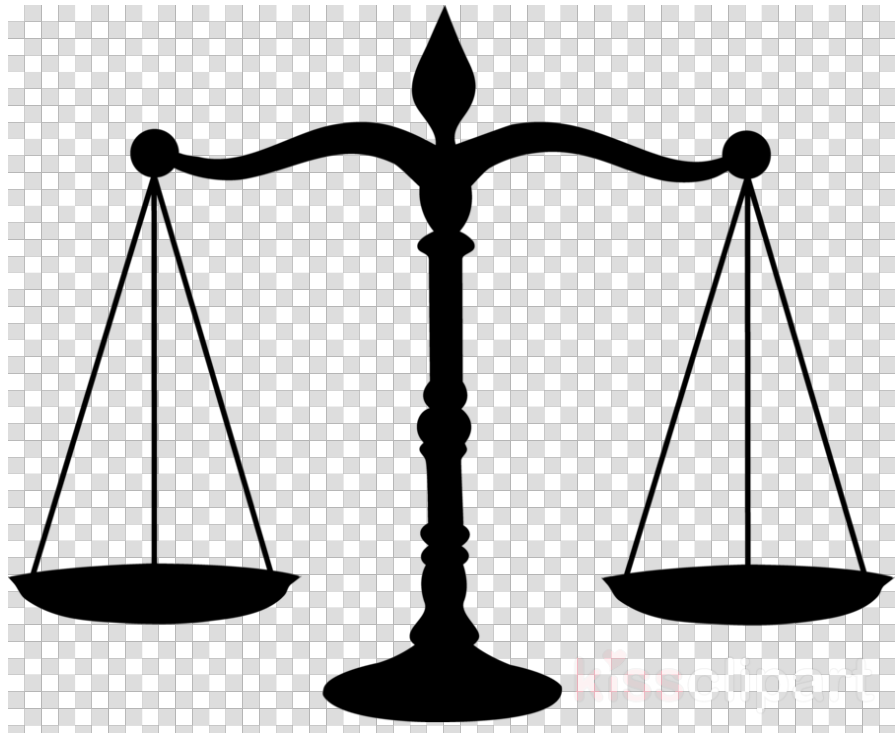




NAFDAC ACT



- **ACT Cap N1 LFN 2004**

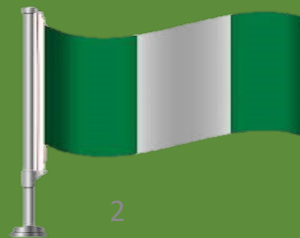
Regulate and control the manufacture, importation, exportation, distribution, advertisement, sale and use of Regulated Products namely:

Food, Drugs, Cosmetics, Medical Devices, Packaged Water, Chemicals and Detergents

