ZAMBIA MEDICINES REGULATORY AUTHORITY

VOL 3

MEDICINES MONITOR

2023 Edition

About Us

The Zambia Medicines Regulatory Authority is a Statutory Body established under an Act of Parliament; the Medicines and Allied Substances Act No. 3 of 2013 to regulate and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances.

The main objective of the Authority is to ensure that all medicines and Allied substances being made available to the Zambian people consistently meet the set standards of quality, safety and efficacy.

Medicines regulation is a combination of Legal, Administrative, and Technical measures taken to ensure the quality, safety and efficacy of medicines, and allied substances as well as the relevance and accuracy of product information. The legal requirements for medicines control provide for effective implementation of various regulatory processes and framework for compliance.

Mission

To effectively regulate medicines and allied substances for quality, safe and efficacious medical products on the Zambian market

Vision

A credible regulator ensuring the protection of human and animal health.

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ACKNOWLEDGEMENTS

Special thanks goes to the following, the Information, Education and Communication (IEC) Committee, Management and all the authors for making this publication possible. Special thanks go to Dr. Sindwa Kanyimba for his dedication to provide content for this publication.

EDITORIAL STATEMENT

Dear Reader,

I wish to welcome you to this edition of the Medicines Monitor, a journal of the Zambia Medicines Regulatory Authority (ZAMRA) whose main purpose is to disseminate information on regulatory matters, especially on what the Authority is doing to protect public health.

In this issue you will enjoy exciting, informative and educative articles on, how to identify substandard and fake medicines; nutritional supplements; what you need to know about self-testing (home use) of In-vitro diagnostic (IVD) medical devices and many other interesting articles from our distinguished contributing authors.

The Medicines Monitor is at the moment an annual publication and an open forum for sharing experiences about various issues related to medicines. We wish to appeal to, and encourage, our healthcare professionals and public to take keen interest in the journal and make contributions to other subsequent publications. We would be more than happy to receive your comments and suggestions on how we can improve the publication to make it much more useful to our readers.

If you would like to submit an article, contribute or comment, please contact the chief Editor at pharmamcy@zamra.co.zm

Thank you for your continued support.

Makomani Siyanga (Mr.)

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Nutritional Supplements

Nutritional Supplements can be beneficial to your health, but they can also pose health risks. Before deciding whether to take a supplement or not it is important to know the facts.

What are Nutritional Supplements?

Nutritional supplements are products that are ingested and intended to add to, or "supplement" the diet. Supplements can come in a variety of forms, including tablets, capsules, drinks, gummies, powders, and energy bars.

Common nutritional supplements include vitamins such as vitamin D; minerals like calcium and iron; herbs such as echinacea and ginger; botanical compounds such as caffeine and curcumin; amino acids like tryptophan and glutamine; probiotics (live microbials) and fish oils.

Benefits

Nutritional supplements can help improve or maintain overall health, and some supplements can also help meet daily requirements of essential nutrients. For example, calcium and vitamin D can help build strong bones. Even though Nutritional supplements are beneficial, they should not replace other foods that are important for a healthy diet.

Note: ZAMRA *does not determine whether dietary supplements are effective before they are marketed.*

Safety and Risk

Many supplements contain active ingredients that can have strong effects on the body. Always be alert to the possibility of a bad reaction, especially when taking a new product.

One is most likely to have side effects from nutritional supplements if they consume them at high doses, or instead of taking prescribed medicines. There is also a possibility of experiencing side effects if one takes different supplements at a goal. Similarly some supplements can interact with other medicines in ways that might cause problems.

If a dietary supplement taken is suspected to have caused a side effect, inform your healthcare provider and report to ZAMRA via the Med Safety app or online on the ZAMRA website (www.zamra.co.zm) or direct link: https://primaryreporting.who-umc.org/ZM.

You can also contact the National Pharmacovigilance Unit for guidance: Email: npvu@zamra.co.zm; WhatsApp: +260 956521094.

How are Nutritional Supplements Regulated?

Sellers of nutritional supplements are responsible for ensuring that the products they sell are safe and properly labeled.

