Updates on the Safety Monitoring of the Malaria Vaccine

Background
On 30th April 2019, the Ministry of Health launched the first malaria vaccine (Mosquirix or RTS,S/AS01) to be given to young children in routine immunization in selected areas of Ghana. Ghana is one of three countries, including Kenya and Malawi, that is taking part in the Malaria Vaccine Implementation Programme (MVIP), coordinated by the World Health Organization (WHO), and with support from partners, including PATH. This pilot introduction of the vaccine follows rigorous testing of the vaccine in Africa; when given in 4 doses, the vaccine significantly reduced malaria among children.

The vaccine, Mosquirix, is being given to children in selected areas with moderate to high levels of malaria where the vaccine is expected to provide the highest benefit to vulnerable children. The phased introduction follows successful Phase 3 clinical trials (2009-2014), a positive scientific opinion by the European Medicines Agency, a stringent regulatory authority, and review and authorization of this use of the vaccine by the Ghana FDA. Information gathered from the phased introduction will be evaluated to inform future policy on the use of the vaccine as an additional tool to complement (not replace) existing preventive, diagnostic and treatment measures to control malaria.

Through this phased introduction of Mosquirix into the routine immunization programme, the malaria vaccine is given to children up to 2 years of age. The phased introduction is taking place in seven regions in Ghana, namely, Ahafo, Bono, Bono East, Central, Oti, Volta and Upper East Regions.

Additionally, 10 districts in the Upper East and Bono East regions are involved in phase 4 studies led by GlaxoSmithKline, the manufacturer of the vaccine. These studies, which are required and standard for a new vaccine, are gathering additional information on the vaccine’s effectiveness and any side effects associated with routine use.

The MVIP is specifically designed to:

- Assess the feasibility of administering the required 4 doses of the vaccine to children during routine immunization;
- Evaluate the vaccine’s potential role in reducing childhood deaths from malaria; and
- Further assess the vaccine’s safety in the context of routine use.
Information and experience generated from the programme will inform future WHO policy on wider scale use of Mosquirix in Africa.

Outcome of the Safety Monitoring

The FDA in collaboration with the Expanded Programme on Immunization (EPI), Ghana Health Service (GHS), has a robust safety monitoring system in place to ensure that any issues that may arise from the use of Mosquirix are promptly reported and adequately assessed to ensure safety of children receiving the vaccine.

A seven-member Safety Committee of independent experts, known as the Joint Malaria Vaccine Committee and constituted by the FDA, is in place to review all adverse events following immunization (AEFI) received from the MVIP and make recommendations to the FDA regarding the continued implementation of the MVIP or otherwise. The Joint Malaria Vaccine Committee has had two scheduled meetings so far (28th June 2019 and 20th August 2019) and reviewed all safety 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 MVIP, healthcare workers were trained to report all AEFIs in children who receive Mosquirix to the FDA.

A total of 101,039 doses of Mosquirix had been given to children to 30th September 2019, with 188 AEFI reports received within the same period.

No adverse events following immunization, or AEFIs, reported during this period were found to be linked to the malaria vaccine.

Specifically, out of the 188 AEFI reports received, five were serious¹ and the remaining 183 were non-serious. Causality assessment performed by the Joint Malaria Vaccine Committee determined there was no link between the vaccine and the serious AEFIs reported.

The FDA with the support of its Joint Malaria Vaccine Committee will continue to monitor the safety of the vaccine in the children receiving it and frequently update the general public and other stakeholders.

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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.