TFDA
Tanzania Food & Drugs Authority

DRUG SAFETY Bulletin

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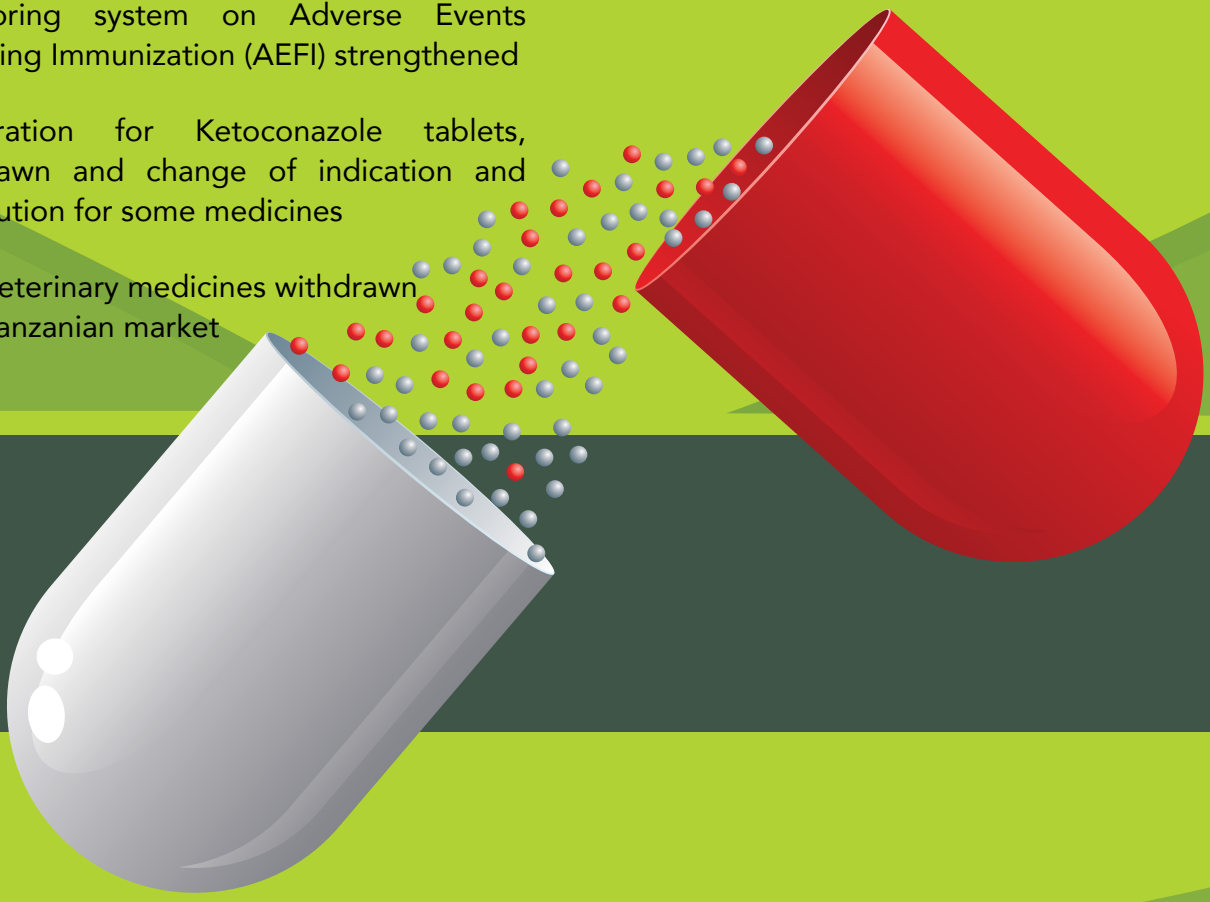

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Mission

To protect and promote public health by ensuring quality, safety and effectiveness of food, medicines, cosmetics and medical devices

Vision

To be the leading African Regulatory Authority in ensuring safety, quality and effective food, medicines, cosmetics and medical devices for all

Philosophy

TFDA strives to offer quality regulatory services in pursuit of protecting public health and environment by using competent and dedicated staff

Dear Readers,

It is my great pleasure to present to you the second issue of the TFDA Drug Safety Bulletin. The aim is to increase awareness on Adverse Drug Reactions (ADR) and Adverse Events Following Immunization (AEFI) amongst healthcare professionals and as well as to promote ADR/AEFI reporting.

TFDA's responsibility is to ensure availability of good quality, safe and effective medicines in the market purposely to protect public health. Monitoring of quality, safety and efficacy of medicines through Post Marketing Surveillance system (PMS) is highly performed by the Authority to minimize substandard and falsified medicines circulating on the market. Regulatory actions include suspension, recall, disposal, and withdrawal of unwanted products from the market.