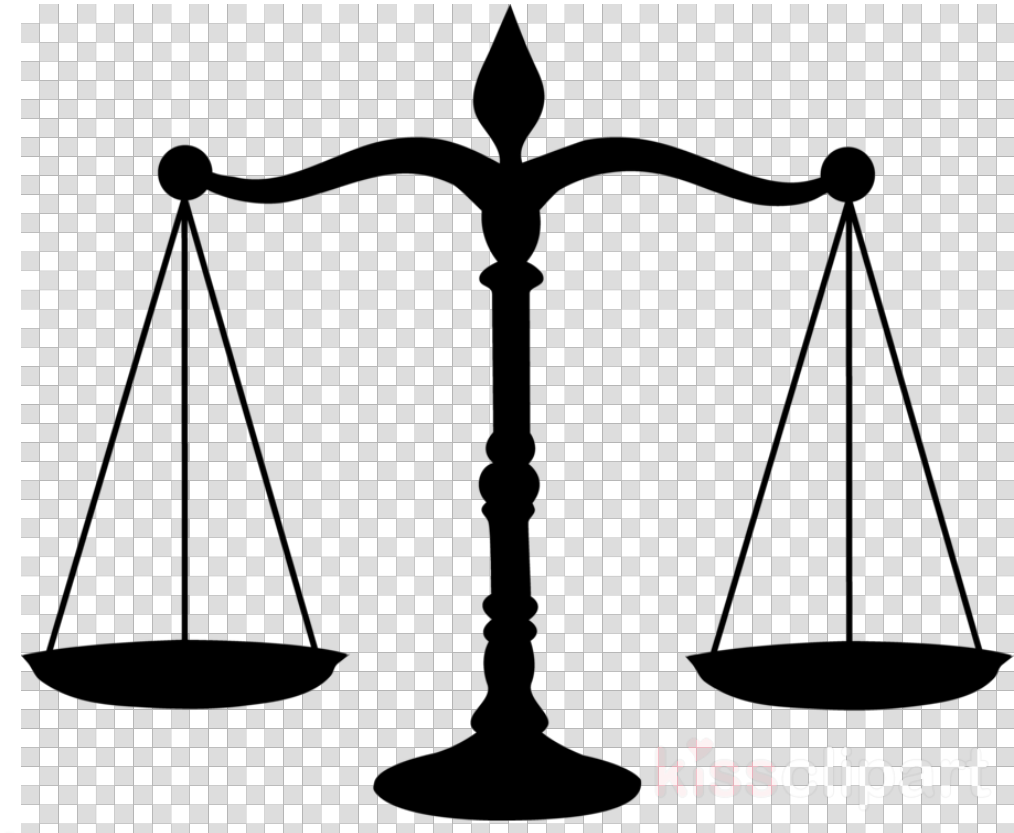


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NAFDAC ACT



Counterfeit and Fake Drugs Unwholesome processed Foods (Miscellaneous Provision) Act Cap. C. 34 LFN 2004.

This law prohibits the sale of counterfeit, fake drugs and unwholesome processed foods. The Law also prohibits the sale and distribution of counterfeit, adulterated, banned, substandard or expired drugs.

Food and Drug Act Cap F. 32 LFN

This law is promulgated to prohibit the sale of certain foods, drugs, cosmetics and devices. The Law also regulates the manufacture, sale and advertisement of food, drugs, cosmetic and medical devices.

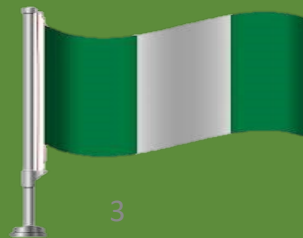
Food, Drug and Related Products (Registration) Act Cap F.33

The Law is promulgated to prohibit the manufacture, sale, distribution, advertisement, importation, exportation , sale or distribution of regulated products

