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UPDATES ON THE SAFETY MONITORING OF THE MALARIA VACCINE

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 will be given to children in two other African countries, Kenya and Malawi.

The malaria vaccine is given to children up to 2 years of age in seven regions of Ghana, namely, Ahafo, Bono, Bono East, Central, Oti, Volta and Upper East Regions.

Outcome of Safety Monitoring

Adverse event following immunization (AEFI) reports received are reviewed by a seven-member Safety Committee of independent experts, known as the Joint Malaria Vaccine Committee. The Joint Malaria Vaccine Committee has had five meetings between June and December 2019 and reviewed AEFI reports received**.**

The 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.

A total of 262,431 doses of Mosquirix had been given to children as at 31st March 2020, with 1,030 (one thousand and thirty) AEFI reports received within the same period. Out of the 1,030 AEFI reports, 999 (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.

Out of the 1,030 AEFI reports received, 96 (9%) were serious[1] and the remaining 934 (91%) were non-serious. Causality assessment by the Joint Malaria Vaccine Committee of the 48 serious AEFI reports showed that there was no direct relationship between the vaccine and the events reported. The remaining 48 serious AEFI cases were scheduled for review by the Committee on 21st April 2020 but was postponed due to the COVID-19

[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.

pandemic, arrangements are being made to organize remote meetings of the Committee to review these reports.

Impact of COVID-19 Pandemic on the MVIP

Vaccine uptake is closely being monitored to assess the impact of COVID-19 pandemic and containment measures on the MVIP.