



PHARMACOVIGILANCE/POST MARKETING SURVEILLANCE NEWSLETTER

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Circulation of Falsified Antimalarials and Antibiotics in Sub-Saharan Africa

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EDITOR'S

We wish to thank all our numerous stakeholders who have been working tirelessly with the National Pharmacovigilance Centre (NPC) to ensure the safe use of medicines in Nigeria. The NPC is committed to making quarterly newsletters available to its stakeholders. The objectives of the Newsletter are to disseminate information on Pharmacovigilance activities nationally and globally, to educate stakeholders on medicine safety issues, to promote rational use of medicines and reporting of Adverse Drugs Reactions (ADRs). This edition of the newsletter focuses on circulation of falsified antimalarials and antibiotics in sub Saharan Africa.

We encourage Health care Professionals and other stakeholders to continue to report all adverse drug reactions. Your valued comments and acknowledgement of receipt of this issue through our email addresses (nafdac_npc@yahoo.com; pharmacovigilance@nafdac.gov.ng, fdic@nafdac.gov.ng) would be most appreciated.

Thank you for your relentless efforts towards strengthening Pharmacovigilance System in Nigeria.

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Text any DRUG RELATED PROBLEM to the SHORT CODE 20543 (For free on MTN, Glo, Etisalat and Airtel) for action by the Pharmacovigilance Centre.

CIRCULATION OF FALSIFIED ANTIMALARIALS AND ANTIBIOTICS IN SUB-SAHARAN AFRICA

Overview

The attention of the National Agency for Food and Drug Administration and Control (NAFDAC), has been drawn to the circulation of falsified antibiotics and antimalarials within sub Saharan Africa countries including Nigeria. The falsified antimalarials and antibiotics include falsified Penicillin-V which was found in circulation in South-West Cameroun, falsified Costrim, Metronidazole, Domiquine, Catrim, Cemtrim 480 and Citrim 480 tablets manufactured by Mr. Emeka Madu (aka. Cabara) in Ikotu Lagos, Nigeria

The manufacture and distribution of falsified medicines is driven by factors such as extreme profits from distribution and sale of falsified drugs; difficulty in detecting falsified drugs from genuine drugs and modest penalties that usually do not serve as deterrent

The World Health Organisation (WHO) defines a falsified medicine as one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Falsification applies to both generic and branded products which are either imported/ smuggled or locally manufactured within a country.

Burden of falsified medicines

Falsified medicines usually do not have the same quality and efficacy as their genuine counterparts. They may contain toxic substances which make them unsafe.

Treatment with such products pose harm to public health in terms of human suffering and burden on health services as patients may not respond to such treatment at all or response may be slow. Also, the toxic substances contained in some falsified medicines may cause serious harm to health or exacerbate the conditions being treated.

Treatment with falsified medicines may have deleterious effect on the population when it involves medicines with widespread use.

The use of falsified medicines may result in patients and care givers loss of confidence in healthcare systems and healthcare professionals. There may also be loss of confidence in the suppliers and sellers of the genuine drugs, the pharmaceutical industry as a whole and even in the National Medicine Regulatory Authority.

Factors facilitating spread of falsified Medicines

The production and trade in falsified medicines is widespread, affecting both developing and developed countries. However, the spread of falsified medicines is generally more pronounced in those countries where the manufacture, importation, distribution, supply and sale of medicines are less regulated and enforcement may be weak.

In sub-Saharan Africa, the circulation of falsified medicines is encouraged by factors such as:

- Porous borders
- Chaotic medicine distribution systems that encourage infiltration of falsified medicines

- Poverty
- Poor healthcare delivery systems

Detection of falsified Medicines

Detection of falsified medicines is a complex task because they are deliberately manufactured to pass for the genuine counterparts. This is further complicated in a clime with complex distribution channels, extreme storage and market conditions.

In a bid to detect falsified medicines and protect patients from harm due to their use, NAFDAC deployed the Mobile Authentication Service (MAS) requiring manufacturers to include a scratch PIN on their products. Consumers are to use the PIN to confirm the genuineness of medicines before purchase. The Agency has commenced the enforcement of this requirement as mandatory for all antibiotics and antimalarials marketed in Nigeria.

The United States Pharmacopoeia through Promoting the Quality of Medicines (PQM) Program has been working with NAFDAC to develop and apply science-based, cost-effective, and customized solutions for testing and monitoring the quality of some pharmaceutical products in circulation in Nigeria thereby strengthening Post Marketing Surveillance. The approach involves checking of quality at all stages of distribution of medicines.

