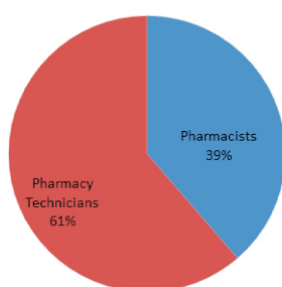


Pharmacy Board of Sierra Leone in 2021 despite the COVID-19 pandemic, made significant progress in regulating the Pharmaceutical Sector in Sierra Leone. The mandate of the Board is to train Pharmacy Professionals, regulate pharmaceutical products, engaged with its clients and build its regulatory system to achieve WHO Maturity Level 2 in five years. It continues to maintain and motivate its staff despite financial and other constraints. We start this edition of our yearly newsletter by providing you a snapshot of the 2021 Annual Report of the Pharmacy Board of Sierra Leone. We also go on to explore issues of significance in the pharmaceutical sector, from drug peddling, medicines exposure amongst school going children, enforcement of narcotics control, creating a favorable environment for the Pharmaceutical Manufacturing Sector and our engagement with our clients across the country.

1. PBSL ANNUAL REPORT 2021 SUMMARY

In 2021, the Board registered and placed in the Pharmaceutical Workforce a total of 51 new Pharmacy Professionals and approved a total of 144

Fig 3: Cadre of Pharmacy Professionals Licensed in 2021

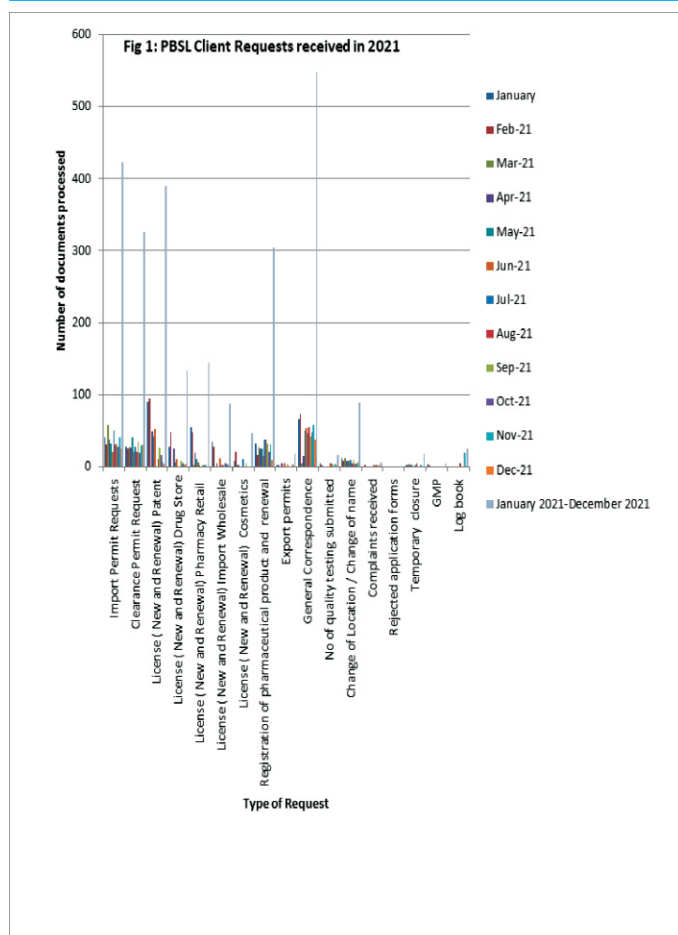


new Pharmaceutical premises including 1 Pharmaceutical manufacturing company. A total of 569 Pharmacy Professionals (220 Pharmacists and

349 Pharmacy Technicians), whilst 1955 premises (different categories) were licensed, of which 1281 were inspected for compliance with Pharmacy Board Standards.

The Board approved 240 of 1168 requests for registration of new Pharmaceutical products and conducted 2 drug audits for Good Storage and Distribution Practices for Pharmaceuticals. It monitored the safety and efficacy of registered and unregistered products reporting a total of 650 Individual Case Safety Reports forwarded to the Uppsala Monitoring Centre. Responding to the COVID-19 pandemic and health needs in Sierra Leone, the Board approved 12 Clinical Trials of which the Board granted two emergency use authorisation to SinoPharm Verocell Inactivated and COVISHIELD Astrazeneca COVID-19 Vaccines. The National Pharmaceutical Quality Control Laboratory also analysed 53.4% of samples received/collected from clients through its internal units.

In order to ensure public health and safety, the Board engaged through its Client Services, Outreach and Media programmes with over two million Sierra Leoneans. In 2021, the Board processed a total of 2575 requests, disaggregated as follows; General Correspondences to the Office of the Registrar (n=548), Import Permit Requests(n=422), License (New and Renewal for patent shops)(n=390), Clearance Permit Requests (n=325), Registration of Pharmaceutical Products(new and renewal)(n=302), License Pharmacy (New and Renewal)(n=145), License Drug Store(New and Renewal)(n=133), Change of Location/Change of name(n=89), License Wholesale(New and renewal)(n=88), License Cosmetics (New and Renewal)(n=46). In 2021, the Board inspected a total of 1367 Pharmaceutical premises in the public, not-for-profit and private sectors. In 2021, 21,368.34g of Narcotics was approved for use in Sierra Leone of a 28005g threshold allocated to Sierra Leone by the International Narcotics Control Board. 221.302.03g of psychotropic substances were approved for use in Sierra Leone of a 220,000g threshold allocated to Sierra Leone by the



International Narcotics Control Board. 522g of precursor chemicals were approved for use of a 0 threshold allocated to Sierra Leone by the International Narcotics Board. The Board continues to adapt in its approach to handling the issue of substandard, fake, counterfeit and spurious medicines proliferation in the Sierra Leone market. Peddler raids are evidence-based approaches to ensuring the distribution of substandard, fake spurious, counterfeit medicines. As such in 2021, the Board conducted 14 peddler raids nationwide and also implemented successful outreach activities with funds from WHO. In 2021, it conducted 2 drug audits of the pharmaceutical sector across the health supply chain.

The Board continue to strengthen Pharmacy Regulation and Pharmacy Service Delivery Oversight through its various committees. In 2021, it held 3 Drugs and Quality Assurance Committee Meetings, 3 Disciplinary Committee Meetings, 3 Education Committee Meeting ,3 Finance and Human Resource Committee Meeting 2 Product Registration Sub-Committee Meeting, 8 Application Sub- Committee Meetings, 2 Laboratory and Scientific Sub-Committee Meeting, 1 Quality Management Systems Sub-committee meeting, 11 Drug Safety and Clinical Trials Sub-committee meeting, Application

Subcommittee Meeting, 3 Budget sub-committee meeting, 2 Procurement Subcommittee Meeting and Integrity Sub-committee Meeting. 4 Board meetings were held.

