

Towards the development of blue print for health security in Nigeria by 2050: A review of drug development, supply of quality medicines and treatment issues

OA Odeku¹, R Adisa², OA Adetunji¹, MA Durowaiye² and OA Kotila³

Departments of Pharmaceutics and Industrial Pharmacy¹, Clinical Pharmacy and Pharmacy Administration² and Pharmaceutical Chemistry³, Faculty of Pharmacy, University of Ibadan, Ibadan, Nigeria

Abstract

Background: Drug development, distribution and supplies require efficient supply chain systems and appropriate regulation to ensure that the medicines that reach the consumer are in their intended qualitative states thereby guarantee rational use and optimal outcome. This review was therefore designed to explore drug development, supply of quality medicines and treatment issues in Nigeria, with a view to develop a blue print for health security in Nigeria by 2050.

Method: A systematic search of relevant studies and documents on drug development, national drug distribution and treatment guidelines was done within a period of three-weeks.

Results: Forty-six percent of the key medicines were available in public health facilities and 23% of the average weekly expenditure of people went into the treatment of an episode of illness in a member of their household. Medicine financing in Nigeria is generally out-of-pocket as the National Health Insurance Scheme is still facing challenges of sufficiently providing needed services to its subscribers. Approximately 70.2% of Nigerians live below the poverty line of less than 1 USD a day, while medicines are unaffordable to 90.2% of Nigerians. Generic medicines were generally more available in all outlets, but the availability of the basket of 34 priority medicines was low in all sectors, especially in the public and private health clinics. Issues surrounding access to medicine in Nigeria range from an uncoordinated medicines supply chain to lack of price regulation resulting in shortage of essential medicines in healthcare facilities across the country.

Conclusion: Concerted efforts should be made to review and implement national, regional and continental strategies towards availability and accessibility of medicines for use in Nigeria and in

Africa as a whole. In general, a pragmatic approach focusing on the short, medium and long-term goals should be vigorously pursued.

Keywords: Drug development, Supply of medicines, Drug distribution, Treatment issues, Health security by year 2050

Résumé

Contexte : Le développement, la distribution et la fourniture de médicaments nécessitent des systèmes de chaîne d'approvisionnement efficaces et une réglementation appropriée pour garantir que les médicaments qui parviennent au consommateur sont dans leur état qualitatif prévu, garantissant ainsi une utilisation rationnelle et des résultats optimaux. Cette revue a donc été conçue pour explorer le développement de médicaments, l'approvisionnement en médicaments de qualité et les problèmes de traitement au Nigéria, en vue d'élaborer un plan directeur pour la sécurité sanitaire du Nigéria d'ici 2050.

Méthode : Une recherche systématique des études et documents pertinents sur le développement de médicaments, la distribution nationale de médicaments et les directives de traitement a été effectuée durant une période de trois semaines.

Résultats: Quarante-six pour cent des médicaments clés étaient disponibles dans les établissements de santé publics et 23% des dépenses hebdomadaires moyennes des personnes étaient consacrées au traitement d'un épisode de maladie chez un membre de leur ménage. Le financement des médicaments au Nigéria est généralement de leur poche car le Régime National d'Assurance de Santé est toujours confronté à des défis de fournir suffisamment de services nécessaires à ses abonnés. Environ 70,2% des Nigériens vivent en dessous du seuil de pauvreté de moins de 1 USD par jour, tandis que les médicaments sont inabordables pour 90,2% des Nigériens. Les médicaments génériques étaient généralement plus disponibles dans tous les points de vente, mais la disponibilité du panier de 34 médicaments prioritaires était faible dans tous les secteurs, en particulier dans les dispensaires publics et privés. Les problèmes liés à l'accès aux

médicaments au Nigéria vont d'une chaîne d'approvisionnement de médicaments non coordonnée au manque de réglementation des prix, entraînant une pénurie de médicaments essentiels dans les établissements de santé à travers le pays.

