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World Health
Organization

WHO INFORMATION NOTE

ASAQ Winthrop® tablets batch recall 28 September 2011

Artesunate Amodiaquine Winthrop® (“ASAQ Winthrop®”), a fixed-dose combination of artesunate and amodiaquine (available in 3 tablet strengths of 100mg/270mg, 50mg/135mg and 25mg/67.5mg), is licensed and marketed by the Sanofi-Aventis Group for the treatment of uncomplicated *Plasmodium falciparum* malaria in some countries of sub-Saharan Africa. ASAQ Winthrop® (WHO prequalified product numbers MA056, MA057, MA058) was prequalified by WHO on 14 October 2008.

A recall is in effect for a limited number of batches of ASAQ Winthrop® 100mg/270mg tablets (MA058), indicated for patients above 6 years of age. The numbers of these batches are 5178, 5190, 5193, 5194, 5195, 5198, 5199 and 5201.

As for all of its medicines, Sanofi performs a series of tests immediately at the end of the manufacturing process to ensure that ASAQ Winthrop® batches meet predefined test limits approved by the WHO Prequalification of Medicines Programme.

After it was released in compliance with approved requirements, batch 5191 of ASAQ Winthrop® was retested and found to be out of specification, with an artesunate content slightly below predefined limits. This batch was successfully quarantined before reaching patients. Investigations revealed that 8 other batches of Artesunate Amodiaquine Winthrop® 100mg/270mg tablets, compliant at the time of release, were also slightly below the predefined limits, namely batches 5178, 5190, 5193, 5194, 5195, 5198, 5199 and 5201, which are currently the object of a recall. There is presently no cause for alarm as a medical assessment has concluded that the lower than expected artesunate content does not expose patients to any safety risk, and that only patients above 90 kg body weight could be exposed to a risk of lesser efficacy.

The WHO Prequalification of Medicines Programme is in close communication with the company, to monitor the progress of this recall, as well as the efficiency and conduct of corrective actions taken by Sanofi. The WHO Prequalification of Medicines Programme has also initiated an independent monitoring of the quality of ASAQ Winthrop tablets.

Treatment regimens dependent on this product should not be interrupted indiscriminately. Should further investigation indicate any causes for concern, Sanofi and WHO will contact relevant parties (regulatory authorities and procurement agencies for this product) or issue an additional information note.