
COUNTERFEIT MEDICINES

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It is always funny to read an article that starts off with a definition or one that quotes Webster's Dictionary, as if from the very beginning the writer fears of giving a false impression. In pharmacy, there should be some general understanding of what a counterfeit medicine is. Dr Sabine Kopp, representing the World Health Organization (WHO), counters this belief by explaining that there are many definitions or misunderstandings of what a counterfeit medicine is. The world was not initially prepared to deal with counterfeit medicines, so in the process many different terms arose: spurious, falsified, falsely labeled, and of course, counterfeit.

It is believed that the art of counterfeiting medications began in the early 1980's and originated in many of the WHO's member states. In 1992, the WHO came up with a definition of counterfeit medicines which has been adopted by many of its member states and reads as "medicines that are deliberately and fraudulently mislabeled with respect to identity and/or source." Since there was a lag time between the realizations of falsified medications in the 80's to the current definition, many terms still exist.

Counterfeit medicines exist everywhere in the world with no one country being immune to its potential dangers (including treatment failure and even death). The practice of counterfeiting medication is illegal in every country mostly due to the breaking of patent laws or copyrights, not because there are sufficient laws and policies put into place to deter these actions. As the WHO states, "counterfeiting is greatest in regions where regulatory and enforcement systems for medicines are weakest. In most countries with effective regulatory systems and market control (i.e. Australia, Canada, Japan, New Zealand, most of the European Union, and the United States of America), incidence of counterfeit medicines is extremely low – less than 1% of market value according to the estimates of the countries concerned."

The plight of counterfeits doesn't just affect name-brand medications, but generics as well, and from every drug class. Examples include anti-diabetic medications,

anti-malarials, medications to treat erectile dysfunction, biologics and neuropsychiatric drugs. The International Medical Products Anti-Counterfeiting Taskforce says, "In developing countries the most disturbing issue is the common availability of counterfeited medicines for the treatment of life-threatening conditions such as malaria, tuberculosis and HIV and AIDS." Dr Kopp states that the "influx of medications into a country is huge and difficult to monitor." Drugs enter a country through procurement agencies, donations, drug programs, and trade. Monitoring all the different ports of entry and all the different methods that drugs can enter a country is difficult even with the proper authorities and procedures in place. However, the "WHO is offering tools, norms and standards, policies, and support for any country that is wanting to decrease the number of counterfeit drugs entering their land" says Dr Kopp.

According to 2008 statistics from the Taxation and Customs Union branch of the European Commission, India accounts as the country of origin for nearly 52% of fraudulent medications intercepted by border patrols for the European Union, down from 75% in 2005. Syria, China, Ukraine, and even the United States of America also appear on their list. Bejon Misra, from Partnership for Safe Medicines in India, was quick to play down India's role in counterfeit medication manufacturing saying that "only 0.3% to 0.4% of samples collected were spurious" and made the audience aware of the country's fine reputation in manufacturing quality name brand and generic drugs. This sentiment was also acknowledged by the Taxation and Customs Union branch of the European Commission.

The reasons for counterfeiting medications are numerous. Some seek medications that are sold cheaply from non-regulated outlets, some have limited access to authentic medications, the selling of fake medications is lucrative, expansion of markets may be too great for the demand of authentic medications to keep up, shortages, a lack of political will to make change, lax sanctions against criminals and a failure by stakeholders to recognize the problem at hand.

While at a press conference discussing counterfeit medications, Dr Michel Buchmann, FIP President, said that FIP, along with the WHO and the World Health Professions Alliance (WHPA) are working together to combat falsified medications. He admits though, that they are on the rise and may in part be due to a "worrying situation that innovation of new drugs is decreasing especially in such areas as HIV, tuberculosis, and malaria. This may be due to increased costs of medicines and higher demands of safety and quality." He suggests all healthcare workers must use medications more responsibly and, even though it is a difficult time in research with the current world economy, that we develop and discover new drug molecules. This in turn can help mitigate the influx of counterfeit medications.

During the group sessions that were focused around case studies, delegates were put to task of coming up with possibilities for reducing falsified medications. During these round-

table discussions, a leader was chosen from each group to act as a mediator to everyone's voice. They offered practical feedback to forms and policies that were drafted before the FIP World Congress. For pharmacy intern Rama Mylapuram, this symposium and discussion group was important to learn about "counterfeit drugs and how to eradicate the problem, not just here (in India), but in other countries. This is my first time seeing the feedback form and how I am to use it to report spurious medications." Mylapuram suggested, "using a tracking system on offenders so that we know where they are at all times," as a way of reducing counterfeit medications. "We need to do something about the policies in place because these criminals are using loopholes in the justice system to become free and then reoffend again."

The impact of counterfeit medicines not only affects human health, but also our economies. The WHO reports that 10% of all drugs on the Russian market are counterfeit; that sales of counterfeit drugs is a staggering \$66 million USD in Peru and in Lima alone, there are currently 1800 illegal pharmacies selling falsified medications; 25% of Indonesia's \$2 billion pharmaceutical market is made up of counterfeits and that the National Quality Control Laboratories in Kenya found some medications to be nothing more than chalk and water.

A lot has already been said on what needs to be done to stop spurious medications, and solutions are often long-winded and arbitrary in every report on counterfeit drugs. Policy needs to be there. Who is going to step up to the plate and make change happen? Who better than a pharmacist that is equipped with the best knowledge on drug behavior to make change? Are you doing all that you can to mitigate this growing problem?

For more information on FIP's involvement in the fight against counterfeit medicines please visit the FIP website at http://www.fip.org/counterfeit_medicines.