Drug Safety Bulletin

TMDA

Tanzania Medicines & Medical Devices Authority

Updates on Spontaneus Reporting of Suspected Adverse Drug Reactions

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Word from Director General

It is my great pleasure to present to you the 4th edition of Drug Safety Bulletin in order to share current information updates on drug quality and safety monitoring.

Tanzania Medicines and Medical Devices Authority (TMDA) is an Executive Agency under the Ministry of Health, Community Development, Gender, Elderly and Children (MOHCDGE). TMDA which was formerly known as Tanzania Food and Drugs Authority (TFDA) was established in 2003 after enactment of the Tanzania Food, Drugs and Cosmetics Act, Cap 219 by the Parliament.

This Act was later amended in 2019 to Tanzania Medicines and Medical Devices Act, Cap 219 after the shift of responsibilities of regulating food and cosmetics to Tanzania Bureau of Standards (TBS). The change in legislative framework which was done through the Finance Act, No. 8 of 2019 also resulted into the change of name to TMDA. TMDA is now responsible for regulating quality, safety and effectiveness of medicines, medical devices and diagnostics.

Its vision of being the leading regulatory Authority in Africa has been realized in 2018 when TMDA attained WHO Maturity Level 3 hence becoming the first country in Africa to achieve that milestone.

To continuously improve regulatory systems, stakeholders involvement through information sharing is an essential component in promoting and protecting public health. TMDA strives to share enough information as much as possible with the public through various portals of communication, one of which being this Drug Safety Bulletin.

The process of connecting and engaging with stakeholders is an ongoing process in order to improve the public awareness on issues related to quality and safety of medicines.

It is from this scenario you will find that this tool of communication will remain to be a priority for TMDA. I am delighted to invite you to read it thoroughly and provide us constructive suggestions you may have for improvement of content and design for the future editions.

It is my trust that you will find this Drug Safety Bulletin useful and interesting.

Enjoy reading!

Adam M. Fimbo
Chief Editor

TMDA
Tanzania Medicines & Medical Devices Authority

Editorial Team

Safety Monitoring during Mass Drug Administration

A meeting with stakeholders to brief prelimary results of the Active Surveillance for Ivemectin and Albendazole

The Tanzania Medicines and Medical Devices Authority (TMDA) collaborates with the National Programme for Control of Neglected Tropical Diseases (NPCNTDs) to monitor the safety of medicines used for preventive chemotherapy given during Mass Drug Administration (MDA).

The MDA is meant to control Neglected Tropical Diseases (NTDs) such as lymphatic filariasis, onchocerciasis, schistosomiasis, trachoma and soil-transmitted helminthiasis.

The Adverse Events (AE) following large-scale preventive chemotherapy interventions can be caused by the action of the medicine or by an operational error or be coincidental events.

Spontaneous reporting of Adverse Events from Preventive Chemotherapy

Reports of AE associated to MDA are channeled spontaneously by use of the same available tools; yellow, green and blue forms, weblink https://imis.tmda.go.tz/arrt/, ADR reporting App, simple text message (by dialing *152*00#) or use of toll free number 0800110084.

Active Surveillance Programmes

Active surveillance programmes are conducted to monitor safety of specific medicines including medicines used for MDA. An active surveillance of Ivermectin and Albendazole used as preventive chemotherapy for Filariasis was conducted between 2018 and 2019 during MDA at Mkinga District, Tanga through PROFORMA Project with support from the European and Developing Countries Clinical Trials Partnership (EDCTP).

The purpose of the programme was to characterize risk factors for ADRs associated with the use of Ivermectin and Albendazole. No any safety issue of concern was observed during the surveillance. This indicates that Ivemectin and Albendazole taken in combination are still safe for use in the NTD Programme. The full report of the surveillance will be disseminated to the public through the TMDA website and other means upon finalization.

A meeting with stakeholders to brief prelimary results of the Active Surveillance for Ivemectin and Albendazole.