NAFDAC with Support from USP has conducted six (6) rounds of Quality survey on some medicines in circulation in Nigerian. The result of the 5th round was presented on 13th March 2019, the result of the 6th round has been prepared and will be disseminated before the end of third quarter of 2019.

Nigeria is a participant in the WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products. The system aims to work with WHO Member States to improve the quality of reporting of substandard and falsified medical products, and, importantly, to ensure the data collected are analysed and used to influence policy, procedure and processes to protect public health, at the national, regional and global level.

Curbing the trend

A standardized distribution system is a major tool in limiting the spread of falsified medicines. Distribution activities are carried out by manufacturers, importers, wholesalers/distributors, retailers and other persons authorized to supply pharmaceutical products in the public and private sectors. Therefore, all these parties are key players in ensuring that falsified medicines are kept out of the system.

A Sustainable approach to Post-Marketing Surveillance is necessary to limit the proliferation of falsified medicines in the distribution system. Consequently, NAFDAC has been working with relevant partners to strengthen PMS, through development of procedures, guidelines and capacity building of personnel.

The NAFDAC Good Distribution Practices (GDP) Guidelines was developed in 2016 as part of the Agency's effort to standardize the Drug distribution system in Nigeria. The GDP guidelines provide appropriate tools to assist all categories of distributors in conducting their activities in order to

maintain the quality of pharmaceutical products and prevent falsified medicines from entering the legal supply chain.

Furthermore, NAFDAC has been advocating for stiffer punishments for counterfeiters to serve as a deterrent. NAFDAC has presented a bill before the National Assembly seeking increased punishments for illicit and falsified drug dealers. The Agency proposed a life jail term to serve as deterrent to unrelenting offenders.

Conclusion

Circulation of Falsified medicines is a potential threat to patients, healthcare systems and public health programs that rely on use of medicines with lifesaving therapeutic effects. It is very difficult to detect falsified medicines that are almost visually identical to the genuine products. However, some can be identified by:

- Carefully examining the packaging for spelling mistakes or grammatical errors.
- Ensuring there is English translation for medicines labelled in foreign languages because NAFDAC requires manufacturers to ensure that there is English language translation on label of products intended for the Nigeria market.
- Checking the manufacturing and expiry dates and ensuring any details on the outer packaging match the dates shown on the inner packaging

- Ensuring that the manufacturer's location address is stated on the packaging
- Ensuring the medicine is not discoloured, degraded or has an unusual odour
- Discussing 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

Consumers are encouraged to carefully observe the packaging of medicines and other regulated products before purchase, any concerns about the physical appearance of the products should be reported to nearest NAFDAC Office.

References

1. Increase Capacity to Detect Falsified, Substandard, and Unapproved Medical Products <https://www.usp-pgm.org/what-we-do/increase-capacity-to-detect-falsified-substandard-and-unapproved-medical-products> viewed 16/07/2019
2. WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products <http://apps.who.int/medicinedocs/en/m/abstract/Js23373en/>
3. Substandard and falsified medical products <https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products>

Public Alerts on Falsified Antibiotics and Antimalarial Medicines placed on NAFDAC website

The National Agency for Food and Drug Administration and Control (NAFDAC) alerts members of the public on the illegal manufacturing, distribution and sale of falsified Costrim tablets, Metronidazole tablets, Domiquine tablets, Catrim tablets, Cemtrim 480 tablets and Citrim 480 tablets by one Mr. Emeka Madu (aka Cabara). These products are falsely labelled with the names of different manufacturers and falsified NAFDAC Registration Numbers to deceive unsuspecting members of the public.

The illegal manufacturing by Mr. Emeka Madu took place in an uncompleted and dilapidated twin building in a very filthy environment at Ikotun, Lagos. The Inspector-General of Police Intelligence Rapid Team (IGP-IRT) discovered the illegal manufacturing following a tip from an informant. NAFDAC and the Police jointly visited the production site where samples were taken for testing and processing. The site or the drugs were not registered by NAFDAC.