In this issue of TFDA Bulletin, information on withdrawal of unfit medicines from the market and changes of indications for some medicines have been highlighted such changes of indication of Sulfadoxine + Pyrimethamin (SP), Kanamycin, Amikacin, Levofloxin and the use of SP from Over The Counter medicines (OTC) to Intermittent Preventive Treatment (IPT). Furthermore, information on the follow up of AEFI in the market, updates on spontaneous ADR reporting and initiatives undertaken by TFDA in collaboration with development partners to overcome the challenges of under reporting ADRs are accentuated.

I urge our esteemed stakeholders to take interest in reading the bulletin and give your advice, comments and opinion for our next edition.

Please enjoy,

Hiiti B. Sillo
Director General

Overcoming the problem of under reporting adverse drug reactions in tanzania: A new light under the tunnel

Monitoring of Adverse Drug Reactions (ADRs) is regarded as an important part of patient care in the healthcare system and public health programs and therefore a responsibility of both medicines regulatory authorities and healthcare professionals. It is a well-known fact that the burden of ADRs may affect full benefits of new medicines in treatment of diseases of public health importance. Therefore, ADRs have impact on the healthcare system due to morbidity, mortality, costs on their management, loss of confidence in the health system, non-adherence to treatment and development of drug resistance.

A system of reporting ADRs was established in Tanzania through prepaid forms commonly known as "yellow forms" scheme since 1989. However, limited knowledge on importance of monitoring and communicating ADRs and other drug related problems by healthcare providers and a less comprehensive pharmacovigilance system within Tanzania pose challenges to TFDA on obtaining safety information and make evidence based regulatory decisions on the registered medicines circulating in the market.

In efforts to overcome the problem of under reporting of ADRs, TFDA in June, 2013 collaborated with the Supply Chain Management Systems (SCMS) Project and came up with new strategies to overcome the challenges and improve the pharmacovigilance system in Tanzanias. The pilot project was developed in 2014, and tested at health facilities including hospitals, dispensaries, health centres, pharmacies and other medicine outlets in four (4) regions namely Tabora, Singida, Dodoma and Kigoma.

Among adopted approaches for the piloted regions included conduction of training to pool of trainers from various healthcare facilities and Public Health Programs (PHP), sensitizing Regional Health Management Teams (RHMTS), Council Health Management Teams (CHMTS) and other stakeholders so as to adopt their responsibilities in pharmacovigilance activities and Health Care Workers (HCWs) to implement those activities by conducting trainings, monitoring and supervisions at facility levels. It was also agreed to perform continuous education on budgeting and planning on pharmacovigilance activities at facility levels and ensure adequate distribution of tools and IEC materials parallel with close monitoring and supervision from TFDA. Adequate and prompt feedback from TFDA from the reports received was also emphasized as an important strategy to improve ADR reporting rates at all levels.

Project outcomes and impact

Todate, a total of 144 HCWs at health facilities were trained as Trainers of pharmacovigilance so as to train other HCWs at their facilities using every possible forums such as clinical meetings Pharmacovigilance activities were included in the supervisor duties conducted by HCWs in some regions with plans to be included in all other regions. Morever, supervision visits were done by TFDA in each quarter to oversee the implementation of pharmacovigilance activities and their respective tools were adequately distributed in all the selected facilities within the regions.

Out of 294 ADR reports received between September 2014 and July 2015 from 18 regions, more than 50% (154) originated from the 4 piloted regions (Table 1). Feedback of the reports from TFDA was done

to the reporters via phone calls, emails and letters. Stakeholders meetings were conducted to share experiences and challenges on implementation of pharmacovigilance activities in various health facilities.

Table 1: ADR reports received by TFDA from piloted regions from September 2014- July 2015

Region	RH	DH	HC	DISP	ADDO	PCY	Consumers	Total
Singida	7	9	-	4	-	1	-	21
Dodoma	19	17	1	1	-	1	3	42
Tabora	4	8	4	15	5	-	-	36
Kigoma	16	14	3	3	3	1	-	40
unknown								15
Total								**154**

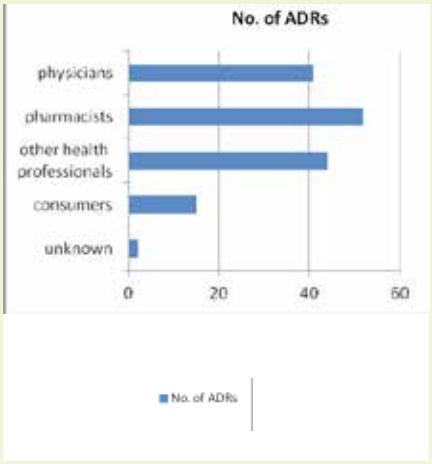
RH= Regional Hospital, DH= District Hospital, HC=Health Centre, DISP= Dispensary, ADDO= Accredited Drug Dispensing Outlets, PCY= Pharmacy

The reporting rate was observed to increase dramatically after the pilot project commenced from zero rate to as high as 42 reports per facility (figure 1). Much as the number of reports is still low compared to the number of inhabitants in these regions, it is quite an improvement in the management of patients in the Tanzania healthcare system.