Updates on Spontaneus Reporting of Suspected Adverse Drug Reactions

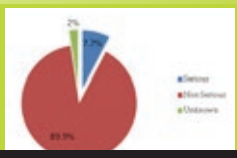

Figure 2: Seriousness of adverse drug reactions

INTRODUCTION

Voluntary reporting of suspected Adverse Drug Reactions (ADRs) by healthcare professionals and consumers is a most important method that enables the Authority to get feedback on the safety of authorized medicines in the market. The current available ADR reporting tools include special forms (Yellow Form for healthcare professionals and Green Form for consumers), weblink https://imis.tmda.go.tz/arrt/, ADR reporting App (by use of smart phone application), simple text message (by dialing *152*00#) or use of toll free number 0800110084. These tools and systems are easily accessible.

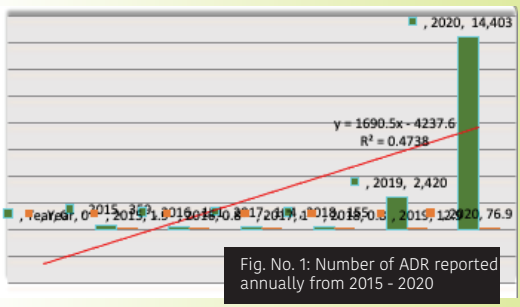

Fig. No. 1: Number of ADR reported annually from 2015 - 2020

NEW DEVELOPMENT

Under reporting of ADRs is considered as a challenge of Pharmacovigilance System in Tanzania despite the fact that recently there is an improvement. According to available national statistics, from the years 2000 – 2018 there was an average of 150 to 300 ADR reports annually. Following the strategies deployed by TMDA to inculcate reporting culture to health professionals and other stakeholders, there is a good progress in the number of ADR reports received. For example, in the year 2019 a total of 2,420 ADR reports were received compared to 14,403 reports as of 25th August, 2020 as stipulated in Figure No. 1 below;

REPORTING BY HEALTH PROFESSIONALS

All healthcare professionals have a pertinent role to play on ADRs reporting. The trend of reporting ADRs from this group by 25th August, 2020 shows that 89.4% of all received ADR reports were reported by Pharmacists, 5.2 % by clinicians and 4.2% by other healthcare professionals. These findings from ADR reporting systems, favours pharmacists as an active cluster in reporting compared to other health professionals categories. Measures should be taken to sensitize the minority reporting groups to impart them with the culture of reporting ADRs among healthcare professionals towards increasing the number of ADRs reports to maintain the quality and safety of medicines circulating in the market.

SERIOUSNESS OF THE REPORTED ADVERSE DRUG REACTION

Sensitivity of an adverse event or suspected adverse reaction is scaled depending on the threat it poses to the consumer. If it results to death, life-threatening, inpatient hospitalization or prolonged hospitalization, disability, or a congenital anomaly the ADR is considered as “serious”. 89.9% of ADRs received at TMDA by 25th August, 2020 were not serious as depicted in Figure 2 below.

REPORTS BY REGIONS

Despite the continuous advocacy activities spearheaded by TMDA on ADR reporting within the country, there is a discernible variation in reporting by regions. Majority of the regions have submitted very few or no reports at all. For instance, from January to June 2020, a total of 11,233 ADR reports were received from all over the country with 10,350 (92.14%) of reports from Dar es salaam and 4053 (7.86%) from other regions. TMDA has intensified well planned awareness campaigns to all regions so as to improve the efficiency of ADR reporting.

Periodic Safety Report an Obligation to Market Authorization Holders

A Periodic Safety Update Report (PSUR) is a pharmacovigilance document intended to provide an update of the worldwide safety experience of a medicinal product to regulatory authorities at defined time points post-authorisation.

The objective of a PSUR is to present a comprehensive and critical analysis of the risk-benefit balance of a product. This accounts for new or emerging safety information in the context of cumulative information on risk and benefits. The evaluation should ascertain whether further investigation need to be carried out or changes should be made to the product information or marketing authorisation.

Sources of PSUR information include but not limited to data from clinical and non-clinical studies, spontaneous reports, drug use information, observational studies and scientific literature.

When should PSUR submitted to TMDA?

The frequency of submission of PSUR shall be calculated from the date of the authorization of the product. The report should be submitted to TMDA at least once in every six months during the first two years following the initial placing of the medicinal product on the market and once a year for the following two years and after that at least once in every three years.

Market Authorization Holders are encouraged to submit PSUR to the Authority timely for the purpose of protecting public health.