The management of Pharmacy Board of Sierra Leone was found to have maintained Good Quality management system when assessed by external international assessors as per ISO9001:2015. Another Quality Management system self-assessment conducted by WHO confirmed the need for improvement of the laws for regulation of medicines (The Pharmacy and Drugs Act)

The Board therefore considered the following as critical to improvement of its functions;

1. Review of the Pharmacy and Drugs Act and dissemination of same to its key stakeholders and the general public
2. Ensuring roll out of an automated Pharmacy Regulatory System starting with the Quality Management System and the PBSL Client Service system located at the Information and Communication Department.
3. Staff capacity building and timely and adequate remuneration of Technical and Administrative staff
4. Strengthening information communication with an emphasis on community engagement through civil societies, traditional leaders and local government on issues relating to drug abuse and irrational medicines use for all age brackets, drug peddling, counterfeit medicines
5. Innovation in ways of funding Medicines regulation
6. Need for a National Pharmaceutical Manufacturing investment code and National Pharmaceutical Master Plan.
7. Establishment of Additional Pharmacy Training institutions in other parts of the country.

MEASURED TO CONTAIN DRUGS PEDDLING , IRRATIONAL MEDICINES USE, DRUG MISUSE, DRUG ABUSE. PBSLAND YOU, OUR CLIENT.

2. The issue of drug peddling, drug misuse, drug abuse and irrational medicines use continue to haunt the Sierra Leonean Society and can be viewed as a silent pandemic. Pharmacy Board of Sierra Leone is ready to work with all our clients to collectively address these issues. To start with , let 's learn about commonly accessed medicines from the pharmaceutical supply chain and also illegally from drug peddlers. The way forward for all is to talk to a Pharmacy Professional (Pharmacist or Pharmacy Technician or to the Board about any, some or all of these medicines or any medicines related issue you may experience. In this our newsletter we want to bring you this simple information to you. Read through and heed the advice of the Board. It starts with you our client.

List of Pharmaceutical products school children from three secondary schools are exposed (heard about and/or used, and/or bought) mostly from drug peddlers		Common Presentations from the literature	Common adherence/compliance issues from the literature	PBSL Tips on how a patient or consumer or pharmaceutical service provider can address this issues
No.	Name of medicine as described by the school pupils			
1	Paracetamol Tablets	Tablets(adults), Syrups (children)	Side effect - Hypersensitivity Formulation/packaging : Bottle cap, blister pack	Consumer: Talk to a Pharmacy Professional (Pharmacist or Pharmacy Technician) NOT A DRUG PEDDLER Pharmaceutical Service Provider : Confirm with the Board whether your product can be registered in Sierra Leone and meets the needs of the SL population
2	ORS	Powder	Formulation/labeling and patient education : Mix-up of types and indications	
3	Calcium Tablets	Tablets	Formulation/Packaging : Age dependent difficulty in opening	
4	Chymoral	Tablets , Box (blister pack)	Side effect - Allergic reaction	
5	Ibuprofen	Tablet. Box(blister pack) , Bottle	Formulation/Packaging: Age dependent difficulty in opening Side Effect: Gastrointestinal Ulceration and/or bleeding	
6	Relief	Tablet , Box(blister pack) bottle	Side effects: Nausea, vomiting , stomachache, heartburn and diarrhea	
7	Atycol			
8	Amoxicillin	Dispersible and non-dispersible Tablets, Capsule, Syrup	Side Effect: Nausea, Vomiting , Diarrhea	
9	Gelosil	Syrup, Chewable tablet	Side Effect: Nausea, constipation, diarrhea or headache	
10	Tramadol	Tablet	Side effect: Sleepiness, Headache, nervousness. uncontrollable shaking of a part of the body.muscle tightness. changes in mood, heartburn or indigestion, dry mouth	
11	Cold cap	Tablet	Side effect : Drowsiness, dizziness, blurred vision, upset stomach, nausea, nervousness, or dry mouth/nose/throat	
12	Calcium	Tablet	Side effect :Bloating , gas and constipation	
13	Ampiclox	Capsules	Side Effect: Diarrhea, rashes , nausea and vomiting	

14	Stopadol	Tablets	Side effect: Dizziness, headache, diarrhea, stomachpain
15	Aspirin	Tablet	Side effect : Upset stomach, heartburn, drowsiness, mild headache
16	Kush	Powder , liquid	Side effect: Paranoia and hallucinations
17	Heroine	Powder, tablet, liquid	Signs of overdose: dangerously low body temperature, slowed breathing, blue lips and fingernails, cold, clammy skin, convulsions and coma
18	Tetracycline	Capsule	Side Effect: Nausea, vomiting, diarrhea, loss of appetite, mouth sores, black hairy tongue, sore throat, dizziness, headache, or rectal discomfort
19	Worms medicines	Tablets	Side Effect: stomach pain, nausea. Vomiting, headache. Dizziness, reversible hair loss.
20	Penicillin	Tablet, injection, suspension	Side Effect: mild diarrhea; headache; black or hairy tongue; or pain, swelling, bruising, or irritation around the IV needle.
21	Artemether Lumefantrine	Dispersible tablets, tablets injection, capsules	Side Effects: headache, dizziness. Weakness, muscle or joint pain. Tiredness, difficulty falling asleep or staying asleep, vomiting, loss of appetite.
22	J & J vaccine	Injection	Side Effect: Headache, Fatigue and Soreness at the Injection Site
23	Malfan	Tablet, Suspension	<ul style="list-style-type: none"> Side Effect: a cough, common cold (nasopharyngitis), dizziness, fever, headache, insomnia, irritation and inflammation of the mucous membrane in the nose (rhinitis), lack of energy, pain in joints (arthralgia), pain in muscles, palpitations, rash serious eating disorder (anorexia) severeinflammatory blisters (acrodermatitis)vomiting
24	Cocaine	Fine white powder	<ul style="list-style-type: none"> Short term effects: Extreme sensitivity to touch, sound, and sight, Intense happiness, Anger/irritability,Paranoia, Decreased appetite
25	Glucose	White powder	Side Effects: confusion; a light-headed feeling, like you might pass out; fever; swelling in your hands or feet; or. Sweating, pale skin, severe shortness of breath, chest pain.

