MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

SIGNAL ON RISK OF HEPATITIS IN PATIENTS AGED 75 AND ABOVE FOLLOWING ADMISTRATION OF CEFTRIAXONE:

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".

This communication is to inform you of a signal generated in regard to the association between ceftriaxone and hepatitis in patients aged 75years and

A recent analysis by the Uppsala Monitoring Center focused on risk group identification looking at various covariates such as age, body mass index (BMI), gender and country. This found an association between ceftriaxone and hepatitis in patients aged 75 years and older.

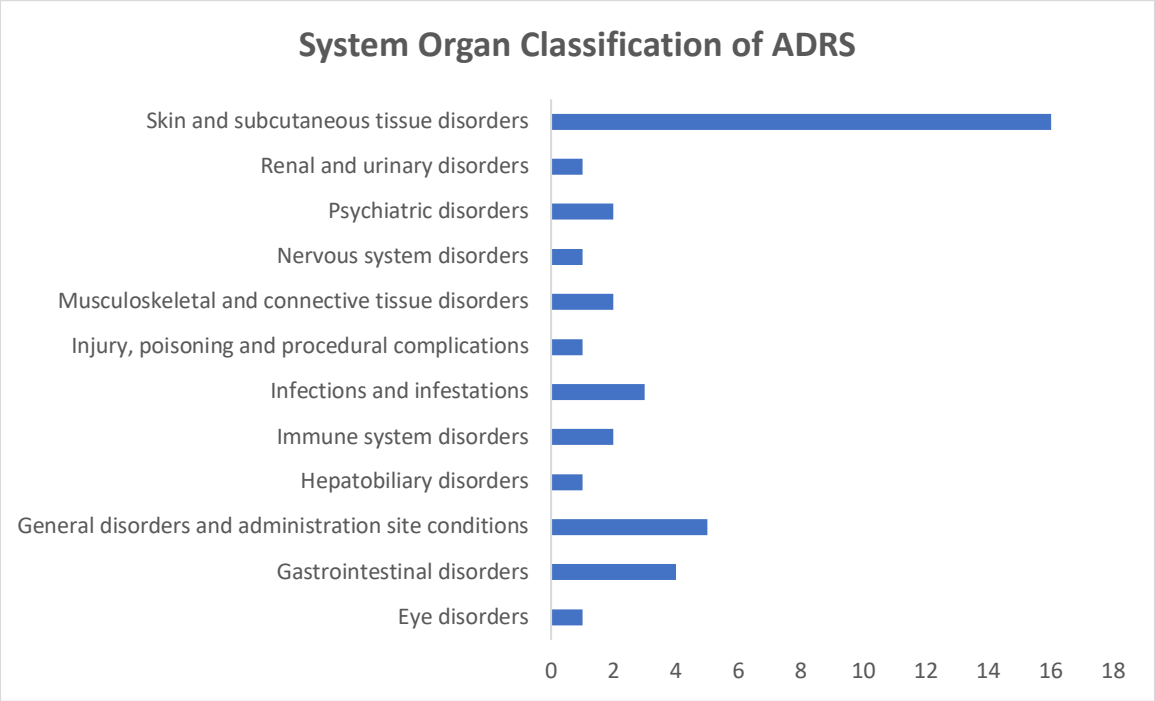
As of 7 October 2017, there are 67 Individual Case Safety Reports (ICSRs) of hepatitis in association with ceftriaxone in patients aged 75 years and older in the VigiBase, the WHO global database of individual case safety reports (ICSRs).

The patients age ranged from 75 to 94 years with a median of 84 years. The gender distribution were 21 males, 45 females and one not specified.

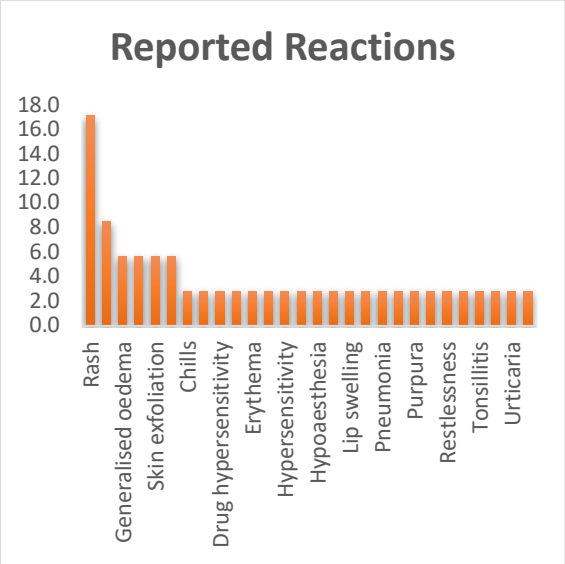
Ceftriaxone was the only drug suspected in 27 of the 67 cases. In the remaining 40 cases, one other drug was suspected in 16 cases and from three to five other drugs suspected in the remaining 24 cases. However, of the suspected drugs which occur most in multiple cases, hepatotoxicity is mentioned as an adverse reaction in the product information for metronidazole, amoxicillin/clavulanic acid, ciprofloxacin, ofloxacin and. levofloxacin, while hepatotoxicity is not mentioned as an adverse reaction in the product information for paracetamol (except in overdose).

