

TRANSBORDER REGULATION AND CONTROL ON DRUGS:

By Pharm. (Dr) John Nwaiwu PhD, FPSN.

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It is with great pleasure and humility that I appreciate the invitation of your President and the Council of the West African Post graduate College of Pharmacists to be with you in your 20th Annual General Meeting and 56th Council Meeting.

I regard it as a great privilege to be given an opportunity to present a paper titled “ Transborder Regulation and Control on Drugs” to this group of Distinguished Professionals. This topic is very germane to the central theme of the conference.

“The Impact of Fake and Substandard Drugs on Quality of Life in West Africa”.

This conference couldn't have come at a better time now the increase of Fake and Substandard Drugs is prevalent in the whole world particularly in most countries within the sub-region of West Africa where illiteracy and poverty provide a fertile ground for its spread with its attendant consequences to quality of life of the citizens.

In line with the theme of the Conference, if drugs are not properly regulated and controlled across borders they could lead to influx of fake and adulterated drugs and it will be catastrophic to human life.

Once more, I salute the organizers of the Conference for deeming it wise to discuss the topic as it concerns nations across borders.

It is important that some of the words in the topic be clearly defined to really appreciate the enormity of the subject matter.

DEFINITIONS:

TRANSBORDER: is the line that separates one country, state, nation etc from another. It is the part or edge of a surface or area that forms it's outer boundary. In other words we talk about boundaries between nations. You cannot cross the border without a visa. Transborder/Cross border is movement from one country to an adjacent country. I am going to restrict myself to the borders in the West African Sub-region because this is the Conference of the West African Post Graduate College of Pharmacists.

There Are Three Types Of Borders:

- Land Border
- Sea Border
- Air Border

Land Border can be:

- Formal Cross Border: Formal Cross border (FCB) are approved routes and stations often referred as customs border or stations.
- Informal Cross Border: Informal Cross border (IFCB) is defined as unapproved routes or crossings.

Land border poses the greatest challenge in the regulation and control of all goods including drugs because of the vast land areas and geographical nature of the countries in the West African Sub-region.

Border stations in Africa are often porous and very diffuse as communities in contiguous countries share common border and sometimes no border at all. The people are culturally integrated and inter marry with each other and may not understand the definition of your border. Informal trade including hawking of drugs is very prevalent. Such communities in the border areas lack basic infrastructure eg Electricity, potable water etc. The standard of living is very low and diseases such as Malaria and typhoid are very rampant.

Drug needs of the people are often dependent on drug hawkers and peddlers who often cross the border at will to sell and buy their drugs. More often than not the drugs they sell are fake or substandard.

When the drugs are even genuine, the poor storage conditions make the drugs less efficacious.

On account of the superstitious belief of the people death as a result of these fake drugs are often blamed on one

unappeased god who has come to take revenge or one great grand father who was not properly buried and has come to punish the people.

A cursory look at a country like Nigeria in the region. Nigeria has a land area of 923,768 sq km and shares land borders with Republic of Benin covering over 773 kilometers in the West, with Republic of Chad and Cameroun in the East covering areas of 87 kilometers and 1,690 kilometers respectively and Niger Republic in the North sharing Land border of 1,497 kilometers. This gives you an idea of the challenges in regulation and control of goods by the regulatory and enforcement agencies.

Let me emphasize that movement of goods including Pharmaceuticals across the border in any clandestine manner is smuggling. The dangers of smuggling of drugs which may be fake and substandard are unquantifiable and definitely impacts on the quality of life in the region.

It also has economic implications because these are unrecorded trade whose records and statistics are unknown therefore are not included in the National planning.

SEA AND AIR BORDER:

The Sea and Air Borders pose very little operational problems because the borders are well defined and properly manned and regulated. They are referred to as approved Wharf and approved Airports respectively. All regulatory and enforcement agencies are present at these borders.

DRUGS: They are substances of vegetable, animal or mineral origin used for internal or external application to the human and animal body in the treatment or prevention of diseases and health disorders.¹ Drugs can be remedial, ineffective or harmful depending on how they are used, manufactured or stored.

