

Counterfeit Medicines: an update on estimates
15 November 2006

For the past few years the public opinion and expert circles have passively accepted the argument that 10% of medicines around the world could be counterfeit. This number however, is not supportable, because this figure fails to reflect the wide range in the proportion of counterfeits across countries and because of the difficulties in measurement that allow only inferences to be made about the potential range of proportion in different regions.

Today, our capacity to collect and analyse available information has improved, providing a better understanding of the situation through initiatives such as the IMPACT, with input from WHO, OECD, IFPMA, the Pharmaceutical Security Institute and others. We feel that an effort to assess the presence of counterfeiting is fundamental, but also that the old 10% estimate needs to be clarified.

According to the WHO, a counterfeit medicine is “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 ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.”

Certain countries have translated this definition into their legislation. The WHO's definition encompasses all the different legal definitions we have identified so far. We consider consistent with the WHO's definition all national legislation that translates “deliberately and fraudulently mislabelled” into “if a product contain less than xx% of the declared active ingredient is considered counterfeit”.

We advise against using a single average figure for global proportion of counterfeit medicines because, besides being necessarily imprecise (i.e. not reproducible in subsequent studies) and inaccurate (i.e. not reflecting the actual value), a single global ratio blurs the real picture and can mislead the public.

Instead, it is necessary to use a range when describing the relevance of counterfeiting, along with the development status of countries affected. Thus, it is reasonable to estimate that the prevalence of counterfeit medicines ranges from less than 1 percent of sales in developed countries, to over 10 percent in developing countries, depending on the geographical area. This range takes into consideration both regional disparities in the presence of counterfeits, and specific global market value shares¹.

Analysis shows that counterfeiting is greater in those regions where regulatory and legal oversight is weaker, and therefore:

- most developed countries with effective regulatory systems and market control (e.g. USA, EU, Australia, Canada, Japan, New Zealand) currently have a very low proportion, i.e. less than 1% of market value. However, we must keep in mind that indications point to an increase in the prevalence of counterfeit medicines even in developed countries;
- many developing countries of Africa, parts of Asia, and parts of Latin America have areas where more than 30% of the medicines on sale can be counterfeit. Other developing markets, however, have less than 10%; overall, a reasonable estimate is between 10% and 30%;
- many of the former Soviet republics have a proportion of counterfeit medicines which is above 20% of market value -this falls into the developing country range;
- medicines purchased over the Internet from sites that conceal their actual physical address are counterfeit in over 50% of cases.

¹ Global pharmaceutical market shares are 83% for developed markets, and 17% for developing world. Based on audited IMS sales data, 2005 publicly available at http://www.imshealth.com/ims/portal/front/articleC/0.2777,6599_77478579_77479643,00.html

Apart from the huge differences between regions, variations can also be dramatic within countries -city versus rural areas, city versus city-, and can even be time sensitive – sometimes counterfeits are openly sold and sometimes not.

The sources of information, of course, also underlie the complexity of any estimation. Detailed data on counterfeit medicines is often difficult to obtain or to publish. How to measure a market that, by nature, is informal and illegal –and where evidence is usually consumed?

Counterfeiters and their allies know they are committing a crime and aggressively seek to avoid detection. They engage in elaborate conspiracies to disguise their activities as the masters remain in the shadows. They establish fictitious businesses and front companies. They exploit weaknesses in border control whenever governments try to promote world commerce by reducing border inspections. They use false documents to obtain essential active pharmaceutical ingredients, as well as manufacturing equipment to replicate genuine products. In sum, their actions disguise the extent of crime and makes detection and reporting extremely difficult.

Currently, the sources of information available include reports from national authorities, such as drug regulatory and enforcement agencies, ad hoc studies conducted on a specific geographical area or therapeutic category, reports from the pharmaceutical sector, reports from NGOs and surveys.

In summary, the estimated range does not aim at providing an exact figure but rather an indication of the different possible levels of prevalence around the world. Even one single case of counterfeit medicine is not acceptable because, in addition to putting patients at risk and undermining the public confidence in their medicines, it also betrays the vulnerability of the pharmaceutical supply system and jeopardizes the credibility of national authorities (health and enforcement alike).

Annex

2006 Reports

Russia: The Federal Service for Health Sphere Supervision (FSHSS) reported that 10% of all drugs on the Russian market were counterfeit. However, other sources estimate that the real figure could be much higher.

Nigeria: The National Agency for Food, Drug Administration and Control (NAFDAC) announced that the prevalence of counterfeit drugs has dropped to 16% at the beginning of 2006.

