

Critics: WHO slow on generics for swine flu

May 11 2009, By MARIA CHENG , Associated Press Writer

(AP) -- As poor countries face a possible swine flu pandemic with only enough Tamiflu to treat a tiny fraction of their populations, some experts are calling for a simple but contentious solution: massive production of generics.

Antivirals such as Tamiflu are believed to be effective against swine flu if administered early, and cheap generics can easily be made in countries like India. Many rich nations sit on stockpiles of expensive Tamiflu bought from Swiss drugmaker, Roche.

Tamiflu is patent protected but World Trade Organization rules allow poor countries to override such rights in a health crisis. Indian pharmaceuticals giant Cipla said it would charge about \$12 per course of a generic Tamiflu. One course of Roche Tamiflu can sell for up to \$100.

That has led critics to question why the [World Health Organization](#) hasn't ordered up batches of generic Tamiflu or encouraged poor countries to do so as it raised its pandemic alert level to phase 5 - signaling it believes a global [flu outbreak](#) to be "imminent."

Some suspect WHO is reluctant to anger drug companies, which supply the agency with stockpiles of drugs, by encouraging the use of generics. Despite WTO rules, Western pharmaceuticals have long fought to keep generics out of the market in all circumstances.

"There needs to be a better system in place so that WHO does not have to rely on the goodwill and charity of drugmakers to get medicines for

poor countries," said Sangeeta Shashikant of Third World Network, a nonprofit development organization.

WHO insists it's doing its best to secure antivirals for poor countries.

"WHO will work on behalf of its member states to secure further antivirals as needed, either through donations or purchase at the lowest possible price, to support developing countries in need," said Elil Renganathan, a WHO official working on antivirals.

Two flu medicines, Tamiflu and [Relenza](#), are mainly used to treat flu, but they only work if started within 48 hours of first symptoms. Studies show they cut the duration of illness by about one day, compared with no treatment.

Little is known about whether these medicines cut the chances of serious flu complications, like pneumonia, and few studies have tested them in children.

Experts say vaccines would offer the best protection against a swine [flu pandemic](#) but they won't be available for months.

And even when they are, rich countries are first in line: Britain, Canada, Denmark, France, the United States and others have all signed deals with vaccine makers to ensure they get the first batches of pandemic vaccine off the production line.

WHO is appealing to vaccine makers to save some of their vaccines for poor countries, but it's doubtful they will get enough to treat a significant portion of the population.

On Monday, Cipla announced it could produce 1.5 million treatments of a generic version of Tamiflu in the next few weeks. But Yusuf Hamied,

the company's chairman, said it is ready to make millions more courses as soon as poor countries and agencies like WHO place orders.

"We could make a lot more, but there needs to be firm commitment from countries and international agencies like WHO," he said. "The ball is in their court."

So far, WHO has not recommended that countries with production capacity start making their own generic supplies of antivirals.

WHO has a stockpile of about 5 million Tamiflu treatment courses donated by Roche, and earlier this week, the agency began sending 2.4 million treatments to 72 poor countries. But such numbers pale in comparison to hundreds of millions of people in the developing world who would be vulnerable in a flu pandemic.

The agency says it is exploring generic production, but no decisions have been made. WHO says it is unsure how much massive generic production could increase the global supply and would not estimate a cost.

Renganathan said WHO wants to ensure any generic medicines meet drug safety standards. He said they are investigating the possibility of generic production with companies wherever they are located.

Still, critics say WHO has been slowfooted on generics.

"I don't know why WHO hasn't pursued generics," said Tido von Schoen-Angerer, director of Medecins Sans Frontieres' Access to Essential Medicines Campaign.

"A big role for WHO is to increase the world's generics supply of antivirals and make sure all countries have access," von Schoen-Angerer

said. "It's not clear why WHO hasn't prioritized this."

With a large supply of generics, developing countries that could afford them, like Thailand and Brazil, could reinforce their own supplies. For poorer nations, agencies like UNICEF might buy the antivirals and distribute them to countries in need.

High rates of HIV, malaria, tuberculosis, malnutrition and other health problems greatly deepen the vulnerability of the world's poorest countries to a flu pandemic.

So far, critics say there's no indication from WHO that generic options will be prioritized for poor countries that can't afford Roche's [Tamiflu](#).

"Countries are going to scramble to get as many medicines as they can in this situation," said Martin Khor, executive director of the South Centre, a think tank focused on developing countries.

"WHO should be helping countries to get stockpiles of antivirals as cheaply as possible."

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