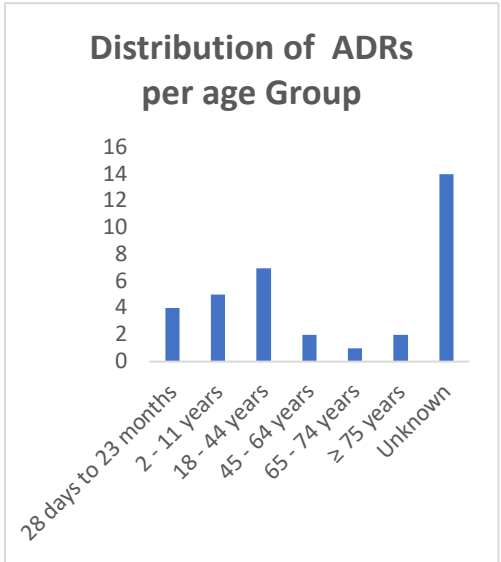
Below is a graphical presentation of ICSRs related to Ceftriaxone submitted to the National PV data base over the last Eight years (since 2010).

Health-care professionals are advised to be more vigilant when administrating Ceftriaxone in this cohort of patients.



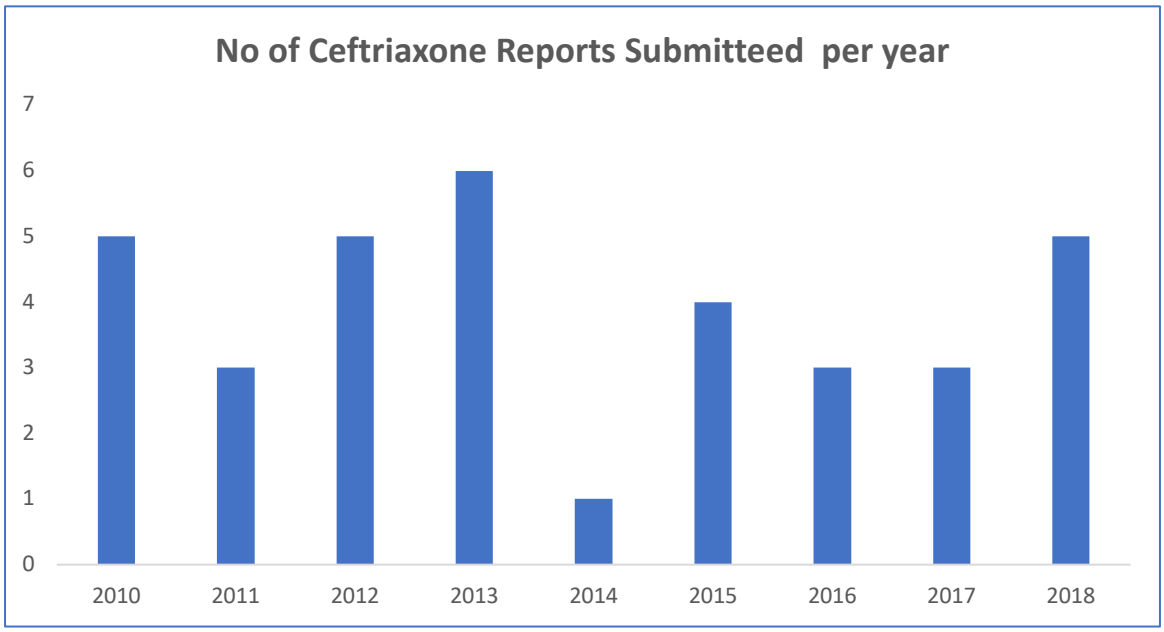
The above illustrates the Adverse Reactions as per System organ Classification with the skin being the most affected.





The most commonly reported reaction was rash followed by generalized oedema, skin exfoliations and chills. The other reactions were equally distributed.

The majority of the ICSRs did not have age indicated hence one cannot conclusively determine the most affected age group.



Have you noted the same or similar Adverse Drug Reactions? If yes, please report to:

The
Pharmacovigilance Division,
Pharmacy and Poisons Board,
Ministry of Health,
P.O. Box 27663-00506
Lenana Road. Nairobi, KENYA

pv@pharmacyboardkenya.org

www.pv.pharmacyboardkenya.org

Tel: 0733884411 / 0720608811

Reference

1. Uppsala Monitoring Centre
2. 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