Reports Before 2006

Dominican Republic: The Public Health Department reported that 50% of the pharmacies operate illegally and that, according to the statistics, 10% of the medicines that arrive in the country are fake. Some of the medicines found have expired over 10 years ago.

El Salvador: INQUIFAR, the association of pharmaceutical companies in El Salvador, has denounced the widespread availability of counterfeit drugs on the domestic market. According to the local drug-maker Gamma Laboratorios, the commercialization of counterfeit medicines currently generates economic losses of around \$40 million per year to the country's pharmaceutical industry.

Indonesia: The International Pharmaceutical Manufacturers Group (IPMG) in Indonesia has estimated that pirated drugs constitute 25% of Indonesia's \$2 billion pharmaceutical market. According to IPMG's vice chairman, those fake drugs hit foreign pharmaceutical companies' bottom lines and pose a potential serious public health threat.

Kenya: A random survey by the National Quality Control Laboratories (NQCL) and the Pharmacy and Poisons Board found the almost 30% of drugs in Kenya are counterfeit. According to Dr. Hezekiah Chepkwony of the NQCL, "Some of the drugs are no more than just chalk or water being marketed as

competent pharmaceutical products." According to figures from the Kenyan Association of Pharmaceutical Industry, counterfeit pharmaceutical products account for approximately \$130 million annually in sales in the country.

Peru: Some \$66 million of counterfeit and adulterated pharmaceuticals are sold in Peru every year. In Lima alone there are 1,800 stores devoted to this illegal business. The General Directorate of Medicines, Supplies and Drugs (DIGEMID) of the Department of Health (MINSA) seized around 460,000 adulterated and expired medicines in 2005.

Angola: According to the head of the National Department of Intellectual Copyright Crime of the Economic Police, Apolinario Antonio Domingos, approximately 70% of medicines used by the Angolan population are forgeries.

Colombia: According to Alberto Brave, Executive President of the Association of Colombian Pharmaceutical Industries (ASINFAR), it has been estimated that of a total of an annual \$1,300 million sold in medicines, near 5 percent (some \$60 million), of the products marketed stem from contraband, counterfeiting or adulteration.

Lebanon: The chief of Lebanon's National Health Commission (NHC), Ismail Sakaria, stated in July 2004 that 35% of pharmaceuticals available in the Lebanese market are counterfeit products.

Mexico: During 2004, federal agents seized in Sahuayo, Michoacán, and in Guadalajara, Jalisco, approximately 60 tons of stolen, expired and counterfeit pharmaceuticals. There is concern in the pharmaceutical industry because of the growth in sales of counterfeit and contraband products. Reportedly, the penetration of these illegal products is about 10% of the pharmaceutical market.

Nigeria: The chairman of Ebonyi State Task Force on Counterfeit and Fake Drugs, Emmanuel Inya-Agha stated that approximately 48% of goods and drugs imported into the country are substandard or counterfeit.

Peru: Around 200 pharmacies operate in downtown Lima with neither registration nor authorization issued by the ministry of health. According to Mr. Javier Llamoza from the municipal health department, they sell 40% contraband pharmaceuticals and 12% adulterated or expired supplied by clandestine laboratories. During 2004, the ministry of health seized ten tons of adulterated pharmaceuticals.

Philippines: The former director of the Bureau of Food and Drug (BFAD), William Torres, was quoted in newspapers saying, "that 30% of drug store outlets visited by food and drug deregulation officers carry and sell counterfeit drugs, as of 2003."

Cambodia: A Cambodian Health Ministry survey conducted in 2002 revealed that 13% of drugs on the domestic market were counterfeit or substandard, especially the anti-malaria drugs and antibiotics.

China: China's Research and Development-based Pharmaceutical Association estimated that about 8% of over-the-counter drugs sold in China are counterfeit.

India: Indian pharmaceutical companies have suggested that in India's major cities, one in five strips of medicines sold is a fake. They claim a loss in revenue of between 4% and 5% annually. The industry also estimates that spurious drugs have grown from 10% to 20% of the total market.

Nigeria: Nigerian health officials estimate that 70% of drugs in circulation in the country are either fake or adulterated.

Peru: The Association of Pharmaceutical Laboratories of Peru (ALAFARPE) estimates that the illegal pharmaceuticals commerce in the country represents around \$40 million. This figure includes medicines that enter the country as contraband, expired, counterfeit, adulterated, with altered or missing labels and those stolen from the warehouses of the Ministry of Health, the armed forces, and police.