Table:1, shows the details of the public alert No. 004/2018 on falsified medicines illegally manufactured by Mr. Emeka Madu (aka Cabara) are:

Table1: Falsified medicines (public alert No. 004/2018) illegally manufactured by Mr. Emeka Madu (aka Cabara)

S/N	Falsified Product Name	Batch Number	Manufacturing Date	Expiry Date	Name & Address of Manufacturer on the Falsified Product	Falsified NAFDAC Registration Number
1.	Costrim Tablets	CST 530	01/2017	12/2020	Coslin Pharma & Chem Ltd, Km 68 Akinola Street, Sango-Ota, Ogun State	04-0546
2.	Metronidazole Tablet	009	02/2018	01/2021	Citicare Lab Ltd, Plot 56 Ire-Akari Estate, Owode, Ifo, Ogun State	02-3055
3.	Domiquine Tablet	117	06/17	05/2021	Dominion Lab, Plot 21 Agbara Industrial Layout, Ogun State	04-4083

4.	Catrim Tablet	CPC 104	Feb. 2017	03/2020	Calion Pharm & Chem Ltd, Omotayo Street off Admin Staff College of Nigeria, Topo-Badagry, Lagos	04-4754
5.	Cemtrim 480 Tablet	542	08/2017	07/2021	Clegs Pharm Ltd, Plot 84 Eniola Estate, Agbara Industrial Layout, Agbara, Ogun State	04-3844
6.	Citrim 480 Tablet	CLL 6702	03 18	02/2021	Citicare Lab Ltd, Plot 56 Ire-Akari Estate, Owode, Ifo, Ogun State	04-0495

The use of falsified medicines (such as Costrim tablets, Metronidazole tablets, Domiquine tablets, Catrim tablets, Cemtrim 480 tablets and Citrim 480 tablets) may result in treatment failures, development of drug resistance or even death.

The Agency has sealed up the illegal manufacturing outfit and confiscated the falsified products

NAFDAC implores distributors, wholesalers, retailers, healthcare providers, program managers and other members of the public to be vigilant and report anybody in possession of any of these falsified medicines to the nearest NAFDAC office.

Consumers are advised to report adverse events related to the use of any of these products to the nearest NAFDAC office, NAFDAC PRASCOR (20543 TOLL FREE from all networks) or via pharmacovigilance@nafdac.gov.ng

Public Alert No: 07/2018 on Falsified Augmentin Products Circulating in Cameroun is also on the NAFDAC website to alert members of the public.

Genuine Augmentin (Amoxicillin + Clavulanic acid) is used to treat a range of bacterial infections and is listed as a WHO Essential Medicine.

The existence of the falsified Augmentin was reported to WHO in early 2018 by a Non-Governmental Organization (NGO) in Table 2. The NGO reported that this product was available at patient level in a street market of Douala, Littoral Region, Cameroun. Samples were sent for quality-assurance laboratory testing and the result shared with WHO. The result of analysis did not identify any of the expected active ingredient.

The packaging of the falsified product appears to be a close imitation of the genuine product manufactured by GSK (GlaxoSmithKline), although there are some mistakes on the packaging

inscription. The source(s) of the falsified product has not yet been identified.

The stated manufacturer (GSK) has confirmed they did not manufacture this falsified version.

Table2: Falsified Augmentin Products (Public Alert No: 07/2018) Circulating in Cameroun

Product Name	Augmentin (Amoxycillin+ Clavulanate potassium)
Batch Number	562626
Expiry Date	MAY 2019
Manufacturing Date	MAY 2016
Declared active ingredient	500mg Amoxycillin Trihydrate E.P 125mg Clavulanate Potassium B.P
Stated Manufacturer	GSK GlaxoSmithKline

PHOTOGRAPHS OF THE FALSIFIED VERSION OF AUGMENTIN



NAFDAC advises wholesalers, distributors and retailers to obtain their medicines from authentic and reliable sources. Increased vigilance is hereby encouraged within the supply chain to avoid infiltration by falsified products.

NAFDAC implores healthcare providers to ensure vigilance to prevent the administration of the falsified product to unsuspecting patients.

Healthcare providers and the general public should notify the nearest NAFDAC office of any information concerning the distribution, sale and use of the falsified Augmentin product.

Report of Round Five (5) Survey on the Quality of Antimalarial Medicines in Nigeria presented by Pharm. Ali Ibrahim fsi (NAFDAC) and Pharm. Mopa Esuga (USP) on 13th March, 2019 at NAFDAC Central Laboratory Complex, Oshodi,

Background of Medicines Quality Monitoring (MQM) in Nigeria

The scourge of malaria remains a huge threat to tropical countries in Sub-Saharan Africa including Nigeria.