The Zambia Medicines Regulatory Authority, has developed guidelines on dietary or nutritional supplements that an applicant can use for guidance in the registration of nutritional supplements. If a product is found to be unsafe or not otherwise in compliance with the law, ZAMRA will remove it from the market.

How are Nutritional Supplements Labeled?

Nutritional supplements are required to have a "Supplement Facts" label that lists the serving size, the number of servings per container, each dietary ingredient in the product, and the amount of certain ingredients per serving. They are also required to have a statement on the label of the product identifying them as a "dietary supplement" or similar term (for example, "vitamin supplement").

Talk with Your Health Care Providers About Nutritional Supplements

Dietary supplements are not medicines and are not intended to treat, diagnose, mitigate, prevent, or cure diseases. Read product labels and tell your health care providers about any dietary supplements you're taking. They can advise which supplement, if any, might be valuable to you and help answer these questions:

- What are its potential benefits for me?
- Does it have any safety risks?
- What is the proper dose to take?
- How, when, and for how long should I take it?

CYPROHEPTIDINE AND DEXAMETHASONE DO NOT ENLARGE HIPS AND BUMS

By Dr Sindwa Kanyimba

It has become a trend for some ladies to take a combination of dexamethasone and cyproheptadine to enlarge their hips.

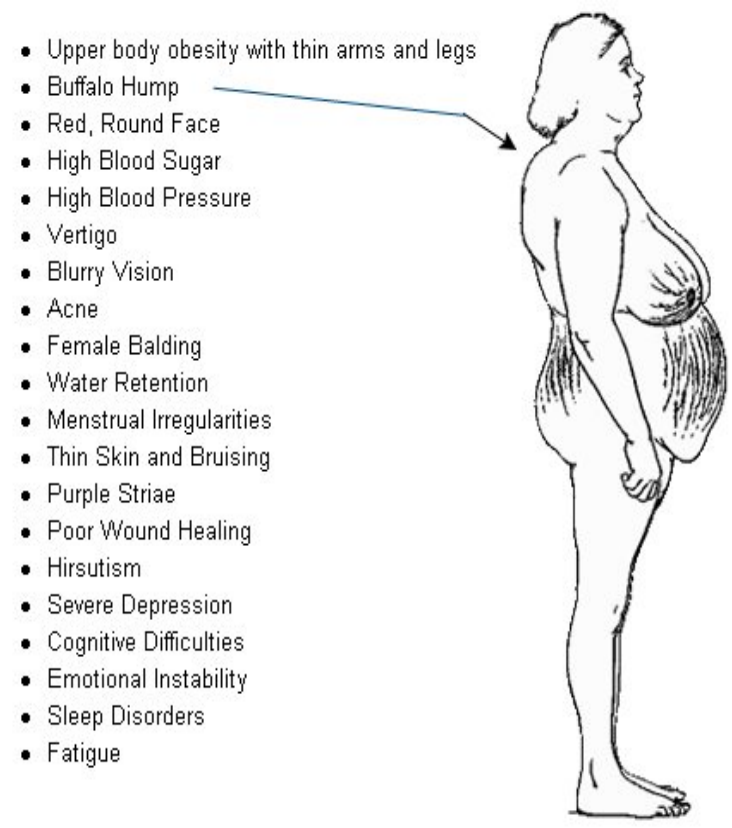
These two medicines will not enlarge your hips and give you that curvy figure you are looking for.

Although they promote weight gain (through appetite stimulation), the weight will not be distributed in the areas you want.

Prolonged use of dexamethasone (anything more than two weeks) will cause a redistribution of fat in your body from the limbs to the trunk and will shrink your muscles making you become flabby. You become fat in the face, neck, shoulder blades and abdomen (pot-belly), while the buttocks, hips and thighs shrink. Eventually you will have a fat body and big tummy, but with thin legs and arms (truncal obesity).

Prolonged use of dexamethasone also damages your skin, lowers your immunity, and increases your risk of developing diabetes mellitus and high blood pressure.

