REGULATION OF MEDICAL DEVICES, VACCINES + COMBINATION PRODUCTS IN NIGERIA

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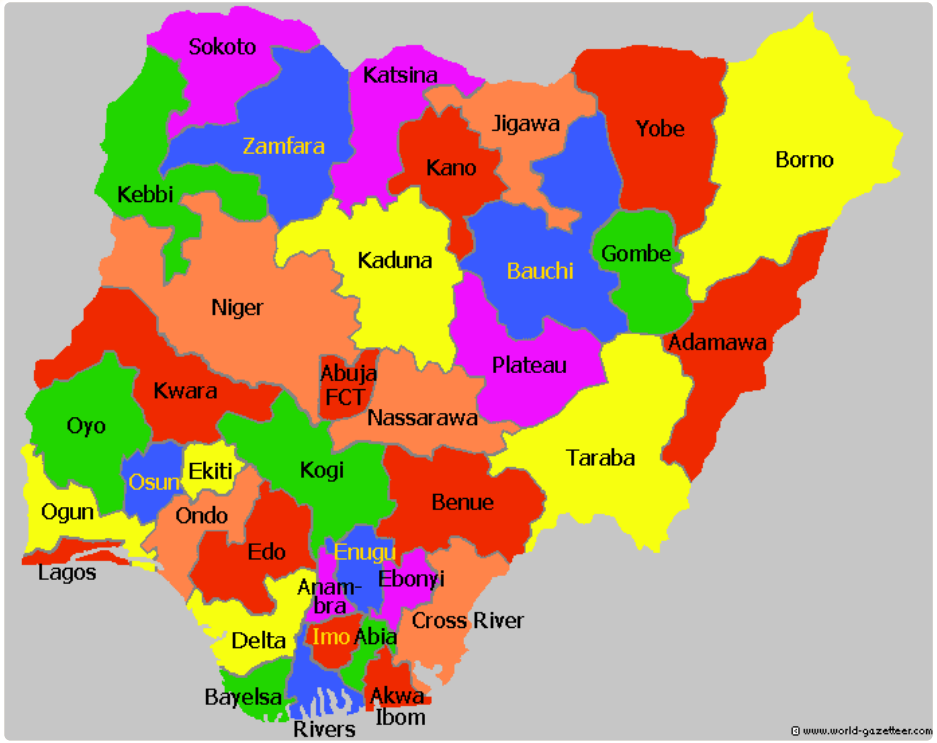
NIGERIA



36 states & Federal Capital Territory (Abuja)