Drugs can be classified as licit or medicines when they are properly used and illicit drugs when they affect the mood hence leading to addiction.

Illicit drugs can be classified as:-

- a). Hallucinogens:- Cannabis etc
- b). Depressants/ Opiates – Opium, Morphine, Heroin, Cocaine etc.
- c). Psychotropic Substances – Drugs of Ectasy – Amphetamine and Amphetamine derivatives.²

These illicit drugs are internationally under prohibition because of the effect they have on persons and society at large. Transborder trafficking of these drugs are under international enforcement. The golden triangle in South East Asia is the main opium producing areas. It is an area of around 367,000 sq miles covering three (3) countries Myanmar, Laos and Thailand. Peru, Bolivia and Columbia are the major countries that produce cocaine. These are the countries in the Americas. The transborder trafficking of drugs in these areas are of International concern.

REGULATION AND CONTROL OF DRUGS: Taking Nigeria as a test case. The agencies charged with the responsibilities of regulation and control of drugs at the borders are:-

1). NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC).

The Agency was established by Decree No.15 of 1993 (as Amended), by Decree No. 19 of 1999 to control and regulate the manufacture, importation, exportation, distribution, advertisement, sales and use of food, drugs, cosmetics, chemical/detergents, medical devices and packaged water including all drinks (referred to as regulated products).³ The scope of this mandate puts the responsibility of safe guarding public health on the Agency and the life of every Nigerian. Their major strategy for the control and regulation of drugs is the process of registration, documentation, inspection for assessment of Good Manufacturing Practice and Laboratory Analysis for quality and safety.

Suffice it to say that the statutory function of NAFDAC is regulatory.

2). NIGERIA CUSTOMS SERVICE: The Nigeria Customs Service derived its powers from Customs and Excise Management Act (CEMA) CAP 84 laws of the Federation 1990 (As Amended).⁴ This act gives the service the enormous power to control the Importation and Exportation into and out of Nigeria irrespective of the route –Land, sea or air.

The law empowers the service to detain, impound and seize any goods whether for importation or exportation

which is not properly entered to a proper officer.

The law also gives the powers of prosecution to the service. The Customs have enforcement powers provided by certain sections of the Act.

Globally Nigeria Customs like any Customs administration is a member of the World Customs Organization (WCO). This organization has a unit called the Central Information System (CIS). They collate and manage drugs seizures information from the Regional Intelligence Liaison Offices (RILO) in the World. This cooperation enables various Customs administrations all over the world to keep abreast with drug seizures so that movement of drugs transborder is monitored through intelligence gathering. The RILO Head quarters in West African Sub-region is in Dakar Senegal.⁵

3). **NATIONAL DRUG LAW ENFORCEMENT AGENCY (NDLEA)**

The National Drug Law Enforcement Agency (NDLEA) is a Federal Agency in Nigeria charged with eliminating the growing, processing, manufacturing, selling, exporting and trafficking of drugs. The Agency was established by Decree Number 48 of January 1990. The NDLEA is present at International Airports, Seaports and Border crossing. They also target leaders of narcotics and money laundering operations.

However, the United Nations Office on Drugs and Crime plays a paramount role in the control of drugs particularly Narcotics and Psychotropic substances globally. They support Governments in the prevention of illicit drug trafficking.

The organization also assists government in strengthening borders control through development of intelligent and law enforcement capacities as well as operational information on cross border crime. International Cooperation on hard drugs is essential. The United States of America donated body scanning machines for the Lagos, Kano, Abuja and Port-Harcourt Airports to combat drug smuggling.

Most countries in West Africa sub-region are not consumers of these hard drugs. They only serve as transit routes to countries in Western World. Nigeria and countries in sub-region have problems of cannabis. Cannabis is widely grown in West Africa and trafficking across border is regular.