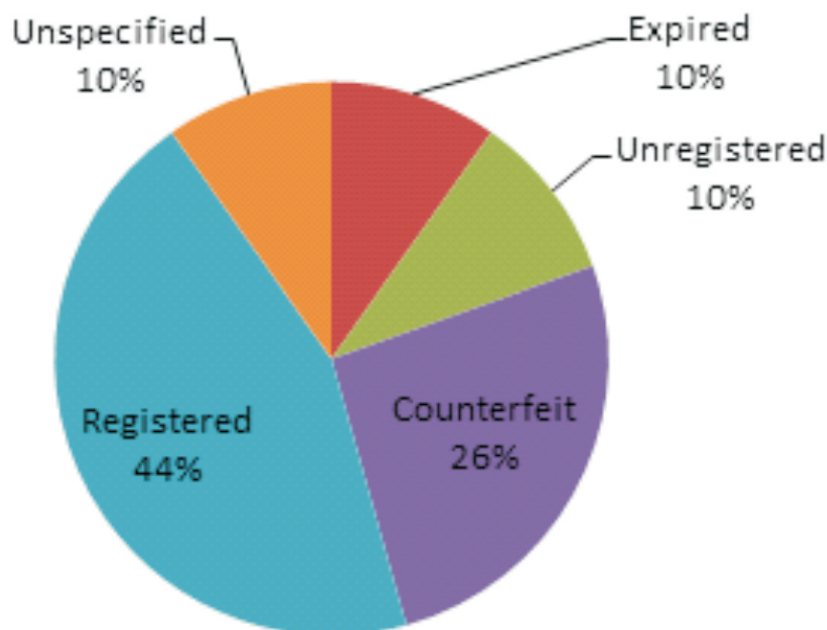
26	Emzor Paracetamol	Tablet , Syrup	Symptoms of overdose: abdominal pain , inflammation of the pancreas, kidney injury caused by damage to the kidney tubule cells, liver failure , loss of appetite, pale color of the skin, presence of an excessive amount of acids in the body, vomiting
27	Diacorte		
28	Pfizer vaccine	Injection	Side Effect: Headache, Fatigue and Soreness at the Injection Site
29	Nugel-O	Suspension,	Side Effect: chalky taste, diarrhea, and constipation
30	Ampicillin	Capsules , tablets	Side Effect: Nausea, vomiting , diarrhea and mouth/tongue sores
31	Co-codamol	Tablets	Side Effect: constipation, feeling or being sick (nausea or vomiting), feeling sleepy headaches
32	Lomotil	Tablets	Side Effect: Drowsiness, dizziness, headache, tiredness, blurred vision, dry mouth, and loss of appetite
33	Erythromycin	Capsule, Tablet, ointment	Side Effect: nausea, vomiting, Diarrhea. Stomach cramps, Loss of appetite, Bloating and indigestion.
34	COVID-19 vaccine	Injection	Side Effect: Headache, Fatigue and Soreness at the Injection Site

3. COMMENTARY ON THE ISSUE OF DRUG PEDDLING IN SIERRA LEONE

The Problem of Sub-standard and falsified medicines in Sierra Leone

In 2019, the Pharmacy Board of Sierra Leone confiscated a total of 92 different brands of medicines from drug peddlers across the Western Area, 41 of which were registered products.

Fig 1: Products confiscated from Drug Peddlers by the Pharmacy Board of Sierra Leone

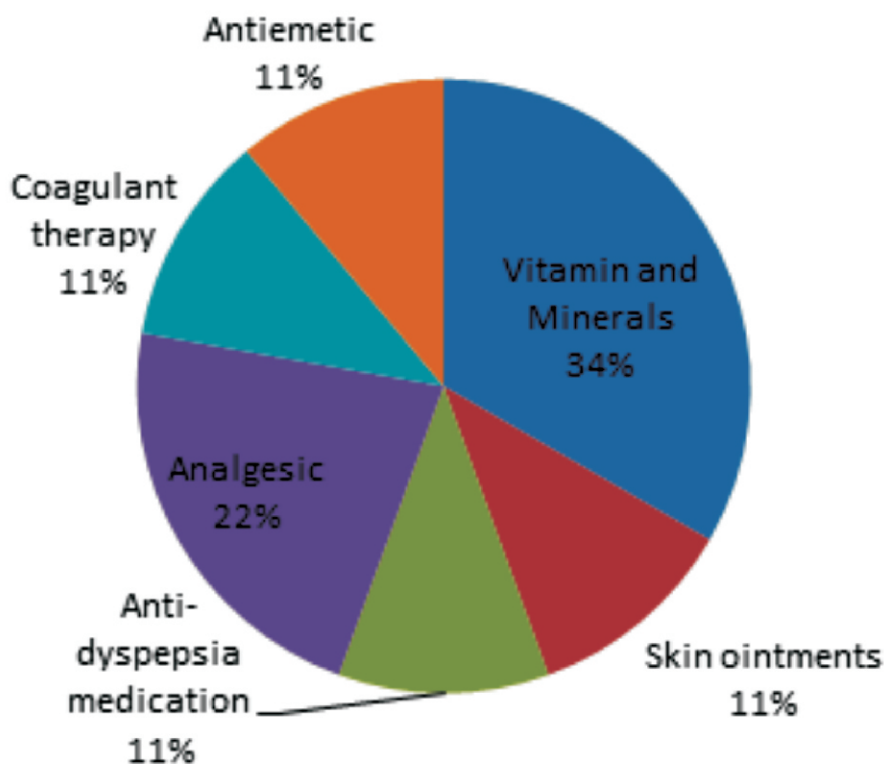


The Registered Pharmaceutical Products fall within the following categories;

Summary of Registered Products Confiscated from Drug Peddler in 2019	
Appetite Stimulant	2
Analgesic	2
Analgesic-antipyretic-antihistamine	2
Antihistamine	5
NSAID	2
Analgesic-antipyretic	14
Antibiotic	1
Cardiovascular Agent	3
Antidiabetic	1

NSAID, Analgesic, CNS stimulant	2
Antifungal	1
Antimalarial	1
Mineral Supplements	1
Haematinic	1
Proton-pump inhibitor	1
Anti-bacterial agent/Anti-Tuberculous	1
Unspecified	1
Total	41

Fig 3: Expired medicines confiscated from drug peddlers by therapeutic class. Year 2019



Drug peddlers continue to pose a serious threat to the credibility of the supply chain in Sierra Leone. As per its legal mandate, the Pharmacy Board of Sierra Leone can confiscate drugs from these drug peddlers but is limited in its powers to prosecute. Drug peddlers are mostly found on the streets of Freetown, in the buses and in overcrowded location hawking medicines and cosmetics to the innocent population. Pharmacy Board of Sierra Leone has established a task force with the Transnational Organised Crime Unit to address the issue of sub-Standard and falsified

medicines. It has also with funding from WHO rolled-out in 2020 a nationwide sensitisation on falsified and sub-standard medicines. WHO estimates that more than one in ten medicines in developing countries is substandard or falsified? The financial and social costs associated with sub-standard and falsified products go beyond purchase to include costs for hospitalisation, strain on family and friends etc.

Table 1: Drugs seized from drug peddlers, counterfeit and substandard drugs

No.	Name of Product	Anatomic Therapeutic Chemical Classification	Status	Pharmacotherapeutic Group
1.	Diclofenac Sodium	M01AB05	Unregistered	Non-steroidal anti-inflammatory and antirheumatic groups
2.	Loperamide Sodium	A07DA03	Counterfeit	Antipropulsives
3.	Apiton (Chlorphenamine 4mg)	R06AB04	Unregistered	Alkylamine Antihistamine
4.	Super para Action (Paracetamol)	N02BE51	Unregistered	Analgesic and antipyretic
5.	KGN Bond Power (capsules) Vitamin B1 2mg)	A11DA	Unregistered	Vitamin and Minerals
6.	Welisulf sulphur ointment	D10AB02	Expired	Dermatologicals (Anti - acne)
7.	Magacol Antacid suspension (200ml)	G04BX01	Expired	Other urologicals (anti-acid secretion)
8.	Extra Strong Exadon (Paracetamol and Caffeine)	N02B E51	Counterfeit	Analgesic
9.	Good Peti (Cyproheptadine	R06AX02		Appetite stimulant
10.	Tabs Puregrey (Sildenafil citrate)		Counterfeit	5-phosphodiesterase inhibitor (Erectile dysfunction and hypertension)

