26th January, 2018

The Director General
National Agency for Food & Drug Administration and Control
Plot 1, Isolo Industrial Layout,
Oshodi-Apapa Express way,
Isolo, Lagos

Dear Madam,

PROPOSAL FOR ACTIVE NAFDAC-ACPN COLLABORATION

I bring you greetings from the entire membership of the Association of Community Pharmacists of Nigeria (ACPN), a technical group under the Pharmaceutical Society of Nigeria. ACPN is the umbrella body for all community pharmacists comprising wholesale and retail pharmacists in Nigeria. We serve as the gate keepers of the drug distribution chain because we man that delicate interface where patients receive their medications. As such, our role in collaborating with NAFDAC to safeguard the health of the nation cannot be overemphasized.

The primary purpose of ACPN is protecting the populace while empowering pharmacists. Over the years, we have collaborated with NAFDAC in the implementation of its various initiatives aimed at safeguarding the populace from the menace of fake and counterfeit medicines. These include the Mobile Authentication Service, Pharmacovigilance, NAFDAC number regime etc. While some of these initiatives were initially received with apprehension at launch, however, through constructive engagement and fine tuning where necessary, we were able to get the collective buy-in of all stakeholders which has largely accounted for the successes recorded.

Due to the ongoing nature of our relationship with NAFDAC, we continually seek ways and platforms to engage with you constructively to address issues as they arise so that our mutual goal of safeguarding the health of the nation can be achieved.

Unfortunately, there are a myriad of challenges we face that make it impossible to operate effectively as professionals, thereby hindering the active partnership we earnestly desire to have with the Agency. These challenges are discussed under two broad headings, namely:

- Regulatory activities
- Service and Orphan Drugs Scheme

1. REGULATORY ACTIVITIES:

While we appreciate the role NAFDAC (both enforcement and pharmacovigilance) plays in ensuring the integrity of products throughout the drug distribution and consumption process, we have some amount of reservations regarding the methods employed to achieve this noble objective.

The act of using policemen and media men during routine inspections of duly registered pharmaceutical premises should be discouraged. While it may be an effective measure in raiding open markets, criminal hideouts, and other illegal operations, we believe this mode of operation is counterproductive when deployed against partners in progress that are otherwise perceived by the public as professional and standards of the practice. An unintended consequence is that it brings the whole profession into ridicule.

A visit by a team of NAFDAC officials to any outlet of its choice is not only needful, it is also encouraged. We however believe very strongly that professional colleagues should be accorded the deserved respect by NAFDAC officials.

We do not believe the relationship between NAFDAC and ACPN should be adversarial but rather collaborative. Hence, these practising colleagues should not be treated as common criminals in the course of their routine business. Pharmacies and Pharmacists suffer a lot of brand and reputation damage when their practice and premises are raided and closed in a military commando fashion.

Our Prayers

- NAFDAC should employ a more civil approach to inspection of retail and wholesale pharmacy premises.
- Unless cases of consistent defiance of earlier summons or clear breach of national security has been established, NAFDAC should desist henceforth from using armed policemen and media personnel to cover these inspections.
- As it is obtained in developed climes, apart from enforcement visits, scheduled compliance visits should be made to Pharmacies with a checklist and to provide guidance where necessary.
- A clear engagement process should be designed, for example,
    i. 1st visit with only NAFDAC officials (if necessary with security personnel waiting in the operational vehicle) - may elicit a letter for the Pharmacist to visit NAFDAC
    ii. Second reminder letter or call
    iii. Third reminder letter or call can then be followed up with confrontational action
- However, once the pharmacist has responded to the summon, confrontational action should be with held until all possible avenues to an amicable settlement has been explored
- A regular engagement platform should be created between ACPN and NAFDAC to ensure that constant flow of information is guaranteed and members self-regulate from an informed position. Once NAFDAC discovers a fake or unwholesome product in circulation, NAFDAC communicates such information to ACPN to circulate to her members for them to take the required action. This is the kind of collaboration and mutual trust that we seek to build.