The high rate of Indian hemp usage among youths in West Africa calls for urgent intervention. Youths engage in violence, thuggery, and all sorts of criminal activities as a result of Indian hemp consumption. Sometimes Indian hemp smoking leads to psychological disorder. Those who trade in Indian hemp make huge profit from it and see it as a lucrative business.

ECONOMIC COMMUNITY OF WEST AFRICAN STATES (ECOWAS) MOVEMENT OF GOODS ACROSS THE BORDERS

Most developing countries including Nigeria are consumer nations and that explains the import of larger proportion of their drug needs, from developed nations. These drugs are imported directly from the country of origin and most times move across borders particularly in the West African Sub-region.

The movement of these drugs across the borders sometimes has genuine intentions but many unscrupulous persons take advantage of ECOWAS trade liberalisation scheme (TLS) to move unregistered drugs across borders.

If you can recall the objective of the ECOWAS Trade Liberalization Scheme (ETLS) is to establish a Customs Union among Member states of the community.⁶

The Customs Union involves apart from other things the removal of non-tariff barriers to ensure free movement of goods and the establishment of the Customs Common External Tariff (CET) to protect goods produced in Member states. There must be a clear proof of country of origin to ensure this objective.

The meaning is that properly registered pharmaceutical companies in Ghana can export their drugs to any country within the sub-region without hindrances or barriers provided all regulations by the various agencies are conformed with.

Similarly, the Customs Common External Tariff (CET) provides that any drug imported into any country in the sub-region from Europe or America enjoys the same tariff regime. Drugs can no longer be imported in any country in the sub-region taking advantage of differential tariff in a country and then smuggled into another country in the sub-region. The establishment of CET, removal of regional trade barriers and strengthening regional integration help countries to integrate into the World markets.

However, there are incidences of drugs and other pharmaceutical products defying rules or origin and brought in through the land borders as made in ECOWAS Countries.

THE ROLE OF PHARMACISTS:

Ordinarily the regulation and control of drugs should not be a problem because only Pharmacists are legally approved to handle drugs. They are professionally trained properly registered by a regulatory agency "Pharmacists Council of Nigeria (PCN)". I am sure the same applies to all Pharmacists in all countries over the world. The Pharmacists are properly regulated even their residential address are known also. The pharmacy in which they practice are inspected and registered. The Pharmacists themselves are re-certificated from time to time. They ensure that the quality of drugs imported with its high quality control is maintained. It is therefore surprising that with these measures we still have the problems of regulations and control.

Only properly registered Pharmacists and Pharmacies are qualified to import drugs. It implies that the importer of drugs, the source of import, the route of importation and the products to be imported are under control in one form or the other.

We must therefore admit that there are interlopers or money bags who have infiltrated into the practice of the profession. They see the business of drugs as lucrative and employ Pharmacists whom they can control and sometimes use to influence the movement of drugs transborder, where the exchange rate of the neighboring country is higher. There is very little compliance to regulations. If Pharmacists insist on practicing the profession properly drugs may not get into the hands of undesirable elements.

Trans border Regulation and Control of drugs involves both importation and exportation of drugs into and out of a country. The world is a global village. People tend to outsource the manufacture of drugs particularly where Government has not provided the enabling environment for the manufacturing sector to operate optimally. This explains why indigenous manufacturers within the sub-region engage in importation of drugs.

IMPORTATION AND EXPORTATION OF DRUGS:

Before any drug can move across the border, that particular drug must be fully registered by the regulatory agency NAFDAC or any other approved drug regulatory agency in any country.

They ensure that only safe and efficacious drugs are imported or exported through Airports, Seaports and Land borders.

It is common knowledge that drugs have been imported into the country in all sorts of clandestine manner.

The drugs have been illegally imported:

- a). Falsely manifested as spare parts used engines or as spare parts completely knocked down (CKD), sanitary levels etc.
- b). Expired or about to expire as donated items.
- c). Drugs defying rules of origin of ECOWAS countries. This occurs through land borders.
- d). Drugs concealed in other goods.
- e). Drugs imported with forged documents etc.

