NIGERIAN PHARMA INDUSTRY – PROGRESS TOWARDS PREQUALIFICATION

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CHAIRMAN, PMGMAN & PRESIDENT, WAPMA
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FACTS ABOUT NIGERIA

- NIGERIA IS A FEDERATION
- ESTIMATED POPULATION= 160 Million
- THE CAPITAL IS ABUJA (FEDERAL CAPITAL TERRITORY),
- THERE ARE 36 STATES APART FROM THE FEDERAL CAPITAL TERRITORY
- 774 LOCAL GOVERNMENT AREAS
## PHARMA INDUSTRY IN NIGERIA

<table>
<thead>
<tr>
<th>MANUFACTURERS</th>
<th>NUMBER</th>
<th>REMARKS</th>
</tr>
</thead>
<tbody>
<tr>
<td>MANUFACTURERS OF ARVs</td>
<td>12</td>
<td>Product of interest for PQ</td>
</tr>
<tr>
<td>MANUFACTURERS OF ACTs</td>
<td>18</td>
<td>Product of interest for PQ</td>
</tr>
<tr>
<td>PROSPECTIVE MANUFACTURERS OF</td>
<td>10</td>
<td>Product of interest for PQ</td>
</tr>
<tr>
<td>ZINC/ORS</td>
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CHALLENGES

- INADEQUATE NATIONAL HEALTH BUDGETS
- LOW PATRONAGE OF MANUFACTURERS DUE TO PRE-CONDITION OF WHO PREQUALIFICATION
- LOCAL MANUFACTURE OF ACTs & ARVs ON THE DECLINE AS A RESULT OF AMFm & DONATED ARVs
PREQUALIFICATION CONSTRAINTS

- SOURCING ACTIVE PHARMA INGREDIENTS
- LIMITED TECHNICAL KNOW-HOW
- LIMITED HUMAN RESOURCES
- LIMITED RESOURCES FOR BIO–EQUIVALENCE STUDIES
- ACCESS TO ACCREDITED CROs
- DAUNTING COST - ESTIMATED AT $10M/COMPANY
- UNCERTAINTIES ABOUT RETURN ON INVESTMENT
UPDATE ON PREQUALIFICATION

- As yet, no manufacturer in West Africa is pre-qualified by the WHO
- Efforts toward prequalification in Nigeria are supported by NAFDAC and the Federal Government
- A special intervention fund has been proposed for Nigerian manufacturers
- Technical assistance received from West African Health Organization (WAHO)
- Nigeria benefiting from capacity building & assistance from WHO/UNITAID
## $1M SUPPORT FROM WAHO

<table>
<thead>
<tr>
<th>Assistance</th>
<th>Beneficiaries</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feasibility Studies</td>
<td>MAY &amp; BAKER NIG.PLC EVANS MEDICAL PLC FIDSON HEALTHCARE PLC</td>
<td>$100,000</td>
</tr>
<tr>
<td>Support to Consultants for GMP Upgrade</td>
<td>MAY &amp; BAKER NIG.PLC EVANS MEDICAL PLC + DAN ADAMS (GHANA) INPHARMA (CAPE VERDE)</td>
<td>$300,000</td>
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<tr>
<td>Further Support to Consultants</td>
<td>6 MANUFACTURERS IN ECOWAS @ $25,000/COMPANY</td>
<td>$150,000</td>
</tr>
<tr>
<td>Three Modules of GMP Training</td>
<td>MANUFACTURERS &amp; REGULATORS IN IN ECOWAS</td>
<td>$450,000</td>
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SUPPORT FROM WHO/UNITAID

<table>
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<tr>
<th>SUPPORT</th>
<th>BENEFICIARIES</th>
<th>REMARKS</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPACITY BUILDING/MEETING IN GENEVA, APRIL 2011</td>
<td>MANUFACTURERS &amp; NAFDAC</td>
<td>Technical assistance initiated &amp; conditions for Assistance agreed</td>
</tr>
<tr>
<td>GMP AUDITS: AUGUST 2011 - NOVEMBER 2011 - JULY-AUGUST 2012</td>
<td>CHI PHARMA LTD EMZOR PHARMA IND EVANS MEDICAL PLC FIDSON HEALTHCARE PLC JUHEL NIGERIA LIMITED MAY &amp; BAKER PLC NEIMETH INTL PHARMA PLC SWISS PHARMA LTD</td>
<td>Audits resulting in CAPA - Improvement plans &amp; (CAPA) implemented - TWO manufacturers at borderline compliance, *ONE able to comply within 2 years</td>
</tr>
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<td>GMP TRAINING MAY 28 - JUNE 1, 2012</td>
<td>MANUFACTURERS &amp; NAFDAC</td>
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**GMP TRAINING**