Reporting of ADRs by profession

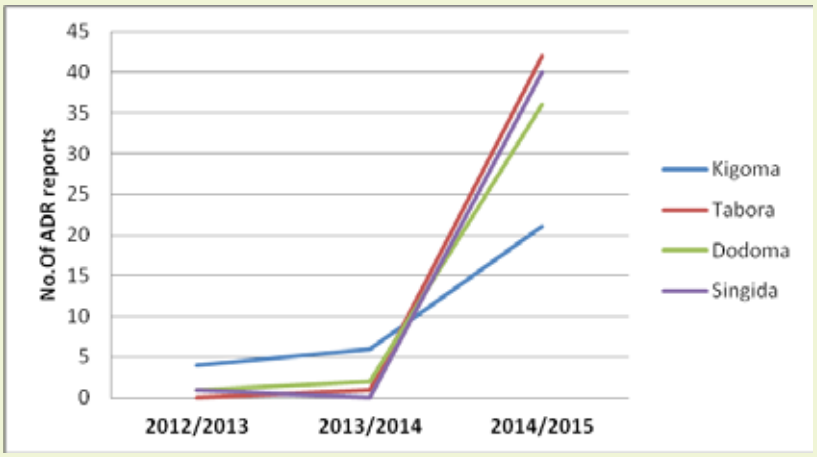
Results of this project indicate clearly that for Pharmacovigilance system to effectively work, multiple approaches should be used in implementation of respective activities. The later ought to be adopted at facility level including inclusion of pharmacovigilance agenda in the clinical meetings, frequent trainings by the trained HCWs themselves, involvement of therapeutic health councils, inclusion of pharmacovigilance in the supervision of health facilities, budgeting and planning of respective activities at facility level by inclusion of the activities in the Comprehensive Council Health Plan (CCHP). From the piloted regions, it is clear that active participation of all health professionals such as physicians, pharmacists, nurses and other health professional play a major role in boosting the reporting rate of ADRs (Figure 2)

Figure 2: Number of reported ADRs by HCPs



In conclusion proper communication channels and links between consumers, health professionals, Pharmacovigilance focal persons and TFDA is of paramount importance to bolstering reporting of ADRs and other health related problems in Tanzania. The efforts done in piloted regions need to be scaled up and replicated to other regions to be able to adequately monitor the safety of medicines registered in Tanzania.

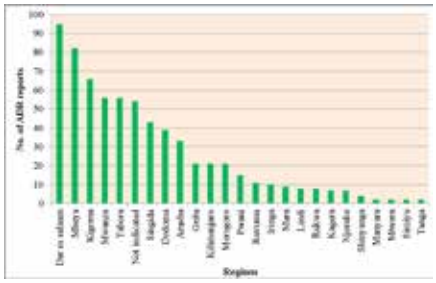
Figure1: Reporting trend of ADR reports in piloted regions from 2012-2015



Updates on spontaneous ADR reporting

TFDA has received a total of 674 Adverse Drug Reactions (ADR) reports in the period between July 2012 and June 2016 that met quality aspects and were entered into the vigiflow database. Among the 674 reports received, 409 (61%) were reports for female patients, 250 (37%) male patients while for the remainder 12 (2%) the sex was not indicated. The majority of them were reported by pharmacists 271 (40%), followed by other healthcare professionals 174 (26%), physicians 155 (23 %), consumers 32 (5%) and 42 (6%) of reporters did not indicate their profession. Most of the reports were from Dar es salaam 95 (14%), Mbeya 82 (12%), Kigoma 66 (10%), Mwanza 56 (8%) and Tabora 56 (8%) as shown in figure 1.

Figure 3: ADR reports received at TFDA and entered in vigiflow from July 2012-June 2016



The number of ADRs increased over the past four years from 83 reports in 2012/2013, 100 reports in 2013/2014, 294 reports in 2014/15 and 288 in the year 2015 /2016. Many ADRs reports were linked to antiretrovirals 304 (35%), antibiotics 270 (31%) and antimalarial 122 (14%). The most suspected drugs to cause ADRs differed in various years, have been shown in Table2.