What should a PSUR contain?

In a minimum, the periodic safety update report contains the following: -

- Summaries of data relevant to the benefits and risks of the medicinal product
- A scientific evaluation of the risk-benefit balance of the medicinal product
- All data relating to the volume of sales of the medicinal product
- Collection of all adverse drug reactions

Tanzania determines to Implement Active Surveillance of Dolutegravir

The Ministry of Health, Community Development, Gender, Elderly and Children started using Dolutegravir (DTG) in combination with other ARVs as default regimen to all people living with HIV since 2019. Dolutegravir is an antiretroviral medication used together with other medication to treat HIV/AIDS. It may also be used as part of post exposure prophylaxis to prevent HIV infection following potential exposure.

The DTG is a drug that is more effective, easy to take and is presumed to have better tolerability levels and lower possibility of causing adverse reactions. However, it is important to continue monitoring its safety in the population. Clinical studies are important and necessary but not exhaustive. Always there is a need for continuous safety profile evaluations of medicines in the community while used.

TMDA monitors medicines safety by using both passive and active surveillance methods. Most of the medicines are monitored through spontaneous (voluntary) reporting system by using various Adverse Drug Reactions (ADR) reporting tools. Even though, spontaneous system is useful in collecting ADRs information. The voluntary reporting system has a challenge of under reporting, thus takes time to detect risks associated with medicine use.

Active surveillance method has vital role that complements spontaneous reporting by providing pertinent data about unique populations and specific medicines.

ARVs like any other medicine may cause ADRs. DTG being a new medicine in a market, its safety profile has not been fully established. In order to address this challenge, TMDA has decided to introduce active surveillance of DTG in the financial year 2020/2021 for the purpose of evaluating its safety profile in the population. The aim of doing this is to improve patient safety, patient care and treatment outcomes for HIV patients exposed to DTG.

Cross sectional study approach will be employed during surveillance to assess safety of DTG among HIV infected individuals attending Care and Treatment Centers (CTC) in Tanzania mainland.

A generic ADRs reporting tool for ARVs with standardized reporting of adverse events, drug interactions and comorbidities adopted from WHO will be used. Congenital anomalies and Pregnancy outcome will be filled for all women attending CTCs who will either deliver (term, premature) or get miscarriage during the study period regardless of the ARV regimen used.

The Quality Control of Medicines

Quality control is an essential operation in determining safety and quality medicines in order to protect and promote public health. However, some studies revealed that falsified and substandard medicines may result into life threatening, financial loss and mistrusted health systems.

In order to ensure that medicines circulating in the market meet quality standards, TMDA has established various control systems which includes laboratory analysis of samples whereby all received samples are analyzed prior to market authorization and through post marketing surveillance programmes.

To facilitate sample testing, TMDA has established two modern and well-equipped quality control laboratories based in Dar es Salaam and Mwanza. The TMDA Dar es Salaam Quality Control Laboratory is among the 55 WHO prequalified quality control laboratories in medicines testing. This means that, the laboratory results provided from the TMDA QC laboratory are accurate and trusted worldwide.

Testing of medicines includes preliminary screening using Global Pharma Health Fund (GPHF) Minilab kits and compendials or non-compendial methods.

So far, TMDA has installed 25 GPHF Minilab kits which are placed into different Quality Assurance (QA) centres in the country. The QA centres are located at ports of entry, Regional Referral Hospitals (RRH) and TMDA zone offices.

GPHF Minilab kit is a simple and relatively easy and quick technique for quality screening of medicinal products in the field. It contains all necessary requirements for testing more than 100

types of medicinal products. The kit is capable of carrying out disintegration tests for oral solid dosage forms and thin-layer chromatography (TLC) for identification of Active Pharmaceutical Ingredients (APIs) present in a formulation.

Specialized equipment for medicines analysis

The use of GHPF Minilab kit is important in combating falsified and substandard medicines as well as reducing the bulk log of samples submitted to the laboratory. This program has shown great success and has been among the model strategies for neighbouring countries.

Test results generated from laboratories and QA centres enables the Authority to make evidence-based decisions in ensuring that products circulating on the market are of good quality.