MAY 28 - JUNE 1, 2012

**SUPPORT FROM WHO/UNITAID**

MANUFACTURERS & NAFDAC

**REMARKS**

Technical assistance initiated & conditions for Assistance agreed

Audits resulting in CAPA - Improvement plans & (CAPA) implemented

**TWO manufacturers at borderline compliance, *ONE able to comply within 2 years**
BENEFITS FROM THE WHO PQ PROCESS

- NIGERIA APPRECIATES CAPACITY BUILDING & TECHNICAL ASSISTANCE FROM WHO/UNITAID
- THE ASSISTANCE AND ADVOCACY VISIT TO GOVERNMENT HAS IMPACTED POSITIVELY ON GMP & PROGRESS TOWARDS WHO PQ IN NIGERIA
- IMPROVED COMMUNICATION BETWEEN MANUFACTURERS & REGULATORS
- IMPROVED COMMUNICATION WITH WHO PQP
- MORE MANUFACTURERS CURRENTLY UPGRADING FACILITIES TO WHO GMP STANDARDS
NEXT STEPS FOR NIGERIA

- IMPROVEMENTS & ADDRESSING GAPS
- GUIDANCE WITH CHOICE OF PRODUCTS FOR PREQUALIFICATION
- TECHNICAL ASSISTANCE WITH DOSSIER DEVELOPMENT
- FACILITIES FOR BIOEQUIVALENCE STUDIES ARE REQUIRED IN WEST AFRICA
- ACCESS & SELECTION OF ACCREDITED CONTRACT RESEARCH ORGANIZATIONS (CROs)
Issues with requested medicine(s) for prequalification

- ASSURANCES AND GUARANTEES OF PATRONAGE ARE A CONCERN TO INVESTORS

- GUIDANCE TOWARDS CHOICE OF PRODUCTS FOR PREQUALIFICATION IS REQUIRED

- INCENTIVES TO INVEST IN CERTAIN PRODUCTS SUCH AS ZINC/ORS REQUIRED BY MANUFACTURERS
Issues of Dossier development

- EXPERTISE IN DOSSIER DEVELOPMENT STILL REQUIRED
- EXPERTISE IN SITE MASTER FILE (SMF) STILL REQUIRED
- INTERNATIONAL CONSULTANTS REQUIRED
- CAPACITY BUILDING REQUIRED IN DOSSIER DEVELOPMENT FOR ALL PHARMA MANUFACTURERS IN ECOWAS
Bioequivalence Studies

- No accredited centre for bio-equivalence yet in ECOWAS
- Bio-equivalence and related studies currently by accredited CROs
- Considerations for bio-waivers required for West African manufacturers to facilitate WHO prequalification in the region
CONCLUSIONS-I

- THE COMMITMENT OF MANUFACTURERS, NAFDAC AND THE FEDERAL GOVERNMENT OF NIGERIA TO WHO PQ HEREBY RE-ITERATED

- PROGRESS ENHANCED BY T/A FROM WAHO & WHO/UNITAIDS

- FURTHER ASSISTANCE IN AREAS OF DOSSIER DEVELOPMENT, BIO-EQUIVALENCE STILL REQUIRED
CONCLUSIONS-II

- IMPROVED COMMUNICATION WITH WHO PQP TO BE SUSTAINED
- MORE CAPACITY BUILDING STILL REQUIRED BY MANUFACTURERS & REGULATORS
- COLLABORATION BETWEEN WAHO & WHO/UNITAID TO BE FACILITATED BY WAPMA
CONCLUSIONS-III

- SOME GUARANTEES OF PATRONAGE IS REQUIRED TO ENCOURAGE MANUFACTURERS

- EXPANSION OF ASSISTANCE TO COMPANIES JUST PROCESSING EXPRESSION OF INTEREST WILL BE A GREAT ENCOURAGEMENT
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