World Health Organization

Statement on Rotarix® and Vaccine Vial Monitor (VVM) compliance

Rotarix® is produced by GlaxoSmithKline Biologicals SA (here below referred to as GSK). It is for the prevention of rotavirus gastroenteritis and is WHO prequalified. The labelled storage conditions indicate storage at 2°C - 8°C with a shelf life of 36 months. The plastic tube presentation supplied through UNICEF has a Vaccine Vial Monitor (VVM) Type 14.

Assignment of a VVM type is dependent on the stability profile at elevated and normal storage temperatures. GSK presented data to WHO concerning an inconsistency between the stability profile tested following storage at 25°C and the assigned VVM type. That is, some batches became below specification following storage for more than 45 days at 25°C.

In response to the situation and as a precautionary measure, GSK has increased the internal release limit for potency so that future batches of Rotarix released are expected to maintain compliance with the required potency specification even if exposed at 25°C for 90 days (the discard point of the VVM14).

However, if this short term measure were to continue, there could be significant reductions in GSK's Rotarix supply in 2017 since only batches with above average titre could be released.

By reducing this internal release limit, GSK have indicated that the impact on supply in 2017 would be minimised. This reduction on the internal release limit would not change the labelled potency nor compliance with the labelled specification throughout the shelf-life of batches of the vaccine when stored at 2-8°C. However, it could result in some batches of vaccine being below specification if incorrectly stored for a cumulative time of more than 45 days at 25°C, without the VVM discard point being reached.

Given the low risk of such an extended temperature excursion and the high benefit of rotavirus vaccination, and the unchanged safety profile of the vaccine, countries with current stocks of Rotarix® or who receive supplies are recommended to continue use, ensuring appropriate cold chain practices are maintained, including continuous temperature monitoring, as per established WHO guidelines.

UNICEF, Gavi- the Vaccine Alliance, and WHO are working with countries to review stock levels and country needs in order to prioritize shipments accordingly. This may impact the timing of planned vaccine introductions in some countries.

In the medium term (expected in Q3 2017) GSK plans to supply this vaccine with a VVM Type 7, following WHO Prequalification Team review and approval.

For further information contact
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