



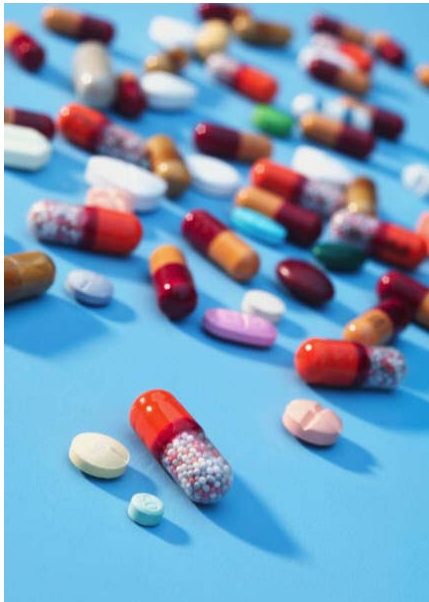
The Threat of Low Quality Cancer Medicine in Latin America

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The Life Raft Group

Disclaimer: All information in this article is provided for information and awareness purposes so readers may make informed decisions. The Life Raft Group does not in any way, shape or form, imply or otherwise claim to be experts in this matter. We share this information with the understanding that the issue of affordable, safe and effective medicine poses various questions and needs further investigation and analysis. The Life Raft Group strongly recommends to all patients to not assume anything with regard to their public health and safety especially with respect to purchasing medicines as standards vary across countries.

Overview



Today, there is an increase demand for affordable medicine. Many people from all over the world are purchasing medicine over the internet, from under developed countries and other means. These drugs are sometimes sold for less than the cost of the actual prescription medicine or are more easily accessible but without the guarantees of quality or safety. In many cases, people are just relying on their government, pharmaceutical companies, and local pharmacists to ensure safe and high quality drugs to cure or alleviate their ailments in order to live a longer and sometimes just a more comfortable life. However, we are facing a time in which there is a great need to be more aware and alert of who and what it is we are investing our trust into with respect to our health. This is a global issue affecting the public health of all.

For the past decade, unsafe drugs also known as counterfeit and substandard medicines are on the rise. Counterfeit and substandard drugs can cause illness and in many cases death. Many people use these terms interchangeably so we have defined them here:

- The World Health Organization (WHO) defines a counterfeit drug as one that is “deliberately and fraudulently mislabeled with respect to identity and/or source.”¹ Counterfeit drugs are usually made without any active pharmaceutical ingredient (API) and are also known as a falsified drug. These drugs may contain contaminants and toxic materials such as boric acid or rat poison.



¹ World Health Organization, “Medicines: counterfeit medicines,” Fact sheet N°275, January 2010

Counterfeit drugs are made relatively easily and inexpensively. The production and distribution of counterfeit drugs is a criminal activity.

- Substandard drugs, as defined by WHO, are “genuine drug products which do not meet quality specifications set for that particular medicine.”² In other words, substandard drugs contain the API but not the appropriate dosage. It is important to note that substandard drugs are produced by manufacturers that may or may not comply with local regulatory practices and official standards for prescriptions. WHO provides a definition and offers guidelines as a reference but it may not be enforceable with local country regulations. If substandard drugs are knowingly produced to make an unlawful product – a fake drug - they too are considered counterfeit.

There is also the category of drugs called generics. A generic drug, as defined by the United States Food and Drug Administration (FDA), “is identical--or bioequivalent--to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price.”³

Some generics may be substandard. Issues with bioequivalence are country-specific and depend on the country’s regulatory agency; therefore, standards vary across countries. Also, bioequivalence may not be the golden rule to approve generics in some countries. As we’ve seen from our research, many countries including many across the developed world are seeing a rise in trends of unsafe drugs due to weak or insufficient quality control and enforcement. According to WHO, less than 20 percent of the organization’s member countries have a well-developed drug regulation system.⁴ The increase in sale of counterfeit and substandard pharmaceuticals, especially in developing countries are due to consumers seeking inexpensive medications. People may also unknowingly purchase a counterfeit or substandard from a legitimate retailer because of the weak/insufficient enforcement.

In doing a quick search on the internet, it was revealed that there is an abundance of cancer drugs available for purchase without a prescription and for sale less than 50 percent the cost to purchase the actual legal or prescribed medicine. WHO estimates that 50 percent of cases of medicines purchased from internet sites will be counterfeit.⁵ There are no known statistics about substandards. In some countries, a drug may be legal yet substandard at the same time.



² World Health Organization, “General Information on Counterfeit Medicines,” 2006.

³ United States Food and Drug Administration, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm>

⁴ World Health Organization, “Effective Drug Regulation: A Multicountry Study,” 2002, p. 11.

⁵ World Health Organization, International Medical Products Anti-Counterfeiting Taskforce (IMPACT), “Counterfeit Drugs Kill!,” May 2008, p. 3.

Therefore, why are countries purchasing and distributing medicines that are not the original brand drug? The main issue here is money and not criminal activity. Many underdeveloped and developing countries cannot afford the original drugs and they have no other means to acquire them. Legitimate generic versions will depend on the level of country controls and regulations and if they are up to “state of the art” standards which should be justified medically and scientifically. For those patients who live in countries with poor access to original drugs, they are faced with options of taking alternatives that are available. Those patients may not know if the drugs they are taking are bioequivalent and have the same standard of quality to the originator. Although country regulatory authorities should look to reference countries to check legitimate quality, safety and efficacy of drugs, this information may not be publicly available yet.