TMDA Quality Control Laboratory (Dar es Salaam)

Regulation of Medical Devices in Tanzania

Experts describe the medical devices as instruments, apparatus, implements, medical equipment, machines, contrivance, implants, in vitro reagents or other similar or related articles.

These are used for, among others, the diagnosis of diseases or other conditions, or in the cure, mitigation, treatment or prevention of diseases, in man or other animals.

Medical devices, if not controlled, may pose serious threat to public health such as impairment or loss of life.

The Tanzania Medicines and Medical Devices Authority (TMDA) started regulating medical devices and in vitro diagnostics in 2009 with the aim of ensuring quality, safety and performance, hence, protecting the public health.

Medical devices Regulatory framework has been set in line with legal requirements prescribed in the Tanzania Medicines and Medical Devices Act, Cap 219.

Regulatory framework for medical devices and diagnostics are implemented through a range of Methods including assessment and issuing marketing authorization to medical devices and in vitro diagnostics through notification and registration, licensing of manufacturers, distributors, importers and exporters.

Others are control of import and export, control of promotion, inspections of manufacturing facilities (Quality audits) post marketing surveillance (PMS) and monitoring of safety and performance of medical devices and diagnostics on the market (Vigilance).

So far, over 6,439 low risk medical devices and diagnostics have been notified and 1,425 have been registered. A total of 111 and 9 overseas and local manufacturers respectively of medical devices and diagnostics have been audited since 2017.

Through a risk-based PMS programme a total of 1,643 samples have been collected and analyzed with regulatory decisions made on failed devices. Experience gained by TMDA in regulating medical devices and diagnostics in the past years enabled the Authority to strengthen the regulatory systems.

TMDA collaborates with MUHAS to conduct outreach program

Improving the quality of life of final consumers of pharmaceutical products need more awareness on the detection, identification, prevention and reporting of ADRs, Adverse Events Following Immunization (AEFI), Medication Errors (ME) and poor-quality products.

From this background, TMDA and Muhimbili University of Health and Allied Sciences (MUHAS) decided to embark on the outreach programme to create awareness.

Medications, biological products like vaccines and medical devices play a central role in the modern health care system.

However, these important pharmaceutical products have inherent characteristics which may render them producing unintended noxious events and/reactions. Events and/or reactions may occur even when pharmaceutical products are used at normal dose or as per manufacturer's recommendations.

The School of Pharmacy-MUHAS through Muhimbili-Bergen University Partnership to enhance pharmacy education and research (PEPER) project has been implementing various initiatives to assist the country in building PV capacity. Likewise, the role of TMDA in PV activities is one of the agenda.

This program is consumers' centred and uses sensitization approach through meeting with consumers at the waiting areas in their respective clinics. Healthcare providers are sensitized through their respective clinical meetings. As a way forward, the team would continue following up sensitized hospitals and roll out the program countrywide.

In the year 2019, the School of Pharmacy under this project in collaboration with TMDA instituted an outreach program. The awareness mainly based on imparting knowledge over the importance of detection, identifying, prevention and reporting of ADRs Consumers and HCPs were also briefed on various PV reporting tools such as yellow, green and blue forms, weblink https://imis.tmda.go.tz/arrt/, ADR reporting App, simple text message (by dialling *152*00#) or use of toll free number 0800110084.

The outreach programme has so far spread awareness to at least 5,000 consumers and 100 Healthcare providers on ADRs, AEFI, ME and poor-quality products through sensitization approach.

Other groups of stakeholders which were reached during the programme for sensitization include pharmacists, medical doctors, nurses and laboratory technicians. A total of 150 yellow forms have been filled in and 400 green forms were distributed to patients.

Facilitators sensitizing patients

So far, three healthcare facilities namely Temeke regional referral hospital, Muhimbili Orthopaedic Institute and Bagamoyo District Hospital of Dar es Salaam and Coast regions, respectively have been visited by a Team of facilitators consisted of TMDA employees, MUHAS academicians and MUHAS students undertaking Bachelor of Pharmacy Degree.

The team managed to solve ADRs related problems of 20 HIV-infected attending care and treatment clinics and those sensitized hospitals have shown massive improvements in reporting ADRs to the TMDA.

Outreach programmes help to expand access to health services such as health education, case management and basic health screening.