In Nigeria, malaria contributes an estimated 11% of maternal mortality and accounts for 60% of out-patient visits, 42% of hospitalizations among children under the age of five (5) with a prevalence of 50% reported in 6-59 months age group.

Prior to 2001, it was reported that 40% of medicines circulating in the Nigerian pharmaceutical supply chain were either substandard, fake or counterfeited (Ogundipe 2011, Bate et al 2009)

According to studies conducted by NAFDAC from 2001 - 2014, there has been a positive trend showing progressive decrease in the counterfeit medicines in Nigeria.

A study conducted in 2005 by NAFDAC in collaboration with WHO and DFID showed a remarkable decrease in circulation of counterfeit medicines from 40% in 2001 to 16.7% in 2005.

The study on the quality of selected antimalarial medicines circulating in Sub-Saharan Africa (QAMSA) in 2008 revealed that Nigeria had a failure rate of 64% whilst 36% passed.

The National Survey on quality of medicines using the Truscan device conducted by NAFDAC across 29 states including the FCT from January 2010 to April 2012 revealed a failure rate of 19.6% for antimalarial medicines.

The MQM program implemented by USP ensures regular monitoring of the quality of antimalarial medicines circulating in the Nigerian market.

NAFDAC in collaboration with NMEP and USP conducted Round 1 survey on the quality of antimalarial medicines in Nigeria in 2014. The report of Round 1 survey presented to stakeholders on 11th August, 2015 revealed that 771 out of 800 samples

(96.4%) passed quality tests while 29 samples (3.6%) failed.

The Agency in collaboration with USP conducted Round 2 survey on quality of antimalarial medicines in 2016. The report of Round 2 survey presented on 11th April, 2017 revealed that 861 samples out of 900 samples (95.7%) passed while 39 samples (4.3%) failed.

As a result of increase in the percentage of substandard and falsified antimalarial from 3.6% to 4.3% in 2016, NAFDAC implemented strict regulatory measures with support of USP before commencing Round 3.

The report of Round 3 Survey presented on 12th December, 2017 revealed that 883 out of 897 samples of antimalarial medicines (98.4%) passed quality tests while 14 samples (1.6%) failed.

The report of Round 4 Survey presented on 13th December, 2018 revealed that 727 out of 741 samples of antimalarial medicines (98.1%) passed quality tests while 14 samples (1.9%) failed.

Round 5 Antimalarial Survey was rolled out with the overall objective to monitor the quality of antimalarial medicines in circulation in Nigeria and specifically to establish the quality of antimalarial medicines supplied at Level 1 of distribution chain [Manufacturers, Mega drug distribution Centres (MDDS), State drug distribution centres (SDDCs)]; establish the quality of antimalarial medicines sold to patients at Level 2 of the distribution chain (public and private hospitals, wholesale pharmacies, retail

pharmacies, PPMV stores and informal markets); estimate the proportion of substandard and falsified, (SF) antimalarial medicines available at different points of the regulated and informal distribution system; demonstrate the appropriateness of the MQM approach to quality monitoring of antimalarial medicine ; and determine the trend in quality status of antimalarial medicines.

Survey Methodology

Samples were procured in each zone (between 22nd to 26th March 2018) by a team of three NAFDAC staff using letter of introduction at level I outlets and posing as mystery shoppers at level II outlets.

The antimalarial medicines collected included Artemether/Lumefantrine (AL), Artesunate/Amodiaquine (AA), Sulphadoxine/Pyrimethamine (SP) and Quinine.

Other commonly used and widely available antimalarial medicines in each zone were also procured so as to have an unbiased representation of antimalarial medicines available in the market.

Programme drugs were procured alongside fully commercialized antimalarial medicines.

All information collected (brand and generic name, address of manufacture, NAFDAC registration number, expiry date, batch number, etc) were entered into a purposely designed Microsoft Excel sheet.

Data was analyzed by statisticians.

The results of Minilab Tests on failed samples were confirmed by NAFDAC ISO 17025 Certified laboratories using relevant Pharmacopeial Standards.

Sampling and Testing Sites:

One state (Table 1) in each of the six (6) geo-political zones of the country was selected for sample collection based on burden of malaria, availability of trained

personnel, and availability of antimalarial medicines in April 2018 for Minilan test and confirmatory testing.