Case Example

There is a documented case of a 36-year-old male patient with chronic myeloid leukemia (CML) who was taking original brand-name imatinib for three years with remission of the disease. Health-care authorities and insurance providers then substituted an alternative version of imatinib because it was found to help reduce costs. After three months on the new drug, the patient experienced significant changes such as anemia, low white blood cell count, low blood platelets, and loss of molecular response. The disease relapsed and soon after the patient went back on branded imatinib which resulted in a reinstatement of response.⁶

There are a few reported cases of CML patients similar to the one described above, but to date, nothing is formally documented regarding the adverse side effects of non-legitimate generic versions of Glivec (or imatinib) on GIST patients. One question to ask is why are reports of adverse events not enforced?

There is currently an active research study by Dr. Matías Chacón from Instituto Alexander Fleming in Buenos Aires, Argentina evaluating the blood level concentration of GIST patients, both those on Glivec and the generic versions. The primary objective of the study is to measure blood level concentrations of different types of GIST patients. In our opinion, it would be interesting to see if the study reveals any new information about the differences between Glivec and its generic versions even if it is not the primary focus of the study.

What We Can Do

As more health authorities are allowing substandard generic drugs to enter their countries, patients' lives are at increased risk. Now is the time to strongly advocate for higher standards of treatment for the cancer patient community. It is important to demand that medicines demonstrate safety, efficacy, and high quality. What does this mean?

Safety is ensured by a system of controls. Medicines are tested prior to being publicly available to make sure they are safe for human consumption.

⁶ Goubran, HA. “Failure of a non-authorized copy product to maintain response achieved with imatinib in a patient with chronic phase chronic myeloid leukemia: a case report.” *Journal of Medical Case Reports*, Vol. 3, Issue 7, 2009.

Efficacy is indicated when a drug produces the desired therapeutic effect on a patient.

High quality means that the medicine meets certain established criteria. The WHO specifies the following to help uphold quality standards: 1) review quality of product registration, 2) formulate norms and standards, 3) begin licensing facilities and personnel, 4) inspect facilities and products, and 5) control the quality of drugs.⁷

In some countries, drugs may not be tested regularly and the quality may not be consistent over time. One test batch of drugs may produce different results than the second batch or the third. Therefore, are physical controls in place to assure good quality?

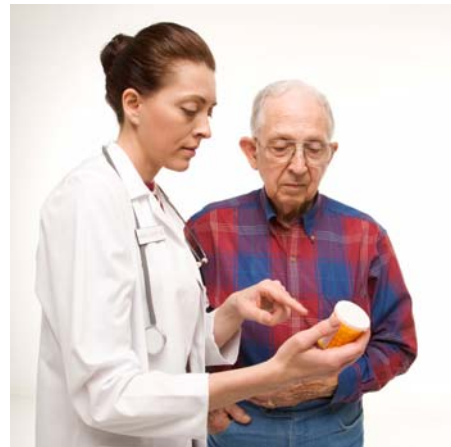
Brazil provides a good case example of how passing legislation helps encourage government agencies to improve the monitoring of safety and quality of pharmaceuticals. In 2003, Brazil introduced a law to phase out substandard generics and to begin to monitor and test pharmaceutical properties of these drugs. Brazil's drug regulatory authority now has a formal system in place to regulate medicines in the market.⁸

Although Brazil is far ahead of other Latin American countries, there is still a long way to go. As a patient advocate, it is important to research and understand what forms of access are available in your country. Learn what the current health law states in your country and how the government regulates pharmaceuticals. Also, understand your patient rights and see how the local laws and regulations affect you as patient.

Here are some suggestions on how to get involved to ensure patients' rights are being heard:

1. Talk to your doctor about your concerns regarding non-original drugs. Ask your doctor about the non-original drugs you are being prescribed. If he/she has information on any adverse reactions to the non-original drug ask that he/she report adverse reactions to the WHO's Rapid Alert System for Combating Counterfeit Medicine at <http://www.counterfeitmedalert.info/> so these types of drugs can be monitored.

Also, you can find out if there are systems that exist in your country that allow you or your doctor to report adverse events and follow up to see if these systems are enforced



⁷ World Health Organization, "How to Develop and implement a national drug policy," 2nd edition, WHO Geneva, 2001, p. 50.

⁸ Torstensson, D. & Pugatch, M., "Keeping Medicines Safe: A Study of the Regulations Guiding the Approval of Medicines in Emerging Markets," Stockholm Network, 2010.

and if they are working.

2. Meet and talk with other GIST patients perhaps through referrals from your doctor or local hospital. Develop a community of patients and/or contact your local patient organization to discuss and collect information on patient adverse reactions to generic drugs. The more information collected and shared the more you build awareness in your country of the sensitivity of this issue and perhaps maybe even save someone's life. With proper reporting, consider publishing the data which may help raise more awareness about this issue.
3. Share your concerns with the media. By shining a spotlight on the topic of counterfeit and substandard medicines, it will encourage government policy makers to pay more attention to the issue.
4. Sign the "Medicamentos Seguros, Salvan Vidas" (Safe Medicines, Save Lives) petition at <http://alianzagist.blogspot.com>. Ask other patients, concerned individuals and local groups to sign the petition as well. This petition can be presented to the media.

There are many ways to get involved in combating the use of counterfeit and substandard drugs. Join us in taking action against this public health threat. Your voice makes a difference for the safety of all. If you are interested in learning more or becoming more actively involved, please contact Sara Rothschild at srothschild@liferaftgroup.org.