NIGERIAN PHARMA INDUSTRY –PROGRES TOWARDS PREQUALIFICATION

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SEPTEMBER 25, 2012

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FACTS ABOUT NIGERIA

- NIGERIA IS A FEDERATION
- ESTIMATED POPULATION= 160Million
- 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

MANUFACTURERS	NUMBER 150++	REMARKS
MANUFACTURERS OF ARVs	12	Product of interest for PQ
MANUFACTURERS OF ACTs	18	Product of interest for PQ
PROSPECTIVE MANUFACTURERS OF ZINC/ORS	10	Product of interest for PQ

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
- LIMTED 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 BT 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 BENEFITTING FROM CAPACITY BUILDING & ASSISTANCE FROM WHO/UNITAID

$1M SUPPORT FROM WAHO

ASSISTANCE	BENEFICIARIES	AMOUNT
FEASIBILITY STUDIES	MAY & BAKER NIG.PLC EVANS MEDICAL PLC FIDSON HEALTHCARE PLC	**$100,000**
SUPPORT TO CONSULTANTS FOR GMP UPGRADE	MAY & BAKER NIG.PLC EVANS MEDICAL PLC + DAN ADAMS (GHANA) INPHARMA (CAPE VERDE)	**$300,000**
FURTHER SUPPORT TO CONSULTANTS	6 MANUFACTURERS IN ECOWAS @ $25,000/COMPANY	**$150,000**
THREE MODULES OF GMP TRANING	MANUFACTURERS & REGULATORS IN IN ECOWAS	**$450,000**

SUPPORT FROM WHO/UNITAID

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

BENEFITS FROM THE WHO PQ PROCESS

- NIGERIA APPRECIATESCAPACITY BUILDING & TECHNICAL ASSITANCE FROM WHO/UNITAID
- THE ASSISTANCE AND ADVOCACY VISIT TO GOVERNMENT HAS IMPACTED POSITIVELY ON GMP & PROGRESS TOWARDS WHO PQ IN NIGERIA
- IMPROVED COMMUNICATION BETWEEN MANUFACRURERS & 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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