Post Marketing Surveillance of Medicines

TMDA continuously monitors and reviews the safety and quality of medicines circulating in the market inspire of meeting drug registration requirements.

Several factors may affect the quality and safety of pharmaceutical products which include but not limited to change in the manufacturing procedures, sources of raw materials, storage conditions, individual genetic variations or use of medicines in populations that were not involved in clinical trials.

Post Market surveillance (PMS) refers to the practice of monitoring quality, safety and efficacy of medicines circulating on the market after they have been registered. There are two approaches used to conduct PMS; Routine Drug Quality Assurance and Structured PMS Programme.

Existence of unofficial ports of entry and failure to adhere to the current Good Manufacturing Practices (CGMP) requirements are among factors contributing to presence of poor-quality medicines circulating on the Tanzanian market. In this regard, TMDA has been implementing PMS aiming at ensuring quality, safety and efficacy of medicines circulating on the market thereby protecting public health.

Since the resources are limited, TMDA has set criteria for selection of medicines to be monitored and regions for sampling in every PMS programme. So far, TMDA has implemented four PMS programmes from the year 2007 to date as shown in table 1 below;

Table 1: PMS programmes and types of medicines selected for monitoring

2007 – 2009	2011 – 2013	2014 – 2017	2017 – 2020
ARVs, anti-malarial, analgesics and Antibiotics	Anti-malarial Antibiotics Analgesics Veterinary Medicines (antibiotics)	Antibiotics, Antihypertensive, Analgesics, anti-diabetics, Antimalarials, Uterotonics, Antiprotozoals Veterinary Medicines (antibiotics, trypanocides, antihelminthics and antiprotozoals/anticoccidals)	Antihypertensive Statins Anti-diabetics Antibiotics Anti-malarial Antifungal Veterinary medicines (antibiotics, trypanocides, antihelminthics and antiprotozoals/ anticoccidals)

All sampled medicines are subjected to quality analysis and results get interpreted for regulatory decisions.

Recall of Substandard and Falsified Medicines

In the year 2020, a total of nine (9) substandard medicines (Table 1) and four (4) falsified medicines (Table 2) were identified circulating on Tanzania market. Among the nine (9) substandard medicines identified (Table 1), four (4) were antibiotics. Out of the four (4) falsified medicines listed below (Table 2), Gentrison cream and Sonaderm cream were also identified in the previous year.

Table 1: A list of substandard medicines identified and recalled from Tanzania market in the year 2020

S/N	Name, Batch No., Manufacturing & Expiring Dates	Description of the issue
1.	Sediton® Cough Lintus; *Batch No. SE901 up to SE916, Manufactured by Mansoor Daya Chemicals Ltd.*	*The product indication on the secondary pack (box) was written 'For treatment of upper respiratory tract 'injection' instead of 'infection''.*
2.	Gentamycin injection; *BP Batch No. V17231, Manufactured on 10/2017 by Vital Health Care Pvt Ltd.*	*Appeared to change colour from colourless to orange colour within the same batch.*
3.	Ketokant (Ketoconazole) 2% w/w; *Batch No.KE9021 & KE8008, Manufactured by SK S Kant Healthcare Ltd.*	*The secondary packaging materials of the batches had a brown colour of different intensities.*
4.	Hydrocortisone sodium injection; *Batch No. HC1701, Manufactured by Flagship Biotech pvt Ltd on 12/2017 and expires on 11/2020.*	*Color of reconstituted solution was creamy /cloudy instead of a clear solution. Also, formation of precipitates was observed*
5.	Spamox (Amoxicilline dry powder for suspension); *Batch No. X0861 and X0862 both with Mfg date 12/2018 and Exp date 11/2020. Also, Batch No. X0910, manufactured on 12/2019 and expires on 11/2021. All batches were manufactured by Sparsh Bio-Tech. Pvt Ltd, India.*	*Mould like formation (fungal growth) at the bottom of the primary packaging material (glass bottle).*
6.	Ferrous Sulphate + Folic Acid tablets; *Batch No. T95071 with Mfg date 10/2019 and Exp date 09/202, Manufactured by Agog Pharma Ltd, India and Distributed by Medical Stores Department (and had words 'msd' and 'GOT' on the secondary pack).*	*Colour change of the tablets, cracks formation and fungal growth.*
7.	MP-Clox (Ampiclox) powder for oral suspension; *Batch DC0011 Manufacturerd by Zenufa Laboratories Ltd, Dar es Salaam on 03/2020 and expires on 02/2022.*	*Fungal growth at the bottom and sides of the bottle.*
8.	Ampizen (Ampicillin) Powder for Oral Suspension; *Batch No. DA9004, Manufactured by Zenufa Laboratories Ltd, Dar es Salaam on 11/2019 and expires on 10/2021*	*Fungal growth at the bottom and sides of the bottle.*
9.	Sulphadar (Sulfadoxine 500mg and Pyrimethamine 25mg); *Secondary Pack (Box of 3's) had Batch No. 170011 manufactured by Shelys Pharmaceuticals Ltd on Mar, 2017 and expires on Feb, 2019.* *Primary pack (Blister Pack) had same batch no. and Mfg date except that, the expire date is Feb, 2021.*	*Inconsistence in expire dates information on Primary pack (Blister Pack) and secondary pack (box of 3's). The expire date on primary pack is Feb, 2021 while the secondary pack is Feb, 2019.*