ROUTE AND DESIGNATED AREAS

The Federal Government of Nigeria through the regulatory Agency NAFDAC has recognized the challenges associated with drug importation decided to canalize the traffic of drug importation. Drugs and indeed Pharmaceutical products can now only be imported through:

- i). Seaports:- Apapa Lagos and Calabar Sea ports.
- ii). Airports:- Muritala Mohammed Airports, Lagos and Aminu Kano Airports, Kano.

Importation of drugs through the land borders or any other route other than the designated areas are banned. Such drugs so imported will be seized and offenders prosecuted.

PROCEDURES FOR THE CLEARANCE OF DRUGS

In Nigeria any person who intends to import any goods including drugs must first process e-form M through any authorized dealer bank irrespective of the value and whether or not it is valid for foreign exchange. The e-form M shall be valid for importation only after acceptance by the Nigeria Customs Service (NCS).⁷

The validity period of an approved e-form M shall be 180days but may be extended for another 180days.

Upon receipt of the e-form M, the importer can now embark on the process of importation of the drugs. When the drugs arrive at the designated port, the accompanying documents i.e

- a). e-form M.
- b). Combined Certificate of Value and Origin (CCVO).
- c). Parking List.
- d). Airway Bill/Bill of Lading/Railway bill/Road Way bill.
- e). Certificate of Analysis/Manufacturer's certificate of product.
- d). Final Invoice.

will be submitted to the authorized dealer bank who in turn will forward them electronically to the Nigeria Customs Service. The NCS will process the documents and if satisfied shall generate the Pre-Arrival Assessment Report (PAAR) within short period of time.

The Importer of Pharmaceutical Product will then submit to NAFDAC clearing documents For First Stamping.⁸

They are:-

- Assessment Report from Nigeria Customs Service.
- A letter of undertaking duly signed by the importer stating the following:-
 - a. That the first stamp serves only as recognition that the imported products(s) are duly registered by NAFDAC.
 - b. That the products will not be sold until satisfactory laboratory report is out.
 - c. That in event of product(s) being substandard, illegal importation or unfit for human consumption the said importer will forfeit the product(s) to the federal Government for destruction.
 - d. The name of the importer and warehouse location address should be included.
 - that the products would not be sold until confirmed fit for human use by NAFDAC.
 - Evidence of payment of a prescribed fee in Bank draft made payable to NAFDAC.
 - Copy of the current Annual Certificate of Registration/Retention of Premises issued by the Pharmacists Council of Nigeria (PCN).
 - Copy of the current Annual License of the Superintendent Pharmacist issued by the PCN.
 - Evidence of Certificate of Registration issued by NAFDAC.
 - Parking List.
 - Pre shipment Information.
 - The Original Certificate of Analysis of the product.
 - QCS report (India)/Tianji Tianshi report (China).
 - Combined Certificate of Value and Origin (CCVO)/Final Invoice.
 - Bill of Lading/Airway Bill.
 - Risk Assessment Report (RAR). now Pre Arrival Assessment Report (PAAR)
 - e- Form M.
 - Form C30 issued by Customs.

OTHER CLEARANCE PROCEDURE

After the first stamping by NAFDAC on the Assessment Report all the documents will be submitted to Customs for the normal Customs clearance procedures to follow. The procedure will follow exactly the same procedure as any other goods for human consumption.

SECOND STAMPING OF DOCUMENTS FOR DRUG IMPORTATION

After the physical examination of the drugs or pharmaceutical products which is jointly done by Customs personnel, NAFDAC personnel and any other relevant Agencies e.g NDLEA, the documents will go for second stamping by NAFDAC before final release by Customs.

