds mothers 2008: closing the survival gap for children under five Publisher: Save the Children Fund, 2008

Worldwide, more than 200 million children aged under five do not get the basic health care they need. This contributes to highly preventable or treatable ailments such as diarrhoea and pneumonia. This ninth annual State of the World's Mothers report by Save the Children shows countries progress in terms of reaching children with basic health measures. It also looks at the survival gaps between the poorest and best-off children in developing countries, and shows how millions of lives can be saved if children, especially the poorest, receive essential, low-cost health care. The report outlines an index which compares the well-being of mothers and children in 146 countries.

Sweden, Norway and Iceland have the best rankings and Niger the worst. Conditions for mothers and their children in the bottom countries are particularly bad. On average, one in twenty-one mothers will die from pregnancy-related causes. More than one in six children die before their fifth birthday, and roughly one in three children suffer from malnutrition. The report finds that a significant number of countries are failing to provide the most basic health care that would save children's lives. In the 55 developing countries which together account for 83 percent of child deaths, more than 30 percent of children do not get basic health care when they need it. The report shows large inequities in health care provided to the poorest compared to the best-off children in almost every country. This is true for both highest and lowest ranked countries. The authors argue that the funding for child survival does not match the need. Worldwide spending on health care disproportionately benefits people living in high-income countries with expensive problems to treat, while most diseases and almost all preventable child deaths occur in developing countries. The report recommends that governments design health care programs to better target the poorest and most marginalised mothers and children and invest in community health workers. In addition governments must deliver a basic package of maternal, newborn and child health care that takes into account the realities for poor people in developing countries.

Available online at: <http://www.eldis.org/go/topics/resource-guides/health&id=40636&type=Document>

5. Freeing up healthcare: a guide to removing user fees

Authors: B. McPake; A. Schmidt; E. Araujo
Publisher: Save the Children Fund, 2008

Evidence shows that user fees prevent people accessing health services, and that poor people are affected the most. This guide argues that it is both necessary and feasible to remove user fees in order to help poorer people access basic healthcare. It describes five steps to follow to successfully remove user fees and maximise utilisation of health services. Using data from a range of countries and worked examples, it demonstrates how to estimate the effect of removing fees on utilisation and the resulting resource

requirements. The guide also looks in detail at the case of Uganda, which removed user fees, discontinuing the policy of cost-sharing, in 2001.

The five steps are:

- analyse your starting position
- estimate how removing fees will affect service utilisation
- estimate additional requirements for human resources and drugs
- mobilise additional funding
- communicate the policy change

Available online at: <http://www.eldis.org/go/topics/resource-guides/health&id=40617&type=Document>

Announcements

Conference: Fourth International Stigma Conference - Together Against Stigma - Stigma & Discrimination: Evidence for Action

Dates: 21-23 January 2009

Location: Royal College of Physicians, London, UK

Registration for this conference, organised by the Institute of Psychiatry, King's College London and the WPA Scientific Section on Stigma and Mental Illness, is now open.

This international conference will bring together global research leaders in stigma and discrimination in mental health. It will focus on the latest knowledge on effective interventions to reduce stigma and discrimination. This event will be of interest to all those active in working together against stigma.

The registration fee is £260 before 15th October 2008, and £300 after this date.

More information: <http://www.eldis.org/go/topics/resource-guides/health/health-events-and-announcements&id=38782&type=Item>

See the complete list of announcements at: www.eldis.org/go/topics/resource-guides/health/health-events-and-announcements

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The HRC provides access to technical assistance and information for the Department for International Development (DFID UK), and its partners, in support of pro-poor health policies as well as health systems, service delivery and public health topics and programmes.

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