Table 2: Identified falsified medicines and removed from Tanzania market in the year 2020

S/N	Name, Batch No., Manufacturing & Expiring Dates	Description of the issue
1	Chloroquine Phosphates 250mg; *Batch No.: 038908 with expire date Jan, 2022 purported to be manufactured by Keko Pharmaceutical Industries Limited.*	*Keko Pharmaceutical Industries Limited does not manufacture Chloroquine tablets.*
2	Gentrison cream 10g; *Batch No. GNTRO X030 with Mfg date 21st April, 2019 and expire date 20th April, 2022 purported to be manufactured by Shin Poong Pharmaceutical Company in South Korea.*	*No active pharmaceutical ingredient. The genuine one had batch no. GNTRO X030 with Mfg date 21st May, 2018 and expire date 20th May, 2021.*
3	Sonaderm Cream 10gm; *Batch No. A1912 with Mfg date Nov, 2019 and expire date Oct, 2021 purported to be Manufactured by Blue Cross Laboratories Pvt Ltd.*	*This was the same batch number from the previous findings in October, 2019. The only difference was the manufacturing and expire dates. The one discovered in Oct, 2019 had Mfg date Mar, 2019 and expire date Feb, 2021. The Manufacturer confirmed the batch was indeed not a product of their plant.*
4	Floxsafe 400 (moxifloxacin 400mg); *Manufactured by MSN Laboratories Limited, India. The primary pack had Batch no. BT1801080C, Mfg date Jan, 2018 and expire date Dec, 2019. The secondary pack had BT1902009C, Mfg date Feb, 2019 and expire date Jan, 2021.*	*Inconsistence of information* *The information on Batch Number, manufacturing date and expiry Date indicated on the primary and secondary packaging materials differs.*

TMDA uses different approaches to monitor pharmaceutical products circulating on the market and facilitates inspectors refreshers trainings annually. These trainings impart knowledge and skills of inspectors for undertaking their duties.

Importance of Vigiflow to Pharmacovigilance

VigiFlow is a web based Individual Case Safety Report (ICSR) data management which is used by national PV centre for collection, processing and sharing of data therefore facilitates data analysis.

VigiFlow is used by many national centers within WHO Program for International Drug Monitoring ("WHO PIDM") to store, analyse and share national data on suspected ADRs and AEFI.

Uppsala Monitoring Center (UMC) have an obligation as the WHO Collaborating Centre for International Drug Monitoring, to support the WHO PIDM with products and services to facilitate pharmacovigilance systems.

Reporting of ADRs to VigiFlow is facilitated by eReporting a standardized online ADR reporting form developed by the UMC to facilitate electronic reporting from consumers and HCPs.

