FDA/SMC/SMD/RMU/20/0387 1st September 2020

UPDATE NO. 4 ON THE SAFETY MONITORING OF THE MALARIA VACCINE FROM 1ST MAY 2019 TO 31ST JUNE 2020

Background

The Ministry of Health launched the first malaria vaccine (Mosquirix or RTS,S/AS01) on 30th April 2019 to be given to young children in routine immunization in selected areas of Ghana. The vaccine is being given to children in two other African countries, Kenya and Malawi.

The malaria vaccine is given to children up to two years of age in seven regions of Ghana, namely, Ahafo, Bono, Bono East, Central, Oti, Volta and Upper East Regions.

What is Adverse Event Following Immunization (AEFI)?

The World Health Organization (WHO) defines an AEFI as any untoward medical occurrence which follows immunization and which **does not necessarily** have any causal relationship with the usage of the vaccine. Before the launch of the Malaria Vaccine Implementation Programme (MVIP), healthcare workers were trained to report all AEFIs in children who receive Mosquirix to the FDA.

Outcome of Safety Monitoring

Review of safety reports by the Joint Malaria Vaccine Committee

AEFI reports received in Ghana are reviewed by a seven-member Safety Committee of independent experts, known as the Joint Malaria Vaccine Committee (JMVC).

The JMVC was constituted to review all safety reports received, carry out causality assessment and make recommendations to the FDA regarding the continued implementation of the MVIP or otherwise. The JMVC has had eight meetings between June 2019 and August 2020 and reviewed data on safety reports received by the FDA between May 2019 to June 2020.

A total of 353,704 doses of Mosquirix had been given to children as at 30th June 2020, with 1,611 AEFI reports received within the same period. Out of the 1,611 AEFI reports, 1,568 (97%) were received from the phase 4 study in the Upper East and Bono East regions where children who received the vaccine are actively followed up and all events after vaccination are documented.

Figure 1 shows the number of AEFI reports received from May 2019 to June 2020.

