



Fake Meds - An Increasing Concern in Western Countries

(Source: An article by Susanne Lundin for Medical Xpress and excerpts from an article published in the Pharmaceutical Journal)

Illegal and substandard pharmaceuticals, otherwise known as “fake medicines”, have been mostly prevalent in low and middle-income countries, that is until recently. Now such products are quickly making their way into the Western world. This raises a myriad of concerns, not the least of which is that these drugs are completely ineffective, and potentially toxic, even fatal.

Part of the challenge in dealing with fake meds is that oftentimes people are not even aware the risks of such products. A study of doctors in Sweden shows that 36.5% had met patients who they suspected had taken fake medications but few knew how to act on their suspicions.

The origin of these fake meds encompasses several spots around the world so it is hard to trace where they are produced. Compounding the problem is the fact that these drugs are so well disguised that they may look, taste and smell exactly like the original drug. In fact, in many cases, only lab tests can determine their actual contents.

According to a WHO report published in 2017, about 10% of all medicines in low and middle-income countries are estimated to be falsified. A study in Africa showed that up to 70% of medicines used against infections in the region were fake. Today, such drugs are increasingly present in high-income countries too. But exactly how prevalent the phenomenon is becoming is difficult to quantify.

Recently, a counterfeit form of the cancer drug *Avastatin* was discovered by a wholesaler in the Netherlands. In Germany, both falsified cancer and HIV drugs have made their way into the legitimate supply chain.

Not all Western countries' formal healthcare systems have been affected, though, as Sweden is the exception. Although regulation of the pharmaceutical market in Sweden and many other European countries is effective, illicit products are showing up in the marketplace so it may just be a matter of time before they do if proactive measures are not taken. In a recent Interpol operation, which included 123 different countries, over 10 million fake medications with an estimated value of US\$14 million were confiscated. As a result, 3,671 illegal websites selling such drugs were closed down. This included 175 sites in Sweden.

A lot of thought has been given to the best way to deal with the problem of fake meds. The first thing required is knowledge. Researchers from medicine, law and public health must focus on the supply side and advocating for international legal frameworks. Information about the demand side is lacking, however.

There is also inadequate awareness by the public regarding these risks. The majority of people asked did not know that the EU requires all legally authorized internet pharmacies to display a common logo certifying the legal status of stores for the prescription medicines. Particularly with regard to online purchases, customers frequently make their purchases from the seemingly best website without doing much, if any, research from whom they are making their purchase.

There is growing concern regarding the infiltration of fake meds into

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- ◆ The convening of the heads of state from the world's largest economies at this year's G20 Summit in Japan included a general declaration committing to advance global health priorities including: commitment to move towards universal health coverage (UHC) through bolstering primary health care and access to medicines; promote healthy and active aging through the prevention of noncommunicable disease; improve emergency preparedness and response; provide support for African countries affected by the Ebola outbreak; and, address antimicrobial resistance by identifying better models for antimicrobial drug research and development.

- ◆ **Sanofi Genzyme**, along with its partner **Sobi**, continued its commitment to assisting patients with hemophilia by donating up to one billion international units of clotting factor in the developing world for up to ten years, including up to 500 million IUs to the WFH Humanitarian Aid Program over a period of five years.

- The **World Health Organization** has approved the use of untested drugs as an acceptable option for fighting Ebola in West Africa. This follows a consultation between the WHO and a team of experts, including Wellcome Trust. It was concluded that the fatality rate of the disease justified the risk involved with these untried medicines.

- Pharmaceutical manufacturer **Gilead Sciences** has announced that they will be providing their anti-HIV medication to over 200,000

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The 72nd World Health Assembly – A Synopsis

(Source: WHO Press Releases and FightTheFakes.org)

This year's World Health Assembly convened in Geneva, Switzerland in late May and addressed important global health challenges with bold initiatives. Below is a synopsis of the week's events:

- Member states agreed to adopt the eleventh revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-11) effective 1 January 2022. ICD-11 has been updated to address concerns for the 21st century and reflects critical advances in science and medicine. It can be well integrated with electronic health application and systems. This new version is fully electronic, allows more detail to be recorded and is significantly easier to use and implement, which will lead to fewer mistakes and lower costs, and make the tool much more accessible, particularly in low-resource settings. Member states noted that it has been produced in a transparent and collaborative manner.

- Member states committed to recognize patient safety as a key health priority, and to take concerted action to reduce patient harm in healthcare settings. The World Health Assembly also endorsed the establishment of an annual World Patient Safety Day on 17 September and called on WHO to provide technical support to countries to build national capacities to access, measure and improve patient safety. The Assembly also requested WHO to formulate a global patient safety action plan in consultation with all relevant stakeholders, to improve and ensure

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the United Kingdom because of the impending Brexit. Martin Sawer, executive director of the Health Distribution Association (UK) stated, “We could be unplugged from [the FMD] on 1 November [2019] because we’d have no access to the EU database that is based throughout the 28 countries.” Consequently he added, “medicines in the UK, we believe, would be less safe.”

Sawer also explained that, in the event of a no-deal Brexit, he “would expect medicines shortages and a lot of price rises for the NHS to happen pretty quickly – some shortages in most constituencies around the UK”.