Currently, there are 140 countries worldwide which have full membership of WHO PIDM including Tanzania mainland, and 31 countries with associate membership. Tanzania became a member of WHO – PIDM in 1993, and since then it is using the vigiflow to store and manage ICSRs. Therefore, VigiFlow is of paramount importance to TMDA and other PV centers as follows:

a) Collection of data concerning ADRs and AEFI hence following up on the cases reported

b) Simplify report management due to systematic data collection

c) Vigiflow support the processing of ICSR data.

d) It permits maximum local control and provides effective means of management review and analysis of national data concerning ADRs and AEFI.

e) Improve data entry options for ADRs and AEFI reports.

f) Possible to capture causality assessment results from different method.

g) Direct access to Vigilyze

h) Identification of signals

How to access VigiFlow

Web address: https://vigiflow.who.umc.org

Internship Experience at TMDA

During my internship at TMDA I have been able to improve my knowledge and skills in different areas including data analysis, evaluation, report writing, effective communication and leadership, commitment to assigned task, teamwork and above all self-discipline and getting things done.

This has truly been a great learning experience which has prepared me for whatever my next position will be as a pharmacist and I am forever indebted to those who gave me a hand.

To all future interns, remember to be friendly, work hard, and always be inquisitive.

Hopefully, you will enjoy your internship at TMDA as I did.

Ms. Jacquiline Frugence – Intern Pharmacist at TMDA

The Success of Pharmacovigilance Activities at Muhimbili National Hospital

Underreporting of ADRs is the main challenge in Sub-Saharan African countries.

The causes of under reporting include but not limited to uncertainty on what to report, lack of time, lack of reporting tools, lack of knowledge and poor attitude, motivation and lawsuit concerns.

Under-reporting negatively affects treatment outcomes of individuals and government economy at large through unnecessary use of limited healthcare resources.

Trainings and continuous education, willingness to participate in PV activities, easy access and availability of PV tools, been reported to increase accuracy and rate of reporting ADRs to regulatory bodies.

Improved spontaneous reporting at the Muhimbili National Hospital

In the past one-year, spontaneous reporting of ADRs has been revolutionized at Muhimbili National Hospital (MNH). The number of ADR reports submitted to TMDA have dramatically increased from 100 ADR reports in 2018 to 2,000 in 2019 and about 10,000 in 2020 (by August).

The following accounts for dramatic improvement in spontaneous reporting at MNH

(i) Training workshop conducted by TMDA in December, 2018 and thereafter continuous in-house training
(ii) Continues supervision and mentorship by TMDA
(iii) Willingness of MNH management to improve spontaneous reporting
(iv) Inclusion of spontaneous reporting in HCPs obligation (job description)
(v) Commitment of hospital chief pharmacist in improving spontaneous reporting
(vi) HCPs encouraged to report any suspected ADR, even if was common or mild in nature or uncertain
(vii) Sensitization of HCPs through clinical meetings
(viii) Stimulated Spontaneous Safety Monitoring conducted by TMDA in collaboration with MNH
(ix) Outreach program conducted by MUHAS students undertaking Bachelor of Pharmacy Degree in year three, aiming at increasing patient's awareness on the importance of reporting any suspected ADRs

Therefore, health care facilities are urged to adopt combined interventions to improve ADR reporting.

E-learning blended training

The TMDA is implementing PAVIA project to support strengthening of PV in the country. PAVIA is a synonym for Pharmacigilance Africa. This project is being implemented in four African countries; Ethiopia, Nigeria, Eswatini and Tanzania.

Through PAVIA project, TMDA organized a PV training using an e-blended-learning programme. The programme included lectures and self-study through e-learning which had two modules, "Basic concepts in Pharmacovigilance" and "Safety on anti-tuberculosis drugs" with more emphasis on new drugs for Multidrug Resistant-Tuberculosis. Tanzania was the first country among PAVIA countries to conduct this type of training. The facilitators for the training were from University of Verona in Italy.

The aim of this training was to impart PV knowledge to participants and prepare trainers who will be responsible for second level training in their respective working places.

In October, 2019 thirty-six (36) participants from various institutions including TMDA, Kilimanjaro Clinical Research Institute (KCRI), National Tuberculosis and Leprosy Programme (NTPL), Regional PV centres and MUHAS were trained and qualified as PV trainers.

To date, the qualified trainers have succeeded to enroll more than 350 participants and among them 105 participants have completed the course and received certificates. This has lead to an increased numbers of ADRs reports being received from healthy facilities.

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