Subdivided into 774 Local Government Areas

Situated in West Africa

Shares land borders with Republic of Benin, Chad, Niger and Cameroon

Coast in the South lies in the Gulf of Guinea on the Atlantic

Area: 923,768 km²

Capital: Abuja

Population: 167 million

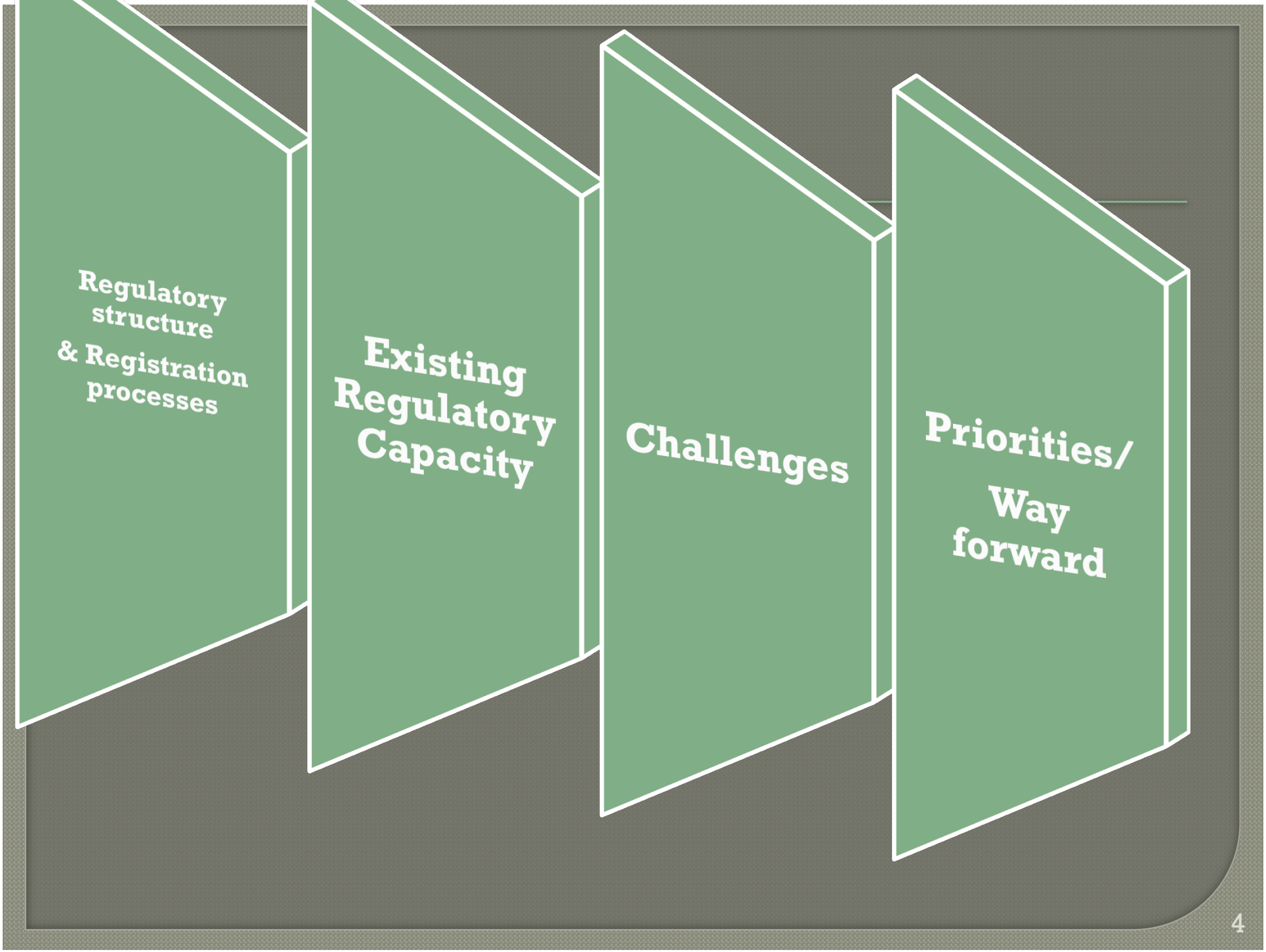
Adult literacy rate : 68%

Below poverty line: 71.5%

GDP Per capita PPP USD: 2,600

HIGHLY DIVERSIFIED: 250 ETHNIC GRPS,
500 LANGUAGES & 4000 DIALETS

The most populous country in Africa and the eight most populous in the world.


Regulatory structure & Registration processes
Existing Regulatory Capacity
Challenges
Priorities/ Way forward

REGULATORY FRAMEWORK.

- The National Agency for Food and Drug Administration and Control (NAFDAC) has the mandate to regulate & control all medical devices and vaccines amongst other products in Nigeria.

OTHER GOVT BODIES

Although NAFDAC is charged with the responsibility of regulating medical devices, other govt organisations do perform some functions, e.g.

- Standard Organization of Nigeria – sets standards of devices.
- Federal Ministry Of Health – conducts field testing to include products in National Algorithm/Immunization prog.