Take not that there is no medicine (conventional or herbal) that will enlarge your hips and give you that greatly coveted pear-shaped figure.



That condoms can protect you from STIs and unwanted pregnancies?
When used properly and correctly, condoms will protect you from most sexually transmitted diseases. Condoms are a safe barrier method of contraception that will prevent unwanted pregnancies.

That condoms are allied substances?
According to medicines and Allied Substances Act, allied substances include acaricides, cosmetics, disinfectants, food supplements, feed additives and supplements, medical and surgical sundries, medical devices and condoms.

That in Zambia, condoms are regulated by ZAMRA?
Part V, Section 39, Subsection 2 of the Medicines and Allied Substances Act (No.3) of 2013 states that; a person who intends to place on the market, advertise, market, manufacture, sell, import, supply, administer or deal in any manner with any medicine or allied substance shall apply to the Authority for a marketing authorisation in the prescribed manner and form.

That condoms are supposed to be registered by ZAMRA?
In accordance with the law, all condoms are supposed to be registered by ZAMRA prior to placing them on the Zambian market. For further information refer to https://www.zamra.co.zm/marketing-authorisation/

That for you to import condoms you need a permit?
ZAMRA issues import permits that allows you to import condoms from other countries to Zambia. Without an import permit it is unlawful to import condoms into the country.

Dolutegravir and Sexual dysfunction

Carlos Melgarejo-González[1], Francis Odipiyo[2], Ismail Ntale[2], Mulubwa Chilambe[3], Joseph Mitchell[1]
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Introduction

Dolutegravir-based antiretroviral regimens for the treatment of HIV have reported high levels of effectiveness and acceptability[1]. It is now a recommended first- or second-line HIV treatment, with the potential to reach 38 million patients worldwide, but concerns have been raised about potential side effects, including sexual dysfunction[2]. However, sexual dysfunction in HIV-infected people can be multifactorial with organic and psychological components[3] and the potential role of other HIV treatments in sexual dysfunction has also been discussed[4].

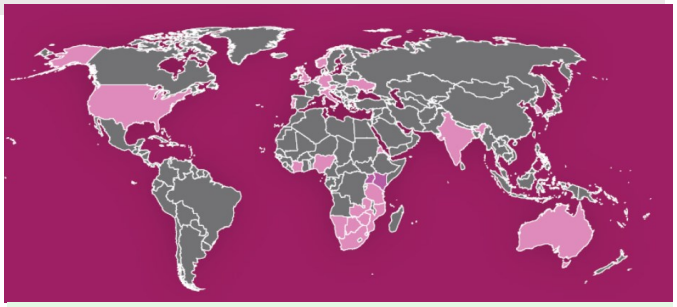

Figure 1. Countries with reports of dolutegravir and sexual dysfunction (SMQ) (pink)

Results

For all dolutegravir-containing active ingredients, a total of 348 reports were identified in VigiBase. The countries that contributed the largest number of reports were Uganda (n=147, 42.2%) and Kenya (n=81, 23.3%) with reports received from 28 countries (see Figure 1), the WHO regions represented being AFR, AMR, SEAR, EUR and WPR. The IC_{025} value for this combination was 2.0, indicating statistically significant disproportionate reporting for this combination. The most common reported MedDRA Preferred Terms were "Erectile dysfunction" (n=201), "Libido decreased" (n=86) and "Loss of libido" (n=48). The results of the vigiPoint analysis are shown in Table 1, with High Level Group Terms and High Level Terms related to sexual dysfunction.

Conclusions

This complex potential signal warrants further investigation. The initial results are supportive but not conclusive. Case-by-case analysis and collaboration with contributing national centres are crucial next steps.

