

**INSIDE THE AFRICAN
PHARMA MARKET –
PRESENTATION BY GERTRUDE
MOTHIBE, CHAIRPERSON,
SAGMA**

**INTERNATIONAL BUSINESS AND INVESTMENT FORUM –
MARCH 2018, BONN, GERMANY**



SAGMA

Access to affordable quality medicines

Southern
African
Generic
Medicines
Association

SOUTHERN AFRICAN GENERIC MEDICINES ASSOCIATION

**REPRESENTING GENERIC
MANUFACTURERS AND
DISTRIBUTORS IN THE
SADC ECONOMIC BLOC**



AS PART OF AFRICA ... 1,216 BILLION PEOPLE



SADC COMPRIZES 16 COUNTRIES IN SOUTHERN AFRICA WITH 257.7 MILLION PEOPLE



SADC COUNTRIES

Angola, Botswana, Comoros, Democratic Republic of Congo (DRC), Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe



SADC HEALTH LANDSCAPE

SERIOUS PUBLIC HEALTH CRISIS WITH HIV/AIDS, TB AND (LESS SO) MALARIA

THE REGION HAS THE WORLD'S TOP 3 HIGHEST PREVALENCE HIV POSITIVE COUNTRIES, CREATING OPPORTUNITY FOR BUSINESS.

UNMET DEMAND: ONLY 50% OF NEED COVERED FOR HIV, 90% FOR DR-TB

ONLY 15% OF GENERIC ARVS PRODUCED IN SADC; 24% OF OTHER DRUGS;

THE BULK OF DRUGS IN SADC ARE IMPORTED MOSTLY FROM INDIA



MARKET SIZE AND GROWTH

ACCORDING TO INFORMATION AVAILABLE FROM SADC, THE REGIONAL PHARMACEUTICAL USE IS ESTIMATED AT MORE THAN US \$3 BILLION.

MORE THAN 50% OF THE ESSENTIAL PHARMACEUTICAL MEDICINES USED IN THE REGION ARE IMPORTED FROM OUTSIDE AFRICA.



MARKET SIZE AND GROWTH

THE PHARMACEUTICAL MARKET IN SADC AND IN SUB-SAHARAN AFRICA IS GROWING AT AN EXPONENTIAL RATE.

FACTORS CONTRIBUTING TO THIS GROWTH IN MOST EMERGING MARKETS INCLUDE:

POPULATION GROWTH

AGEING POPULATION (THE PARADOX OF THIS AGAINST THE RAVAGES OF HIV AND A DECLINING LIFE EXPECTANCY OVERALL)



MARKET SIZE AND GROWTH

GROWING MIDDLE CLASS – MORE DISPOSABLE INCOME

DOUBLE DIGIT GROWTH IN GENERICS

**GOVERNMENT SUPPORTED INITIATIVES TO INCREASE GENERIC
UTILISATION**

HIV/AIDS



HIV AND AIDS

**14.7 MILLION HIV+, 11.7MILLION NEED ARVS, ONLY 6MILLION GET ARVS.
GAP OF 5.7MILLION**

**14 IMPORTANT ARVS USED; ONLY 15% OF THE VALUE IS MADE IN SADC,
85% IMPORTED**

**SADC USES: 95% 1ST LINE, 5% 2ND LINE, FEW 3RD LINE (\$2000/YEAR), FEW
PAEDIATRIC ARVS**

- **ONLY 2 MANUFACTURERS ARE WHO PREQUALIFIED IN SADC (ASPEN, VARICHEM)**

HIV AND AIDS

SADC COUNTRIES HAVE ACCEPTED TEST & TREAT AS STRATEGY TO CONTROL NEW INFECTIONS! WITH MORE PEOPLE LIVING LONGER THIS PRESENTS OPPORTUNITY FOR BUSINESS.

