

Ref: B/279/35/01/2019

21st January 2019

Circular 1 of 2019

To:

- 1) Retail and Hospital Pharmacies
- 2) Zimbabwe Medical Association (ZiMA)
- 3) Pharmaceutical Society of Zimbabwe (PSZ)
- 4) Retail Pharmacists Association

Dear all

Re: Notification of a potential risk of non-melanoma skin cancer (basal cell carcinoma, squamous cell carcinoma) in patients treated with hydrochlorothiazide

The Authority has become aware of a safety issue identified from two recent pharmaco-epidemiological studies conducted in Danish data sources (including Danish Cancer Registry and National Prescription Registry) which showed a cumulative dose-dependent association between HCT and NMSC (basal cell carcinoma, squamous cell carcinoma). Photosensitizing actions of HCT could act as a possible mechanism for this risk.

Please note that the identified potential risk was based on findings in a Dutch registry, where the population is mostly of Caucasian origin and non-melanoma skin cancer is a rare event. Incidence rates highly depend on skin phenotypes and other factors, which leads to different baseline risks and varying incidence rates in different countries. Most of the published studies focused on white populations in Europe, the U.S.A. and Australia; however, limited data were available for other skin types in regions such as Africa.

Ongoing monitoring will continue as part of the strengthening of pharmacovigilance of all medicines. Healthcare professionals are urged to report all suspected adverse events associated with all hydrochlorothiazide containing medicines as well as other medicines to the MCAZ using the available reporting tools. Data gathered from such reports will enable the Authority to make informed risk assessments for the Zimbabwean population.

Yours faithfully

MEDICINES CONTROL AUTHORITY OF ZIMBABWE



PP G N Mahlangu (Ms)
DIRECTOR-GENERAL
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