Table2: Commonly reported medicines to cause ADRs in years 2013-2016

Year	Commonly reported Medicines	No. of reports
2012/2013	Artemether/ Lumefantrine	23
	Nevirapine	12
	Cidex (Activated Glutaraldehyde Solution)	11
	Co- trimoxazole	8
2013/2014	Lamivudine/ Zidovudine/ Nevirapine	16
	Artemether/ Lumefantrine	15
	chloramphenicol sodium succinate	11
	Co- trimoxazole	8
2014/2015	Lamivudine/ Zidovudine/ Nevirapine	30
	chloramphenicol sodium succinate	17
	Co- trimoxazole	17
	Artemether/ Lumefantrine	14
2015/16	Lamivudine/ Efavirenz/Tenofovir	34
	Sulfamethoxazole/ Trimethoprime	22
	Emtrictabine/ Efavirenz/Tenofovir	11
	Rubella/Measles vaccine	11

Of the 122 reports of antimalaria medicines, Artemether/ Lumefantrine (ALu) was reported 57 times. The reported reactions for the ALu were mostly skin and subcutaneous conditions (64.1%). However the safety profile of the medicine was still favourable. For antiretrovirals, 58 (19%) were linked to Efavirenz/ Lamivudine/Tenofovir and Efavirenz/Emtricitabine/ Tenofovir and 45 (14%) related to Zidovudine/Lamivudine/ Nevirapine. Generally, the ADRs observed in the ARVs combination were not new and had been documented in the literature (Table 3). Summary of the reported.

It was further noted that 50 % of ADRs related to Co-trimoxazole were serious. The reported ADRs were mostly reported by the people living with HIV/AIDS that use co-trimoxazole for prophylaxis. The ADRs could therefore been attributed to the underlying conditions and concomitant medication that were taken together with the prophylaxis. The reported ADRs were those involving skin and subcutaneous.

A total of 28 ADRs were received by TFDA in 2014 which were suspected to be related to Chloramphenicol sodium succinate injection. The ADRs reported only occurred from the product that was manufactured by Lincolin Pharmaceuticals Ltd. Of the cases reported 89.2 % were serious. Due to the fact that the ADRs reported are not in line with the pharmacology of the drug, positive de-challenge for 2 cases and the fact that the events occurred in one brand only the product was withdrawn from the market for further analysis for root cause of the problem. Laboratory

analysis concluded that the product had quality issues which required intervention by the manufacturer. The Authority decided to cease the use of chloramphenicol injection from Lincoln Pharmaceuticals. This decision does not affect other brands of chloramphenicol injection from other manufacturers. In the meantime the Authority continues to closely monitor all chloramphenicol products in the market to ensure that the safety profile continues to be favourable.

Table 3: ADRs reported by commonly reported medicines July 2012- June2016

Medicine	Reaction	No. of reactions
Artemether + Lumefantrine	Skin and subcutaneous conditions	38
	Fever	4
	Vomiting	3
	Palpitations	3
	weakness	2
	Others (frequency of one case)	7
Lamivudine/Zidovudine/ Nevirapine	Skin and subcutaneous conditions	28
	Generalized swelling	4
	anaemia	2
	Headache	2
	Peripheral neuropathy	2
	Others (frequency of one case)	7
Co- trimoxazole	Itching	11
	Rash	10
	Steven Johnson's syndrome	5
	Oral ulcerations	2
Chloramphenicol sodium succinate	Difficulty in breathing/ Dyspnoea	15
	Chest tightness/pain	5
	Anaphylactic reaction	5
	Palpitations aggravated	3
	Excessive sweating	3
Cidex (Activated Glutaraldehyde Solution)	Headache	3
	Eye irritation	2
	Throat irritation	2
	Burning sensation	2
	Muscle spasticity	1
	Pain in face	1
	Upper respiratory tract infection	1
	Chest pain	1

Cidex (Activated Glutaraldehyde Solution) that is used to sterilize medical equipment was reported by one facility to cause ADRs such as skin irritation, eye irritation and respiratory problems. The ADRs occurred to the healthcare staff performing the sterilization process. It should be noted that the manufacturer clearly indicated that precautions should be taken when handling cidex and contaminated instruments by wearing protective gear that includes gloves, eye protection and fluid-repellent gown. Precautions should therefore be taken to avoid unnecessary ADRs from occurring when handling products that are toxic and appropriate training should be done to the personnel handling the products.

Some of the ADRs reported are consistent with those provided with the manufacturer during market authorisation and some are new or unexpected. Consolidated reports from various healthcare workers can be used to make regulatory decisions that are evidence based. Each report is therefore very important to be able to establish the safety profile of a particular medicine. Healthcare workers therefore play an important role in providing information on safety of medicines during their daily practice. TFDA therefore urges all stakeholders to provide reports as soon as they occur to assist in making regulatory decisions regarding the products circulating in the market.

Monitoring system on AEFI strengthened

Adverse Event Following Immunization (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.