Methods

A search of VigiBase, the WHO global database of individual case safety reports, was performed on 11 April 2023. Cases were identified when they reported both a reaction in the Standardised MedDRA Query (SMQ) "Sexual dysfunction (narrow)" and dolutegravir-containing products in the WHODrug Standardised Drug Grouping (SDG) "Drugs for treatment of HIV infections". Disproportionality measures, using the information component values, were calculated for the combination of the SMQ and dolutegravir-containing products. An IC_{025} of greater than 0 indicates positive disproportionate reporting with statistical significance[5]. vigiPoint[6] was used to compare reporting for medications containing dolutegravir with medications that do not contain dolutegravir in the WHODrug SDG "Drugs for treatment of HIV infections". The positive lower end of the 99% credibility interval for the calculated shrinkage log odds ratio (SLOR) highlights variables with an overrepresentation among the dolutegravir subset. A threshold of greater than 0.5 for the lower end of the 99% credibility interval ($SLOR_{005}$) highlights substantial deviation.

Table 1. vigiPoint results for MedDRA High Level Group Terms and High Level Terms related to sexual dysfunction when comparing dolutegravir-containing HIV treatment to non-dolutegravir containing HIV treatments. Total case count for DTG: 26,589; for all anti-HIV excluding DTG: 321,610. Abbreviations: DTG – dolutegravir; SLOR – Shrinkage Log Odds Ratio; $SLOR_{005}$ refers to the lower end of the 99% credibility interval.

MedDRA Level	Term	DTG% (N reports)	Other anti-HIV % (N reports)	$SLOR_{005}$
Higher Level Group Term	Sexual dysfunctions, disturbances and gender identity disorders	1.3% (353)	0.2% (647)	0.80
Higher Level Group Term	Sexual function and fertility disorders	1.2% (318)	0.2% (715)	0.69
Higher Level Term	Sexual arousal disorders	0.8% (201)	0.1% (361)	0.48
Higher Level Term	Erection and ejaculation conditions and disorders	0.8% (206)	0.1% (418)	0.48
Higher Level Term	Sexual desire disorders	0.6% (150)	0.1% (255)	0.35
Higher Level Term	Sexual function and fertility disorders NEC	0.4% (115)	0.1% (313)	0.19
Higher Level Term	Sexual dysfunction NEC	0.03% (9)	0.02% (67)	-0.21

References
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[2]Zakumumpa H, Kitutu FE, Ndagije HB, Diana NK, Ssanyu JN, Kiguba R. Provider perspectives on the acceptability and tolerability of dolutegravir-based anti-retroviral therapy after national roll-out in Uganda: a qualitative study. BMC Infect Dis. 2021 Dec 7;21(1):1222.
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THE FARM TO FORK CONCEPT – THE ROLE OF ZAMRA

By Dr. Tipezenji Sakala

Veterinary medicine is the branch of medicine dealing in the prevention, control, diagnosis and treatment of disease and injury in animals. It also plays a vital role in animal husbandry, breeding, research on nutrition and product development, and is a sensitive aspect of the farm to fork conception. The holistic farm to fork concept is introduced early in the Veterinary Medicine studies' timeline to create awareness and sense of responsibility in one undertaking these studies. It is the Veterinary medicine paradigm that serves as a pillar in the community livestock food systems at farm level, within the farm to fork structure. With the expanse of food systems, it has been noted that current agricultural practices are heavily dependent on the use of pharmacologically active compounds: drugs in the raising of animals for food. This is fundamental to animal health and well-being, as well as to economics of the food industry, and calls for responsible use of these drugs or medicines. The Medicines and Allied Substances Act No. 3 of 2013 of the Laws of Zambia, provides for the regulation and control of the manufacture, importation, storage, distribution, supply, sale and use of veterinary medicines and allied substances. This is important as it ensures that all veterinary medicinal products intended to be marketed in Zambia meet acceptable standards of quality, safety and efficacy, and they are also manufactured in facilities which comply with current Good Manufacturing Practices (cGMP). The ZAMRA Medicines Veterinary Unit is one of the units under the department of the Medicines Control whose responsibility is to conduct assessment and surveillance. Firstly the Unit ensures the safe and effective use of all animal medications, secondly, it safeguards the residual effect on the human communities interacting with and consuming previously medicated animals.