Conclusion: Des efforts concertés devraient être faits pour examiner et mettre en œuvre des stratégies nationales, régionales et continentales en vue de la disponibilité et de l'accessibilité des médicaments à utiliser au Nigéria et en Afrique dans son ensemble. D'une manière générale, une approche pragmatique axée sur les objectifs à court, moyen et long terme doit être vigoureusement poursuivie.

Mots-clés: Développement de médicaments, Fourniture de médicaments, Distribution de médicaments, Problèmes de traitement, Sécurité sanitaire d'ici 2050

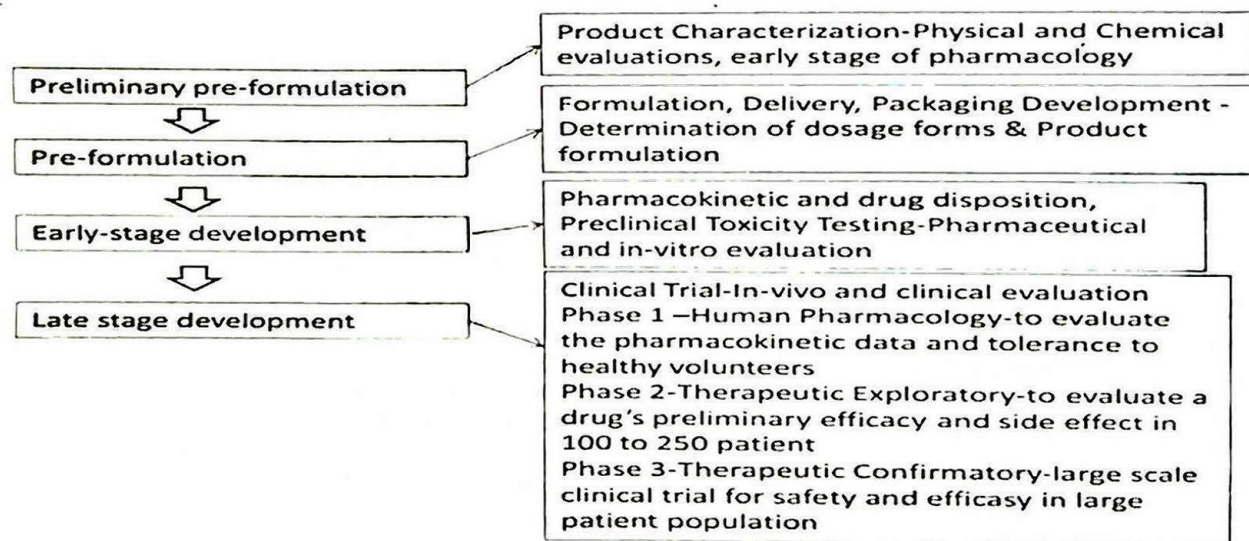
Introduction

Drug development is the process of bringing a new pharmaceutical drug to the market once a lead compound has been identified through the process of drug discovery. It includes pre-clinical research on microorganisms and animals, filing for regulatory status for an investigational new drug to initiate clinical trials on humans, and may include the

design, efficiency, effective management, and standard logistic management information system [2-4]. International treaties and governments all over the world recognize health care as a fundamental human right. Therefore, without access to essential medicines, this fundamental right as well as the United Nation's Millennium Development Goals cannot be realized [3-6]. Medicines are meant to do good by alleviating unwanted symptoms, however, in Nigeria, we have so many instances of therapeutic misadventure, particularly when:

- Medicine is not available at the point of need.
- Medicine is available but not at the right time and quantity.
- Medicine is available as adulterated or as outright fake.
- Medicine is available and can be accessed in or at wrong places
- Medicine is available, but in the hands of non-professionals. Thus, the availability, affordability, accessibility and acceptability (the 4A's) of essential medicines to the populace is critical to the success of our healthcare delivery services [7, 8].

In addition, distribution of drugs requires efficient supply chain systems and appropriate



step of obtaining regulatory approval with a new drug application to market the drug. The high risk of failure in drug discovery and development throughout the pharmaceutical industry statistically shows that, on average, only 1 in 5,000 to 1 in 10,000 compounds screened in research will reach the market [1].