Each sampling site was allocated a total of 150 samples, except South West that has 157 making a total of 907 samples from the six geopolitical zones.

Results were collated and presented in May 2018.

Table 1: States where samples were procured

S/No	Zone	State	NAFDAC Laboratory	Code
1	North Central	Kogi	Kaduna	NC/KG
2	North East	Borno	Lagos	NE/BN
3	North West	Katsina	Kaduna	NW/KT
4	South East	Ebonyi	Agulu	SE/EB
5	South South	Bayelsa	PH	SS/BA
6	South West	Ondo	Yaba	SW/ON

Sample Collection Tool

- Samples were collected using specially designed sample collection form.
- 25% of samples that passed Minilab testing were randomly selected

and subjected to confirmatory testing.

The testing was conducted using Visual inspection, Simple disintegration and Thin layer chromatography

Results

A total of 907 Samples procured from the public & private sector were tested using GPHF-Minilab Test Kits and NAFDAC laboratories.

The confirmatory tests were carried out in the ISO 17025 NAFDAC laboratories, at Yaba, Lagos

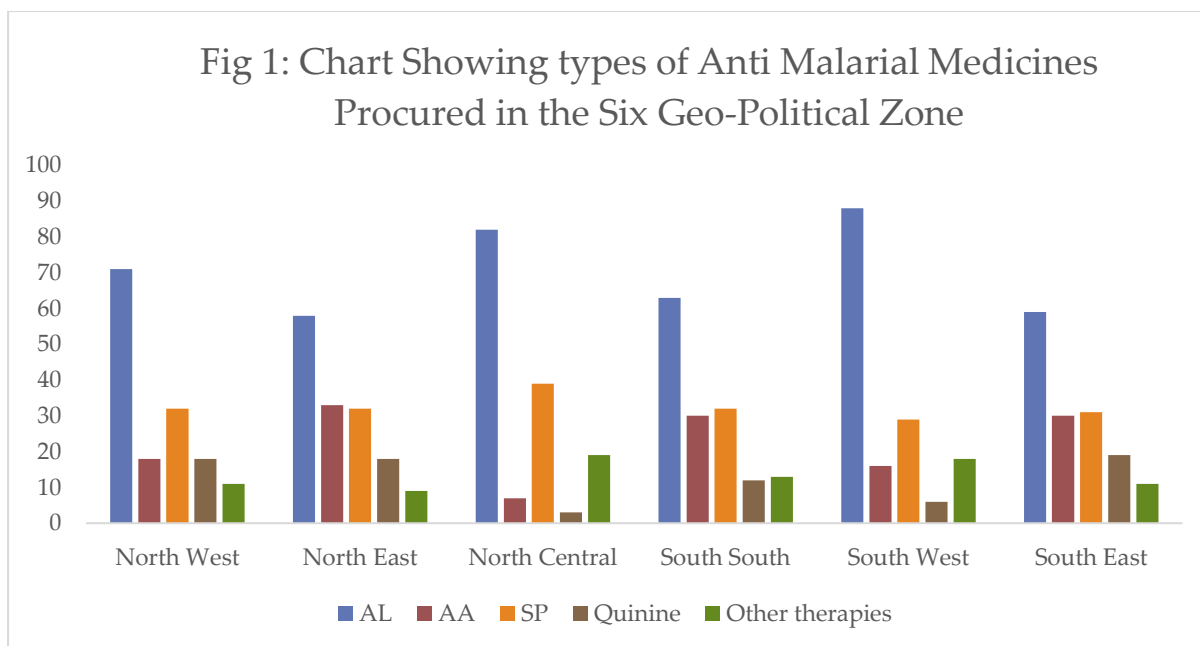
807 samples were procured from the private sector, representing 89.0 percent of the total sample.

100 samples (11.0%) were procured from the public sector.

ACTs represented the largest share of samples collected. The (ACTs included Artemether+Lumefantrine with 421 (46.4%), and Artesunate+Amodiaquine with 134 (14.8%)), while 195 (25% samples) of the samples collected was of Sulfadoxine Pyrimethamine. were procured, representing 21.5% percent of the total samples, 76 (8.4%) of the samples of was Quinine and 81 samples of others representing 8.9% of total sample. These are also further presented in figure 1 for emphasis.