The ZAMRA Veterinary medicines unit, through product evaluations for marketing authorisation, serves to ensure use of these medicines in a way in which they are safe and authorized to be used i.e. for the approved species and age of the animal, at the approved dose rate. This is through evaluation of a summary of product characteristics, chemistry, manufacture and quality control data including that of the active pharmaceutical ingredient(s) and the pharmaceutical dosage form. The provision of an animal medicine only once a disease has been diagnosed, in conjunction with strict requirements for correctly labelled categories of distribution, allow for responsible guidance on safe and prudent use of medicines including, antihelmintics, antibacterial agents, antifungal agents, anti-inflammatory agents, antineoplastic agents, antiseptics, antiviral agents, ectoparasiticides, growth promotors and vaccines. This sequentially prevents resistance to medication and other potentially dangerous outcomes including toxic effects at handling and environmental pollution. Stability testing within the recommended container closure system and available pack sizes is assessed to ensure evidence is provided on how the quality of a medicine substance or product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light. This will enable maintenance of recommended precise storage conditions, and in turn the safety and efficacy of the medicine.

Substandard and Falsified Medical Products – A Growing Danger

By Elimas Jere

Substandard and Falsified medical products expose patients, communities, nations and every region of the world to increases in disease burden, economic losses, and drug resistance. For example, in the last decade, ineffective antimicrobial drugs have compromised the treatment of many deadly diseases in poor countries.

Key facts

◊ Substandard and falsified medical products may cause harm to patients and fail to treat the diseases for which they are intended.

◊ They lead to loss of confidence in medicines, healthcare providers and health systems.

◊ They affect every region of the world.

◊ Substandard and falsified medical products from all main therapeutic categories have been reported to WHO including medicines, vaccines and medical devices.

◊ Anti-malarials and antibiotics are amongst the most reported substandard and falsified medical products.

◊ Both generic and innovator medicines can be falsified, ranging from very expensive products for cancer to very inexpensive products for treatment of pain.

◊ They can be found in illegal street markets, via unregulated websites through to pharmacies, clinics and hospitals.

◊ An estimated 1 in 10 medical products in low- and middle-income countries is substandard or falsified.

◊ Substandard and falsified medical products contribute to antimicrobial resistance and drug-resistant infections.

◊ Substandard and falsified medical products are often produced in very poor and unhygienic conditions by unqualified personnel and contain unknown impurities and are sometimes contaminated with bacteria.

Identifying a substandard or falsified medical product

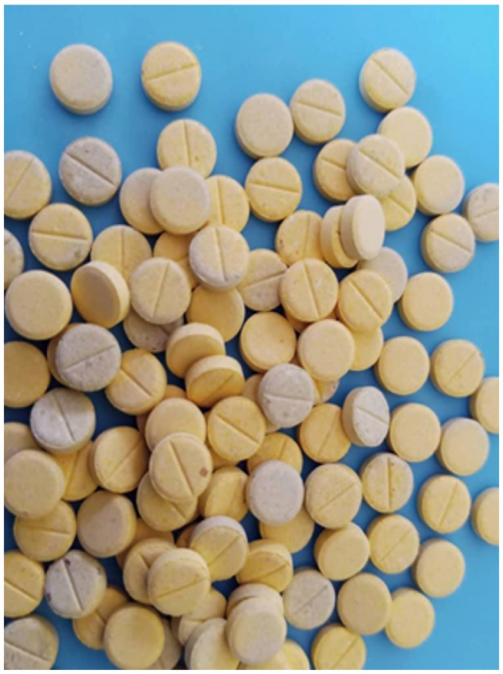
• Examine the packaging for condition, spelling mistakes or grammatical errors;

•Check the manufacture and expiry dates and ensure any details on the outer packaging match the dates shown on the inner packaging;

• Ensure the medicine looks correct, is of the right colour, degraded or has an unusual smell;

•Discuss with your pharmacist, doctor or other healthcare professional as soon as possible if you suspect the product is not working properly or you have suffered an adverse reaction.