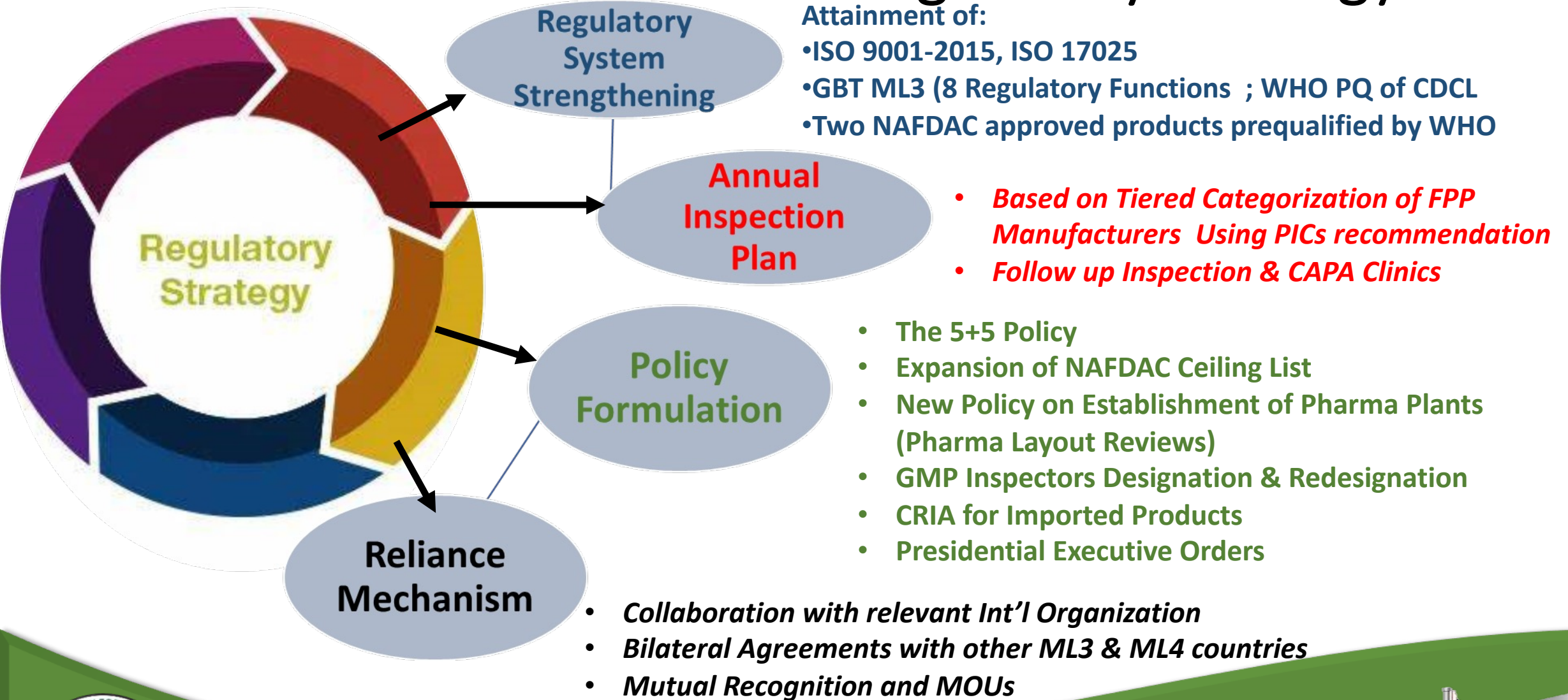


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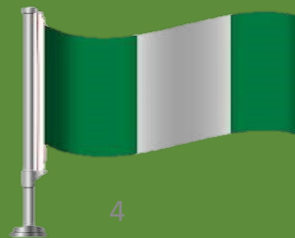


Overview of National Regulatory Strategy



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Policies Targeted at Enhancing Local Manufacturing

1

The 5 + 5 Policy

2

Expansion of NAFDAC's Ceiling List

3

New Policy on Establishment of Pharma Plants In Nigeria

4

Presidential Executive Order

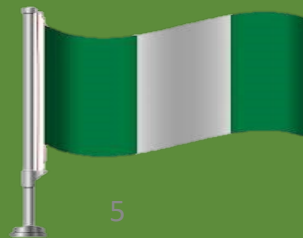
5

Periodic Stakeholders Collaboration



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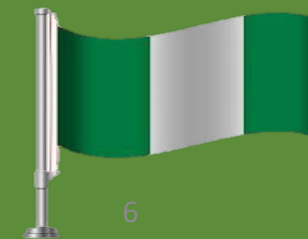
Policies Targeted at Enhancing Local Manufacturing

S/N	POLICY	PURPOSE
1	The 5 + 5 Policy	<i>Aimed at migration of previously imported products to local manufacturing after two rounds of registration</i>
2	NAFDAC's Ceiling List	<i>To reduce importation of medicines that can be manufactured locally (currently 36 products are on the list)</i>
3	New Policy on Establishment of Pharma Plants In Nigeria	<i>Enables existing and intending FPP manufacturers to obtain regulatory approval of their facility design right before retrofitting or erection of new pharma plants</i>
4	Presidential Executive Order	Increasing local production of healthcare products, reducing costs of healthcare equipment and consumables, and promoting local investments.
5	Periodic Stakeholders Collaboration	Through periodic engagements, issuance of notes to industry, regulatory meetings etc.



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Access to Nigeria's Pharmaceutical Market By Foreign Manufacturers

 **Detailed Guidelines for Importation of Pharmaceuticals available at** Guidelines – NAFDAC (Registration, Dossier submission, GMP Inspection etc.)

 **Respect for National Policies on Local Manufacturing**

 **Tiered Categorization of Foreign Manufacturers (Based on PIC/s Recommendation)**

 **Clean Report of Inspection and Analysis (CRIA) Scheme**

 **Reliance Mechanism Through:**

- ✓ Harmonization Initiatives and Regulatory Convergence
- ✓ *Collaboration with relevant Int'l Organizations*
- ✓ *Bilateral Agreements with other ML3 & ML4 countries*
- ✓ *Mutual Recognition Agreements and MOUs*



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*Thank
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