11.	KVA Royal (Chest and Lungs)		Counterfeit	
12.	Tab's Boksa		Counterfeit	
13.	Inj Vitamin K3	br08303	Expired	Antihaemorrhagic
14.	Tab's Declonova 100 (diclofenac 100mg)	M01AB05	Counterfeit	Non-steroidal anti-inflammatory and antirheumatic groups
15.	Tab's stomacool		Counterfeit	
16.	Tab's Connfo		Counterfeit	
17.	All pain (Diclofenac sodium 100mg)		Unregistered	Non-steroidal anti-inflammatory and antirheumatic groups
18.	Tab's C olo caps Corhensa		Counterfeit	Cold and flu
19.	Zynac Forte (Diclofenac + caffeine)	N02AJ15	Unregistered	Pain
20.	Octea		Counterfeit	
21.	Inj. Benzathine penicillin	J01CE08	Unregistered	Antibiotic Agent (Infections)
22.	Tab's Painmax			Analgesic (Pain)
23.	Ward Pepti tabs		Counterfeit	Gastrointestinal distress
24.	Tab's Heptin (Cyproheptadine)	R06AX02	Counterfeit	Antihistamine and Appetizer
25.	Tab's Amipara plus (Paracetamol 325 mg + Caffeine 30 mg + Diclofenac sod. 50mg)		Counterfeit	Analgesic (Pain)
26.	Tab's Metoclopramide (10mg)	A03FA01	Counterfeit	Antiemetic agent
27.	Caps Pirocap (Piroxicam) KVA	M01AC01	Counterfeit	Non-steroidal anti-inflammatory and antirheumatic groups
28.	Tab's Enalapril maleate	C09AA02	Unregistered	ACE Inhibitor

29.	Tabs Folic acid	BO3B B01	Expired	Vitamin and Minerals
30.	Multivitamin & minerals	B03AE04	Expired	Vitamin and Minerals
31.	Tabs Vitago extra		Deteriorated	
32.	Emzor Paracetamol Tablet	N02BE01	Expired	Analgesic
33.	Apitin (Cyproheptadine 4mg)	R06AX02		
34.	Zukaan (para phenylephrine, caffeine, cetirizine)	R01BA53		
35.	Omeprazole 20mg	A02BC01		Gastro-oesophageal reflux disease
36.	Diarraeshif (Loperamide)2mg	A07DA03		Antipropulsives
37.	ORS	A07CA		Rehydration Therapy
38.	Amodiaquine HCL 20mg	P01BA06		Antimalarial
39.	Uni-Konsted (Diclofenac sodium tabs 50mg)	M01AB05	Counterfeit	Non-steroidal antiinflammatory drug
40.	Siopronmax (Diclofenac sodium 100mg)	M01AB06		Non-steroidal antiinflammatory drug
41.	Octeo (Nimesulide 100mg)	M02AA	Counterfeit	Anti-inflammatory and Antirheumatic
42.	Anipara Plus		Counterfeit	
43.	Lydia Oral Contraceptive	G03AD02	Registered	Hormonal Preparations
44.	Cimetidine 400mg	A02BA01	Counterfeit	Antihistamine
45.	Ibupex (Ibuprofen 100mg, Para162.5mg) 100ml	M01AE01	Counterfeit	NSAID
46.	Aldomet 250mg	C02AB.	Counterfeit	Antihypertensives

47.	Augmentin (Amoxicillin + Clavulanate potassium 625mg)	J01CR02	Counterfeit	Antibiotic Agent (Infections)
48.	Theopen DSR (Pantoprazole and Domperidone)	· A02BC	Counterfeit	Gastrooesophageal distress
49.	Mefinac forte		Counterfeit	Analgesic (Pain)
50.	Lariact Disp Art 20mg Lume12mg		Counterfeit	Antimalarial
51.	Bon Apeti		Counterfeit	
52.	KGN Levita (Multivitamin with cyproheptadine)			Multivitamin and Minerals
53.	Diazole (Loperamide) 2mg	A07DA03	Counterfeit	Antipropulsives

What are falsified and sub-Standard medicines?

Substandard also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both.

Unregistered/unlicensed medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

Falsified medical products that deliberately /fraudulently misrepresent their identity, composition or source .

Falsified medical products may contain no active ingredient, the wrong active ingredient or the wrong amount of the correct active ingredient.

Dangers of falsified and sub-Standard medicines

- Increase disease prevalence
- Exacerbate antimicrobial resistance
- Cause serious adverse health effects,
- Waste resources
- Result in economic loss
- Increase out-of-pocket spending on medical treatment.
- Loss of confidence in the health system

Implications for Regulation in Sierra Leone

- Up-regulation of pharmaceutical products to fill-in the gap created by falsified and sub-standard products
- Intensify prevention, detection and response of sub-standard and falsified medicines
- Strengthen National Quality Control Laboratory especially for priority list of essential medicines
- Intensify monitoring of rational medicines use and Pharmaceutical systems strengthening

- Roll-out a nationwide cGood Storage Practice training for Pharmaceutical Service Providers
- Stakeholders commitment in joint enforcement policies and procedures

4. Outreach Programme

The Pharmacy Board of Sierra Leone has as it's mandate the Regulation of the Profession of Pharmacy and the regulation of Pharmaceutical products. Critical to the implementation of it's mandate is the adolescence population represented in this report as in-school pupils mostly from the Senior Secondary School Cohort. This population sub-set are engaged in development through the role they often play as change agents in their schools, communities and families. The Pharmacy Board of Sierra Leone has a school-outreach programme that has been operational since 2020. The model of engagement with school-



going pupils is often via assembly discourse with short duration timespans. However, this year, 2022, Pharmacy Board of Sierra Leone has initiated a deeper discourse with the school going population on it's mandate and on medicines use. The aims of the intervention has been to ;

- Reinforce an understanding of the Board's mandate and the mandate of Pharmacy professionals
- Deepen understanding of medicines, the medicines use process , drug peddling , counterfeit and substandard medicines

Over a period of a month and half, the Pharmacy Board of Sierra Leone interacted with three schools and with the central mosque using the following methodology.

- Focus Group Discussions
- Key informant interviews
- Assembly discussions

List of Pharmaceutical products school children from three secondary schools are exposed (heard about and/or used and/or bought) mostly from drug peddlers	
No.	Name
1	Paracetamol Tablets
2	ORS
3	Calcium Tablets
4	Chymoral

5	Ibuprofen
6	Relief
7	Atycol
8	Amoxicillin
9	Gelosil
10	Atycol
11	Relief
12	Tramadol
13	Cold cap
14	Calcium
15	Ampiclox
16	Stopadol
17	Declorforte
18	Aspirin
19	Relief
20	Atycol
21	Tramadol
22	Kush
23	Heroine
24	Amoxicillin
25	Tetracycline
26	Worms medicines
27	Penicillin
28	Chloroquine
29	Artemether Lumefantrine
30	Malfan
31	Atycol
32	Cocaine
33	Tramadol
34	Glucose
35	Emzor Paracetamol
36	Diacorte
37	Nugel-O
38	Ampicillin
39	Extra-grip
40	Paracetamol
41	Co-codamol
42	Lomotil
43	Erythromycin
44	Tetracycline
45	COVID-19 vaccine

PBSL NEWS LETTER 2022

A total of 16 pupils per school participated in the focus group discussions, whilst the key informant interviews targeted the Principals and Vice Principals of the school depending on their availability. The findings of the school outreach programme show a general awareness of the mandate of the Pharmacy Board of Sierra Leone and identified the 'Pharmacist' and in general terms Pharmacy Professional as the first point of call for the initiation and sometimes completion of the medicines use process and as trusted advisors on medicines. Next in line were the doctors, a

registered health care provider and a community health officer. Pharmacies and Pharmacists were identified as the main health care providers for school pupils. Nonetheless, school pupils identified with drug peddlers and drug peddling as a reasonable quantity had at least once procured medicines from drug peddlers.