AEFIs may occur due to various factors related to vaccine product, quality defect, immunization error, immunization anxiety and could be coincidental. All vaccines used under the national immunization program are of good quality, safe and effective. However, it is well known that no vaccine is completely without risk and adverse events even if administered appropriately.

In view of this, measures still need to be put in place to monitor and prevent occurrence of these events. Moreover, since there have been introduction of other new vaccines in the routine immunization program such as Measles and Rubella (MR), Human Popillomavirus (HPV), Rotavirus vaccine and pneumococcal vaccines, there is a need of active monitoring of AEFI from these products.

In order to detect, evaluate, manage, prevent and respond efficiently safety issues related to vaccines, TFDA in collaboration with Immunization and Vaccine Development Programme (IVD) and the World Health Organisation (WHO) have put in place measures to strengthen the AEFI Surveillance system. Among the measures which were set are development of respective guidelines on AEFI and capacity building to important stakeholders including TFDA staff.

Development of Guidelines for Surveillance of AEFIs

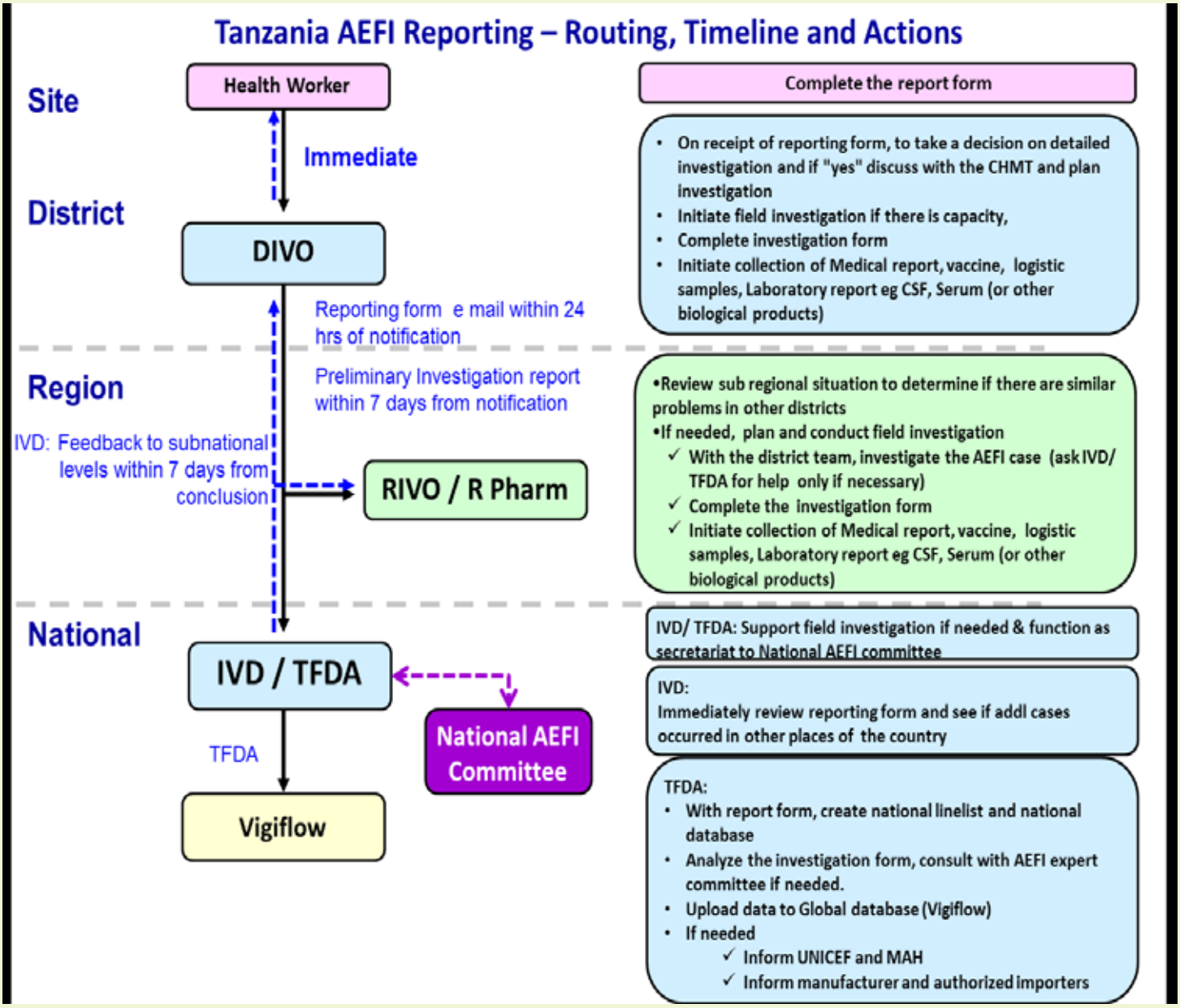
These guidelines which were established in December 2014, highlight the concept of vaccines and AEFI, prevention and management of AEFIs, reporting structure of AEFI, overview of AEFI causality assessment, actions and responses towards AEFI and communication and media management. They are intended to be used by Healthcare workers, Immunisation officers, vaccines manufacturers, Laboratories, IVD and TFDA.