We appeal to the public to report suspicious medical products to Zambia Medicines Regulatory Authority (ZAMRA). Reporting can be done via pharmacy@zamra.co.zm or +260211220429



What You Need to Know About Self-Testing (Home Use) *In-Vitro* Diagnostic (IVD) Medical Devices

by Kapunda Masuwa

What is an In Vitro Diagnostic (IVD) Medical Device?

In-vitro diagnostic medical devices are used for examination of biological samples to provide information about a person's health. The term "medical device" generally refers to any instrument, apparatus or appliance that is used for diagnosis, treatment or monitoring of disease and injuries of human beings.

What are Self-testing IVD Medical Devices

Self-testing IVD medical devices are meant for use by the general public. These devices are, therefore, designed to have relatively simple and easy operating procedures compared with professional/laboratory IVD medical devices providing similar functions.

Potential Risks from the Use of Self-testing IVD Medical Devices

Self-testing IVD medical devices should be properly understood as their improper use may lead to inappropriate response of the users, thus, posing risks to their health. Some common problems are as follows;

- The device fails to operate properly because it has not been appropriately maintained.
- Users fail to conduct the test correctly owing to poor user techniques and/or failure to follow proper operating procedures.
- Users act on inaccurate test results which arise from the inherent limitations of the device.
- Users may fail to interpret the test results correctly due to insufficient knowledge on the tests taken or inadequate training in test results interpretation.
- Users fail to take necessary follow-up measures timely on the basis of the test results.

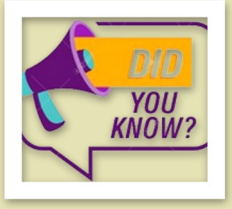
Safe Use of Home-use IVD Medical Devices

The information listed below can help to prevent and/or reduce the potential risks that can be caused by improper use, storage and interpretation of results of self-testing IVD medical device.

1. Store and maintain the device according to the manufacturer's storage instructions.
2. Follow the instructions of use when conducting the test, including device settings and specimen collection.
3. Understand the purpose of the test, its limitations, the meaning of test results and whether the test suits the user's needs before conducting the test.
4. Take appropriate follow-up measures in accordance with the test results obtained. You are always advised to visit the nearest heath facility for further investigations following positive test results.
5. Seek medical advice in case of doubt or occurrence of suspicious symptoms, despite a normal (negative) test result.
6. Never replace/override the health care provider's diagnosis with self-testing IVD medical device test results, as these results are for general monitoring and reference only.

Where to report suspected quality and/or safety matters concerning Self-testing IVD Medical Devices

All quality and/or safety concerns should be reported to ZAMRA by providing the details of the name of product used and the type of the quality and/or safety problem that occurred for further investigation and record.



⇒ Cotton wool, methylated spirit and tooth paste, should be registered with the Authority

⇒ There are more than 8000 medicines and allied substances registered with the Authority. The register can be accessed online on www.zamra.co.zm

⇒ There more than 1600 licensed pharmacies , health shops and agrovet shops around the country where you can access quality and safe medicines and allied substances.

CIPROFLOXACIN (FLOUROQUINOLONES) – A DOUBLE EDGED SWORD

By Dr Sindwa Kanyimba

Ciprofloxacin is a broad-spectrum antibiotic, effective in treating a wide range of bacterial infections. However, due to serious harmful effects it can have, it should not be used for infections where other antibiotics are equally effective. It is reserved for severe bacterial infections that do not respond well to other antibiotics, and for serious conditions such as typhoid & anthrax. Serious harmful effects that have been associated with the use of ciprofloxacin include;

Damage to tendons (tendons are fibrous tissue that connect bone to muscle)

Tendons of the shoulders, hands and ankles are usually affected leading to pain in these areas. Other areas can also be affected. The tendons may rupture (get torn) resulting in difficulties in moving the affected parts. The patients most susceptible to tendon rupture are the elderly, patients with rheumatoid arthritis & other connective tissue disorders, and patients taking corticosteroids (e.g. prednisolone, dexamethasone)

Weakening of the walls of the aorta

This results in outward bulging of the walls of the aorta (aortic aneurysm). In severe cases, the wall of the aorta gets torn (aortic dissection; a life-threatening condition that can cause sudden death)

