MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

SIGNAL ON ARTEMETHER/LUMEFANTRINE(AL) SUSPECTED STEVENS-JOHNSON SYNDROME (SJS)

WHO definition of a signal:
"Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously".

An additional note states: "Usually more than one report is required to generate a signal, depending on the seriousness of the event and the quality of the information".

As of March 2017, there were 19 cases of the combination AL and SJS among a total of 832 ADR reports due AL, in VigiBase, the WHO global database of individual case safety reports (ICSR). The reports originated from Tanzania (7), Ghana (5), India (3), **Kenya (2)**, Democratic Republic of Congo (1) and Zambia (1). This assessment was based on data entered into the database since 2008.

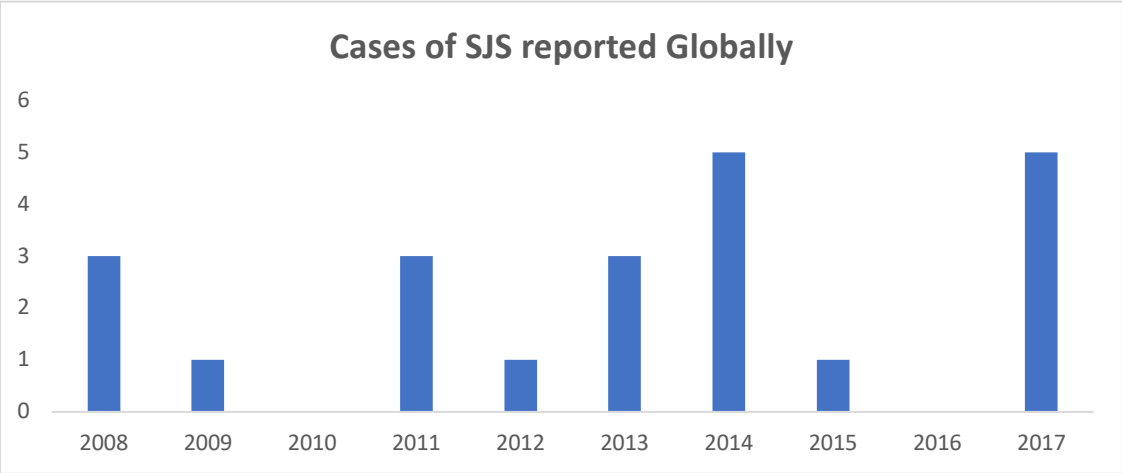
All the 19 cases were reported as fulfilling serious criteria, with five explicitly stating the condition to be life-threatening and one having a fatal outcome. At the time of reporting and apart from the patient who died, 13 of the patients had recovered or were recovering, two had not yet recovered and for three, the outcome was unknown or not reported.

In most reports the case descriptions are very brief with only limited clinical data. Some merely state the diagnosis as SJS while others describe in more detail skin blistering with desquamation and mouth, eye or genital ulcerations.

A few cases note a general spreading of the syndrome giving a suspicion they would fulfil the clinical definition of SJS/TEN or TEN. None of the reports contain any relevant history of previous use of, or reactions to, this or other drugs.

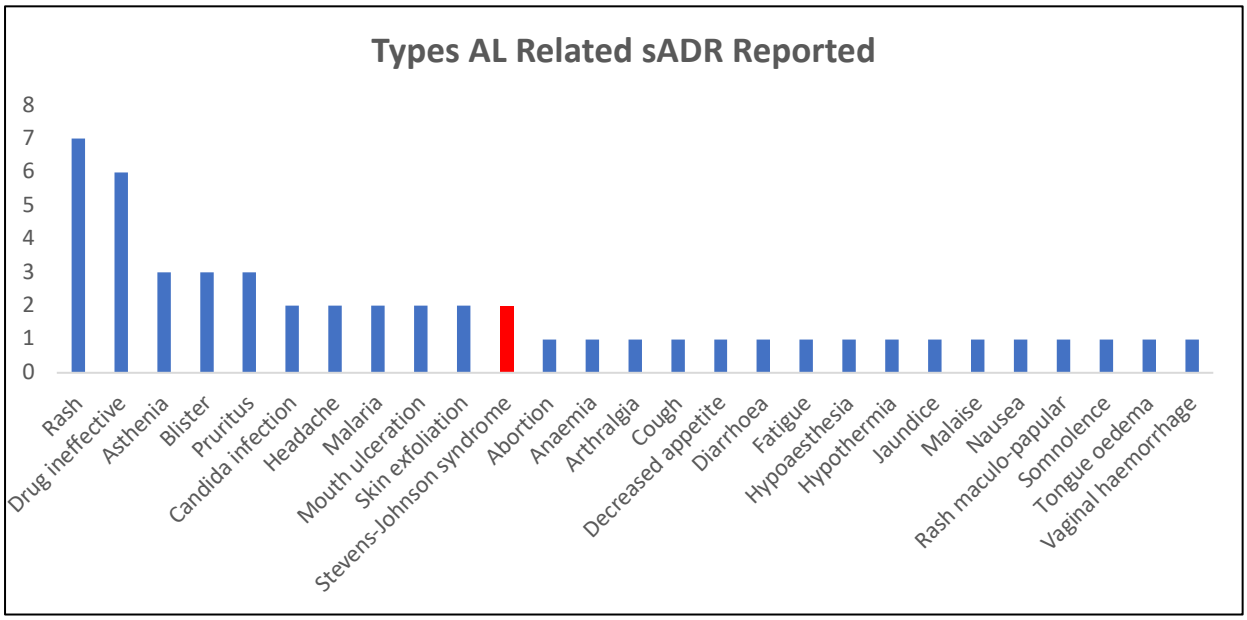
The product labelling includes serious bullous skin reactions which could potentially include cases of SJS. The VigiBase case series gives some suspicion of a causal association between AL and SJS