The following medicines were also associated with purchase by school pupils on their behalf or someone in their household or community.



Emerging Themes From The Public's Perspective On The Legal Mandate Of The Pharmacy Board And The Profession Of Pharmacy

1. Awareness of the roles and functions of the Pharmacy Board and the Pharmacy Profession
2. Interest in Pharmacy Board and Pharmacy as a career destination and to serve as active participants in enforcement of legislation on access to medicines and monitoring of use of medicines including prosecution for those who sell or misuse or abuse drugs or medicines
3. Uncertainty of scope of the Pharmacy Board and what Pharmaceutical work entails and the roles and functions of the Pharmacy Professionals and its relative position and difference to other health professionals (CHOs Physician Assistants Doctors Nurses Midwives SECHNs Physician Assistants Nursing Aides etc)
4. Exposure(heard about and/or bought and/or used heard about and/or bought and/or used
5. Acceptance of the Pharmacy Board amongst the interviewed/engaged population subsets.
6. Eagerness to explore Pharmacy and Pharmacy Professionals knowledge for clinical care and growth of the Pharmaceutical Sector to access information on medicines and on the legal mandate of the Board and Pharmacy Professionals and to better understand the Pharmacy and Drugs Act 2001
7. Recognition of the legitimacy of Pharmacist and the Pharmacy Board of Sierra Leone
8. Exasperation with drug peddlers and drug peddling and the perpetuation of production and use of hard drugs
9. Willingness to escalate the information in their households and amongst worshippers
10. Understanding of medicines misuse and/or abuse based on lived experiences identification of cough medicines and kush as commonly misused medicines
11. Understanding of the legal implications of drug peddling i.e police custody jail term etc adequate understanding of safe medicines use of drug counterfeiting and drug smuggling
12. Emphasis on accessing medicines from a trained

and qualified Pharmacy Professional or a registered/licensed Pharmaceutical Premises

13. Colloquial understanding of side effect adverse drug reactions etc of medicines(bad effect)

Recommendations

- For the child and adolescence population, review of the Pharmacy and Drugs Act should incorporate the needs of school-going children in-terms of the age limits for accessing certain medicines and medical devices. It should also consider the requirements for self medication and medication under the supervision of a registered Pharmacist or Pharmacy Professional, Pharmacy or other licensed health care provider. The formulation and presentation of pharmaceutical products to ensure child-friendly products should also be reflected in the listing of pharmaceutical products approved for use in Sierra Leone in the Pharmacy and Drugs Act. Also the range of products targeting minor ailments and disease conditions that is perceived within the purview of the Pharmacy professional should be expanded. The role of Pharmacists in diagnosis, prescribing and administering and caring for other categories of child and adolescence disease conditions and risk factors including preventative therapy approaches would need to be reflected in the Pharmacy and Drugs Act.
- It is a priority that the standards for maintaining school-going children from medicines misuse, medicines abuse and irrational medicines use are reviewed. This is because it relates to accessing medicines from illegal channels including drug peddlers and that across healthcare institutions, medicines use experience by school-going children and adolescence is actively captured by the Pharmacist and Pharmacy Professional. The legal authority should be reflected in the revised Pharmacy and Drugs Act and in the Hospitals and Health facilities act. This should extend across all ages, however the school outreach programme provides an entry point

for the school-aged population and the Pharmacy Board of Sierra Leone Outreach Programme.

5. The Board convenes Precursor Chemicals meeting

The Pharmacy Board of Sierra Leone has on the 25th January 2022 held a meeting with Pharmacy Board regulators, the Executive Director National Drug Law Enforcement Agency, PRO National Drug Law Enforcement Agency, the Research Officer Office of National Security and Precursor Chemical Importers at the Pharmacy Board of Sierra Leone Headquarters Central Medical Stores Compound New England. The meeting focused on the legal and illicit sale, distribution and use of precursor chemicals like Cocaine, Heroin, Amphetamine in Sierra Leone, legally in consonance and illicitly in violation respectively of the Pharmacy and Drugs Act 2001.

Precursor Chemical Meeting

The meeting started with individual silent prayers. In his opening remarks, the Deputy Registrar Dr Mohamed Sesay welcomed and thanked all to the Pharmacy Board of Sierra Leone and address all seated that they are in the business of precursor chemicals together. He highlighted that precursor chemicals are used for different purposes, for instance paints, medicines, textiles etc. He furthered by stating that criminals misused precursor chemicals for other illegal purposes like the manufacturing of amphetamines and methamphetamines. Lastly, he welcomed all seated on behalf of the Acting Registrar Dr James P. Komeh.

In her presentation, the Head of Enforcement and Narcotics Department, Dr Joy Johnson stated that precursor chemicals also known as scheduled substances or drug precursors are chemicals that are known to be used in the illegal manufacture of narcotic drugs and psychoactive substances. In addition, she highlighted that these precursor chemicals also have legitimate commercial uses and are legally used in a wide variety of industrial processes and consumer products, such as medicines, flavourings and fragrances like in the production of

penicillin, perfume etc.

Furthermore, the Head of Enforcement and Narcotics Department Dr Joy Johnson outlined the list of precursor chemicals regulated by the Pharmacy Board of Sierra Leone:

- Acetic anhydride
- N-acetylanthranilic Acid
- Ephedrine
- Ergometrine
- Ergotamine
- Lysergic acid
- Norephedrine
- Phenyl acetic acid
- 1-phenyl-2-propanone
- Piperidine
- Potassium permanganate
- Pseudoephedrine
- Safrole
- Acetone
- Hydrochloric acid
- Sulphuric acid
- Ethyl ether
- Toluene
- methyl-ethyl ketone

Dr Joy Johnson emphasized on the need to control precursor chemicals, with the ultimate goal of avoiding diversion which will eventually lead to the production of other products for illicit use like Cocaine, Heroin, Amphetamine etc. Lastly, she outlined the procedure for the importation of controlled substances into the country. Starting from the receipt of request from importer, to the advice of receipt (a document that an importer of a precursor chemical substance is required to submit upon receipt of a consignment of a controlled substance covered by an import permit), returns (returns are documents submitted by importers of controlled substances that show how the controlled substance has been utilized) and follow-up audit inspections (follow-up Audit inspections are conducted at the importers premises and a series of questions i.e. a checklist is used to cross examine the reporting documents that have been previously submitted by them to the Authority to validate authenticity of the usage of the controlled substances).

The Executive Director of the National Drug Law Enforcement Agency, Abdul S. Kargbo thanked the Pharmacy Board for a job well done. However, he emphasized on the enforcement aspect in the Pharmacy and Drugs Act, noting that there is potential for criminals to diverting these precursor chemicals for illicit use. He concluded by saying the control of precursor chemicals is a legitimate concern from all levels. He suggested for PBSL to add punitive measures in case of defaulters in the revision of the Pharmacy and Drugs Act 2001

The Research Officer of the Office of National Security, Sylvester Laggah applauded the Pharmacy Board of Sierra Leone for convening such a meeting and pleaded with PBSL authorities to continue with such meetings. He called for more inter-agency collaboration as this will help in controlling precursor chemicals effectively and efficiently. He recommended that another meeting be convened.

In his closing statement the Deputy Registrar, Dr Mohamed Sesay thanked all seated for attending the meeting amidst their busy schedules. He stated that bringing these businesses in compliance is a serious challenge. However, he highlighted that Pharmacy Board of Sierra Leone is the competent national authority in Sierra Leone for the control of precursor chemicals, empowered to regulate or enforce national controls over precursors and essential chemicals in accordance with the provisions of article 12 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances in 1988. He ended by saying Pharmacy Board of Sierra Leone has established mechanisms to control the import, export, use and diversion of precursor chemicals.

The meeting ended with silent individual prayers.

For more information, please contact the Board on info@pharmacyboard.gov.sl and telephone number +23299117117/073994830

6. Why I shouldn't buy medicines from a drug peddler!- Medicines drug peddlers sell kill. (Include a diagram of a dead person who took a fake medicine from a drug peddler)

- Medicines drug peddlers sell make you sicker.
- I would be involved in a criminal offence
- I may later become a criminal myself .
- Do not Take these products and so Do not buy from Drug Peddlers

7. Common Side effects of medicines- Antihypertensive medicines

Beta-blockers- Block hypoglycemic awareness (Diabetes) – (Picture of an adult male(I don't experience feelings of low sugar in my blood)

Atenolol- Tiredness, Wheezing, Bradycardia, Erectile impotence (Pictures of a man, tired, exhausted on climbing few stairs, a man with a floppy penis)

Diuretics- Worsen glucose tolerance (Now I don't feel fed easily – put a before and after picture- An adult woman, Eating an average- Then another picture with her eating a huge meal

Thiazide Diuretics (Bendroflumethiazide) - Acute attacks of gout

ACE Inhibitors – A dry cough (Picture of a man coughing)

Doxazosin: Postural hypotension(Picture of an adult man whose head swoons on standing)

Nifedipine: Flushing and headache(Draw a picture of a young man with a flushed face and holding frontal lobe)

- 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; (Draw a picture of a person discussing with a health care professional)
- reporting suspicious medical products to your National Medicines Regulatory Authority. (draw a picture of a person on the phone with Pharmacy Board of Sierra Leone)

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

9. What is a suspected adverse drug reaction?

Active ingredient- Phenylephrine – nasal vasoconstriction

Active ingredient - Dextromethorphan - Blurred vision, confusion, difficulty in urination, drowsiness or dizziness, nausea or vomiting (severe), shakiness and unsteady walk, slowed breathing, unusual excitement, nervousness, restlessness, or irritability (severe)

Active Ingredient-Codeine- lightheadedness, lightheadedness, dizziness, nausea, vomiting, shortness of breath, sedation, allergic reactions, constipation, abdominal pain, rash, and itching.

8. Easy ways to identify a counterfeit medicine: Identifying a substandard or falsified medical product

Some falsified medical products are almost visually identical to the genuine product and very difficult to detect. However, many can be identified by:

- examining the packaging for condition, spelling mistakes or grammatical error (draw a picture of a person checking a medicine with wrong spelling)
- checking the manufacture and expiry dates and ensuring any details on the outer packaging match the dates shown on the inner packaging; (draw a picture of a person checking a medicine with wrong spelling)
- ensuring the medicine looks correct, is not discolored, degraded or has an unusual smell; (draw a picture of a medicine which is coloured off-white to yellow, Draw a picture of a person smelling a syrup bottle contents)

e.g 2 Cough syrups

Examples of ADRs include:	
Medicine	Type of Adverse Drug Reaction
Amidopyrine (for inflammation)	White blood cell disorder
Clioquinol (for skin infections)	Visual impairment
Erythromycin estolate (antibacterial)	Hepatitis (liver disorder)
Oral contraceptives	Thromboembolism (blood clots)
Statins (for controlling cholesterol)	Muscle degeneration
Thalidomide (for managing morning sickness)	Phocomelia (disfigured infants)

10. Top ten things to know if I want to open a Pharmacy Business?

1. I need to have a Business Licence from the Registrar General's Office and a tax certificate.
2. I need to have a physical space
3. I need to have a registered Pharmacy Professional
4. I need to apply for Pharmacy Business

Licence to the Pharmacy Board of Sierra Leone

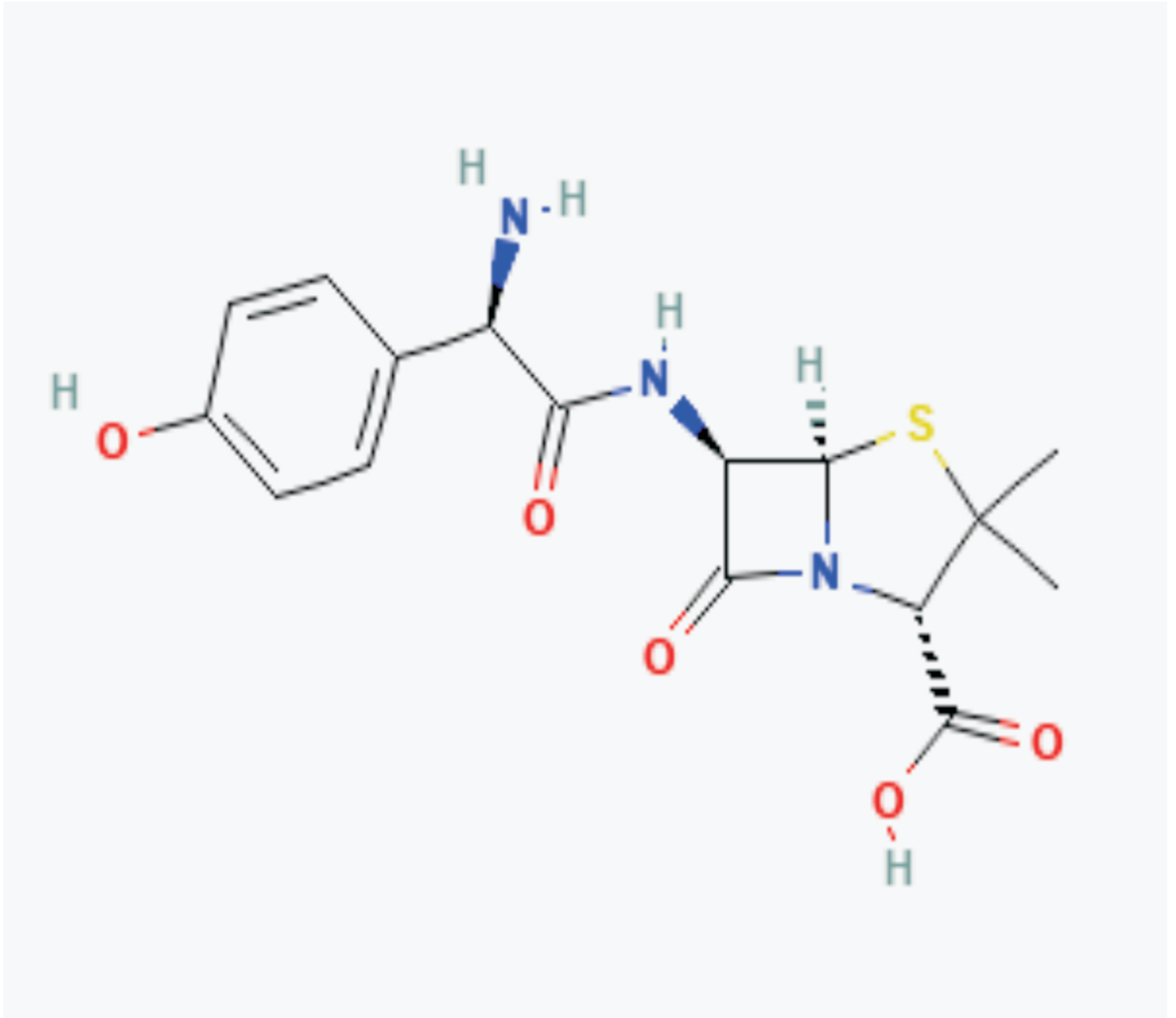
5. I need to have my premises inspected by the Pharmacy Board Inspection Department
6. I need to pass the Pharmacy Board of Sierra Leone Interview for Proprietors and their Pharmacy Professionals
7. I need to pay my Pharmacy Business Licence fee on a yearly basis
8. I need to have a contract agreement between the Proprietor and the Pharmacy Professional
9. I need to know registered pharmaceutical wholesalers and companies to procure pharmaceutical products from.
10. I need to understand the Pharmacy Board of Sierra Leone guidelines for opening a Pharmacy Business and follow the Pharmacy Board on it's facebook, twitter and website addresses.

13. Antimicrobial Resistance Brief Stop and think before your prescribe antimicrobials!

Commonly prescribed and /or dispensed antimicrobials and their modes of resistance

Antimicrobial	Site	Mode of resistance	Prescription Level
Amoxicillin	Cell wall	beta-lactamase cleavage of beta lactam ring	Prescription only medicine
Ampicillin	Cell wall	beta-lactamase cleavage of beta lactam ring	Prescription only medicine
Erythromycin	cell wall, ribosome,	Change in receptor by methylation of rRNA	Prescription only medicine
Tetracycline	Cell wall	Reduced uptake or increased export of drug from the cytosol of the bacteria	Prescription only medicine

14. Drug Profile: Amoxicillin



IUPAC NAME: (2S,5R,6R)-6-[[[(2R)-2-amino-2-(4-hydroxyphenyl)acetyl]amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid

CHEMICAL CLASS: Pharmaceuticals

GROUP: Antibiotics

15. RECALL ALERT : PHARMACY BOARD OF SIERRA LEONE HAS THROUGH THE IMPORTER GLOBAL DISTRIBUTION –UBIPHARM LTD 54 REGENT ROAD HILL STATION RECALLED FROM IT'S PHARMACEUTICAL SUPPLY CHAIN PANTOPRAZOLE 40MG(PANTODENK 40) DUE TO THE PRESENCE OF CONSIDERABLE IMPURITIES

16. WHO ALERT: Falsified Soliris identified in WHO regions of the Americas, Europe and South East Asia

22 December 2021 Medical product alert Geneva Reading time: 1 min (311 words)
Alert Summary

This WHO Medical Product Alert refers to several batches of falsified Soliris (eculizumab) identified in Argentina, Estonia, India and Uruguay and reported to WHO between November and December 2021. The genuine manufacturer of Soliris, has confirmed that the products listed in this alert are falsified. The falsified products were reported at patient level and regulated supply chains in the above-mentioned countries.

Genuine Soliris is indicated for the treatment of paroxysmal nocturnal hemoglobinuria (PNH), atypical hemolytic uremic syndrome (aHUS), generalized Myasthenia Gravis (gMG) in adults, and neuromyelitis optica spectrum disorder (NMOSD).

The products identified in this Alert are confirmed as falsified on the basis that they deliberately/fraudulently misrepresent their identity, composition or source.

Product Name	SOLIRIS 300mg			
Stated manufacturer	ALEXION			
Lot	1012401	1013715	1001600	1001701
Expiry date	SEP 22	FEB 22	03/2023	03/2023
Packaging language	Spanish	Spanish	English	Turkish
Identified in	Argentina, Uruguay	Uruguay	Estonia	India
Photographs	WHO currently does not have photographs to share			

All medical products must be obtained from authorized/licensed suppliers. The products' authenticity and physical condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.

If you are in possession of the above falsified products, please do not use them.

If you have used these products, or you suffered an adverse reaction/event having used these products, you are advised to seek immediate medical advice from a qualified healthcare professional, and to report the incident to the National Regulatory Authorities/National Pharmacovigilance Centre.

17. Pharmacy Board hosts One of Egypt's largest Pharmaceutical investors

Central Medical Stores Compound, New England Ville, Freetown, 15 February, 2022.



The leadership of Pharmacy Board of Sierra Leone has played host to HARCO Pharmaceuticals, which is considered to be one of the largest Egyptian Pharmaceutical products manufacturing company.

Stating the motives of their visit, the Corporate Market Access Director, Shady Murad, said they aspire to cooperate with Sierra Leone in detecting generic ailments including hepatitis B and C in patients and treating infected cases. He added that they were also ready to supply the Government and

private sectors in Sierra Leone with medical products for affordable prices.

"Our company is the largest manufacturer of pharmaceutical products in the MENA region, which focuses on research formulation, manufacturing and commercialization of pharmaceutical products. We export our products to about 50 and more countries," he explained.

In response, the Acting Registrar of PBSL, Dr James P. Komeh, welcomed the Egyptian investors led by the Sierra Leone Ambassador to Egypt, Dr. Sadiq Silla. He thanked them for choosing Sierra Leone to be amongst the countries to which their products will be exported, adding that the cooperation would be a step towards achieving the Government's dream of giving its citizen access to quality medicines.

However, Dr. Komeh informed the entourage that PBSL has some regulatory mandates to follow before medical products are allowed to be circulated into the market. Among other things, he said all products should be tested and certified by PBSL and that the investors should have a local pharmacist that would serve as intermediary between them and the Agency. He assured that his management team will go through the document that contains the list of products that the investors want to import into Sierra Leone and get back to them within the shortest possible time.

He ended by reiterating his gratitude for the visit and optimized for a fruitful partnership between the investors and the health sector in Sierra Leone.

18. The Expert Committee on Drug Safety and Clinical Trials of the Board conducted 10 meetings from quarter 1-2 of 2021 to review 10 clinical trial applications.

Summary

No	Name of trial	Type of application	Status
1.	CLINICAL TRIAL PROTOCOL EVALUATION REPORT FOR PUBLIC HEALTH EMERGENCY SOLIDARITY PLUS TRIAL An international randomised trial of additional treatments for COVID-19 in hospitalised patients who are all receiving the local standard of care	New application	Approved
2.	Report of the expert committee meeting on drug safety and clinical trials for the review of an open-label study to evaluate the safety and immunogenicity of an Ad26.ZEBOV booster dose in children previously vaccinated with the AD26.ZEBOV AND MVA -BN-FILO VACCINE REGIMEN (3 rd Dose trial) V.1	New application	Approved
3.	Evaluation of The Impact on Childhood Mortality of Azithromycin Plus Intermittent Preventive Treatment Administered Through the Expanded Program on Immunisation in Sierra Leone (Icaria Improving Care Through Azithromycin Research for Infants in Africa) V.3	Protocol amendment	Approved
4.	VAC52150EBL3005 (EBOVAC-Salone Extension) A cohort study to evaluate the long-term safety and immunogenicity of the candidate Ebola vaccines Ad26.ZEBOV and MVA -BN®-Filo in adults and children Protocol VAC52150EBL3005 15/01/2021 - Protocol amendment	Protocol amendment	Approved
5.	Expert Committee Review Meeting on Drug Safety and Clinical Trials for The Introduction of COVISHIELD Astrazeneca Covid-19 Vaccine in Sierra Leone	Emergency use authorisation including review of the Risk Management plan	Approved
6.	The Expert Committee Review Meeting on Drug Safety and Clinical Trials for The Introduction of Sinopharm Covid -19 Vero Cell Inactivated Vaccine in Sierra Leone	Emergency use authorisation including review of the Risk Management plan	Approved
7.	Expert Committee Meeting on Drug Safety and Clinical Trials for The Review Of The World Health Organization* Clinical Protocol For The	Expanded Access/Compassionate use	Approved

	Deployment And Effectiveness Of A 2 Dose Vaccine Against Ebola By Mobile Teams In The Context Of An Active Ebola Outbreak - Protocol VAC52150EBL4005; VAC52150 (Ad26.ZEBOV/MVA -BN-Filo [MVA-mBN226B])		
8.	Evaluation of The Impact on Childhood Mortality of Azithromycin Plus Intermittent Preventive Treatment Administered Through the Expanded Program on Immunisation in Sierra Leone (Icaria-Improving Care Through Azithromycin Research for Infants in Africa) V.4	Protocol amendment	Approved
9.	Partnership for Research on Ebola Vaccination (PREVAC)- 6.0	Protocol amendment	Approved
10.	Report of the expert committee meeting on drug safety and clinical trials for the review of an open label study to evaluate the safety and immunogenicity of an Ad26.ZEBOV booster dose in children previously vaccinated with the AD26.ZEBOV AND MVA -BN-FILO VACCINE REGIMEN (3 rd Dose trial) V.2	Protocol amendment	Approved
11.	Partnership for Research on Ebola Vaccination (PREVAC)- 7.0	Protocol amendment	Approved
12.	Evaluation of The Impact on Childhood Mortality of Azithromycin Plus Intermittent Preventive Treatment Administered Through the Expanded Program on Immunisation in Sierra Leone (Icaria-Improving Care Through Azithromycin Research for Infants in Africa) V.5	Protocol amendment	Approved

19. Causality assessment and signal detection

In-house causality assessment and risk assessment were done for the following Adverse Drug Reaction(ADR) reports and feedback provided. No signal was detected.

- o Jadelle implant
- o Bendroflumethiazide 2.5mg
- o Artefan(AL)
- o Nimerix
- o Prazosin
- o Contrimoxazole, phenytoin, DTL, Amlodipine
- o Omeprazole
- o Benzylpenicillin & Amoxicillin
- o Malfan
- o Amlodipine & Atenolol
- o Rifampicin
- o Zidovudine, lamivudine, nevirapine
- o BCG Vaccine
- o TLD
- o RHZe/RH

Tips from Pharmacy Board on Medicines Use

Don't know medicines by their colours

Take medicines according to the Pharmacist, Doctor, Nurse or other Health professional's prescription

Check medicines containers for the batch numbers and expiry dates before you dispense or use them

Check if your Pharmacy where you procure medicines is registered

Call: +232 99 117 117 from registered Pharmaceutical Outlets

Don't buy medicines from drug peddlers

PHARMACY BOARD IS INFORMING THE GENERAL PUBLIC THAT **WORLD HEALTH ORGANISATION (WHO)** HAS ISSUED A MEDICAL ALERT FOR 4 CONTAMINATED COUGH SYRUPS FOR CHILDREN(PAEDIATRIC).

THE PRODUCTS HAVE BEEN FOUND TO CONTAIN UNACCEPTABLE AMOUNTS OF DIETHYLENE GLYCOL(DG)AND ETHYLENE GLYCOL(EG). TOXIC CHEMICALS I.E THEY ARE POISONOUS

PLEASE DO NOT BUY OR RECEIVE THESE PRODUCTS(PICTURES BELOW) FROM ANY LICENSED HEALTHCARE INSTITUTION, LICENSED HEALTHCARE PROFESSIONAL OR FROM THE STREETS ILLEGALLY

IF YOU COME ACROSS THESE PRODUCTS IN SIERRA LEONE

A. Medical Products

- 1. Promethazine Oral Solution**
- 2. Kofexmalin Baby Cough Syrup**
- 3. Makoff Baby Cough Syrup**
- 4. Magrip n Cold Syrup**



- DO NOT BUY THESE PRODUCTS

- CALL PHARMACY BOARD OF SIERRA LEONE ON 073994830 or 099117117/ if you come into contact with these products anytime

- REPORT any medicine related sign and symptom by calling PBSL on 099117117 or send an email to info@pharmacyboard.gov.sl OR

- Download, fill and submit via email the Individual Case Safety Report Form (Adverse Drug Reaction Form) from our website www.pharmacyboard.gov.sl.

This newsletter is published by the Information and Communication Department of the Pharmacy Board of Sierra Leone with approval by the Editorial Committee of the Board. For further enquiries you can contact the Board on info@pharmacyboard.gov.sl or 099117117

AVOID FAKE

MEDICINES



ALWAYS TALK ABOUT IT

CHECK YOUR MEDICINES BEFORE TAKING THEM



The Pharmacy Board of Sierra Leone is the National Medicines Regulatory Agency in Sierra Leone. It is a semi-autonomous agency under the Ministry of Health and Sanitation established by the Pharmacy and Drugs Act 1988. The Board is charged with the responsibility of regulating medicines (drugs), cosmetics, chemicals and reagents and other related pharmaceuticals and medical products. The Board also regulates the Pharmacy Profession and is also responsible for medicines safety and public wellbeing.

This newsletter is published by the Information and Communications Department of The Pharmacy Board of Sierra Leone.

For more information on medicines use or the regulation of the Pharmacy Profession in Sierra Leone, please contact: Pharmacy Board of Sierra Leone, Central Medical Stores, New England Ville, Freetown.

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