The following documents are required by NAFDAC for second stamping:-

- i) Original NAFDAC Receipt
- ii) Original NAFDAC Sampling Form
- iii) Photocopies of the following:-
 - a). Assessment Report stamped by NAFDAC
 - b). PAAR (Pre-arrival assessment report) by Customs

- c). Certificate of Analysis & QCS Stamped by NAFDAC
- d). Bill of Lading (BL) or Airway Bill (AWB)
- e). Packing List and Final Invoice
- f). NAFDAC Import Permit (for Narcotics)
- g). e-Form M
- h). NAFDAC Receipt
- i). Evidence of NAFDAC Registration

In essence the role of Customs Service in drug importation is to ensure that duty of the drugs is collected for the Federal Republic of Nigeria. It has the role of effecting the release of the drugs after ensuring that NAFDAC requirements are fulfilled. The service in addition has the role of anti-smuggling of drugs. Drugs not properly declared, concealed etc are seized and handed over to relevant Agency NAFDAC for investigation and prosecution.

DRUG ON THE FEDERAL GOVERNMENT IMPORT PROHIBITION LIST

- A. Paracetamol Tablets and Syrups.
- b. Cotrimoxazole Tablets and Syrups.
- c. Metronidazole Tablets and Syrups.
- d. Sulphadoxine Pyrimethamine Tablets.
- e. Chloroquine Tablets and Syrups.
- f. Haematinic Tablets (such as Ferrous Sulphate and Ferrous Gluconate And Folic Acids Tablets).
- g. Vitamin B Complex Tablets (Except Special Formulations)
- h. Multivitamin Tablets, Capsules and Syrups (Except Special Formulations).
- i. Aspirin Tablets (except modified release formulations and Soluble Aspirin).
- j. Magnesium Trisilicate Tablets and Suspension
- k. Piperazine Tablets and Syrups
- l. Levamisole Tablets and Syrups.
- m. Clotrimazole Cream.
- n. Ampicillin/Cloxacillin Combinations, Ointment, Penicillin/Gentamicin.
- o. Intravenous Fluid (Dextrose, Normal Saline)
- p. Pyrantel Pamoate Tablets and Syrup.
- q. Disinfectants and Germicides.

Recently NAFDAC has published a list of Regulated products and their HS Codes. ⁸

EXPORTATION REGULATIONS AND CONTROL

NAFDAC was established by Decree 15 of 1993 (now NAFDAC Act Cap N.1 laws of the Federation of Nigeria 2004) to regulate and control the importation, exportation, manufacture, advertisement, distribution, sales and use of food, drugs, cosmetics, medical devices, package water/drinks, chemical and detergent referred to as regulated products⁹ Exportation of drugs transported through the Land borders requires that the exporter submit an application for export certificate to the Agency indicating:-

- 1). Name of Exporter and Address
- 2). Product intended for Export/Quantities in carton/net weight, Batch Number, Expiration date and Production date, Pack size Specified in 1kg) and NAFDAC Registration No,)
- 3). Name of Manufacturer
- 4). Distributors Name
- 5). Route of Dispatch
- 6). Consignee's Name and Address
- 7). Name and address of clearing Agent

- 8). Gross Weight
- 9). Way Bill/Truck Number

Other requirements include photocopies of the following

- i) Way Bill
- i) Packing List
- iii) Proforma Invoice
- iv) Nigeria Export Proceeds (NXP) Form
- v) Clean Certificate of Inspection (CCI)
- vi) Certificate of Origin
- vii) Movement Certificate
- viii) Nigeria Export Promotion Council (NEPC) Certificate
- ix) Certificate of Incorporation
- x) Certificate of Analysis.

TRANSIT OF GOODS:

ECOWAS TLS provides member countries to transport goods across borders without much hindrances or barriers. The inter-state road transit (ISRT) of Good Regime provides facilitation of goods among member states.

The Regime facilitates the transportation by road of goods from a Customs Office in one member state to a Customs office in another member state without payment of duties and taxes and waiver of all prohibitions and restrictions.

Goods carried under the cover of the ECOWAS ISRT must be carried in special container type vans having fastenings which are capable of being officially wired and plumbed.

Vans which have been loaded, locked and sealed are not to be opened at any place between the port or place of entry or loading and the place of exit except in case of accident or other emergency where a report is to be made to Customs Officer in charge at the earliest opportunity and give full account of the goods taken and thereafter the goods are transferred to another van which must also be sealed.¹⁰

All goods under transit must be escorted by a Custom officer who must collect certificate of Landing to the next Customs formation.