Global reports on SJS from the Global Database as of 2017

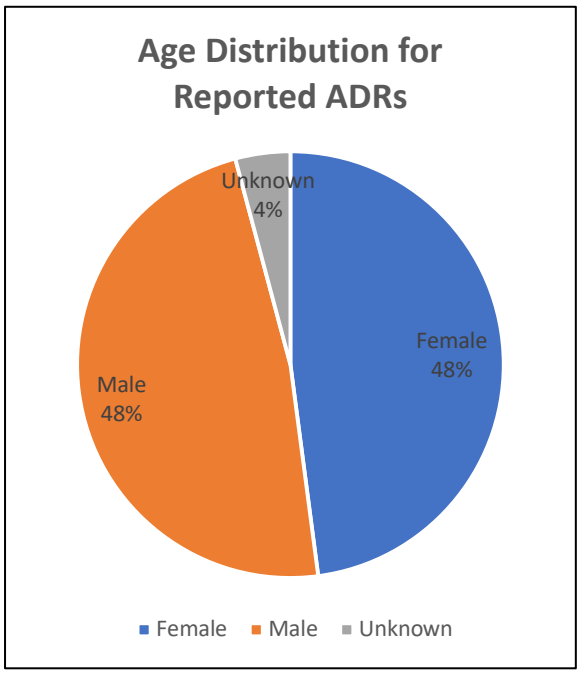


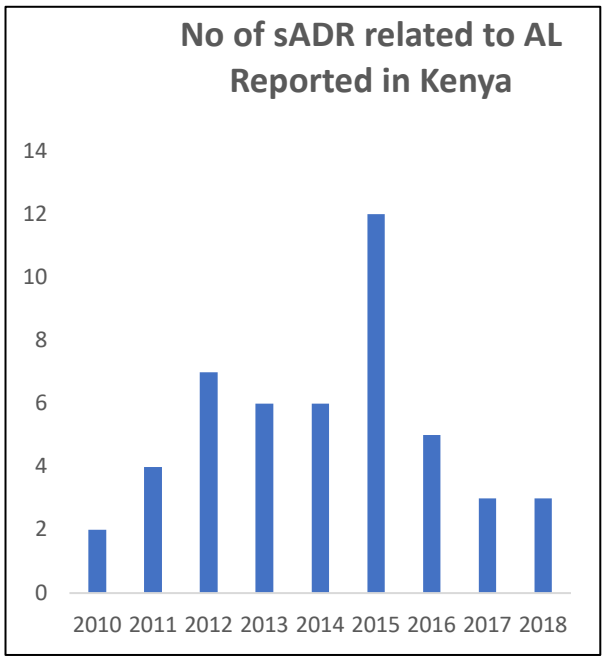
Kenyan Data on Artemether Lumefantrine Individual Case Safety Reports over the past 9 years:

A total of 48 ICSRs related to Artemether Lumefantrine have been reported in Kenya. Of these reports majority were reported as Rash and Drug ineffective issues with 2 cases of reported SJS that contributed to the signal detection



"You need not be certain...Just be suspicious". Report all SUSPECTED adverse drug reactions and SUSPECTED poor quality medical products and health technologies





Health Care providers in malaria endemic areas should be aware of this potential issue and be more vigilant when prescribing and dispensing the medicine to patients.

Report any suspected Adverse Reactions to us @

www.pv.pharamacyboardkenya.org

pv@pharmacyboardkenya.org

Tel: 0733884411 / 0720608811

Reference

1. WHO Pharmaceutical Newsletter Volume 2 ,2018.
2. Uppsala Monitoring Centre
3. Kenya , Pharmacovigilance Electronic Reporting System.

Thank you for your continued support in patient safety monitoring

Dr Christabel Khaemba,
Pharmacovigilance Division
For Registrar

"You need not be certain...Just be suspicious". Report all SUSPECTED adverse drug reactions and SUSPECTED poor quality medical products and health technologies