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## Drugmaker tells doctors of Lariam warnings

By Mark Benjamin and Dan Olmsted

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WASHINGTON, Oct. 1 (UPI) -- The maker of the controversial anti-malaria drug Lariam wrote last week to more than 120,000 doctors and pharmacists in the United States to tell them of new warnings about the drug, including rare reports of suicide.

The letter from Hoffmann-La Roche -- in an envelope marked "Important Prescribing Information" in large block type -- was sent to inform health professionals of changes to the official product information sheet that were made in July, Roche spokesman Terry Hurley said Tuesday.

United Press International, which has been conducting an eight-month investigation of Lariam, reported in May that evidence suggests the drug has caused mental problems so severe that in a small percentage of cases it has led to suicide. Also in May, Roche settled a lawsuit brought by an Ohio woman who claimed her husband had committed suicide after taking the drug. The terms were not disclosed.

Internal Roche documents obtained by UPI show the drug company discussing as early as 1994 whether to mention reports of suicidal thinking on the label, but concluding that because the reports were "isolated," the term "depression" was sufficient. The company first mentioned such reports on the label in 1999.

Lariam's label also has a new warning that mental problems can last "long after" taking the drug. Previously, the label said problems might last "for several weeks." UPI reporters found that some people who had taken Lariam reported symptoms that persisted for years and had not cleared up. Some of those cases ended in suicide.

The drug has made headlines recently because three soldiers -- two of whom committed suicide -- allegedly killed their wives near Fort Bragg this past summer after taking Lariam in Afghanistan.

While aggression is listed on Lariam's label, Roche said that Lariam has not been associated with violent criminal conduct. The House Armed Services Committee is considering looking at possible links between Lariam and the killings at Fort Bragg. The Army is conducting its own review of the deaths.

The July changes to Lariam's label were made in consultation with the Food and Drug Administration, and also include warnings to quit taking the drug if mental problems begin. Lariam has been taken by 5 million Americans and a total of 25 million people worldwide, Roche says, and is prescribed in the United States more than 300,000 times a year.

The letter outlines these key changes and additions to the product information sheet:

-- The drug should not be prescribed to people with a recent history of depression, anxiety disorder, psychosis, schizophrenia or other major psychiatric disorders.

-- Lariam, known generically as mefloquine, "may cause psychiatric symptoms in a number of patients, ranging from anxiety, paranoia and depression to hallucinations and psychotic behavior. On occasions, these symptoms have been reported to continue long after mefloquine has been stopped."

-- "Rare cases of suicidal ideation (thinking) and suicide have been reported though no relationship to drug administration has been confirmed."

-- People taking the drug should be told that if they develop psychiatric symptoms such as acute anxiety or depression, that could be the precursor to "a more serious event." "In these cases, the drug must be discontinued and an alternative medication should be substituted."

Roche Spokesman Hurley said that the changes to the label were part of the drug's company's ongoing effort to reflect the latest science and studies about its drugs.

He said the drug "has been taken safely" by 25 million people over 17 years, and that the label has properly cautioned about possible side effects since Lariam was approved for use in the United States in 1989.

"Roche takes issues of safety very seriously and is diligent in monitoring the safety of all our products," he said, noting that "Lariam remains one of the drugs of choice of the Centers for Disease Control and the World Health Organization."

The risk-benefit ratio for Lariam remains positive, he said, adding that malaria can be a fatal disease.

In September, a spokesman for the Army said that it had only recently learned of the label changes and was seeking "clarification" of them from Roche.

Jeanne Lese, information director of the activist group Lariam Action, said that the Roche letter wouldn't make up for a lack of awareness in the United States that the drug can cause severe and prolonged health problems in an unacceptably high number of users.

"Americans are tragically behind the rest of the world when it comes to understanding Lariam," Lese said. "It will take much more than a warning letter to change this. The CDC has ignored research from the rest of the world, so our doctors still prescribe Lariam routinely. Every day we hear from people who were not warned about adverse effects."

The CDC says it is conducting a planned review of its malaria recommendations and will announce any changes early next year.

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