Nerve damage

This may present as numbness, tingling, pain, and weakness of arms or legs

Examples of other flouroquinolones include, levofloxacin and moxifloxacin

TAKE HOME MESSAGES

◊ Avoid self-medication with antibiotics
◊ Avoid flouroquinolones in mild bacterial infections
◊ Avoid flouroquinolones in pregnancy, lactation, children, patients with epilepsy & patients with certain heart conditions

* The National Drug Quality Control Laboratory (NDQCL) located at the ZAMRA Head Office conducts quality tests on medicines and allied substances in Zambia. The NDQCL analyses more than 400 samples per annum. This helps to ensure only good quality medical products are made available on the market.

Good Manufacturing Practices (GMP) for Safer Medicines

Good Manufacturing Practices (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

Are All Manufacturers Expected to Comply to GMP standards?

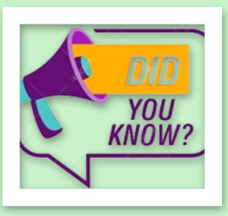
Yes! All manufactures that supply medicines and allied substances to the Zambian market, whether based in Zambia or overseas, are expected to comply to GMP standards. Currently, ZAMRA requires that all manufactures comply to the World Health Organization (WHO) version of GMP, which is used by both regulators and industry in over 100 countries.

How does ZAMRA ensure that medicines used in Zambia come from GMP compliant manufactures?

In order to determine that a manufacturer is GMP compliant, GMP inspections must be carried out. These may be on-site inspections or desk review of documentation for a particular site. For on-site inspections, inspectors need to visit these facilities and review documentation, interview people and physically inspect premises and equipment. GMP inspections are usually carried out by officers called GMP Inspectors. A typical on-site inspection may last from one to several days depending on the type of GMP inspection or how complex a site is, among other things. Inspections are transparent and fact based. All findings during the inspections, both positive and negative, are documented in an inspection report and sent to the manufacturer who is expected to offer solutions to the negative findings. These are called corrective and preventive actions (CAPAs).

Why is GMP important?

GMP protects patients by ensuring that they receive medicinal products of uncompromised high quality, thereby, safeguarding their health. Compliance with these quality standards is imperative during the manufacture, processing, packaging and storage of medicinal products. Manufacturing authorisation may be denied, suspended or revoked to any company that fails to comply with GMP standards.



- That you can apply for an import permit, license, clinical trial, marketing authorisation etc... from the comfort of your home or office. The Integrated Regulatory Information Management System (IRIMS) brings the regulatory services right to your doorstep. Log onto the IRIMS portal on https://www.zamra.co.zm/e-services-portal/.
- You can reach our IRIMS support team on WhatsApp;

+260 763 784 047
Online Self Service Portal Support

Some facts about commonly used vaccines

Oral Cholera Vaccine (OCV) as a Cholera Prevention Tool

Oral Cholera Vaccine (OCV) provides protection against cholera by stimulating the intestinal immune response. This intestinal immune response limits cholera bacteria growth in the gut if one is subsequently exposed.

OCV is used as part of an integrated cholera control strategy (including safe water, improved sanitation, and high quality case management). The vaccine reduces the risk of getting sick with or dying of cholera.

The vaccines currently recommended by the WHO are killed, whole-cell vaccines that are orally administered. Shanchol, Euvichol, Euvichol-Plus are examples of killed oral vaccines that have the same composition. These vaccines have been used in Zambia before. Shanchol and Euvichol are presented in single dose vials containing 1.5 ml liquid.

Individuals taking the vaccine should mix the vaccine by shaking the vial, opening it by breaking the seal at the top, and then drink the contents directly from the vial.

Two doses of vaccine are recommended with the second dose given about two weeks after the first. This provides protection for about 3 to 5 years.

Safety and Side Effects of OCV.
Common side effects include, nausea, diarrhea, fever, vomiting, dryness of the mouth, abdominal pain, itching, rash, weakness, cough and vertigo. Less common side effects include, oral sores, sore throat and yellowing of urine.