Table 2: Types of Antimalarial medicine procured by zones

Zones	AL	AA	SP	Quinine	Other therapies
North West	71	18	32	18	11
North East	58	33	32	18	9
North Central	82	7	39	3	19
South South	63	30	32	12	13
South West	88	16	29	6	18
South East	59	30	31	19	11
Total	421	134	195	76	81
Percentage	46.4	14.8	21.5	8.4	8.9



In fig 2, a total of 12 samples out of 907 (1.3%) failed quality testing, as they did not conform to specification. The failed samples included **2 Artemether + Lumefantrine tablets, 5 Sulfadoxine Pyrimethamine tablets, 2 Quinine Sulfate tablets, 1 Artesunate+Amodiaquine tablet and 2 Others.**

Eleven samples have Low Assay representing 1.2%; One (1) product (0.1%) has high Assay content.

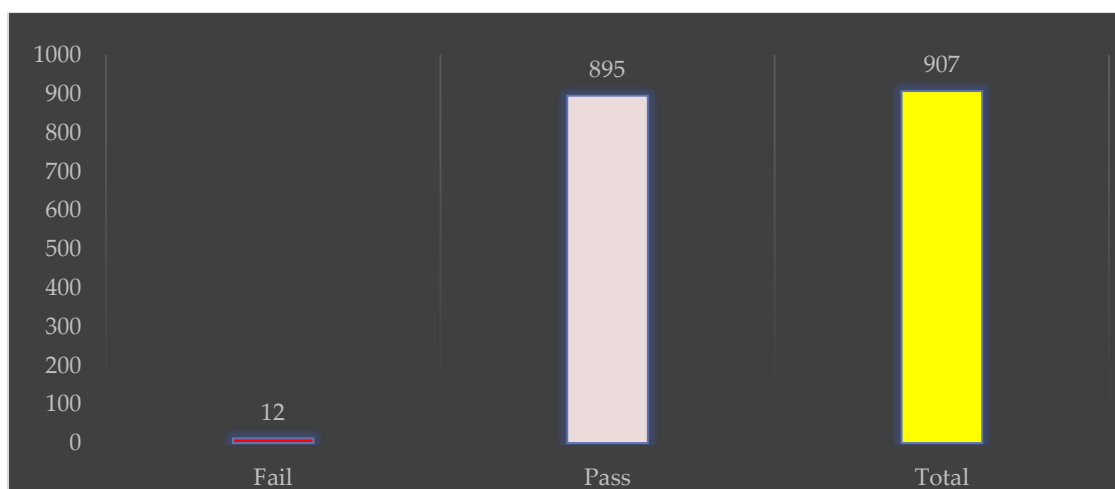


Figure 2: Percentage Pass & Failure of Samples

Table3, shows the frequency distributions of number of samples failed or passed by zones. North-West has the highest number of failures as 7(4.7%) out of the 150 samples collected failed the tests. This is

followed by North central and South-South with 2(1.3%) each. No sample failed the tests in North-East and South-West as all the 150(100%) samples passed the tests

Geopolitical Zone	No of passed samples N = 895 (98.7%)	No of failed samples N = 12 (1.3%)	Total No of samples N = 907 (100%)
North Central	148 (98.7)	2 (1.3)	150 (16.54)
North East	150 (100.0)	0 (0.0)	150 (16.54)
North West	143 (95.3)	7 (4.7)	150(16.54)
South East	149 (99.3)	1 (0.7)	150 (16.54)
South South	148 (98.7)	2 (1.3)	150 (16.54)
South West	157 (100.0)	0 (0.0)	157 (17.30)