CHALLENGES ON TRANSBORDER REGULATION AND CONTROL OF DRUGS

Challenges experienced in transborder Regulation and Control of drugs could be quite enormous.

Indiscriminate fiscal policies of various government administrations within the sub-region are often enacted. Even when a product is registered in the country of origin and all information provided, crossing the borders can be quite challenging and difficult, imposition of fines and additional duties on drugs are often rampant among ECOWAS countries.

Sometimes outright banning or prohibition of certain pharmaceutical products hinder trade movement within the region.

Thus intra-regional trade is not very much based on the Common External Tarriff (CET) and this presents barriers to regional integration.

Other challenges experienced are:-

- 1). Porosity of the borders leads to poor policing of the borders, the result is that fake and counterfeit drugs are likely to be smuggled through the porous borders. The lack of an appropriate mechanism for monitoring movements across the borders will engender cross border criminal activities which may undermine good governance and security with negative impact on the rule of law, economic activities and growth. It increases chances of transnational organized crime.
- 2). Complex Regulatory requirements for registration of drugs.
The procedure is very cumbersome and expensive although well intended may lead to evasion of procedure

by some unscrupulous people.

- 3). Perceived conflict among Regulatory Agency and Enforcement Agencies Importation of Narcotics and highly controlled drugs causes some authorization conflict between NAFDAC and NDLEA.
- 4). Judicial Punitive Measures.
- 5). High rate of duty on drugs: A properly registered drug may have false declaration in order to evade high duty.
- 6). Evasion of Export Certificate:
Drugs are freighted without NAFDAC Certificate and do not comply to Export requirements.
- 7). Pervasive public ignorance predicated on low illiteracy.
- 8). Low compliance to rules and regulations governing trans border trade.
- 9). Problems of exchange rate among countries in the sub- region.
- 10). Multiplicity of check points hindering trade facilitation.
- 11). Multiplicity and arbitrary taxation of drugs which are vital to health.
- 12). Drug information and education: Regulatory Agencies should embark on public enlightenment campaign on new regulations and guidelines.
- 13). Cooperation among law enforcement and regulatory Agencies particularly at the border stations.
- 14). Governments commitment ECOWAS to Trade policies. Non compliance to agreed CET or lack of functional Customs Union in West Africa Countries apply their own tariff regimes.
- 15). Poor remuneration of regulatory and Enforcement Agencies.

Mr. Agyarko, the CEO Food and Drugs Board Ghana in his keynote address at The PSN 79th AGM Conference in Nigeria summarized these challenges by emphasizing that in the fifteen countries that constitute the ECOWAS there are no effective legislations for medicines control and as a result illicit trade in Pharmaceuticals remains one of the most lucrative trades in West Africa.¹¹

CONCLUSION

This lecture has addressed the following issues:

- 1). Highlighted the challenges of transborder trade.
- 2). Roles of the regulatory and Enforcement Agencies involved in transborder regulation and control of drugs.
- 3). Policies of the economic country of West Africa States (ECOWAS) and their trade policies.
- 4). Procedure for the clearance of drugs through approved routes (Land, Sea and Air).
- 5). Exportation procedure via approved borders particularly through land borders.
- 6). Challenges on transborder regulation and control of drugs.

I am therefore advocating that since our founding Fathers have deemed it wise to establish Customs Union within the countries in the Sub-region leading to ECOWAS Trade Liberalisation Scheme (ECOWAS TLS), the Drug Regulatory Agencies within the sub-region should harmonize their legislative drug policies on distribution, importation, exportation, manufacturing, sales and the national use of drugs in the countries within the ECOWAS zone. It will help improve the practise of the Pharmacy profession hence the quality of life of the citizens.

Finally, I wish to thank the organizers of this conference for once more inviting me and for fruitful deliberations throughout the conference. I hope that the outcome of the discussion on the regulation of drugs both legal and illegal drugs in this conference will help improve the quality of life of members of the West Africa states.

Thank you.

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