Capacity Building

In August 2014, the WHO in collaboration with TFDA and IVD organised training to TFDA staff, IVD staff, AEFIs members and healthcare workers to increase their understanding and skills in monitoring and assessment of AEFIs during immunization. In addition, the training program's objectives were to establish communication links on vaccine safety issues among health care workers, IVD and TFDA; to identify roles and responsibilities of various stakeholders, as well as to enhance national capacity for AEFI data analysis and data management.

Various stakeholders for Pharmacovigilance during one of the training for monitoring medicine safety in Tanzania

Figure 4: AEFIs Reporting System in Tanzania



Outcome

Since introduction of these initiatives, TFDA has been able to receive for the first time 22 AEFI case reports from five regions namely Mwanza, Arusha, Dodoma Iringa and Kigoma during the Measles Rubella (MR) campaign conducted in October 2014. Among the case reports,12 (54%) were received from Mwanza region, 5 (23%) from Arusha, 3 (14%) from Dodoma, 1 (4.5%) from Iringa region and 1(4.5%) from Kigoma region. The reported AEFI cases included facial and body rash, itching, swelling at the injection site, fever, running nose, vomiting and general body malaise. All cases were associated with vaccines but were basically not serious.

Withdrawal of registration of ketoconazole tablets and change of indications and distribution for some medicines

Introduction

One of the core functions of TFDA in executing its duties is to evaluate regulated products' informations including medicines' applications before registration and marketing authorization. TFDA continuously monitors and reviews the safety and quality of medicines even after marketing authorization despite the fact that the products did meet safety, quality and effectiveness parameters during registration. This is due to the fact that product's quality and safety may change after registration due to several factors such as changes in the manufacturing procedures, sources of raw materials, storage conditions, differences in genetic makeup of some individuals and also use of medicines in populations that were not involved in clinical trials to just name a few.

Between 2013-2015, Ketoconazole tablets and several other medicinal products were withdrawn from registration due to changes of their safety profiles. Furthermore, there are several products whose indications have been reviewed and changed for safety and efficacy reasons as indicated hereunder.

Withdrawn Ketoconazole tablets

Ketoconazole is a broad spectrum antifungal medicine that has been used for a long time as first line treatment of fungal infections and was also registered in Tanzania for the same indication. In 2013 several reports of increased liver injury that led into liver transplantation or death from various countries led to the conclusion that the risk of liver injury outweighs the benefit of treatment of fungal infections. Moreover oral ketoconazole was also known to cause other serious adverse reactions such as adrenal insufficiency and several known drug interactions. In view of this it was recommended that other alternative antifungals with less safety issues should be used and therefore discourage the use of oral ketoconazole. Based on the recommendations from the WHO and accumulated data on liver hepatotoxicity from other countries, in 2014 TFDA decided to withdraw registration of all oral ketoconazole products from the market.

A total number of 18 ketokonazole oral dosage forms in tablets that were registered in Tanzania by various manufacturers were withdrawn from the market (Table 4). Consequently importation, distribution, sale and use of such formulations has been prohibited. However, these restrictions do not apply to other dosage forms of Ketoconazole such as topical preparations i.e creams, ointments, lotions and shampoossince they do not have any adverse drug reactions due to their route of administration. These formulations will therefore continue to be available in Tanzania market.

Table 4: Oral ketoconazole products withdrawn from registration in Tanzania

S/N	Medicine name and manufacturer
1.	Nizoral Tablets manufactured by Janssen Pharmaceutica N.V, Belgium,
2.	Nizoral, Kezole Tablets manufactured by Intas Pharmaceuticals Limited, India,
3.	Ketrozol Tablets manufactured by Remedica Limited, Cyprus,
4.	Ketrozol, Tinuvin Tablets of Medochemie Limited, Cyprus,
5.	Antanazole Tablets manufactured by Shin Poong Pharmaceutical Co. Limited, Korea,
6.	Ketarin Tablets manufactured by Flamingo Pharmaceuticals Limited, India,
7.	Kezole Tablets manufactured by Keun Wha Pharmaceuticals Co. Ltd, Korea,
8.	Nidrox Tablets manufactured by Caps Rallis Private Limited. Zimbabwe,
9.	Ketozol Tablets manufactured by Kunwoong Pharmaceutical Co. Limited. Korea,
10.	K- Zole Tablets manufactured by Shelys Pharmaceuticals Limited, Tanzania,
11.	Phytoral Tablets manufactured by Micro Labs Limited, India
12.	Ketoral Tablets manufactured by Bilim Pharmaceutials A.S, Turkey,
13.	Ketocoze Tablets manufactured by Seoul Pharma.Co.Limited. Korea,
14.	Dermizol Tablets manufactured by Astralifecare (India) Private Limited, India,
15.	Ketovid Tablets manufactured by Hovid Bhd. (Ipoh Plant), Malaysia,
16.	Konazol Tablets manufactured by Lincoln Pharmaceuticals Limited India,
17.	Ketovate Tablets manufactured by Bal Pharma Limited, India and
18.	Ketoconazole Tablets manufactured by Zhejiang Holley Nanhu Pharmaceutical Co. Limited, China