Table 3: Distribution of failed and passed samples by zones

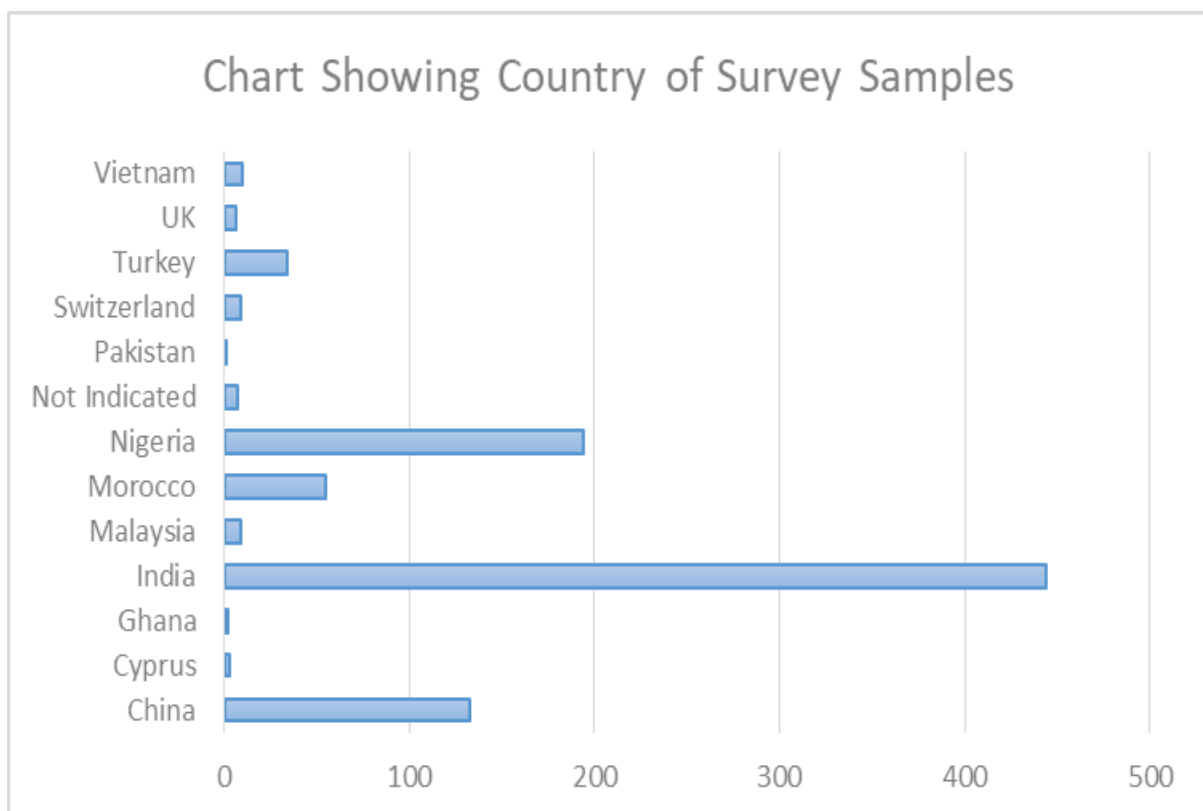


Table 6: showing Distribution of samples by country of manufacture

S/No	Country of Manufacture	No of Samples	Percentage %
1	China	133	14.7
2	Cyprus	3	.3
3	Ghana	2	.2
4	India	444	49.0
5	Malaysia	9	1.0
6	Morocco	55	6.1
7	Nigeria	194	21.4
8	Not Indicated	7	.8
9	Pakistan	1	.1
10	Switzerland	9	1.0
11	Turkey	34	3.7
12	UK	6	.7
13	Vietnam	10	1.1
	Total	907	100.0

Table 7: showing percentage Pass and Failure by Countries of Manufacture

S/No	Country of Manufacture	HPLC Result		
		Unsatisfactory	Satisfactory	Total
1	China	3 (2.3%)	130 (97.7%)	133
2	Cyprus	0 (0%)	3 (100%)	3
3	Ghana	0 (0%)	2 (100%)	2
4	India	2 (0.5%)	442 (99.5%)	444
5	Malaysia	0 (0%)	9 (100%)	9
6	Morocco	0 (0%)	55 (100%)	55
7	Nigeria	5 (2.6)	189 (97.4)	194
8	Not Indicated	0 (0%)	7 (100%)	7
9	Pakistan	0 (0%)	1 (100%)	1
10	Switzerland	2 (22.2%)	7 (77.8%)	9
11	Turkey	0 (0%)	34 (100%)	34
12	UK	0 (0%)	6 (100%)	6
13	Vietnam	0 (0%)	10 (100%)	10
	Total	12 (1.3%)	895 (98.7%)	907

Challenges

- In the South East, sampling from a few importers and distributors was difficult because their location addresses were difficult to access.
- Majority of patent medicine dealers in the South East opened for business mainly in the evenings and as such sample collectors had to put in extra hours to achieve the objective of the study.
- Some distributors insisted on wholesale purchases.