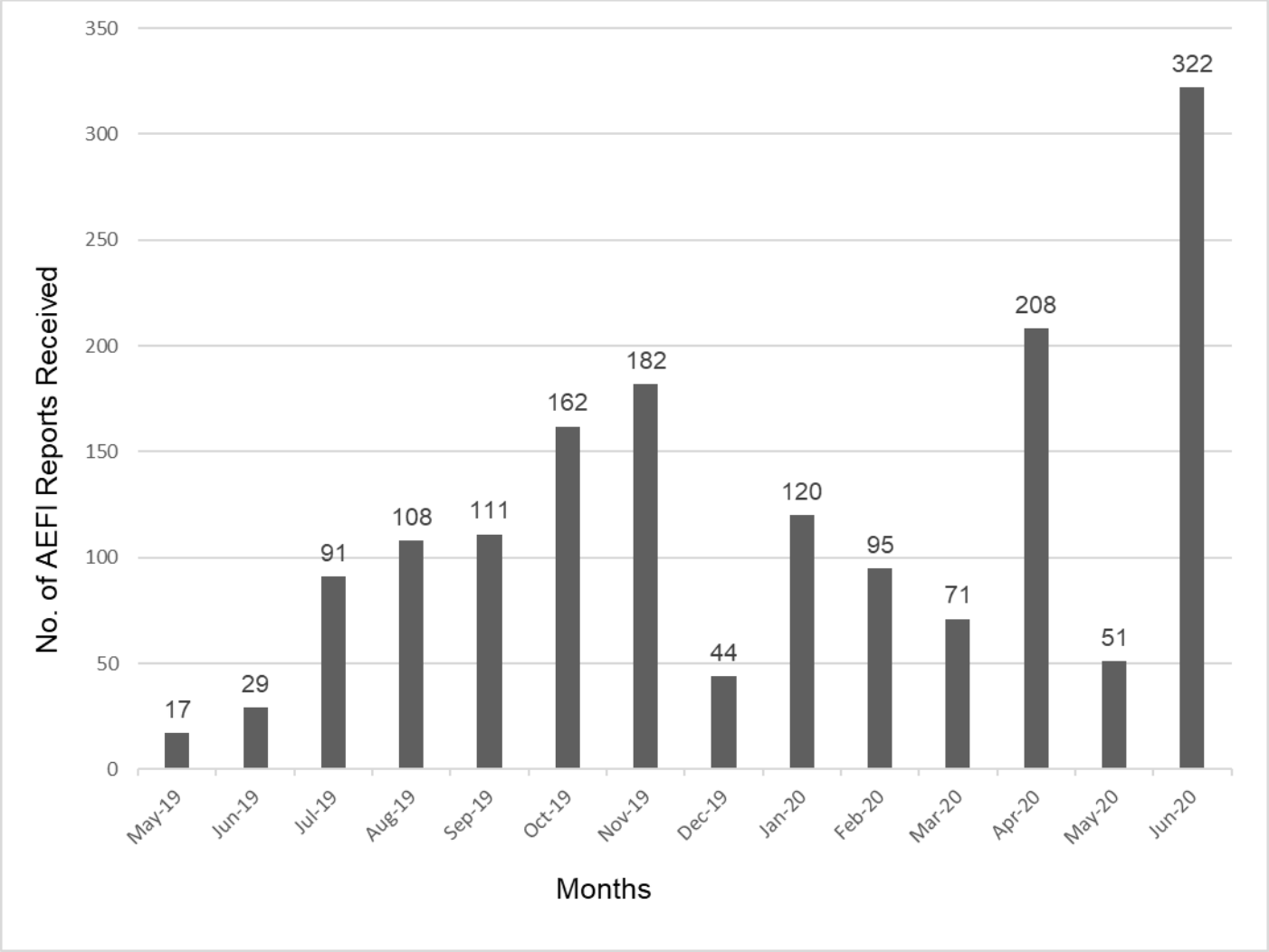

Figure 1: Number of AEFI reports received by month from May 2019 to June 2020

Out of the 1,611 AEFI reports received, 163 (10.1%) were serious[1] and the remaining 1,448 (89.9%) were non-serious. Causality assessment by the Joint Malaria Vaccine Committee of the 127 serious AEFI reports showed that there was no direct relationship between the vaccine and any new AEFIs reported with the exception of fever, gastroenteritis and allergic reaction which were listed in the product information.

[1] An AEFI is serious if it results: in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, or requires intervention to prevent permanent impairment or damage.

Review of Safety Data by the Data Safety and Monitoring Board

In order to safeguard the well-being of children participating in the MVIP, a seven member Programme-specific Data Safety and Monitoring Board (DSMB) was set up by the World Health Organization which also regularly review the safety data from the three countries in order to identify, assess causality and monitor any accumulating safety signals.

The fourth meeting of the DSMB was held on 7th and 8th July 2020, the DSMB concluded, after the review of the safety data, that there were no significant safety concerns which negatively affect the benefit-risk profile of the vaccine. The DSMB therefore, concluded that the MVIP should continue.

Safety Data Exchange

The FDA also continue to share safety data received from MVIP with GlaxoSmithKline, the manufacturer of the vaccine to independently carry out review of the safety data as required.

Impact of COVID-19 Pandemic on the MVIP

There has not been any effect of the COVID-19 pandemic on the safety monitoring of the vaccine. Vaccine coverage has generally remained stable over the period but with a slight increase in drop-out rates over the last quarter (Drop-out rates for first quarter and second quarter RTS,S dose 2 were 2.3% and 5.3% respectively. Drop-out rates for first quarter and second quarter RTS,S dose 3 were 3.7 % and 6.9% respectively). Immunization, safety monitoring and other essential services are currently being provided under strict adherence to COVID-19 safety and preventive protocols.