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Dear readers, the law of goodwill says that “make better the current situation than it was before”. On that note make the clarion call upon self to report adverse events/experiences more frequently than ever before so that together we can elicit solutions to seemingly challenging problems.

After having been latent for a while, here we are, as Pharmacovigilance & Clinical Trials Division to brace you up with latest safety updates. We are proud to have finally launched our new e-PV system, which is a web application available on our website: www.mcaz.co.zw. In principle pharmacovigilance underscores monitoring and evaluation as a continuous surveillance of medicines over the entire value chain and it extends beyond the scope of unexpected reactions. Space and time presents itself to expand pharmacovigilance activities to Results Based Management (RBM) of prominent medicine related safety, effectiveness and quality concerns. The reporting of ADRs by health professionals is still lagging behind but it is of great importance that reporting be done. Optimization of therapy and risk mitigation can greatly be met through reporting of ADRs since risk concerns that predispose most patients to harm can be identified. Professor David Finney opines that “The aim must be to create conditions under which hitherto unsuspected associations between a drug and a reaction in a patient are recognised as early as possible” I therefore take this opportunity to thank all health professionals that continue to exercise the principle of goodwill.

As asserted by Professor David J Finney:

“The aim must be to create conditions under which hitherto unsuspected associations between a drug and a reaction in a patient are recognised as early as possible”

Thank You

Priscilla Nyambayo

Head: Pharmacovigilance & Clinical Trials Division (MCAZ).
The Authority launched the e-ADR and e-CTR online systems on the 25th of June 2019, the platforms are accessible to all our stakeholders and the user manuals are accessible on the MCAZ website:

i. Browser-based Web application - https://e-pv.mcaz.co.zw
ii. Android mobile application (MCAZ Pharmacovigilance)
iii. IoS mobile application (iPhone, iPad) - (MCAZ Pharmacovigilance)
iv. Windows Desktop application
v. Mac Os Desktop application (MacBook)
vi. Linux Desktop application

Please note that to promote patient safety the MCAZ will still accept hardcopy ICSRs (ADRs, SAEs, AEFIs and AEFI case investigation reports) from those who are unable to access the online reporting tools. Completed signed and scanned ADR forms may also be emailed to MCAZ email address: mcaz@mcaz.co.zw. All ICSRs (ADRs, SAEs, AEFIs and AEFI case investigation reports) received by MCAZ are processed for causality assessment monthly by the Pharmacovigilance and Clinical Trials (PVCT) expert Committee that is also the National AEFI Committee. All ICSRs are also uploaded in an anonymous format onto the MCAZ-WHO Vigibase database with inbuilt capabilities for To al reporters and publishes safety articles in drug information bulletins, peer reviewed journals, and gives presentations at stakeholders' forums and pharmacovigilance trainings.

We would like to take this opportunity to thank all reporters who have submitted Individual Case safety reports (ICSRs) (Adverse Drug reactions (ADRs), serious adverse events (SAEs) and/or adverse events following immunization (AEFIs) reports) to the MCAZ. Please keep up the good work in reporting all known and unknown ICSRs that are of concern to the patient or public. Reporting of known, unknown or seemingly 'unimportant' adverse reactions may assist to pinpoint a signal or batch related medicine problem that may be minimized if risk mitigation measures are taken early and promote patient safety.

REFERENCES
1. www.mcaz.co.zw

Protecting Your Right to Quality Medicines and Medical Devices
This article seeks to reinforce the safety information about the serious but rare disabling and potentially permanent side effects associated with Fluoroquinolone and Quinolone antibiotics, after reviewing a notification recently issued by the European Medicines Agency (EMA). Health care professionals are therefore being advised and reminded of the following:

i. Fluoroquinolone and quinolones are associated with prolonged (up to months or years), serious, disabling and potentially irreversible drug reactions affecting several, sometimes multiple, systems, organ classes and senses. The serious side effects include tendonitis, tendon rupture, arthralgia, pain in extremities, gait disturbance, neuropathies associated with paraesthesia, depression, fatigue, memory impairment, sleep disorders, and impaired hearing, vision, taste and smell.

ii. Fluoroquinolone antibiotics have been associated with serious low blood sugar levels and mental health side effects. Health care professionals should therefore be aware of the potential risk of hypoglycemia sometimes resulting in coma, occurring more frequently in the elderly and those with diabetes taking oral hypoglycemic medicines or insulin.

iii. Tendon damage (especially to the Achilles tendon but also other tendons) can occur within 48 hours of starting Fluoroquinolone treatment, but the damage may persist several months after stopping treatment.

iv. Patients who are older, have renal impairment or have had solid organ transplantation, and those being treated with a corticosteroid are at higher risk of tendon damage. Concomitant treatment with a Fluoroquinolone and a corticosteroid should be avoided. Fluoroquinolones and quinolones treatment should be discontinued at the first sign of tendon pain or inflammation, and patients should be advised to stop treatment with a Fluoroquinolone and speak to their doctor if they experience symptoms of neuropathy such as pain, burning, tingling, numbness or weakness, so as to prevent development of potentially irreversible conditions.

v. Fluoroquinolones and quinolones should generally not be used in patients who have had serious adverse reactions associated with the use of quinolone or Fluoroquinolone medicines in the past.

vi. Health care professionals are encouraged to use these antibiotics with caution and where it is necessary. It is advised not to prescribe Fluoroquinolones and
quinolones to patients who have other treatment options for acute bacterial sinusitis, acute bacterial exacerbation of chronic bronchitis, and uncomplicated urinary tract infections and other uncomplicated conditions because the risks outweigh the benefits in these patients.

vii. The Authority urges health care professionals to monitor and report side effects involving Fluoroquinolones and quinolones antibiotics or other medicines to the Medicines Control Authority of Zimbabwe. Adverse drug reactions forms may be downloaded from the MCAZ website: www.mcaz.co.zw. Alternatively, reports can be submitted electronically on http://www.mcaz.co.zw/index.php/2016-01-08-06-40-00/e-reporting.