Recommendations

- Pharmacovigilance/Post Marketing Surveillance Directorate should sustain the mop up of failed samples to prevent exposure of the members of the Public to substandard and falsified antimalarial medicine.
- Drug Evaluation and Research Directorate should strengthen monitoring of Good Manufacturing Practices of manufacturers of antimalarial medicines, especially the manufacturers of failed samples.
- The Port Inspection Directorate should sustain the surveillance on imported antimalarial medicines to ensure that only good quality antimalarial medicines are imported into Nigeria.
- NAFDAC Zonal and state officers should intensify the monitoring of

distribution and retail outlets, especially in rural areas to ensure that antimalarial medicines are stored under suitable conditions.

- Distributors, Wholesalers and retailers of medicines should ensure proper transportation and storage to ensure that quality of medicines is maintained along distribution chain.
- Manufacturers and Marketing Authorization Holders should ensure that their products are distributed and transported under suitable storage conditions along the distribution chain up to the retail level, to ensure that their quality are retained.
- Programme Managers of Public Health Programmes should make adequate provision for quality assurance of medicines, especially antimalarial medicines.

Conclusion

The successful completion of the Round 5 Survey has laid a solid foundation for effective post marketing surveillance of antimalarial medicines.

The report of Round 5 Survey revealed that 895 out of 907 samples of antimalarial medicines (98.7%) passed quality tests while 12 samples (1.3%) failed.

The failure rate of antimalarial medicine in Round 5 survey is 1.3% as against 1.9% in Round 4.

There is need to strengthen NAFDAC's collaboration with PMI/USP, USAID, NMEP, NPSCMP & other relevant stakeholders to ensure that the level of substandard and falsified antimalarial medicines in Nigeria is reduced to the barest minimum.

Acknowledgements

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- ▶ Presidential Malaria Initiative/United States Pharmacopia (PMI/USP)
- ▶ Federal Ministry of Health- Abuja
- ▶ National Product Supply Chain Management Programme (NPSCMP)
- ▶ National Agency for Food and Drug Administration and Control (NAFDAC).
- ▶ National Malaria Elimination Programme (NMEP)

References

- World Health Organization 2016. World Malaria Report 2016).
- National Population Commission (NPC) [Nigeria], National Malaria Control Programme (NMCP) [Nigeria], and ICF International. 2012. Nigeria Malaria Indicator Survey 2010. Abuja, Nigeria: NPC, NMCP, and ICF International.

National Malaria Elimination Programme (NMEP), National Population Commission (NPopC), National Bureau of Statistics (NBS), and ICF International. 2016. Nigeria Malaria Indicator Survey 2015. Abuja, Nigeria, and Rockville, Maryland, USA: NMEP, NPopC, and ICF International

Guide to Nigeria NPC Adverse Drug Reaction (ADR) Electronic Reporting (eReporting) System

The Nigeria NPC has deployed eReporting of ADRs. You may access this through the NAFDAC website:

<https://www.nafdac.gov.ng/>

click on Pharmacovigilance & PostMarket Surveillance link under **Services**. (bottom-left of the home page)

Select NAFDAC ADR eReporting Form under **useful resources** (right side of the page).

In filling the form:

- Please fill all Mandatory field(s) (*)
- Please indicate the “Weight” if available
- You can add as many reactions as possible by clicking on the “Add another reaction/symptom” box.
- Please indicate the “Outcome of reaction e.g. Recovered/Resolved
- Please indicate if the reaction(s) led to any of the following:
 - Caused/prolonged
 - hospitalization,
 - Disabling/incapacitating
 - Congenital anomaly/birth defect,
 - Life threatening, Results in death,
 - Other medically important condition.
- It is important to report the following very important details even if they are not tagged as mandatory field (*)
 - Medicine producer of medicine Probably causing the reaction,
 - Strength (as stated on medicine packet)
 - Dosage (as taken)
 - Route (as administered or taken)
 - Place where medicine was obtained,
 - End date or duration,
 - Reason for taking the medicine
 - What else did you do (Action taken with medicine)
 - Has the medicine caused a similar reaction before?
- You can add as many medicines as possible by clicking on the “Add another medicine” box.
- DATES MEDICINES AND REACTIONS STARTED ARE VERY IMPORTANT.
- Please add any “Additional information” relevant to this case as stated in the form.
- Click on the “Next page” to proceed to the “Summary” page.
- View the summary of the report
- Submit by clicking the “Submit” box.
- After submitting, an acknowledgement is sent by WHO-UMC to the email address used for reporting the case.
- THANK YOU FOR REPORTING