2. ORPHAN AND SERVICE DRUGS SCHEME

A major topical issue that has led to the constant faceoff between NAFDAC and individual members of ACPN has been the issue of orphan and service drugs. As laudable as the initiative is, there are some gaps that need to be filled.

While this scheme has helped greatly in bridging the gap created by the statutory registration requirement, its implementation has been the bane of the frosty

relationship between ACPN and NAFDAC. The orphan drug scheme is largely well defined and running fairly smoothly, the service drug scheme has however been fraught with many challenges, which has led to embarrassing raids of our colleagues as well as untoward delays in clearing of imported goods that lead to significant economic losses and threat to the lives of the patients who depend on these withheld medicines.

To resolve this matter, we seek to create an avenue to give NAFDAC full visibility and regulatory insight into everything happening within the retail and wholesale space especially as it concerns orphan and service drugs. We hereby assure you that we have nothing to hide.
By way of definition,

1. **Orphan Drugs** are medicinal products intended for diagnosis, prevention, or treatment of life-threatening or very serious diseases or disorders that are rare. This category of drugs also cover for instances where it is determined that there is an unmet medical need.
2. **Service Drugs** shall include only medicines and healthcare products that are not registered by NAFDAC because of their limited demand yet are beneficial and necessary and are prescribed by doctors and demanded by the public. Service drugs can also include generic medicines, branded medicines, and healthcare products not currently in the manufacturer's or their representative's portfolio in Nigeria and are not obtained from Asia.

It is very instructive to state at this point that ACPN fully supports the efforts by the Federal Government and by extension NAFDAC, in building the domestic capacity and capability of our local industries to meet the drug needs of Nigeria. Leadership of ACPN and members are working closely with Pharmaceutical Manufacturing Group of Manufacturers Association of Nigeria (PMGMAN) and other relevant stakeholders to help achieve self-sufficiency in drug production in the medium to long term. It is also important to state that ACPN strongly condemns parallel importation of registered and available pharmaceutical products. We hereby commit to working with you and brand owners to rid the pharmaceutical landscape of parallel imports

Meanwhile, there is a dire need to bridge the ever-recurring gap we see in the drug supply system. We believe very strongly that there are valid reasons why the service drugs scheme should not only be sustained but indeed enhanced.

These include:

- When drugs which are originally registered, and imported by some companies are in short supply e.g Anusol Suppository
- When drugs registered are not imported by the registering importers e.g Janumet by MSD
- When specialized products meant to cater for a small population living with special needs are required such as sugar-free formulations, gluten free formulations, yeast free formulations and medications for patients with lactose intolerance or brands with specific nutrient fortification e.g Polyvisol with Iron
- When medications are needed and preferred by an increasing number of expatriates coming into the country due to the government's aggressive drive for foreign direct investment.

- When patients have clinically proven idiosyncratic preferences for some OTC medications. e.g Haliborange and Lemsip
- In cases of global mergers and acquisitions, the franchise holders for some registered products become the weaker party and the larger organisation isn't interested in continuing the business with Nigeria. This gives rise to scarcity of previously registered products. E.g Wassen-Efalex UK merger, Pfizer -Wyeth merger

In some instances, there are clear processes to address these gaps but in other instances the processes are either non-existent, unclear, or ambiguous, leading to loss of time, money, delays in treatment, disenfranchisement of the patients, and very poor health outcomes, in a manner that paints the profession and the regulatory agencybadly in the eye of the patients/clients.