References

Protecting Your Right to Quality Medicines and Medical Devices
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.

References:
Dolutegravir (DTG) and Neural Birth Defects

Based on new evidence assessing benefits and risks, the WHO recommends the use of the HIV drug Dolutegravir (DTG) as the preferred first-line and second-line treatment for all populations, including pregnant women and those of child-bearing potential.

Initial studies had highlighted a possible link between DTG and neural tube defects (birth defects of the brain and spinal cord that cause conditions such as Spina bifida) in infants born to women using the drug at the time of conception. This potential safety concern was reported in May 2018 from a study in Botswana that found 4 cases of neural tube defects out of 426 women who became pregnant while taking DTG. Based on these preliminary findings, many countries advised pregnant women and women of childbearing potential to take Efavirenz (EFV) instead.

New data from two large clinical trials comparing the efficacy and safety of DTG and EFV in Africa have now expanded the evidence base. The risks of neural tube defects are significantly lower than what the initial studies may have suggested.

The guidelines group also considered mathematical models of the benefits and harms associated with the two drugs; the values and preferences of people living with HIV, as well as factors related to implementation of HIV programmes in different countries, and cost.

DTG is a drug that is more effective, easier to take and has fewer side effects than alternative drugs that are currently used.

DTG also has a high genetic barrier to developing drug resistance, which is important given the rising trend of resistance to EFV and Nevirapine-based regimens. In 2019, 12 out of 18 countries surveyed by WHO reported pre-treatment drug resistance levels exceeding the recommended threshold of 10%.

All of above findings informed the decision to update the 2019 guidelines.

In 2019, 82 low- and middle-income countries reported to be transitioning to DTG-based HIV treatment regimens. The new updated recommendations aim to help more countries improve their HIV policies.

As is the case for any medications, informed choice is important. Every treatment decision needs to be based on an informed discussion with the health provider weighing the benefits and potential risks.

WHO also stresses the importance of providing information and options to help women make an informed choice. To this end WHO has convened an advisory group of women living with HIV from diverse backgrounds to advise on policy issues related to their health, including sexual and reproductive health. WHO highlights the need to continually monitor the risk of neural tube defects associated with DTG.

References

With the sprouting of unregulated outlets on the streets of Zimbabwe, common questions that are raised include:

(i) What is the Medicines Control Authority of Zimbabwe (MCAZ) doing about these street vendors?

(ii) Is the law against unregulated markets and proliferation of substandard and falsified (SF) medicines being actively enforced?

There is no doubt that this is a new challenge for MCAZ considering the risks involved with the use of SF medicines. The risks associated with buying medicines from the street include exposure to counterfeit medicines and toxic substances. Infiltration of SFs onto the Zimbabwe market may also contribute significantly to antimicrobial resistance (AMR), ineffective therapy for emerging health threats and an increased double burden of diseases, i.e., communicable and non-communicable diseases among others.

Globally, medicines regulation is constantly evolving while regionally spirited efforts to harmonize regulatory standards of medical products have been seen. However, MCAZ attempts to stay abreast of current trends in medicines regulation.

In spite of the rather strong regulatory framework for the regulated market that the MCAZ has major control over, and its demonstrable regulatory prowess over the last 20 years as a National Medicines Regulatory Authority (NMRA), MCAZ is increasingly challenged to take a leading role in addressing this rising phenomenon.

MCAZ has attempted to address the problem through collaboration with the Zimbabwe Republic Police (ZRP), public education and inspections by port officials at ports of entry. However, the problem still persists. A general lack of concrete qualitative and quantitative data on the commonly encountered SF medicinal products on the Zimbabwe market is another major issue. This is evidently a multi-layered problem and as the Shona adage goes “chara chimwe hachitswanye inda” (loosely translated “one thumb cannot crush all lice”), there is need for engaging local and regional partners in a bid to fulfil the MCAZ’s mandate of protecting public health by ensuring medicines and medical devices intended for sale and distribution in Zimbabwe, are safe, effective and of good quality.

References

EDITORIAL NOTE

DEAR READER
We would like to thank you for taking interest in reading our first volume of the Medicines Bulletin for 2019 and your continued support in reporting ADRs and AEFIs to the MCAZ National Pharmacovigilance Centre. We are excited to have published a manuscript from the TSR programme and we are hoping for more in the coming year. We cherish your reports and will continue the publication of the information bulletin as one of the ways of disseminating Drug Safety information to Healthcare professionals. Please note that the reporting of a seemingly insignificant or common adverse reaction or side effect may help pinpoint a more widespread adverse effect or prescribing problem. If you have questions on any area of concern, please write to us on 106 Baines Avenue, Harare or call us on 708225/792165, Cell: 0772145191-3.

THANK YOU FOR READING

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Are you taking medicines and experiencing any SIDE EFFECTS?

Now you can tell us by reporting through our reliable and convenient electronic Adverse Drug Reaction platform

For more information

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MCAZ Medicines Control Authority of Zimbabwe

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