OTHER GOVT BODIES.....CONTINUED

- Advertising Practitioner Council of Nigeria – controls Advert
- Consumer Protection Council – Consumer complaints
- Ministry of Finance & Nigeria Customs Authority – Bans or Prohibits importation of devices (Economic Reason)

NOTE: Functions are a times overlapping & uncoordinated

NAFDAC LEGAL FRAMEWORK

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT CAP N1 LFN 2004 (AS AMMENDED)

This law empowers the Agency to regulate and control drugs, food, medical devices, chemical and packaged water.

Sections 5 (1) and (2) NAFDAC Act (as ammended)

This empowers NAFDAC to regulate and control clinical trials in Nigeria

NAFDAC ENABLING LAWS

FOOD AND DRUG DECREE NO 21 OF 1999 (AS AMMENDED)

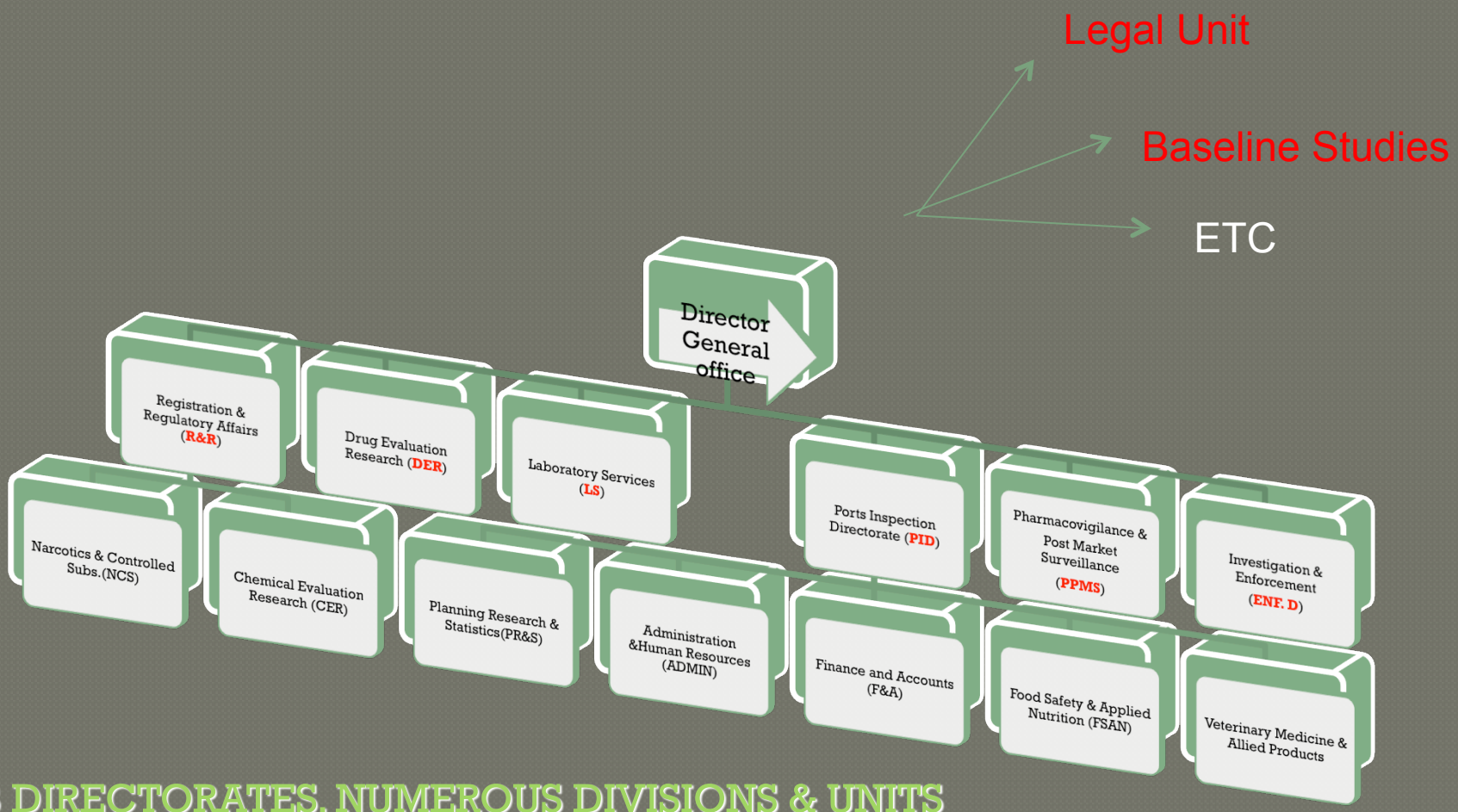
FOOD AND DRUG DECREE ACT CAP F32 LFN 2004