Withdrawal of Solid and liquid preparations containing Amodiaquine as monotherapy

Monotherapy means treatment with a single medicine (either a single active compound or a synergistic combination of two compounds with related mechanism of action). Several products containing amodiaquine as monotherapy were registered in Tanzania for treatment of plasmodium falciparum malaria. However, it has been demonstrated over the years that the use of monotherapies for treatment of malaria lead to parasites resistance and therefore resulting in ineffectiveness of the medicines in the treatment of this disease which has a high public health risk. The WHO recommends to cease manufacturing and registration of oral antimalarial monotherapies in favour of fixed dose combination (FDC) antimalarial medicines in countries where malaria is endemic.

Considering the rapid increase in resistance of malaria parasites to several monotherapy antimalarial medicines and the data from the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) that Amodiaquine resistance has reached an average of 11.5% (from 6.3 to 18.2%) after five years of introduction in Tanzania as a second line treatment for malaria, the 2013 Policy and Standard Treatment Guidelines for Malaria was reviewed to exclude amodiaquine as a second line treatment. It was recommended Artemesinin based Combination Therapies (ACTs) should be used as first line treatment of malaria.

Consequently, TFDA decided to withdraw registration of all monotherapy solid and liquid preparations containing Amodiaquine. A total number of 7 Amodiaquine brand were de-listed from the database of registered products (Table 2). Formulations containing Amodiaquine as a combination with other antimalarials such as artesunate are not restricted for registration since they do not pose a risk of resistance.

Table 5: Amodiaquine monotherapies withdrawn from registration in Tanzania

S/N	Medicine name and manufacturer	Manufacturer
1.	Amobin Tablets manufactured	Regal Pharmaceuticals Limited
2.	Emoquin Suspension manufactured	Elys Chemical Industries Limited
3.	Emoquin Tablets manufactured	Elys Chemical Industries Limited
4.	Amodar Suspension manufactured	Shelys Pharmaceuticals Limited
5.	Amodar Tablets manufactured	Shelys Pharmaceuticals Limited
6.	Laeoquin Suspension manufactured	Laboratories & Allied Limited and
7.	Malaridose Tablets manufactured	Zenufa Laboratories (T) Limited ,

Review of indications and Changes in use of SPs

Sulphadoxine/ Pyrimethamine and Sulphamethopyrazine/ Pyrimethamine (SPs)

It has been well established that the use of SPs in treatment of malaria has lead to high resistance of parasites against these medicines. In Tanzania the parasite resistance to SPs went as high as 25.5% in the sentinel sites (Range from 7.8 to 60.5%). Based on the fact, the MoHCDGEC decided that the use of SPs should be limited to Intermittent Preventive Treatment (IPT) of malaria in pregnancy. In this regard, TFDA reviewed SP indications in accordance with National directives through the Ministry. Furthermore, all the manufacturers were directed to revise the prescribing and patient information to reflect these changes.

Change in use of Medicines containing Kanamycin, Amikacin and Levofloxacin

Aminoglycosides are group of antibacterials used for the treatment of various Gram-negative bacteria. In order to prevent and delay emergence of resistance by bacteria causing Tuberculosis disease, the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) restricted the use of these medicines containing Kanamycin, Amikacin and Levofloxacin for treatment of Tuberculosis only to designated hospitals, health centres and dispensaries with effect from January, 2015.

TFDA will continue to evaluate the quality of these products and provides the public with all updates regarding the safety and efficacy of these medicines.

UNFIT VETERINARY MEDICINES WITHDRAWN FROM TANZANIA MARKET

In executing its mission of protecting and promoting public health, TFDA has established regulatory systems in ensuring quality, safety and effectiveness of veterinary medicines which include registration process including laboratory analysis, good manufacturing practice (GMP) inspection and post-marketing surveillance (PMS) on quality aspect. Through PMS program, TFDA collects samples of medicines from various regions and conduct thorough investigational analysis to confirm if they maintain their standards after being registered in the country.

