

Roche considers licensing companies to make oseltamivir

Janice Hopkins Tanne *New York*

With the gradual spread of avian influenza from East Asia to Europe, many countries were this week seeking supplies of the antiviral drug oseltamivir (Tamiflu), which lessens the effects of flu when taken at an early stage of the illness.

Cipla, an Indian company which specialises in generic drugs, said last week that it would make its own generic version of the drug. Cipla said it could market the drug by December and could make a million 10 capsule courses of treatment by next July, a report in *New Scientist* says (2005;188:14).

A spokesperson for Roche, the manufacturer of oseltamivir, said that the company would discuss sublicensing to increase supplies of oseltamivir, provided the companies could meet stringent manufacturing require-

ments. Making oseltamivir is a year long process involving many steps, some of them possibly explosive, she said. "We're looking for companies to approach us so we can assess their capabilities," she added.

Two US senators said that Roche had agreed to talk with four companies. The Roche spokesperson said the company had received many requests from companies and governments to scale up production, and it would be considering them.

Roche has been challenged by Gilead Sciences, which developed oseltamivir and licensed it to Roche. In June 2005, Gilead sent a message to Roche terminating the agreement by which Roche manufactured oseltamivir.

In documents filed with the US Securities and Exchange

Commission, Gilead Sciences say that Roche has performed poorly in the five years during which it had been licensed to market oseltamivir and that Gilead was acting to protect its shareholders. It also says that health professionals and patients need improved access to information about the drug and to the drug itself.

Gilead charged that Roche had failed to commercialize the drug through promotion and marketing, including a failure to launch it in markets where the drug had been approved, and that Roche had failed to properly calculate and pay royalties to Gilead.

A Roche spokesperson told the *BMJ* that the dispute was in arbitration.

The two drugs most effective in treating ordinary flu and bird

flu are both neuraminidase inhibitors—oseltamivir, an oral pill, and zanamivir (Relenza), an inhaled medication, made by GlaxoSmithKline. A report in *Nature* last week raised the possibility that a prophylactic regimen of oseltamivir might lead to partial resistance to the drug, however (2005;437:1107). The article suggested that governments should consider stockpiling zanamivir as well as oseltamivir.

Anne Moscona, professor of pediatrics at New York-Presbyterian Hospital and author of a *New England Journal of Medicine* review (2005;353:1363-73), told the *BMJ*, "These drugs are remarkably effective if given early... but we need new flu antivirals that attack the virus at different points in its life cycle." (See p 975.)

Bird flu poses no immediate threat to Europe, leading virologist claims

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Albert Osterhaus, the chairman of the European scientific working group on influenza, said this week that isolated outbreaks of avian influenza in western Europe did not "substantially increase the risk of a flu pandemic."

It was important not to confuse the threat posed by highly pathogenic avian flu with that of a human flu pandemic. The threat at the moment was to animal welfare and the economy, rather than to public health.

Professor Osterhaus, a professor of virology at Rotterdam's Erasmus Medical Centre, said, "The pandemic risks are directly proportional to the numbers of people who become infected." South East

Asia was most at risk because avian flu was "more or less endemic" there.

"I think we can protect people well enough preventatively against the isolated outbreaks of avian flu in western Europe. We know how to protect the people involved in the culling and slaughtering of birds, especially after the Dutch outbreak of 2003 which caused the death of a vet" (*BMJ* 2003;326:952).

Professor Osterhaus, who helped in 2003 to identify the virus for severe acute respiratory syndrome (SARS), told the *BMJ* two years ago that no country in the world "is sufficiently prepared if we get a new pandemic outbreak of flu. My

suggestion to policy makers is: why don't you stockpile antivirals?"

He told the *BMJ* this week: "I am completely in favour of taking all the precautionary measures for a pandemic but I think the fact that there is so much attention now is wrong because it is really a threat to animal welfare and an economic, not so much a public health, problem."

Meanwhile his European scientific working group on influenza has called for a European task force that would monitor birds, stockpile oseltamivir, coordinate scientific research, increase human flu vaccination levels, and form a public-private partnership for testing prototype vaccines against avian influenza.

Testing the prototype vaccines for safety and efficacy could and should happen tomorrow, he believes. (See News Extra on bmj.com.) □



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