# How NAFDAC'll eliminate substandard, fake medicines importation-DG

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Professor Moji Adeyeye

The Director-General of the National Agency for Food and Drug Administration and Control (NAFDAC), Prof. Mojisola Adeyeye has announced the agency's readiness to eliminate substandard and falsified medicines in the country through partnership with pre-shipment agents in China and India.

The move is part of the agency's efforts to take the war against importation of illicit drugs to the source countries.

Prof Adeyeye said: ''safeguarding the health of Nigeria means making sure that all regulated products that NAFDAC is in charge of have the expected quality". This means ensuring robust control of the manufacture, the distribution, the advertisement, the sale and the use of these products using international standards, in line with our mandate.

Speaking on ‘’NAFDAC And Your Health’’, in Abuja, against the background of Nigeria’s 60th Independence Anniversary, Prof. Adeyeye noted that 70 per cent of the medicines used in Nigeria are imported while only 30 per cent are produced locally, stressing that attention must be paid to both imported and locally made drugs by the agency

She said imported drugs used in Nigeria are mostly from China and India, noting that ‘’NAFDAC is now going to the source to ensure that we do pre-shipment analysis’’. She noted that although pre-shipment analysis had always been there even before she came on board as the DG of NAFDAC, there were loopholes in that process that are now blocked.

She stated that she travelled to China and India with a few staff last year to meet the agents that were given the responsibility many years back, adding that the riot act was read to them and they now understood that they are responsible for making sure that the products samples and analyzed by them in their home countries are of quality.

The laboratories were approved based on the analysis they do on the products that are shipped to Nigeria. The NAFDAC boss however said loopholes were found in the process and NAFDAC had to withdraw the approval granted to one of the Clean Report Inspection Agents (CRIA) and several laboratories.

She further stated that ‘’In the past, the laboratories used to be under the control of the agents. We visited about 19 laboratories across China and India. And we gave them the criteria that they must meet before we choose them as laboratories that can be analyzing products that will come to Nigeria’’, she said.

Prof. Adeyeye stated that both NAFDAC and the agents are now on the same page, adding that the CRIAs now work closely with the laboratories, insisting that they have to ensure that the laboratories have the equipment and wherewithal to do the analysis.

She explained that NAFDAC now receives CRIA agents’ reports almost daily on consignments that are suspect, saving the country the huge impact of being turned into a dumping ground for counterfeit medicines. This stringency has started yielding dividends as NAFDAC now has encouraging reports from the CRIA Agents and NAFDAC now deals directly with the laboratories used in China and India by the pre-shipment agents.

‘’We are starting from the source to ensure that the medical products or drugs that come into Nigeria are of quality’, she said.

Prof Adeyeye said even now, few unscrupulous merchants of death would sometimes get their shipment without the approval of the CRIA agents by doctoring CRIA approval.

She however, sent a strong warning to such unscrupulous elements that they would meet the waterloo at the ports here in Nigeria where NAFDAC's Port Inspection directorate officials are working round the clock to intercept illicit consignments.

''We wait for them at the port. Many times, we intercept them because the CRIA agents would have told us about those companies that ought to have gone through them for inspection but did not go'', she said.

According to Prof Adeyeye, a staff of NAFDAC has developed a software that helps the agency to track and monitor ships on the high sea. She said this has assisted the agency in apprehending defaulting importers of falsified medicines at the point of entry in Nigeria. ''The point is that we are tackling the issue of substandard, falsified medicines from the source. These are the ones coming from China or India'', she said.

A major achievement of her leadership, following her relentless efforts, she said, was the return of the Agency back to the Ports in May 2018 (all thanks to the Office of the National Security Adviser); coupled with rigorous inspection and enforcement activities.

She disclosed that because of this, the Agency has, in collaboration with Nigerian Customs Service, seized and destroyed SFs, unwholesome foods and other regulated products worth over N4b in exercises across the nation. She also stated that Tramadol with estimated street value of N1. 7 Trillion have also been seized

The Agency, she explained, has sharpened its focus on increasing access to quality and efficacious medicines through local manufacture. Some of the successes in this area include the development of guidelines for Active Pharmaceutical Ingredient (API).

Prof Adeyeye added that the Agency, through the support of its development partners, carried out assessments of one hundred and sixty-five (165) Local Pharmaceutical Manufacturers in Nigeria as part of the current Good Manufacturing Practices (cGMP) Roadmap for NAFDAC and the pharmaceutical industry.

She is enthused that the outcome enabled NAFDAC to make risk-based GMP categorization that is being used to guide companies on the path to GMP Certification and ensure compliance.

''Let me emphasize that promotion of local manufacturing has been premium on my priority list. This is to reverse the trend of 30% locally manufactured drug products toward 70%'', she said.

"It is not just that we are getting stricter on the ones overseas, we are getting stricter by using global best practices on the local manufacturing companies as well. For local companies, we check their products randomly. If a product manufacturing line does not meet the standards, we shut the line down until they meet these standards and specifications before they can begin to operate the line again''. The new paradigm is based on the Quality Management Systems and

WHO Global Benchmarking Audits the Agency had in 2018/2019. ‘’Those two auditing that we have gone through and which we are still going through in an effort to meet the recommended corrective actions are part of the Agency’s quality assurance toward continued safeguarding the health of the nation.