OTHER ENACTMENTS ENFORCED BY NAFDAC

FOOD DRUGS AND RELATED PRODUCTS (REGISTRATION ETC) ACT CAP F33 LFN 2004

IMPORT (PROHIBITION) ACT CAP I 13 LFN 2004

NAFDAC ORGANISATIONAL CHART
(simplified version)



13 DIRECTORATES, NUMEROUS DIVISIONS & UNITS
STAFF STRENGHT; APPROX 2,500
OFFICES: ALL THE STATES NATION WIDE

NAFDAC REGISTRATION OF DEVICES/VACCINES (1)

- 6 of these Directorates are directly/ indirectly involved with regulatory processes of medical devices/vaccines viz; R&R, DER, LS, PID, PPMS, ENF
- R&R Directorate which houses the vaccine & medical devices registration unit plays the leading role.

NAFDAC REGISTRATION OF MEDICAL DEVICES (1)

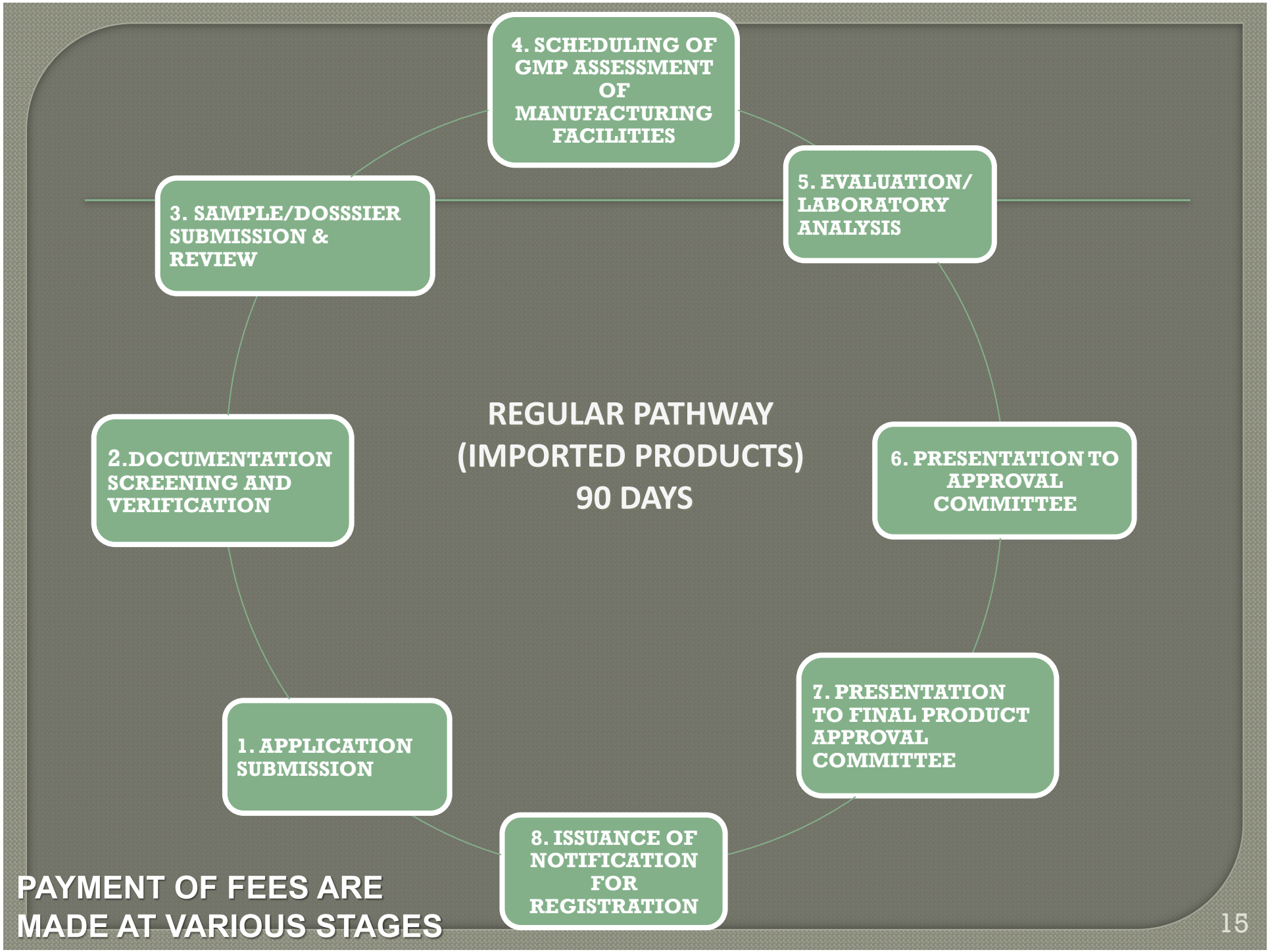
- R & R Directorate coordinates the entire registration process & collaborates with LS, DER, Legal Unit and Pharmacovigilance .
- Four major functions of R&R with respect to licensing are;