Efforts are underway to tackle the ever-growing problem of fake meds. Europe has put in place the Falsified Medicines Directive, or FMD, which requires that each package have a unique bar code to trace the products and check contents. The FMD is a milestone political intervention in the EU pharmaceutical supply chain.

It is important to understand that while no one wants to expose themselves to illegitimate medicines, online purchases are convenient and often a common alternative to a prescription from a doctor. This crucial understanding to the demand side helps to map social conditions and health-seeking behaviors of consumers. For example, why does a young man prefer to purchase *Viagra* from an obviously illegal online pharmacy? Likewise, what leads a woman to act in a similar way to obtain diet pills rather than go to a doctor? Clearly this could be attributed to feeling ashamed to openly admit to sexual dysfunction or being overweight. Also, more often we are seeing a shift of identity from case-seeking patients to care-competent consumers. Many people read up on drugs before going to their healthcare provider. If the doctor denies their request for a certain drug, they may go to an illicit place to buy the drug on their own.

Ultimately, societies must act on many different fronts – from broad international cooperation between researchers, police, legislators and the pharmaceutical industry to understanding social issues and identity patterns of the general public in order to combat these fake medicines.

IFPW is the Secretariat for the global Fight the Fakes campaign. For more information on fake medicines, visit www.FightTheFakes.org.

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patient safety globally.

- Member states agreed to pave the way for better and faster services for time-sensitive health conditions, including injuries, heart attacks, mental health conditions, infections or pregnancy complications. It was established that a functional emergency care system is essential to universal health coverage, and investing in front line care saves lives, increases impact and reduces costs in other parts of the health system. Member states stressed that timeliness is an essential component of quality care, and that millions of deaths and long-term disabilities could be prevented by the establishment of adequate emergency care systems and services that are accessible to patients.

- Member states agreed to a new resolution to improve safe water, sanitation and hygiene (WASH) services in health care facilities around the world. In light of a lack of basic water and sanitation services in 20-25% of healthcare facilities, the resolution asks member states to develop national roadmaps, establish and implement standards, and invest in systems to support sustainable WASH services. It also tasks WHO with providing leadership to help mobilize resources for investment, issue reports on global progress, and (in emergencies) help coordinate and implement WASH and infection prevention.

- Member states agreed to a five-year global action plan to promote the health of refugees and migrants through universal health coverage with the highest attainable standard of health. The plan includes

both short- and long-term steps to mainstream refugee and migrant health care, enhance partnerships, strengthen health monitoring and information systems, and counter misconceptions about migrant refugee health.

- The World Health Assembly adopted a resolution on improving the transparency of markets for medicines, vaccines and other health products to improve and expand access. The resolution urges member states to enhance public sharing of information on actual prices paid by governments and other buyers for health products, and greater transparency on pharmaceutical patents, clinical trial results and other detriments of pricing along the value chain from laboratory to patient.

- The World Health Assembly requested the Director-General to broaden engagement with member states, the Secretariat of the Convention on Biological Diversity, relevant international organizations and relevant stakeholders, to provide information on current pathogen-sharing practices and arrangements, the implementation of access and benefit-sharing measures, as well as the potential public health outcomes and other implications. The request followed a review of the WHO’s Secretariat’s report on the public health implications of implementation of the Nagoya Protocol, an international agreement on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization.

Also of note, the Fight the Fakes Campaign, in conjunction with the UCL School of Pharmacy, hosted a panel discussion on the latest technological developments used in the fight against fake meds.

The panel was composed of two sections – one made up of tech entrepreneurs and the other of representatives from pharmaceutical academia. Included in the panel were: Adebayo Alonge, co-founder and CEO of RxAll; Raja Sharif, CEO of FarmaTrust; Israel Bimpe of Zipline International; Edward Kelley, Director of Patient Safety Programme at WHO; Dr. Suburi Muvungi, Representative of the Ministry of Health of Rwanda; Professor Catherine Duggan, CEO of the International Pharmaceutical Federation; Cyntia Genolet, Head of Health Systems and Africa Policy for IFPMA; and, Professor Serge Rudaz from the University of Geneva.

Each panelist reiterated the need for innovation to tackle falsified medicines around the world and pledged their support for young people and entrepreneurs in the field. To access a video of the panel discussion, visit <https://www.youtube.com/watch?v=bck2tS0qWS4>.

For more information on the 72nd World Health Assembly, visit <https://www.who.int/about/governance/world-health-assembly/seventy-second-world-health-assembly>.

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uninsured Americans who are at risk of contracting the infection. The medication donation, which is being called “the largest ever in the United States” is part of the company’s “national efforts to help prevent HIV and end the epidemic.” The drug *Truvada* is a combination of two drugs that interferes with an enzyme that is used by HIV-infected cells to produce new viruses.

- ♦ The **Partnership for Safe Medicines** has launched an advertising campaign in the state of Florida to raise awareness and express opposition to the importation of medications. The current proposed bill *No. 1528* would open the state’s drug supply to dangerous counterfeit medications, according to the Partnership, which has been steadfast in its opposition to importation proposals, as they endanger public health.

(Sources: Good News Network, Health Policy Watch, World Pharma News, and World Pharmaceuticals)