Determining the Quality of Oseltamivir (Tamiflu)

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[Ted Pestorius] Hello. I'm Ted Pestorius, speaking today with Dr. Michael Green, a chemist here in the Division of Parasitic Diseases at CDC. We're here to talk about an article in the April 2008 issue of Emerging Infectious Diseases about a test to determine the quality of oseltamivir, also known as Tamiflu. Now Mike, you developed the new test to check the quality of Tamflu. Can you explain what the test does?

[Mike Green] Certainly. Essentially, this test measures the amount of the active ingredient that is present in Tamiflu. The active ingredient is part of the medication which kills the organism that causes the disease. The active ingredient in Tamiflu is oseltamivir. In this test, a red color develops when oseltamivir is present in the drug. The intensity of the red color depends on how much of the oseltamivir is present.

[Ted Pestorius]. So what's oseltamivir?

[Mike Green] As I mentioned before, oseltamivir is the active ingredient in Tamiflu. It was developed for use as an antiviral medication and has been recommended by the CDC for the prevention and treatment of influenza, such as avian flu.

[Ted Pestorius] So, why was it important to develop a test like this?

[Mike Green] The possibility of an avian flu pandemic has given Tamiflu a lot of attention. Because of a fear of the pandemic, this drug has been in high demand. As a result, unscrupulous people have tried to take advantage of this situation and sell bogus medication. Several international drug counterfeiting operations already exist. The World Health Organization estimates that about 25 percent of drugs worldwide are fakes. The counterfeiters tend to target drugs that are in high demand, such as antimalarial medications. A few years back, when the potential of an avian flu pandemic was made public, counterfeit Tamiflu started to pop up on the Internet. Recently, US Customs seized counterfeit Tamiflu upon its entry into the U.S. The bogus products contained nothing but vitamin C and lacked the active ingredient of oseltamivir phosphate. These products were destined to be sold over the Internet. Therefore, I wanted to develop a test that was simple and affordable and that could assess the quality of the products purporting to be oseltamivir.

[Ted Pestorius] In your study, you purchased the Tamiflu off the Internet. What did you find?

[Mike Green] A search was conducted on the Internet. We found at least 40 online sources for Tamiflu. We sorted them according to price and bought the 6 cheapest products that didn't require a prescription. Two samples originated from Greece and one from India. The seller from India requested that I send him a copy of my driver's license. Of course I refused, but he ended up selling it to us anyway. We then tested the products for the active ingredient—oseltamivir phosphate.

[Ted Pestorius] And did the product test positive for that?

[Mike Green] Yes. According to the tests, they all contained the proper amount of oseltamivir.

[Ted Pestorius] Okay. So, the products you bought on the Internet were Tamiflu. So can I go buy Tamiflu off the Internet? Is that safe?

[Mike Green] No. We only tested 6 samples just to show that the test worked. A larger sampling may have given different results. Many times, counterfeit drugs will contain little or none of the active ingredient. The color test will easily spot them, but sometimes counterfeiters resell expired drug and reformulate them. Also, oseltamivir may be produced illegally under poor manufacturing conditions. Therefore, the color test cannot detect all fake drugs. It is simply a rapid and inexpensive way to screen for drug quality based on the presence of oseltamivir. Unless you are able to test the product bought online, you have no way of knowing if it is legitimate. Also, if there were an influenza pandemic, antiviral medications would be in short supply. Those who are sick would be given the first priority for these medications. If people unnecessarily stockpile medications, it may mean that they won't be available for those who are sick. Finally, it is never a good idea to purchase drugs over the Internet if you're not sure of its source.

[Ted Pestorius] Okay. But can I purchase the test that you developed on the internet?

[Mike] Not at this moment.

[Ted Pestorius] So, ultimately what's the public health importance of your study?

[Mike Green] If a pandemic were to occur, many countries do not have the sophisticated instruments required to test the drug. Because of the high demand and the possibility of an ensuing panic, bogus drugs will be expected to circulate. At CDC, we have already developed color tests for certain antimalarial drugs that are being widely counterfeited in Southeast Asia. These tests are being used by laboratories and hospitals to check drug quality. The impetus behind developing these tests is to give people a simple and cheap test so they have confidence that the Tamiflu they purchase actually contains the active ingredient needed to kill the virus.

[Ted Pestorius] OK. Well thank you very much Dr. Green. Our discussion with Dr. Green was prompted by an article about a test to determine the quality of oseltamivir, published in the April 2008 issue of Emerging Infectious Diseases. This article, and others on emerging bacterial and viral diseases, can be read online at www.cdc.gov/eid. Again, that's www.cdc.gov/eid. You can submit your comments on this interview to eideditor@cdc.gov. For Emerging Infectious Diseases, I'm Ted Pestorius.

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