- Registration of New Applications & Issuance of NAFDAC Registration number
- Suspension or Revocation of License
- Processing Variation or Changes in Products post registration
- Renewal of Product License after 5/2 years post registration

REGULATORY PATHWAY

Regulatory stages involve;

- Documentation screening (critical point for harmonization)
- Evaluation of products
- Approval committee meetings
- Post market Activities


4. SCHEDULING OF GMP ASSESSMENT OF MANUFACTURING FACILITIES
5. EVALUATION/ LABORATORY ANALYSIS
6. PRESENTATION TO APPROVAL COMMITTEE
7. PRESENTATION TO FINAL PRODUCT APPROVAL COMMITTEE
8. ISSUANCE OF NOTIFICATION FOR REGISTRATION
1. APPLICATION SUBMISSION
2.DOCUMENTATION SCREENING AND VERIFICATION
3. SAMPLE/DOSSSIER SUBMISSION & REVIEW
REGULAR PATHWAY
(IMPORTED PRODUCTS)
90 DAYS
PAYMENT OF FEES ARE MADE AT VARIOUS STAGES

REGISTRATION PATHWAY FOR LOCALLY PRODUCED/PACKAGED DEVICES

- The cycle is similar to that of imported products.
- The major difference;

- Lower fees (approx 200 - 500$)
- Application is first made to DER for production inspection before registration with (R&R) commences

IMPORTED/LOCALLY MANUFACTURED DEVICES/ VACCINES

- All vaccines used in Nigeria are imported
- Over 90% of medical devices used in Nigeria are produced outside Nigeria.
- No vaccine delivery device is produced locally
- Local packaging of 6 point o care diagnostics
- Only low risk devices such syringes, sanitary napkins & cotton wool are produced locally

DOCUMENTS SUBMITTED (IMPORTED DEVICES)

- A Completed NAFDAC Application form
- Notarized power of Attorney

- Certificate of manufacture and free sale
- Certificate of Pharmaceutical Products (vaccine)

- Evidence of product registration from country of origin (GMP Certificate)

- Clinical trial documents and or dossier or documentary evidence/studies to determine the safety and efficacy of the product (no specific format)

DOCUMENTS SUBMITTED.....continues

- Certificate of incorporation of the local company Registering the products.
- Letter of invitation from Manufacturer for the Agency's GMP visit
- Evidence of trademark registration and Notarized declaration by applicant.