We have critically looked at the spectrum of drugs in circulation and have identified several gaps. These gaps make the orphan and service drugs scheme an invaluable initiative that must be enhanced to make it more impactful in our quest to provide quality pharmacare to the Nigerian populace.
We believe it is also important to classify the products that fall into the Orphan and/or service drug scheme. By doing this, we are able to treat each class on its own merit rather than treating them all as one group of unregistered products. Our attempt to unbundle the unregistered products baskets is found below

1. **Generics not registered in Nigeria**- There are specific moieties that are not registered in Nigeria that are not necessarily orphan drugs. In some instances, some patients require alternate salts of the available registered drugs due to their medical conditions; such cases can be seen in renal or hepatically compromised patients. Example: Tetracycline Hydrochloride 250mg and Tetracycline phosphatecomplex 250mg

2. **Registered brands that are currently in short supply in the country.** Allowance should be made to bridge the gap with alternative brands pending the time the importer/producer of the registered brand would be able to resume importation or production. For example: plain betamethasone drops and Anusol suppository.

3. **Unregistered Brands by companies registered in Nigeria:** There are internationally recognised and relevant brands that are readily available in other parts of the world but the brand owners have refused to register them locally, probably due to economic considerations. For example Ventolinnebules by GSK, Prep H ointment and suppository by PFIZER and Sinemet tabs (levodopa/carbidopa) by MSD

4. **Unavailable Registered brands:** In some instances, the products are registered but the registered importing company has not imported any shipment into the country since registration or stopped importing the brands awaiting very large demands that may take years to achieve. for example: Dalacin T lotion by Pfizer, Janumet by MSD

5. **Unregistered brand extensions by registered companies:** There are brands which are registered locally, but some clinically relevant extensions of the brand are not registered by the companies for example CLEXANE (Enoxaparin) 120MG Inj (only 40mg and 20mg registered), ASPIRIN 75mg soluble tabs (only plain tablets registered) and Sugar free variants of some registered preparations

6. **Brand owners are not interested in coming to Nigeria:** There are some clinically relevant brands whose franchise holders and manufacturers have refused to establish a business presence in Nigerian, neither have they appointed a business representative. Some of these organisations have some very important lifesaving formulations which have no local variant or substitute. In the absence of these products, pharmacists and physicians are sometimes forced to give a whole cocktail of medicines when they could get the desired result from a single formulation E.g the HealthAid range

7. **Supplements:** A recent survey has shown a very high level micronutrient deficit in Nigeria. This has been pointed out as one of the sources of chronic illnesses and susceptibility to communicable diseases. While most of these supplements are not consumed in commercial quantities, they are crucial in the management of some medical conditions. Likewise, the rise in drug induced nutrient depletion has given rise to an increased demand of these products such as CoQ-10, L-carnitine supplement, Inositol supplements and Zinc in prostate health

As stated earlier, the orphan/service drug scheme is a very laudable initiative that helps bridge the gaps in our healthcare delivery system. However, there are number of procedural hurdles that make it difficult and sometimes impossible for our members to leverage this brilliant scheme to provide quality Medicare to patients. These include

1. **Emergency requests:** Currently, there is no clear-cut process for addressing emergency, live saving requests. We regularly get requests from ICU/ Emergency Room specialists for live saving medications on very short notice. Sometimes, we are compelled to turn down these requests due to the risks associated with importing them without following the cumbersome, time consuming laid down processes. In other circumstances, our members go ahead and bring the product on compassionate grounds. As responsible professionals, members of ACPN would love to follow the rules but in these critical instances, it is totally impossible to start and conclude the application process in a reasonably short time if the life is to be saved. Examples of drugs requested on emergency basis (sometimes required in 24-72 hours) include Adrenaline autopen injection, Clexane 120mg injection, among several others
2. **Sampling:** We believe that there should be a separate sampling procedure for orphan/service drugs. Since these drugs come from recognised sources and sometimes in very limited quantities, we believe sampling should be waived or very limited samples taken to avoid making the units left unnecessarily much more expensive for the patients as importers/retailers are left with no choice but to pass on the costs to end users. E.g Nexplanon implants, Surfactants, Tenecteplase tablets and injection and Calcium folinate injection and tablets

Our Prayers

- A revised or new process for requesting emergency drugs in very limited quantity which would bypass the current regulatory hurdles. This should probably be limited to notifying the Agency (which could also include submission of a prescription/letter from a prescriber/hospital) and granting express waiver by NAFDAC. This would be done on trust and any colleague who breaches the trust will never be able to use that express window again (Nigerian Customs Service approach). However, all relevant documentation will still be filed with NAFDAC while all is done to meet the emergency need. This window will only be for products that are clearly ICU/Emergency based.
- All updated guidelines should be made available to ACPN for onward dissemination to members. This would reduce the number of people who unwittingly break the rules. ACPN believes increased information dissemination will significantly improve compliance and provision of pharmacare services in a manner that aligns with NAFDAC's mandate.
- The time taken to process and issue permits should be reduced and such time frame should be communicated to applicants to enable them make necessary plans such as informing their patients / clients of expected delivery time of their medication. A time estimate will enable both Pharmacist and patient determine whether their needs will be met within the stipulated time.
- A dedicated sampling process should be developed for service/orphan drugs with much needed education, training and retraining of the regulatory teams on the unique pharmaceutical nuances of some of these drugs. This process should be made available to all those involved in the process.
- Due to the high cost and limited quantities of some orphan/service drugs, sampling makes the process financially unviable as the cost of the expensive samples collected will be transferred to the patient especially when total number of products imported is very small. It is recommended that such products should be exempted from the sampling process. When sampling must be done, the process should be accelerated due to the urgency in the requirements for this ~~category~~ class of products.
- In instances, where unavailable or unregistered products of a registered multinational in Nigeria is required, a letter of no objection would be sought from the registered company.
- A modified listing approach (similar to global listing) used in the supermarket segment should be considered for supplements and OTCs coming in from the UK and USA . This will allow wholesalers and retailers bring in limited amounts of products that serve the unmet needs highlighted in this document. Key learnings from the Global listing initiative should be taken into consideration so that any risks identified in the supermarket approach can be mitigated
- Another viable approach is to apply an annual levy on all retailers or wholesalers desirous of bringing in these products. NAFDAC can therefore monitor closely the activities of these businesses. NAFDAC still reserves the right for approving all products intended for importation per shipment. This replaces the levies placed on individual products
- Extending the Service/Orphan drug scheme to Pharmacist wholesalers would go a long way in resolving most of the issues highlighted in this document. These wholesalers will be able to sell to retailers who are unable to undertake

the cumbersome, time consuming process of direct importation, yet are wide spread across the country and have unmet demands by their communities. A clear process for tracking and tracing products must be instituted by the wholesalers and ACPN will join hands with NAFDAC to ensure this process remains transparent. This would create the much desired visibility and control that has been missing in the implementation of the service drug scheme

- Creation of a window for representatives of multinationals (NIROPHARM Members) to bring in limited quantities of clinically relevant pioneer molecules. These imports would be closely monitored and subsequently recommended for registration once the quantities reach a pre-agreed commercial quantities.
- Constitution of a high-power stakeholder committee comprising ACPN members and senior NAFDAC officials in relevant and strategic departments of the Agency to ensure that regular and relevant communication lines are maintained.

CONCLUSION

In conclusion, the ACPN, on behalf of its members seeks to create a clear channel of communication with NAFDAC, on a two way basis, both to escalate issues and to disseminate information so wholesale and retail pharmacists in practice are guided.

We seek to form a tight partnership with a win-win outcome for both the fulfilment of NAFDAC mandate and successful pharmacare services to the 170 million Nigerians and residents who have come to trust registered pharmaciesand pharmacists for genuine medicines.

We look forward to meeting with you and your management team to discuss the content of this proposal in detail with a view to creating a long lasting partnership that would help to safeguard the health of the nation

Yours sincerely,
for the Association of Community Pharmacists of Nigeria (ACPN)

Dr. Kelong Albert Alkali *(JP), MCPA, FPCPHARM*
National Chairman