Generally, the drug development, distribution and supply of quality medicines lies on good system

regulation to ensure that the medicines that reach the consumer are in their intended qualitative state, supported with the required infrastructure to ensure rational use [4, 5, 9]. However, in developing countries like Nigeria, the drug distribution infrastructure is fragmented and inefficient, resulting into a preponderance of fake, adulterated and substandard products infiltrating the market because of the

activities of unscrupulous elements [3, 4, 10]. This is unlike what obtains in developed countries where there is a cohesive drug distribution and effective regulatory framework to assure the quality of the final product that reaches consumers [5, 8, 9]. The National drug distribution guidelines (NDDG) policy, which aimed at establishing a well-ordered drug distribution system in Nigeria, is a cumulative effort of stakeholders in the health sector from 2009 to 2012 [11], with a view to ensuring that all drugs in the NDDG are safe, efficacious, effective, affordable, and of good quality. The NDDG framework was initially composed of Mega Drug Distribution Centers (MDDCs), State Drug Distribution Centers (SDDCs), Wholesalers and retail outlets in a hierarchical order to be operated by the private and public sectors. Regulatory agencies such as the Pharmacists Council of Nigeria (PCN) and the National Agency for Food and Drug Administration and Control (NAFDAC) were recognized within the framework. The NDDG prescribed drug entry into the distribution cycle through the importers and manufacturers who must have been registered by the PCN [2-4, 12]

This review therefore aimed to explore the drug development, drug distribution, supply of quality of medicines, and treatment issues in Nigeria as a contribution towards the development of blue print for health security in Nigeria by 2050.

Situation analysis

Baseline assessment of the Nigerian Pharmaceutical Sector in 2002 showed that only 46% of the key medicines were available in public health facilities and 23% of the average weekly expenditure of people went into the treatment of an episode of illness in a member of their household [11, 13]. These figures show poor access to essential medicines although the exact scale has not been accurately estimated. Medicine financing in Nigeria is generally out of pocket as the National Health Insurance Scheme (NHIS) is still facing challenges of sufficiently providing needed services to its subscribers, thereby contrasting the third sustainable development goals (SDG), which emphasizes Universal Health Coverage for the citizenry. In addition, 70.2% of Nigerians live below the poverty line of less than 1 USD a day [6, 11]. Therefore, issues concerning prices of medicines are key to improving access to essential medicines in Nigeria.

Poor medicines financing by the government visibly results in delayed treatments and poor access to most innovative and lifesaving medication in public facilities. Studies showed that generic medicines were generally more available in all outlets, but the

availability of the basket of 34 priority medicines was low in all sectors, especially in the public and private health clinics [13, 14]. In addition, medicines are unaffordable to the majority of Nigerians (90.2%), who live below the income level of US\$ 2 a day as well as the government worker that earns a minimum wage of US\$1.4 per day. The issues surrounding access to medicine in Nigeria range from an uncoordinated medicines supply chain to lack of price regulation resulting in shortage of essential medicines in primary healthcare facilities across the country [6, 15-17].

In Nigeria today, it is common knowledge that drugs are treated as general merchandise, which can be obtained easily from open markets, moving vehicles, faceless medicine stores, ferries, and even in the provision stores [18-21]. This is because the drug distribution business has been left in the hands of non-professionals who just want to make profit at the expense of the consuming public. Poor people are faced with a confusing myriad of health providers and drug sellers [21-23].

The problems of fake drug proliferation in Nigeria have affected the credibility of the Healthcare system with negative consequences on the consumer resulting to illness; disability and even death [19-21]. These issues are all indicative of poor health system governance and weak coordination between health system leadership and operations. In spite of the policies and standard practice guidelines in place as evident in the national essential medicine list, the challenge appears to be that of implementation, regulation, monitoring, synergy among stakeholders and sustainability of initiatives/projects [14].

Nigeria has consistently scored low in synthetic and herbal drug development. The current situation in Nigeria is that less than 20% of the pharmaceutical manufacturing plants in Nigeria are actually involved in drug development, while none is involved in the development of Active Pharmaceutical Ingredients (APIs). Local drug manufacturers, thus, depend on importation of excipients and APIs [11, 12, 14]. Ninety-eight percent of raw materials being used in the production of drugs in Nigeria are imported, and around 70% of drug in Nigeria are imported with India as a major drug exporter to Nigeria [11, 12, 24]. Obviously, government has an important role to play in facilitating investments in the pharmaceutical sector if the country is willing to harness the huge potentials that abound in this sector [11, 12].

Forecast to 2050

By 2050, if there is continuing weak regulations, poor enforcement of existing regulations, unregulated

markets, scarcity of supply of basic medicines, and unaffordable prices, then the issues/problems of fake drugs and chaotic drug distribution may remain unabated. The overall effect of all these is that the quality, safety and efficacy of drug products in the country will not be guaranteed. Consequently, ban on the sale of drugs made in Nigeria by neighboring countries [10], embarrassment of our healthcare providers, denied confidence of the public on the nation's healthcare delivery system due to treatment failures, organ dysfunction or damage, worsening of chronic disease conditions and the death of many Nigerians may continue. The situation may become so bad that even when patient is treated with genuine drugs, there may be no response due to resistance caused by previous intake of fake drugs. WHO statistics have shown that medicines are too expensive to 90.2% Nigerians who live below 2 US dollars a day, with the percentage of Out-of-Pocket expenditure as a proportion of private expenditure on health about 94.5% [3, 7, 17, 24]. Thus, a drastic and progressive measures to reduce out-of-pocket expenses on treatment, as well as a realistic medicine pricing policy is advocated to solve these problems

By 2050, it is estimated that the population of Nigeria will be approximately 400 million, and if the present economic situation still abounds, then the competitiveness issues where Nigeria has consistently scored low will continue. This low competitiveness will continue to prevent Nigeria from benefiting from the "flying geese" economic theory model with respect to drug development as there will be an upsurge of pharmaceutical companies that are interested in marketing finished pharmaceutical products than developing drugs. It is therefore imperative that, all stakeholders must work together, so that by 2050, Nigeria should have the capacity to manufacture more than 75% of the total medications needed in the country with the right quality. In addition, we should be able to export locally manufactured medicines to other parts of Africa.

SWOT analysis

Strength

- A growing population with over 180 million currently, the largest in Africa
- Human and natural resources abounds in the country
- Existence of drug regulatory agencies such as NAFDAC, PCN, NDLEA etc, which can be strengthened to achieve the desired goals
- Abundance of medicinal plants with excellent medicinal properties that can be cultivated all-

year round as sources of drug development for therapies in non-communicable diseases (NCDs) among other priority diseases

- Some of the medicinal plants that have proven cases of effectiveness are yet to be properly researched into.
- Availability of private and public tertiary institutions as well as research and development (R & D) establishments such as NIPRID, operating in Nigeria that can attract funds for research purposes because of their reputation and set up
- The achievements of some of the universities and R & D establishments had placed them in the mould of centres of excellence and as such, they could be helpful in research and development aspects of pharmaceutical industry demand.
- As one of the largest producers of crude in the world, there is also the likelihood of investment interests in the petrochemical industry. If that happens, production of Active Pharmaceutical Ingredients (APIs) will boost investments in the industry.

Weakness

- Poor implementation of existing drug laws/ inadequate legislation
- Flaws in the existing drug laws which have encouraged the operations of counterfeiters and hamstrung regulatory agencies especially NAFDAC in effecting prosecution of offenders
- Overlapping and sometimes conflicting drug laws resulting to a legal framework that will fail to deter drug offenders or moves very slowly when allegation of wrongdoing is identified, making it difficult to try the offenders
- The chaotic drug markets that stand as source for drug purchase and distribution has lowered the goal in creating a country free from fake drugs.
- The cost of developing a drug product is financially demanding and indigenous manufacturers do not have the capital to start and sustain such a project
- The infrastructural decay is a major source of worry for local manufacturers of medicines, as well as stakeholders in healthcare systems in Nigeria
- Unfavourable policies of government over the years
- Poor funding of healthcare systems, and consequently resulting to inadequate funding of drug supply and drug control activities
- Inadequate facilities for storage, transportation and distribution of drugs

- Poor selection and procurement practice, especially with the involvement of unqualified persons in procurement, distribution and sale of drugs
- Poor infrastructural maintenance culture
- General lukewarm attitude of healthcare professionals to consumer of medicine (i.e. patients) at various levels of healthcare systems
- Insufficient healthcare facilities to cater for the alarming populace

Opportunity

- Over 180 million individuals that need access to safe, effective and quality medicines will ensure that the pharmaceutical companies remain in business
- Likelihood of increasing burden of communicable/infectious and non-communicable diseases due to outbreaks and rising adoption of western diet and sedentary lifestyle among the citizenry, thus possible escalating demand for pharmaceutical products
- Pharmaceuticals no doubt are an extraordinarily profitable business; the most profitable, looking at reported figures of past years and the future projections by industry watchers and experts
- With a population of over 180 million currently, as well as abundance of human and natural resources, investment in the industry has a high potential of succeeding faster than any other country in the region
- Nigeria now has four pharmaceutical companies that have been certified as compliant with WHO Good Manufacturing Standard Population. These companies can be used as template for drug (API) and excipient development, leading eventually to finished products formulation.

Threat

- Chaotic and unorganized drug distribution system and continued proliferation of open drug distribution network without being able to curtail their activities
- Lack/weak enforcement of drug laws
- Legislation could influence negatively by averting sanctions to violators
- Non-availability of enough pharma companies that are certified to manufacture drug products at global standards
- Non-availability of locally manufactured drug products to the average Nigerian
- Lack of harmonized consensus in the Nigeria Pharma Industry
- High lending interest rate to local manufacturers

- The absence of stable electricity has forced manufacturing companies to spend huge sums of money in alternative sources of power such as generators, solar energies and inverters among others
- Staggering/unstable foreign exchange policy of government coupled with inaccessibility to forex by local manufacturers to source finished products, active pharmaceutical ingredients and other excipients will naturally breed out of stock syndrome in the inventory (this may be dangerous in case of life saving drugs)
- Brain drain of healthcare professionals especially physician, pharmacist and nurse leading to dearth of qualify healthcare personnel to work in semi-urban and rural healthcare facilities
- Disparity in emolument and allowances of different categories of healthcare professionals coupled with the general poor remunerations and condition of services of healthcare workers resulting in incessant industrial strike action

Short, Medium and Long term Plans with Deliverables and Budget Estimates

A. Short-term plan (< 5 years)

- Encouraging more pharma companies to be WHO compliant with respect to GMP.
- Providing financial support to indigenous manufacturers and academia to strengthen R & D.
- Improvement of access to medicines through quality local production and implementation of the Good Manufacturing Plan Road Map
- Carrying out a product wide survey on availability and accessibility of all essential medicines in Nigeria as a preliminary action towards closing identified gaps in drug supplies.
- Prioritization of medicines procurement through strict adherence to essential medicines list and standard treatment guideline for public hospitals and health centres.
- Standardization of the procurement mechanism for medicines and other health commodities to include professionals in that field of practice.
- Strengthen the existing supply chain management and ensuring adequate and appropriate storage conditions at public and private sector levels across the country
- Provision of adequate drug funding for the procurement of essential medicines across the various levels of healthcare delivery in the country.
- Ensuring appropriate financing mechanism for different cadre of the society such as community

- financing, national health insurance, private health insurance etc.
- Strengthen accountability and autonomy in the management of medicines at all levels of healthcare delivery system.
 - Adoption of best practices in the management of unwanted medicines and other pharmaceutical products
 - Immediate implementation of NDDG network and creating a good drug distribution chain that is licensed for easy monitoring- from manufacturers to wholesaler to pharmacy to patients
 - Urgent review of the National Drug Policy 2005 in line with the current realities of today.
 - Training program especially for the enforcement officers, as well as ensuring availability of trained officers and collaboration with other drug agencies can help.
 - Review of drug importation tariff because it creates high cost in the market as importers want to make back what they lost during registration, while poor people who cannot afford the genuine drug because of price goes for the cheap types that might be fake.
 - Tight security at all ports of entries in Nigeria should be encouraged in order to curb the activities of illegal drug importers
 - Ensuring that every state in the country where NAFDAC is situated to have its mini laboratory for prompt analysis, thereby reducing the stress of staff traveling very long distance with loads of product for registration
 - Further empowering NAFDAC by provision of adequate workforce, equipments and materials for enforcement activities as well as provide finance for building of well-equipped quality assurance laboratories in every state of the country so as to reduce the workload of staff and increase efficiency.
 - Strategic measures should be in place to enhance affordability of medicines, possibly by adopting a pricing policy aimed at reducing the high price and disparities between prices
 - Review of existing policy on patents and proprietary medicine vendors that are non-professional in drug business
 - Institute an organized program under the care of PCN to improve the services of mini drug outlets and medicine vendor, by training them on basic pharmacy ethics
 - Enforcement of adherence to all stipulated regulations of WHO and Drug Regulatory Agencies of both the country of manufacture and export.
 - Development of strategy by manufacturers to monitor tightly their products in the legal drug supply chain to ensure that their products are not faked and diverted.
 - Ensuring and encouraging genuine manufacturer to brand their products by imparting vital product information and designs on them for easy identification.
 - Public awareness to enlighten consumers/buyers to purchase drugs only from registered sources by PCN and only products registered by NAFDAC,
 - Public awareness to alert consumers at all time in double checking what they buy, and being alert to detect differences in quality of packaging, label and ensure the drug has leaflets and NAFDAC registration number before consumption, while consumers should report immediately of any drug whose quality is in question or adverse reaction felt for any drug product.
 - Strengthen the partnerships between the private sector and the various Faculties of pharmacy.
 - Harmonization of allowances and emoluments as well as salary structure of healthcare professionals across board with all sense of sincerity and fairness
- Deliverables*
- Formal public and private inter-sectorial partnership involving the Federal Ministry of Health, Federal Ministry of Trade and Industry, NAFDAC, PGMAN, PCN and the multilateral agencies need to be deployed to make this happen. This we can do with adequate government support and creating another unit called Good Distribution Practice (GDP) that monitors drug distribution as is done by UK MHRA.
- B. Medium-term plan (> 5 to 10 years)**
- Strengthen the National Medicine Regulatory System
 - Enhancement of basic infrastructural support for drug development such as affordable electricity and good road network
 - Develop our human resources and local technical capacity through relevant education and training
 - Adoption and implementation of the Pharmaceutical Road Map for Africa as put forward by African Union.
 - Development of a functional and integrated drug management information system for proper coordination of public drug supply. This will be

invaluable for tracking, effective system control, and good storage, and handling facilities at all strategic points.

- Development and standardization of indigenous traditional medicines into more acceptable and safe dosage forms.
- Achieve full implementation of the National Drug Distribution Guideline.
- Enforcement of deadline by Government of the closure of Open Drug Markets
- Organizing mandatory capacity building workshop and training for all would be operators in the national drug distribution guideline to ensure smooth implementation of the guideline.
- Provision of adequate support in the form of grants and incentives to the pharmaceutical industry in Nigeria.
- Implementation of a drug price control regime for sales of medicines across retail and wholesale premises.
- Increase in local production capacity to a level where 70% of total output satisfies at least 60% of national drug requirements of essential drugs while the balance is exported by 2025.
- Promotion of joint reviews by National Drug Regulatory agencies within West African Sub-region will allow for quicker entry to the markets for new drug molecules thereby increasing access to medicines.
- Ensuring a well-defined drug laws that must be compulsorily implemented by government and by every arm of the legislation such as the judiciary that handle cases of violators, without fear or favor of anyone
- Ensuring that drug offence is taken more seriously because it involves human lives; any one that violates the drug law resulting to death of people should as well receive stiff penalty or life imprisonment as the maximum punishment.
- Provision of good quality, affordable medicines in government clinics and hospitals.

Deliverables

Provision of constant supply of electricity and good road network. Regular and mandatory supply of essential health commodities, essentially quality medicines into all public healthcare facilities at the federal, state and local government levels with wider coverage of rural health facilities at subsidized rates.

C. Long-term plan (>10 years)

- Create incentives to move our local companies progressively along the pharmaceutical industry

value chain from importation of finished products to local manufacturing.

- Provision for incentives could including tax reductions on locally developed drug products, import-substitution model etc
- Building world class pharmaceutical companies that have WHO pre-qualification approval for manufacturing site and products, so as to enable international competitiveness while achieving global standards for drug manufacturing.
- Sustained financial support provision to research organizations and universities as well as pharmaceutical scientists for the development of patented medicines towards local production.
- Engaging as research partner R & D establishments such as NIPRD and special research units in the universities like the Drug Research and Production Unit, OAU, Ife, Centre for Drug Discovery, Development and Production at University of Ibadan and others in local production of API and drug development
- Setting up a pharmaceutical hub for production of Active Pharmaceutical Ingredients, excipients and other raw materials within an approved free trade zone or other suitable locations.

Deliverables

Government must deploy incentives that moves local players increasingly from importation and distribution of finished pharmaceutical products (Level 1 of the pharmaceutical value chain) to packaging and labeling of imported bulk finished products (Level 2) and then to real product manufacturing which is the manufacturing of finished products from imported active pharmaceutical ingredients (APIs) Level 3, and then to local Active Pharmaceutical Ingredient manufacturing in Nigeria at Level 4) and ultimately Research and Development of new chemical or biological entities(Level 5) .

Sources of funding

- Federal Government budget
- State and Local government budget
- External/international donors and Non-governmental organisation
- Investors from Big Pharma Companies in Europe and United States

- Availability of Grants specifically for local drug development
- Private individuals/organisation donations or endowment fund on health specifically medicine supply
- Creation of special trust fund by federal and state government solely for ensuring medicine availability in all healthcare system in the country

Monitoring and evaluation

- Strengthen regulatory bodies (NAFDAC, PCN etc) to ensure that handler of medicines strictly adhere to drug regulations, and pharma companies adhere to cGMP with respect to drug development.
- Post market surveillance of any finished pharmaceutical product obtained from local drug development.
- The overall intent behind monitoring and evaluation is to inform policymakers, practitioners, and stakeholders of the progress of the drug development programme in achieving its intended results
- A need for appointment of independent consultants for monitoring and evaluation of key sectors of the supply chain. Such key performance indicators tools should be developed for assessment at the national, state and local government levels
- To ensure that all gaps are covered and for easy case report and management, the enforcement and intelligent group of our drug regulatory agencies can be further subdivided into four organized groups i.e. Intelligence group, Operations, Prosecutions and Business as found in some developed countries including the Medicine and Healthcare products Regulatory Agency (MHRA), London (MHRA, 2008). One major way in which MHRA has successfully reduced the fake drug proliferation in their market is by licensing all steps of medicine distribution channel from manufacturing, distributing, drug storage through the supply chain down to dispensing. This can be emulated to strengthen the existing regulatory framework in Nigeria.
- In addition, government should give full support when legislated sanctions are given to drug offenders, while the indigenous pharma company may be provided with financial support, reduced import tariff and incentives geared towards enhancing local drug production.
- Authorities in charge of drug control/regulation including the federal government agencies, international committee, drug manufacturers and pharmacists, all sectors, the health system down to the consuming public irrespective of status should stand together.
- There is need to scientifically standardize commercially available herbal products, which are pathways towards globally acceptable finished drug product.
- Concerted efforts should be made to review and implement national, regional and continental strategies towards availability and accessibility of medicines for use in Nigeria and in Africa as a whole. The effort should support the production of these medicines on the continent.
- In general, a pragmatic approach focusing on the short, medium and long-term recommendations as enumerated above should be vigorously pursued.

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Conclusion

- Government should have a clear, firm and equitable legislation that addresses all important issues with appropriate sanctions for drug violators, provide financial support to the drug regulatory agencies especially in the areas of staffing. Good Manufacturing Practice inspection, Quality Control Laboratories and Enforcement should stand its ground in defense of situation concerning public health.

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