DOCUMENTS SUBMITTED (local products)

- Certificate of incorporation of the local company Registering the products.
- A Completed NAFDAC Application formNotarized power of Attorney
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EXEMPTIONS TO REGULATORY CYCLE

Products may be exempted from the entire cycle if there is national interest such as

- Emergency
- Urgent National project/Donation
- Research needs
- Specific urgent need by identified Establishment e.g multinationals

(Specific quantities are approved for use & basic tests are conducted)

GUIDELINES FOR EXEMPTED DEVICES

- Product must meet the specification and guideline for similar registered products
- Product must be registered in country of origin

- List of product, quantity, source and recipient to be submitted before shipment

- Products must at least be accompanied with certificate of analysis, safety report and production details.

POST REGISTRATION ACTIVITIES

- Lot release is done before distribution of vaccines
- AEFI is key & collaborative efforts among stakeholders
- Post marketing activities for devices; basically passive based on consumer complaint or investigative reports e.g PEPFAR

EXISTING REGULATORY CAPACITY

- Rudimentary knowledge global best practices for regulating medical devices & combination devices
- Leverage on existing competencies of other regulated products e.g drug
- Use of regulatory decisions in other jurisdiction (Documentation review)
- Mentorship programme with Health Canada on regulation of vaccines
- Regional Harmonisation effort (PAHWP, WAHO, AMRH)

REGULATIONS AND GUIDELINES

- The current guideline for regulating devices is a modified version of drug registration guideline.
- Guideline does not consider combination products (component of higher risk given priority)
- All classes of devices follow the same registration pathway
- Development of a new guideline is ongoing

CHALLENGES

- Inadequate capacity/ personnel
- Nomenclature and definitions
- Diversity of products grouped as devices
- Classification of combination products
- Evaluation of devices & combination products
- New technologies consistently emerge
- Less focus on devices than other regulated products (food & drug admin)

CHALLENGES.....continued

- Feed back mechanism not well established (PMS)
- Uncoordinated activities amongst relevant agencies/ stakeholders
- Inaccessibility to research publications
- No MOU, mutual recognition & Regulatory covergence amongst NRAs'

PRIORITIES/WAY FORWARD

- Development of regulations and guidelines for licensing of medical devices & combination products
- Capacity building & development of expertise for registration & evaluation of devices & vaccine delivery devices
- Making regulation of vaccine delivery device a separate entity
- International collaborations with developed Health partners
- Stepped up post marketing surveillance & pharmacovigilance

PRIORITIES/WAY FORWARD..... continued

- Involvement of Health Institutions & Manufacturers in PMS
- Harmonization of Regulatory requirements amongst Region
- Mass Public enlightenment on health importance of devices
- National coordinated regulatory activities
- Mutual recognition amongst NRA

References

- NAFDAC, 2004. Registration of NAFDAC Regulated Products: *NAFDAC Consumer Safety Bulletin*. 3(1)
- NAFDAC, 2004. Registration of NAFDAC Regulated Products: *NAFDAC Consumer Safety Bulletin*. 3(2)
- NAFDAC, 2005. Statutory Functions of NAFDAC: *NAFDAC Consumer Safety Bulletin*. 4(3)
- NAFDAC Official Website www.nafdac.gov.ng

DISCLAIMER

The information and opinion expressed in this presentation are those of the presenter based on the presenter's expertise/experience. These do not represent the official statement of any organisation.

THANK YOU!! FOR YOUR ATTENTION

.....if indeed I had it!!!

CHI CHI ILONZE