IMPORTANT SAFETY UPDATE OF PRESCRIBING INFORMATION FOR LARIAM® (Mefloquine)

Subject: **Direct Healthcare Professional Communication**

Date: 16 /July/2013

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Dear Healthcare Provider,

F. Hoffmann-La Roche Ltd (hereafter referred to as Roche) would like to inform you about important new safety information for Lariam® (mefloquine) regarding visual disturbances including optic neuropathy, which has resulted in updates to the Warnings & Precautions and Undesirable Effects sections of the Lariam® Prescribing Information in addition to the recently published information stating that the use of Lariam® could lead to risk of serious psychiatric and nerve side effects,

Summary

- **Treatment with Lariam® may be associated with an increased risk of eye disorders, including cataract, retinal disorders and optic neuropathy which may occur with latency during or after treatment.**
- **These eye disorders can present with visual impairment and blurred vision.**
- **In some cases the event recovered very slowly but there were also reports of permanent Sequelae.**
- **Any patient on treatment with Lariam® who experiences visual disorders should be referred to his treating physician as certain conditions (such as retinal disorders or optic neuropathy) may require stopping treatment with Lariam®**
- **Lariam® is indicated for the chemoprophylaxis, therapy and stand-by treatment of malaria. These updates to the prescribing information do not change the overall positive benefit-risk profile of Lariam®.**
- **Neurologic side effects can occur at any time during drug use, and can last for months to years after the drug is stopped or can be permanent. Patients, caregivers, and health care professionals should watch for these side effects.**

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INDICATIONS AND POTENTIAL USES:

Prophylaxis, treatment, and stand-by treatment of malaria:

- **Prophylaxis:** Chemoprophylaxis with Lariam is recommended in particular for travellers to malarious areas in which there is a high risk of infection with strains of P. falciparum that are resistant to other antimalarials.
- **Treatment:** Lariam is indicated for the oral treatment of malaria, particularly when caused by strains of P. falciparum resistant to other antimalarials. It may also be used for the treatment of P. vivax and mixed malaria.
- **Stand-by treatment:** Lariam® can also be prescribed for travellers as a stand-by medication to be taken as an emergency measure for suspected malaria when no physician is available within 24 hours or the drug is not easily obtainable locally.

Risk of serious psychiatric and nerve side effects

The Saudi Food and Drug Authority (SFDA) is advising Health Care Providers about strengthened and updated warnings regarding neurologic and psychiatric side effects associated with the antimalarial drug mefloquine hydrochloride. A boxed warning, the most serious kind of warning about these potential problems, will be included in the local Summary of Product Characteristics (SPC) and patients information leaflet. The neurologic side effects can include dizziness, loss of balance, or ringing in the ears. The psychiatric side effects can include feeling anxious, mistrustful, depressed, or having hallucinations.
Neurologic side effects can occur at any time during drug use, and can last for months to years after the drug is stopped or can be permanent. Patients, caregivers, and health care professionals should watch for these side effects. When using the drug to prevent malaria, if a patient develops neurologic or psychiatric symptoms, mefloquine should be stopped, and an alternate medicine should be used. If a patient develops neurologic or psychiatric symptoms while on mefloquine, the patient should contact the prescribing health care professional. The patient should not stop taking mefloquine before discussing symptoms with the health care professional.

Safety Information
Because of the long half-life of Lariam®, adverse reactions may occur or persist up to several weeks after discontinuation of the drug.

This letter is sent in agreement with the Saudi Food and Drug Authority

Reporting Adverse Events
Roche will continue to monitor the safety of Lariam through established reporting mechanisms and notify regulatory authorities of any serious adverse events for evaluation. We will continue to provide you with the most current Prescribing Information for Lariam® moving forward. You can assist us in monitoring the safety of Lariam® by reporting suspected adverse events associated with the use of Lariam® to:

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Hoffmann La-Roche
Saudi Import Company
Najoud Centre, Gate A, 1st Floor.
Prince: Mohamed Bin Abdulaziz St.
Fax: 009662 2847198
Email: hazem.dajani@roche.com

Alternatively, report this information to:

The National Pharmacovigilance & Drug safety Centre (NPC)
Saudi Food and Drug Authority (SFDA)
Fax: +966-11-2057662
Email: npc.drug@sfda.gov.sa
online: http://ade.sfda.gov.sa/

Sincerely Yours,

Hazem Al-Dajani
Local Safety Responsible

8/9/2013

Nasser Al-Rajhi
Scientific office & regulatory affairs director

8/9/2013

Tamer elmahallawy
Medical Director

8/9/13