FDA - Adverse Event Reporting System (FAERS)

FOIA Case Report Information

Case ID: 8504150

Case Information:

Case Type: EXPEDITED (15-DAY) **eSub:** Y **HP:** Y **Country:** USA **Outcomes:** OT **(A)NDA/BLA:** 019591 /

FDA Rcvd Date: 11-Apr-2012 **Mfr Rcvd Date:** 29-Mar-2012 **Mfr Control #:** US-ROCHE-1054403

Patient Information:

Age: **Sex:** **Weight:**

Suspect Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date
1	LARIAM				PRODUCT USED FOR UNKNOWN INDICATION		

#	Product Name	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler
1	LARIAM							

Event Information:

Preferred Term (MedDRA Version #: 16.0)	Start Date	End Date	ReC
HOMICIDE			

Event/Problem Narrative:

Initial Information for this Spontaneous case, AER number 1054403, was received on 29/Mar/2012 from a Pharmacist and concerns a patient of unknown demographics who was treated with Mefloquine Hydrochloride (Lariam) for an unknown indication. Medical history included TBI (Traumatic brain injury). No concurrent illnesses were reported. No concomitant medications or past drugs were reported. On an unknown date, the patient started Mefloquine Hydrochloride (dose, form and frequency not reported). On an unknown date the patient who was a soldier in the US Army developed homicidal behavior and led to Homicide killing 17 Afghanis. It was reported that this patient was administered Mefloquine in direct contradiction to US military rules that Mefloquine should not be given to soldiers who had suffered TBI (Traumatic brain injury) due to its propensity to cross blood brain barriers inciting psychotic, homicidal or suicidal behavior. The outcome of Homicide was not Reported. There was insufficient information regarding the therapy ongoing status of Mefloquine Hydrochloride. The reporter did not provide the seriousness criteria of the event of Homicide and its causal relationship with Mefloquine Hydrochloride. The company assessed the event of Homicide as medically significant. No further information was available.

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Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?	
Medical History Product(s)	**Start Date**	**End Date**	**Indications**	**Events**

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name	Dose/ Frequency	Route	Dosage Text	Indications(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study Report?: No **Sender Organization:** ROCHE

Literature Text: