NAFDAC news

Issue 11, February 2023 | Safeguarding the Health of the Nation | ISSN: 1118-4086

Adeyeye returns with zest

- Hits the ground running with second tenure transformative agenda

"Doing the right things makes a nation great ...Not doing the right things brings setbacks
– Prof. Mojisola Christianah Adeyeye"

- NAFDAC makes landmark seizure of imported Tramadol in The Republic of Benin

...Upgrades Dossier Review Management

- NAFDAC fights corruption with effective leadership, ethical values

CONTENT

Editor's Note

The reward for hard work is more work as the Director – General of NAFDAC, Prof. Moji Christianah Adeyeye wasted no time in unveiling her second tenure transformative action plans immediately she resumed office. This maiden edition of e – NAFDAC News Letter chronicles the transformative agenda and beams a searchlight on the fast unfolding regulatory activities that define the renewed vigour and constructive engagement of Prof. Adeyeye. The debut of this e -NAFDAC News Letter is one of the quick proactive steps taken by the erudite Professor to reinvigorate the Agency's internal and external communication and information dissemination channels.

A wide range of regulatory activities such as Administrative restructuring for Effective Regulatory Performance, Track and Trace Programme, newly introduced Modern Performance Management System, Dossier Review, NAFDAC – Danish Embassy Partnership on Food Safety, Leadership and Anti – Corruption Lecture Series among others are news worthy materials for you to read in order to keep abreast of unfolding events in the Agency.

Dr. Abubakar Jimoh

A monthly Publication of the Public Affairs, Office of the Director-General, NAFDAC, Plot 2032, Olusegun Obasanjo Way, Wuse Zone 7, Abuja.

Tel: 07066925562
08063311590

Email:
newsletter@nafdac.gov.ng

www.nafdac.gov.ng

In this edition

Public Alert No. 02/2023 – Alert on Substandard (contaminated) AMBRONOL syrup and DOK-1 Max syrup

January 9, 2023,

The National Agency for Food and Drugs Administration and Control (NAFDAC) is notifying Healthcare providers that one batch of substandard (contaminated) METHOTREXTM (methotrexate) 50mg, have been identified in two countries (Yemen and Lebanon) in the WHO Eastern Mediterranean region.

The stated manufacturer, CELON Laboratories Pvt Ltd., has confirmed to WHO that the stated batch number, manufacturing and expiry dates combination referenced on the product match their internal records. Although, they have not had access to samples of the suspect products for their own confirmatory testing.

On the other hand, the health authorities in both Yemen and Lebanon conducted microbiological testing on the remaining unopened vials of METHOTREXTM 50mg following reports of adverse events in pediatric patients receiving the medication. Results in both countries were positive for Pseudomonas aeruginosa, indicating contamination of the products.

Pseudomonas aeruginosa bloodstream infection is a serious infection that may lead to death and any product that has any contamination and is administered directly in the body would present serious risks to patients.

Methotrexate is a chemotherapy agent and immune system suppressant. It is used for the treatment of a wide variety of cancers as well as severe psoriasis, severe rheumatoid arthritis, and juvenile rheumatoid arthritis. It may be given by intrathecal, intramuscular, intravenous, or intra-arterial routes. Patients receiving methotrexate treatment may have weakened immune systems and be more vulnerable to opportunistic infections.

Product details

The details of the contaminated product are as follows:

Product Name	METHOTREXTM 50mg
Declared active ingredient	Methotrexate 50mg/2mL
Stated Manufacturer	CELON LABORATORIES, PVT LTD – Telangana State, India
Stated to be marketed by	RMPL PHARMA LLP – Mumbai
Batch number	MTI2101BAQ
Expiry date	12/2022
Date of manufacture	01/2021

METHOTREXTM 50mg batch MTI2101BAQ was intended to be sold exclusively on the Indian market. Availability of the batch in Yemen and Lebanon proves the product was procured outside the regulated supply chain. Therefore, the stated manufacturer cannot guarantee the safety of this product which was not destined to these markets.

However, it is likely that this product may have been distributed to other countries through informal markets. It is important to detect and remove this contaminated product from circulation to prevent harm to patients. Substandard medical products are products that fail to meet either their quality standards or specifications and are therefore "out of specification".

The product is not in NAFDAC's database. However, NAFDAC implores importers, distributors, retailers and healthcare providers to always exercise caution and vigilance within the supply chain to avoid the importation, distribution, sale and administration or use of falsified or substandard medicinal products. All medical products must be obtained from authorized/licensed suppliers. The products' authenticity and physical condition should be carefully checked.

Healthcare professionals and consumers are advised to report any suspicion of adverse drug reaction, substandard and falsified medicines to the nearest NAFDAC office, NAFDAC on 0800-162-3322 or via email: sf.alert@nafdac.gov.ng

NAFDAC……..Customer-focused, Agency-minded.

Signed Management

Lead Story

Adeyeye returns with zest

•Hits the ground running with second tenure transformative agenda

It is often said that 'the reward for hard work is more work.' True as this is, it is oftentimes seen as a proof of the fulfilment that comes with satisfactory rating of one's performance.

This is the case of Prof. Mojisola Christianah Adeyeye.

Having been found worthy and outstanding in her professional sojourn, which traversed various climes, Professor Adeyeye was appointed the fourth substantive Director General of Nigeria's premier food and drug regulatory body, the National Agency for Food and Drug Administration and Control (NAFDAC).

Within five years, she was able to justify the decision by President Muhammadu Buhari to pick her for the number one position in the Agency rated as one of the most important in Nigeria as far as public safety is concerned.

The records of the transformation she brought to NAFDAC within five years were plain to see. Such was the consideration when President Buhari gladly returned her to the stead for another new tenure of five years as Director General.

Upon returning, Professor Adeyeye has wasted no time, as she has hit the ground running with a bang, unveiling a robust transformative agenda that will drive her second term in office.

In her second Term Resumption Speech, Professor Adeyeye affirmed her knowledge of the task she had undertaken and the road she is to travel, when she said, "Doing the right things makes a nation great or, simply stated, Righteousness exalts a nation."

On the contrary, she said, "Not doing the right things brings setbacks."

In the speech delivered to members of staff on 4th January, 2023 in Abuja, Professor Adeyeye was full of gratitude to President Buhari and a host of institutions that were instrumental to the successes she achieved in her first tenure.

"I am immensely grateful for the Presidency and the efforts made to ensure that I got the second term," Professor Adeyeye stated.

Looking at the feats achieved so far, Professor Adeyeye recalled how unnerving the task seemed at the onset.

She said, "Upon my assumption of duty on November 30, 2017, I listed the following cardinal points as the goals to be achieved to include maintaining a well disciplined and motivated workforce, working towards eliminating substandard and falsified medicines (SFs), unsafe or illicit drugs, unwholesome foods, chemicals and other products and aligning NAFDAC with international standards in food, drugs and other regulated products regulation."

Other tasks on Professor Adeyeye's to-do list upon resumption during her first tenure include reconstruction of NAFDAC web presence and streamlining the submission and approval of dossiers for registration of drugs, food, and water, working towards eliminating overlaps among sister agencies, such as FCCPC, SON, NESREA, NAQS and PCN, engagement of Micro, Small and Medium Enterprises (MSMEs)

Providing much needed Transportation and logistics to inspection sites as part of concerted efforts to strengthen our enforcement activities.

While taking a retrospective assessment of all these, the NAFDAC DG said, "I thank God that all these and much more have been achieved."

She attributed the successes to the support the Agency received from various persons and institutions, including the National Assembly, the Leadership of the Federal Ministry of Health, NAFDAC Council, Sister Agencies with which NAFDAC collaborate and other Stakeholders.

She also took time to commend NAFDAC staff members for making her first tenure worth the time.

She said, "My first tenure wouldn't have been successful without the dedicated NAFDAC staff who placed the Agency and the country first above themselves, and worked hard for the international recognition that NAFDAC now enjoys in both food and drug administration, and control. I appreciate them very much."

Similarly, she was full of gratitude to the African Medicines Regulatory Harmonization (AMRH) of African Union Development-Agency-New Partnership for Africa's Development or AUDA-NEPAD, whose steering Committee Professor Adeyeye chaired for almost five years, and WAHO/ECOWAS-MRH for their understanding during the wait for the second term.

"I am also grateful to the Pharmaceutical Manufacturing Group of Manufacturing Association of Nigeria that had been in the tunnel with me since 2017, and especially over the last few weeks in ensuring that the industry is strengthened and becomes

R-L: SA-DG (Abuja), Mr. Dadi Nantim, SA-DG (Lagos) Dr. Gbenga Fajemirokun, Director (PRS), Dr. Abimbola Adegboye, DG, Prof. Mojisola Christianah Adeyeye, Director (F & A), Mr. Ayanwande Ayangbenga Olusegun and the Director (HRM), Mr. Joseph Aina during the unveiling of the second Tenure Action Plan of the DG.

Prof. Adeyeye being received by members of staff upon resumption for her second term

competitive globally," the Professor Adeyeye said in appreciation of the support she received from the industry.

Speaking about how ready the Agency is for the next level, she said, "NAFDAC, as Maturity Level 3 regulatory agency is now guided by international standards to ensure that the regulated products are of quality, safe and efficacious, thus safeguarding the health of consumers."

Considering the fact that NAFDAC's activities are global, and that the products that the Agency regulates are traded on international platforms, the DG underscored the need for use of international standards.

Consequently, she outlined the Agency's strategic action plan to include the following:

- Ensuring Good Governance, Financial Management and Intensive Public Enlightenment Campaigns.
- Attain WHO ML4 and World Listed Authority (WLA) status which will enable global trade and competitiveness of Nigerian – made pharmaceutical products.
- Attain Vaccine Lot Release ML4 to position Nigeria strategically for vaccine manufacturing
- Create Office of Women's Health
- Supply chain Monitoring and continual vigilance to reduce substandard and falsified, counterfeit medicines and Narcotics.
- Continuous strengthening of Regulatory activities.
- Expand Post Marketing Surveillance (PMS)
- Increase Collaboration with Academia, NDLEA, other Sister Agencies and Development Partners.

The Director General said the action plans were geared towards consolidating and widening horizon of the successes and achievements recorded in her first tenure and bid to launch NAFDAC into the Ivy League of World listed Regulatory Authorities.

In concluding, Professor Adeyeye said, "NAFDAC has achieved much success under my leadership in the last five years. We look forward to building on these achievements while working even harder to record more achievements and successes in the coming years."

Professor Adeyeye is walking her talk already, as she has commenced tours of some factories to ascertain their levels of compliance to regulations. She has also been going around on continued advocacies to key stakeholders towards ensuring that Nigeria is rid of fake medicines, foods and other regulated products.

DG (NAFDAC), Prof. Adeyeye seeks to entrench anti-corruption, effective leadership and ethical values in the work place

The Director-General NAFDAC in her drive for Staff training and capacity development prioritised staff expertise on the job and approved a training on anti-corruption, leadership in the 21st century and ethical values in the work place. The DG-NAFDAC has authorised that this training be conducted for all staff in the Agency to ensure the creation of a strong, effective, and futuristic NAFDAC that is able to cope with the new changes evolving and challenging current crop of leaders. Meanwhile all DDs and ADs in the Agency have been trained while plans are underway for other staff.

Workplace values have eroded and disappearing very fast leaving unappetizing taste when people come together at workplaces. The training is bringing staff together to jointly write communique for each session, emphasizing importance of NAFDAC to be more customer-centric, to display emotional intelligence that mitigates negative behaviours, arrogance and ignorance, low knowledge management, lack of empathy, evasion of duties, sheer laziness, and corrupt tendencies.

Training Module:

Each training session was conducted for three days, and each day had two sessions with different modules.

The first day captured topics on anti-Corruption, Leadership and Ethical Values in NAFDAC for the first session. The second session looked at the future of quality leadership in the 21st century with emphasis on emotional Intelligence; a visual presentation to guide Syndicate Group Discussion and concluding with questions and answers. In the second day, the Role of the Employee Lifecycle in the Development, Enhancement and Sustenance of Organizational Leadership in NAFDAC was discussed. The second session examined the impact of Organizational Values on Institutional Strengthening such as NAFDAC and a visual presentation to guide Syndicate Group Discussions. The third concluded with a review of the two days' activities, individual participants' assessment of instructor and the programme, presentations of certificates to participants, Group photograph and closing remarks by the Consultant.

The benefit of this training is yet to be harvested following the robust number of top leaderships of the Agency who have already been trained and counting. A total number of Two Hundred and Sixty-Seven (267) Deputy Directors and Assistant Directors have participated in the training so far held in Abuja, Lagos, and Port Harcourt.

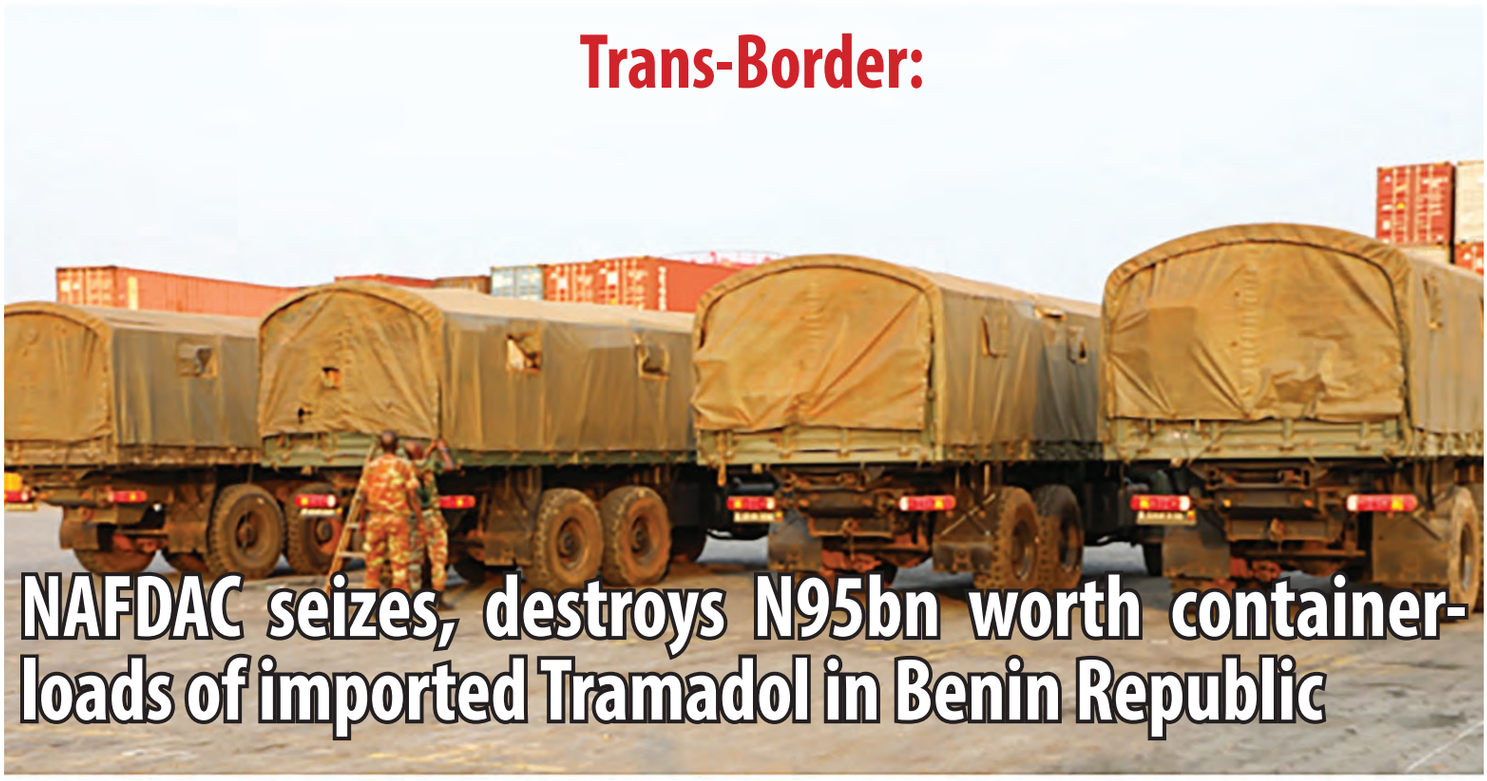
To ensure NAFDAC continues to retain the top ranking as an organization with trusted integrity and practices, The DG NAFDAC has vowed to step up on trainings and capacity development.

The need for the Agency to exude our core values of Professionalism, Resilience, Integrity, Dedication and commitment, and Excellence (PRIDE) is never more needed, than at this point when many officers who have groomed themselves both technically and emotionally with these core values and are gradually easing out of service or jetting out with their skills to other seemingly greener pastures.

It is an amazing step taken by the DG NAFDAC to ensure that corruption vicesis nipped in the bud and values that build the Agency are restored and practiced intentionally in the organization.

We wish her an amazing cruise as she takes on the challenge of stamping out corrupt tendencies and entrenching a legacy of PRIDE!

Trans-Border:



NAFDAC seizes, destroys N95bn worth container-loads of imported Tramadol in Benin Republic

Truck loads of Tramadol seized in Benin Republic by NAFDAC

On December 21 and 22, 2022, the National Agency for Food and Drug Administration and Control (NAFDAC) recorded a historic milestone when the Agency destroyed over Ninety-five billion naira (N95 billion) worth unregisteredimported substandard and falsified Tramadol tablets in Cotonou, Benin Republic.

This landmark event was a culmination of pain staking and extensive intelligence and tactical operations between 2018 and 2022.

In August 2018, NAFDAC received an intelligence report from the Presidency on the intention of some unscrupulous importers to ship thirty-one (31) containers of unregistered pharmaceutical products, including tramadol 200mg and above, from India to Nigeria.

The containers were alleged to be labelled as building materials and meant for bonded terminals. The Director-General of NAFDAC (DGN), Prof Mojisola Christianah Adeyeye,swung into action and immediately directed the Director of Ports Inspection Directorate (DPID), Prof. Samson B. Adebayo, to ensure those products do not find their way into circulation in Nigeria.

The DPID, working with his Intelligence & Monitoring Unit, commenced surveillance and tracking of the reported containers from the ports of loading to the successive ports where they were transloaded along the sea routes.

The directorate collaboratedextensively with the Nigeria Customs Service (NCS)and eventually, twenty-one of the containers were intercepted and discharged at the Apapa port in Lagos, Nigeria as manifested. One container however could not be tracked because of a missing container number. Amongst the 21 containers intercepted, only two contained building materials.

With this development, the Agency observed that the importers changedtheir strategy and diverted the remaining containers away from the Nigerian ports.

It was observed that four of the remaining containers were discharged at transhipment in Malaysia. One container was transferred to Cotonou port in the Republic of Benin, while the remaining four were initially diverted to Tema Port in Ghana but later diverted to

DG (NAFDAC), Prof. Moji Adeyeye flanked by Director (PID) Prof. Samson Adebayo, Director (F & A), Mr. Ayanwande Ayangbenga Olusegun, Director (HRM), Mr. Joseph Aina, Director (Public Affairs), Dr. Abubakar Jimoh and other management staff during a World Press Conference on a Joint International Destruction of N95billion Container-loads of Imported Tramadol in Benin Republic.

Cotonou port.

Using the tracking system, the Agency was ahead in the game and had contacted the Ghana Food and Drug Agency. This made it impossible for the importers to receive and discharge the four containers at Tema port.

With five containers now in the Republic of Benin, the threat to Nigeria was real. The DGN in her proactive nature, immediately contacted the then Ambassador of Nigeria to the Republic of Benin, His Excellency Kayode Oguntuase, for assistance in ensuring that the authorities in the Republic of Benin effected the seizure of the five containers on the request of NAFDAC.

This paid off as the containers were held throughout the duration of the covid-19 pandemic. The new Ambassador, His Excellency Olukayode O. Aluko continued in the strides of his predecessor and never relented in his effort at ensuring that all five (5) containers were released to NAFDAC for destruction in Cotonou, despite a one and half year's court case instituted in the Benin Republic against this move. A team of NAFDAC officers, including Investigation & Enforcement Directorate officers, led by the DPID took part in the destruction exercise in Cotonou. This international landmark achievement has never been recorded in the history NAFDAC and both countries.

Details of the products found in the five containers during the joint physical examination is seen below.

S/N	BRAND NAME	GENERIC NAME	DETAILS
1	TAMRAL 225 TABLETS	TRAMADOL HCL	1,276 CTNSX50 ROLLSX10X10 TABS
2	TAMRAL 250MG TABLETS	TRAMADOL HCL	571 CTNS X50 ROLLSX10X10 TABS
3	TRAMADOL 120MG CAPSULES	TRAMADOL HCL	129 CTNS X30ROLLSX20X10 CAPS
4	TRAMADOL 225MG TABS	TRAMADOL HCL	415 CTNSX50 ROLLSX10X10 TABS
5	REALLY EXTRA DICLOFENAC TABLETS 50 MG	DICLOFENAC & CAFFEINE	58 CTN X 50 X 10 X 10 TABS
6	RELITY EXTRA DICLOFENAC TABLETS 50 MG	DICLOFENAC	24 CTN X 50 X 10 X 10 TABS

The street value of the drugs destroyed was estimated at N95 Billion (Ninety-five billion Naira).

PHOTOS FROM THE SEIZURE

Adulterated drugs being prepared for destruction

Drug destruction exercise

Performance Evaluation:
NAFDAC begins Implementation of PMS

Dr. Folashade Yemi-Esan, Head of Service

The National Agency for Food and Drug Administration and Control (NAFDAC) has commenced the implementation of the Modern Performance Management System recently circulated by the Office of the Head of Service of the Federation.

This modern Performance Management System was initiated in the Public service to reposition the Service for efficient and effective service delivery. The President and Commander in Chief of the Armed Forces of the Federal Republic of Nigeria, President Muhammadu Buhari directed the commencement of the PMS to replace the Annual Performance Evaluation Report with Effect from 1st January 2023.

It will be recalled that the Annual Performance Evaluation Report system was froth with inefficiencies and inability to actually measure the performance of staff as it is subjective and many staff have betrayed their supervisors to award marks out of emotions than from actual performance.

A number of tools to be used in implementing the new appraisal system across the federal Ministries, Departments and Agencies have been posted on the website of the Office of the Head of Service – www.phcsf.gov.ng. Some of the tools include – the Policy on Performance Management System for Federal Public Service, guidelines on performance management system for FederalPublic service, federal public service comprehensive competency framework and template for the development of job description for posts in MDAs.

Meanwhile, the Director General of NAFDAC, Professor Mojisola Christianah Adeyeye has directed that a circular to this effect dated 21st December 2022 be circulated for immediate implementation. To manage the process, NAFDAC will be required to constitute teams, and institute an implementation strategy and many other steps necessary for monitoring.

So far, NAFDAC, through the proactive leadership of Professor Adeyeye has instituted a number of these requirements and almost set to commence full implementation.

As part of the orientation, all staff of the Agency have been urged to ensure that they comply with the implementation process deployed and provide performance reports that are top rated and internationally accepted.

Professor Mojisola Christianah Adeyeye, NAFDAC DG

NAFDAC tightens post marketing surveillance

•Rejigs PV/PMS Directorate to enhance efficiency

Irked by the rampant reports of non-compliance by manufacturers and importers of regulated products to laid down guidelines after registration, the National Agency for Food and Drug Administration and Control (NAFDAC) has rejigged its operational structure to focus on the post marketing surveillance of registered and other regulated products that have not been captured during the registration process.

A bold step taken by the Director General NAFDAC Professor Mojisola Adeyeye to this effect is to separate the Post Marketing and Surveillance Division from the Pharmacovigilance and Post Marketing Surveillance Directorate to report directly to the DG (NAFDAC) in the meantime.

This newly created PMS Unit will be headed by Pharm. Bitrus Fraden, a Deputy Director who is widely versed in Post Marketing Surveillance. His background as a field Officer having served in the States as a State Coordinator, worked in Investigation and Enforcement Unit and managed the PMS Division in Lagos has set him as a proper driver for this new Unit.

The Post Marketing Surveillance Unit headquartered in Abuja will be distinct from the PV Directorate.

The action was necessitated by reports that products that underwent NAFDAC's rigorous registration process are seen to be violating basic registration requirements like labelling compliance, correct ingredients and approved quantities, storage requirements, appropriate transportation system, warehousing requirements, appropriate sale, and approved advertisements post registration.

NAFDAC is particularly concerned that many products do not comply on the shelf for sale or mid transportation.

The Agency has taken a bold decision to clampdown on violators, to curb situations where duly approved product labels are changed from the approved colour combinations, designs, pictorials and packaging type and quality continued to be pushed into the markets, leaving the consumers confused on how to identify genuine versions of the affected products.

According to the Director General, Professor Mojisola Christianah Adeyeye, achieving good result in this regard "would require a more focused and deliberate post marketing surveillance activities to be emplaced."

Apart from labelling violations, there are reports of other violations like the transportation of regulated products without special temperature and light exposures by ill equipped vehicles, poor storage warehouses and monitoring systems, illegal distribution systems and reckless display of regulated products in approved distribution and retail outlets.

These have continued to put pressure on the management to look for better ways to curb post-marketing violations.

"While wishing the new Unit best wishes and effective and efficient surveillance activities with outstanding successes, it is hoped that the Agency will continue to record amazing feats as we step into the markets and look at what the consumers are accessing," the DG stated.

Danish Embassy strengthens bilateral ties with NAFDAC

•Partners agency to build capacity of staff

The National Agency for Food and Drug Administration and Control (NAFDAC) and the Government of Denmark, through the country's embassy in Nigeria have formed a collaboration that would raise the quality of services offered by NAFDAC through the improvement in capacities of staff and equipment.

The Director General of NAFDAC, Professor Mojisola Christianah Adeyeye who has already taken steps to strengthen NAFDAC's relationship with the Danish Embassy in Nigeria through the coordination of the Agency's Office of Trade and International Relations (OTIR), said the bilateral deal signed with the Embassy of Denmark has been one of the best things that happened in the year 2022.

A major fallout of this collaboration is that many staff of the Agency have benefitted from several scholarship offers through the Danida Fellowship Centre.

NAFDAC has so far released a total of 46 staff who were nominated to attend various trainings in different areas in Denmark and other African locations like Tanzania.

"The bilateral deal NAFDAC signed with the Embassy of Denmark has been one of the best things that have happened in the year 2022 asidefrom attainment of WHO Maturity Level 3. This has resulted in theprovision of several scholarship offers through the Danida Fellowship Centre on behalf of the "Embassy" to NAFDAC," NAFDAC DG stated.

So far, the Agency released a total of 46 staff who were nominated to attend various trainings in different areas in Denmark and other African locations likeTanzania.

A broad break down of the number shows that 12 Staff from the Food safety Directorate, three (3)from Public Health/ AMR in Animal and Human, 17 from Human Resource Development and four (4) from Environmental Impact have so far benefitted from this opportunity.

Meanwhile, 27 (Twenty seven staff have completed their training, awarded certificates and have since resumed back to work impacting their spaces. There are currently seven(7) Staff scheduled to travelbetween February and June 2023 for more trainings on the same scholarship scheme.

The selection process for this scholarship offers requires staff to fill a form, write a motivation for the particular course that they are recommended for and how they will use it when they return. A final selection is done by the Danida FellowshipCentre in Copenhagen.

In a recent visit by His Excellency Sune Krogstrup, The Danish

Ambassador to Nigeria, in response to a meeting requested by the Sector Counsellor, Food, Agric & amp; Fisheries, Royal Danish Consulate General,Lagos to discuss possible areas of NAFDAC regulatory support for theArla Farm in Kaduna, the DG NAFDAC Professor Mojisola Christianah Adeyeye recalled that, over time, with NAFDAC's relationship with the Danish Government spanning about three yearsnow, has seen their commitment to scientific approach in terms ofensuring food safety. She noted the meticulous approach to productionand packaging of milk (a high-risk product) as one of the best around the world, an approach NAFDAC has been using in her Quality Management System.

She noted the meticulous approach to production and packaging of milk, a high-risk product, as one of the best around the world. An approach

Director-General of NAFDAC, Prof. Mojisola Adeyeye addressing the Danish Ambassador to Nigeria H.E Sune Krogstrup, his team and representatives from Arla Foods during a courtesy visit to NAFDAC

Danish Embassy partners NAFDAC to build capacity of staff

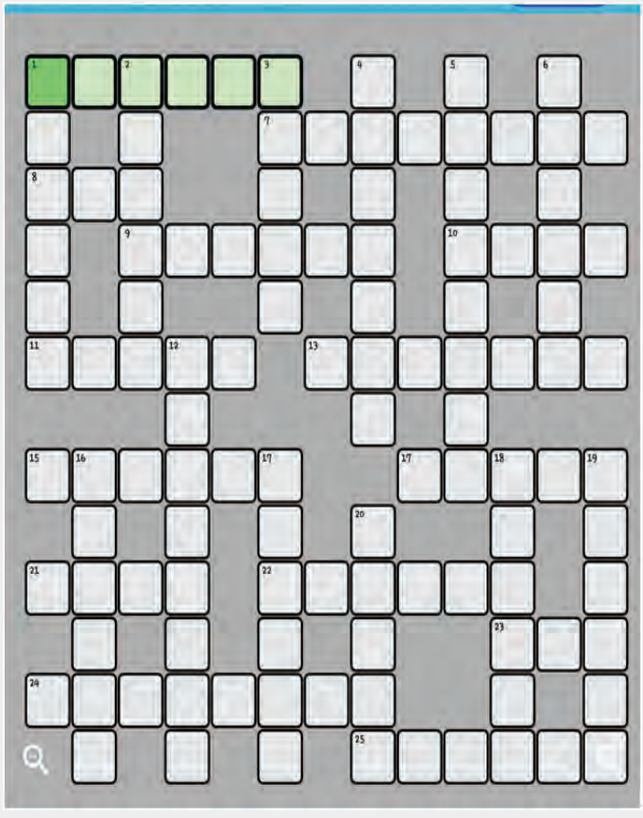
NAFDAC is seeking to employ through her Quality Management system.

She further appreciated the Embassy for the capacity it has built for NAFDAC staff in terms of training and exposure to best practices available in both food and feed safety as well as human resource development and environmental impact assessments. She also thankedthe Danish Embassy for the support NAFDAChas received in recent times that has built the capacity of the staff in various fields.

Meanwhile there has been step-down trainings conducted to cascade the trainings received as it relates to a specific target audience, just as post-training Impact Analyses were conducted to understand how well the learners received the program and provide valuable insight into the program's effectiveness.

Also, reports from the trainings, the training materials, and other Step-down presentation slides for step-downshave been archived for reference.

R-L: Lettecia (South Africa), Lebo (South Africa), Mr. Omolehin Adeyemi (Nigeria), Lydia (Ghana) and SA-DG (NAFDAC), Mr. Dadi Nantim during NAFDAC-Danish Bilateral engagement in Denmark.



CROSSWORD PUZZLE

HORIZONTAL

1. Unexpectedly quick
7. Not fully developed,juvenile
8. Adult male person
9. Assemble
10. Chance,fortune
11. Body trunk
13. One celestial body obscures another
15. A field which has grass and flowers growing
17. Brother of one's father
21. Succeed in an examination
22. Military greeting
23. Snake-like fish
24. Bear in mind
25. Depository for displaying objects of historical interest

VERTICAL

1. Apex
2. Hazard
3. Wall recess
4. Clasp another person in the arms
5. Adult male horse
6. What a Police bloodhound does
12. A physical motion to avoid or dodge something
16. Substance covering the crown of a tooth.
17. Sushi condiment
18. Dairy Product
19. Insignia
20. Clock that wakes a sleeper at a present time.

NAFDAC restructures management for better delivery of its mandate

As part of efforts to strengthen the regulatory and operational efficiency of the Agency, there was a need to move some Directors around in recent times. Such administrative exercise was needed at a time when the Director General is starting a new term and focusing on new goals for the next five years. The renewal of the appointment of the Director-General of NAFDAC is an opportunity to refocus the Agency towards greater productivity. To achieve that the personnel setup is being reviewed for optimum performance.

The reorganization of the Directorates was inspired mostly by the fact that some of the Directors in the technical directorates have been in their present position for five or more years. Although they have been seen to haveperformed well, there is a need for new ideasto be infused in the Directorates to upscale the performance of the Directorates.There were also complaints about the performance of some Directorates by our stakeholders and the problem could be traced to the leadership style of the Directorate.

It should be noted that, movements of Directors/Permanent Secretaries are a norm in the public service as it serves as a tool to rejig and strengthen the system.

The process of re-deploying some staff at the lower grades, especially those staff who have spent five years and above in their present post is still on-going and will be released appropriately. Meanwhile, the recent posting of Director's has been effected and details are seen in table …

S/N	Name	Present Posting	New Posting
1.	Dr. Monica Eimunjeze	Drug Registration & Regulatory Affairs Directorate	Lagos State Office
2.	Prof. Samson B. Adebayo	Ports Inspection Directorate	Planning, Research & Statistics Directorate
3.	Barr. Kingsley Ejiofor	Investigation & Enforcement Directorate	Legal Services Directorate
4.	Mrs. Edosa Ogbeide	Narcotics & Controlled Substances Directorate	Drug Registration & Regulatory Affairs Directorate
5.	Mrs. Yedunni Adenuga	Laboratory Services Agulu, Anambra State	Narcotics & Controlled Substances Directorate
6.	Dr.Abimbola Adegboye	Planning, Research & Statistics Directorate	Ports Inspection Directorate
7	Mr. Augustus Babarinde	Lagos State Office	Laboratory Services, Agulu
8	Mr. Francis Ononiwu	South-South Zonal Office	Investigation & Enforcement Directorate
9.	Mr. Chike L Obiano	Rivers State Coordinator	Rivers State Coordinator/Deputy Director i/c South-South Zone.
10.	Mr. Collins Ogedegbe	Enugu State Coordinator	Anambra State Coordinator, Onitsha

PRODUCT TRACEABILITY

NAFDAC, stakeholders review feedbacks from track and trace technology deployment

Riding on the successes recorded with the COVID-19 Traceability Pilot which began in March, 2021,during the first term of Professor Mojisola Adeyeye as Director General, the track and trace agenda for pharmaceutical products of the National Agency for Food and Drug Administration and Control (NAFDAC) has continued to record milestones with.