Pregnant women and children can safely take the OCV.

Direct and Indirect (Herd) Protection
OCV provides significant protection for those who receive the vaccine. If a large proportion of the community receives the vaccine, the vaccine protects the community better.

BCG vaccination for babies

The Bacillus Calmette-Guérin (BCG) vaccination is given to new born babies at risk of getting tuberculosis (TB). TB is a very serious infectious disease that can cause TB meningitis in babies.

The BCG Scar

Immediately after the injection, a raised blister will appear. Within two to six weeks of the injection a small spot will appear. This may be quite sore for a few days, but it will gradually heal leaving a small, flat scar.

If you are worried or you think the sore has become infected, seek help from the clinic.

Other side effects

Like all medicines, BCG Vaccine can cause side effects, although not everybody gets them. These include, redness and/or a small lump at the injection site, followed by a small ulcer (an open sore) a few weeks later.

All side effects can be reported to ZAMRA using the following avenues:

e-Reporting form using the link below.

https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=ZM

Mobile App "***MEDSAFETY***" available on Google Playstore® and Appstore®

+260 956 521 094

Scan QR code

Hardcopy reporting form mailed or delivered to;

The National Pharmacovigilance Unit

Zambia Medicines Regulatory Authority

Plot No. 2350/M Off Kenneth Kaunda International Airport Road

ZAF – KKIA Bypass Route Between Hitachi and Delta Auto

P.O Box 31890, Lusaka, Zambia

Phone; **+260-211-432350**

npvu@zamra.co.zm

What you need to know before you crash or split a tablet

By Mulubwa Chilambe

Have you, or someone you know, been in any of the following situations?

* Have a child who is unwell but the only available tablet is for an adult.
* Have a child who is unwell but the only available medicine is in tablet form and the child needs a syrup or a liquid form of the medicine.
* Have a condition that requires a lower strength or dose of a tablet, but the only one available is a higher strength or a tablet but it is too big to swallow.

Should you cut or crash the tablet to suit your needs? Well here is what you need to know:

First of all, in many cases, the appropriate tablet sizes, strengths and formulations are available for any of the situations above. All you need is to find the right one. You can get all the information you need from the leaflet that comes with the medicine or from your local healthcare provider, such as a Pharmacist.

There are rules that govern the splitting and crushing of tablets. These rules depend on the way the tablet was made or manufactured. Some tablets are coated with some materials that protect the contents of the tablets (active ingredients) from the harsh environments in the human body, such as acid found in the stomach. Other tablets are coated with materials that delay, prolong or modify the release of the active ingredients into the body. Breaking or crushing such tablets may negatively affect the way such tablets were designed to work, and this may result in lack of therapeutic efficacy as the active ingredients may be destroyed by the harsh body environments. For tablets designed to release the active ingredients slowly, breaking or crushing of such tables may results in rapid release of the active ingredients. This may result in toxicity and other unwanted effects.

Some tablets will have a break-mark, break-line or "score line" which shows that the tablet may be split along that line. There are two main reasons for the break-line on tablets:

1. To divide the tablet into equal halves. In this case, ZAMRA will require that the manufacturer submits results from experiments that support reproducible dividing of the tablets.
2. The score line is only to facilitate breaking for ease of swallowing, and not to divide into equal doses.

For all tablets with a score line, always check the leaflet to see if the score line is for dividing the tablet into equal halves or is for ease of swallowing.

PHOTO FOCUS

Group Photo of stakeholders at a media engagement meeting in Lusaka

Women's Day Aerobics - Manda Hill

Stakeholder sensitisation meeting - M'kango Golfview – Lusaka

Hon. Masebo and EU Commissioner for International partnerships -Jutta Urpilainen jointly cut the ribbon to mark the official launch of the ZAMRA Office Complex

UTH Pharmacovigilance training workshop - Ndozo Lodge

REPORT UNDESIRED DRUG EFFECTS USING THE MED SAFETY APP

ZAMRA's mobile reporting app - **Med Safety**, makes it easy to report adverse effects of medicines.

GET IT ON Google Play

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