Unfit veterinary medicines are liable to endanger health of the treated animals due to resistance to some animal diseases; toxicity and even death hence eventually jeopardize public health and aggravate poverty.

As per available data, samples of three different types of veterinary medicine namely Diminazene injection, Isometamidium chloride hydrochloride injection and Homidium injection for treatment of Trypanosoma were collected in 2012/13 in order to assess their quality status in the Tanzanian market. The samples were collected from five regions namely Arusha, Mbeya, Kigoma, Lindi and Shinyanga and were analysed for amount of Active drug content present. The outcome of the laboratory tests provided acceptable results, whereby 77% of diminazene samples passed the test and 100% of tested samples of Isometamidium and Homidium also passed the test. These results suggest that veterinary medicines of such category which are available in the market are of acceptable quality.

Moreover in 2014/15 and 2015/16, Abendazole oral suspension samples manufactured by 20 different manufacturing companies were collected from five regions namely Dodoma, Kilimanjaro, Mwanza, Mbeya and Dar es Salaam and analyzed. The analytical results revealed that four (4) samples manufactured by three different companies found to contain low levels of active ingredient to the extent of 10 - 82.9% contrary to the acceptable standard of 90-100%. As a result these products were withdrawn from the market. The findings were communicated to the Marketing Authorization Holders for further investigation on manufacturing processes and eventually provide corrective and preventive measures.

Table 6: Substandard Albendazole oral suspension withdrawn from the markets

S/N	Product name	Batch/Lot number	Manufacturing date	Expiry date	Manufacturer
1	ALBEN Blue 2.5% Oral suspension	14405	01/07/2013	01/06/2015	Vetagro and Pulpers Co. Ltd, Kenya
2	Albendazole 2.5% Oral suspension	1209095	01/04/2013	01/04/2016	Bajuta International, Tanzania
3	Ashialben 10% Oral suspension	ALS-2084	01/07/2015	01/06/2016	Ashish Life Science PVT Ltd, India

Similarly, two (2) unregistered Veterinary Albendazole oral suspension manufactured by Asia Animal Health of unknown country were discovered circulating in the market and were also confirmed to be substandard, and were confiscated and destroyed by TFDA.

Table 7: Unregistered and substandard Albendazole oral suspension confiscated

S/N	Product name	Batch/Lot number	Manufacturing date	Expiry date	Manufacturer
1	Albendazole 2.5% Oral suspension	7345	01/03/2015	01/05/2019	Asia Animal Health Ltd,
2	Albendazole 2.5% Oral suspension	7403040	01/03/2015	01/03/2019	Asia Animal Health Ltd,

Ongoing analytical investigation of veterinary medicines

Three types of veterinary medicines namely Amprolium powder for reconstitution, Diminazine injection and Levamisole powder for injection are currently undergoing investigational analysis as part of continuous PMS programme for veterinary medicinal products circulating in Tanzanian market. The primary objective is to ensure that veterinary medicines continue to maintain their quality standards throughout their registration lifecycle.

Future plans

Through the PMS programme, TFDA plans to extend coverage of sample collection to include more categories of medicines, to reach more regions in the country and to perform analytical investigations. The ultimate results will be used in decision making processes including withdrawal of substandard products from the market.

TANZANIA FOOD AND DRUG AUTHORITY

TFDA
Tanzania Food & Drugs Authority

A USER GUIDE TO ELECTRONIC SYSTEM FOR REPORTING ADVERSE DRUG REACTION

Introduction

The Tanzania Food and Drugs Authority (TFDA) has established an electronic system for reporting Adverse Drug Reaction (ADR) was launched on 12th October 2016.

How can you access the e-reporting tools for ADR?

Access to the tool by using a Computer connected to the internet

The tool is accessed through the link http://www.tfda.go.tz/adr/. Three forms will be displayed appearing in green, yellow and blue.

	A form for consumer reporting of suspected ADRs
	A form for reporting suspected ADRs by healthcare providers
	A form for reporting poor quality

Access to the tool by using a mobile phone connected to the internet

The smart phone (android app) can be downloaded from 'play store'andinstalled on the phone. A few steps below provide a simple way to get the tools installed on the phone;

1	Go to 'Play Store' item on the phone	
2	Search for 'ADR Reporting Tool'	
3	Select and accept the 'TFDA Reporting'	

4	Install the application	
5	Open the installed application	
6	Get onto the tool's displaying the three forms	Reporting by Consumers Reporting by HealthCare Workers Reports of Product Quality Products

The Minister of Health, Community Development, Gender, Elderly and Children, Hon. Ummy Mwalimu seated (at the centre) with other staff from TFDA, University of Dodoma and MUHAS during the launching of electronic system for reporting Adverse Drug Reaction which was held at TFDA venue on 12th October 2016.

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