At a three (3) day workshop which was held in Port Harcourt, Rivers State from the 25th to 27th January 2023 relevant staff of NAFDAC and stakeholders reviewed the draft NAFDAC Traceability of Pharmaceutical Products Regulation 2023.

The workshop was a collaborative effort between NAFDAC, NACA and GS1 to review, harmonize and adopt the draft regulation which had been published in the Agency website for the mandatory 60 days window period to allow for input from all concerned stakeholders.

The workshop also provided a forum for the involvement of critical stakeholders in the regulation development process.

During the workshop, there were deliberations on the responses received from key stakeholders within the sixty (60) days the draft regulation was published on the website, harmonization of the responses which were adopted into the draft regulation to enhance the acceptability of the final draft as well as the Agency's regulation drafting process, focusing on the legal implication of regulations and the GS 1 Standards and Traceability Frame Work.

No fewer than 32participants, including staff of NAFDAC and key stakeholders participated in that meeting.

Some of the stakeholder groups represented at the workshop include Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMG-MAN); Association of Pharmaceutical Importers of Nigeria (APIN); Pharmacists Council of Nigeria (PCN); Pharmaceutical Society of Nigeria (PSN); Association of Community Pharmacists of Nigeria (ASPN); National Institute of Pharmaceutical Research and Development (NIPRD); Federal Ministry of Health (FMoH); Nigeria Representative of Overseas Pharmaceutical Manufacturers (NIROPHARM); Association of Hospital and Administrative Pharmacists of Nigeria (APIN); National Tuberculosis and Leprosy Control Program (NTBLCP); NAPA Delta State University and National Aids and STI Control Program (NASCP).

NAFDAC was represented by staff of the traceability project office as well as others from the Registration and Regulatory Affairs Directorates.

Dossier Review Management System via electronic portal

NAFDAC commenced the electronic submission of Common Technical Documents (CTD) for drug registration in January 2020 and has transited from physical submission of bulk documents known as dossier to submission in an electronic format using pen drives or Compact Disks to submission using cloud-based storage such as Dropbox.

The increasing volume of applications received by NAFDAC coupled with dossier review administration issues, resource constraints, and outdated manual document management systems resulted in the development of a significant backlog in medicine registration and prolonged review timelines.

NAFDAC management has been working to increase resources and improve its processes by injecting quality into its regulatory review process and along with other initiatives and interventions.

One of such initiatives is the development of a state of Art solution called Dossier Review Management System (DRMS) to drive the quality, consistent and reliable regulatory review process in compliance with the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) requirements.

Dossier Review Management System Processes

- Registration: The applicant initiates the process by registering their profile on the the platform which would be verified before the user could be able to upload the electronic dossier into the system.
- Submission: Follow ICH CTD folder structure and upon the successful submission, the dossier is evaluated in two steps:
- Screening: checked for completeness (are all relevant documents uploaded, including manufacturer information?). If a submission fails at the screening stage, the applicant will receive a feedback specifying the reason for the failure.
- Review: Dossiers that scale through the screening stage are assessed for safety, efficacy and quality; any submission that scales through the review process is presented for approval at the monthly products approval meetings after all other requirements has been met.

Benefits of the Dossier Management system:

- State-of-the-Art platform that automates/digitizes all the tasks in the Dossier Management division with central dashboard.
- User Friendly and provide end-to-end paperless processing.
- Provide an easy-to-follow CTD folder structure standard (Bookmarking and Structured file upload)
- Facilitate online submission and tracking of applications.
- Streamline the regulatory review process allowing for simultaneous Reviewer processes.
- Enhanced stakeholders' relationship through improved communication and transparency
- Ensure consistent, defensible, and predictable decision making.
- Performance monitoring features for dossiers and users
- Notification when dossier window is opened.
- Track-able Feedback to Dossier owner (via email)
- Reduce administrative workload by 35% internally.

In Conclusion, Dossier Review management System provide an opportunity for the regulators to use modern Information Technology based tools for making Dossier review process more efficient in a way to ensure quality, efficacious and safe medicinal products are made available and accessible in a timely manner to the general public.

Toll Free Lines for Enquries Call:
0700-1-NAFDAC OR 0700-1-623322

For Complaints Call:
0800-1-NAFDAC OR 0800-1-623322

Reforms Hotlines for Complaints:
09097630506, 09097630507

EMAIL: nafdac@nafdac.gov.ng
reforms@nafdac.gov.ng

NAFDAC Website: www.nafdac.gov.ng
Facebook: @NafdacNigeria
Intagram: @nafdac_ng
YouTube: NAFDACNIGERIA

Text only: 08033630600, 08058741647

NAFDAC: Customer-focused, Agency-minded.