EXISTING AND NEW ARVS ARE STILL IN MEDICINES PATENT POOL

- **OPPORTUNITY - PRODUCTS CAN HOPEFULLY BE DEVELOPED IN COLLABORATION WITH TT OF BIG PHARMA, AND TAKE ADVANTAGE TRIPS FLEXIBILITIES**

TB

INCREASING RESISTANCE; POOR TREATMENTS AND RESULTS; HIGH PRICES

POINT OF CARE DIAGNOSTICS NEEDED;

EXISTING DR-TB FAILURE: TREATMENT TOO LONG, NOT SAFE, NOT VERY EFFECTIVE

NEW PRODUCTS ARE NOT IN PATENT POOL,

- **OPPORTUNITY FOR SADC TO DEVELOP THEM WITHOUT ORIGINATOR TT**

MALARIA


- **PRODUCTION OF ARTEMISININE API UNRELIABLE (SEASONAL)**
- **PRODUCTION IN SADC ONLY IN MADAGASCAR (CAN EXPAND)**
- **PAEDIATRIC DOSAGE FORMS NEEDED**
- **SEMI-SYNTHETIC ARTEMISININE (MOROCCO) TOO COSTLY/DIFFICULT?**

NEW PRODUCTS (MMV) STILL IN EARLY STAGES

BED NETS: ONLY 1 SADC MANUFACTURER (TANZANIA)

DDT: ONLY ONE FACTORY LEFT (INDIA) – SUPPLY SECURITY RISK

REGIONAL STRENGTHS

- **WRITTEN, OFFICIAL POLICIES AND BUSINESS PLAN**
 - **EVERYONE WANTS LOCAL PRODUCTION**
 - **EXISTING PRODUCTION BASE (15-24%)**
 - **ZAZIBONA FAST REGULATORY APPROVALS**
 - **TRIPS FLEXIBILITIES (3/16 ARE LDC)**
 - **CENTRES OF EXCELLENCE – FOR REGULATION AND HUMAN RESOURCE TRAINING**
 - **CLINICAL TRIALS CAPACITY**
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REGIONAL STRENGTHS

AS AN ECONOMIC BLOC, SADC HAS TRADE POLICIES THAT ALLOW FREE TRADE AMONG ITS MEMBER STATES. THIS DIFFERENTIATES IT FROM OTHER BLOCS IN THE CONTINENT.

EACH STATE THEN CAN BENEFIT FROM THE TRADE STRENGTHS OF FELLOW MEMBER STATES LIKE



REGIONAL STRENGTHS

SIZEABLE LOCAL MARKET FOR THE PRODUCED MEDICINES;

**LOGISTICS: HARBOUR, EASY TRANSPORT TO OTHER SADC COUNTRIES;
HIGH QUALITY INFRASTRUCTURE, ALLOWING FOR RAW MATERIALS
(IMPORTED FROM ABROAD), PACKAGING MATERIALS, EQUIPMENT,
BUILDING MATERIALS, FINISHED GOODS ETC. TO BE SHIPPED IN AND
OUT OF THE PLANT FACILITY.**



REGIONAL STRENGTHS

ACCESS TO HOSPITALS FOR BIOEQUIVALENCE STUDIES AND CLINICAL TRIALS;

**RELATIVELY INTERRUPTION-FREE ELECTRIC POWER SUPPLY,
CLEAN WATER SUPPLY, MINIMIZING THE COST AND ENERGY OF FURTHER
PURIFICATION**

RELATIVELY STABLE POLITICAL ENVIRONMENT



REGIONAL STRENGTHS

REGULATORY EFFICIENCY & EFFECTIVENESS

INDUSTRY/ACADEMIA COLLABORATION (R&D; TRAINING)

ACCESS TO QUALIFIED CROs / CENTRES FOR BIO-EQUIVALENCE STUDIES

ECONOMIC INCENTIVES

EFFECTIVE COMMON MARKET

REGIONAL PREFERENCES IN GOVERNMENT TENDERS

UNIFORM TREATMENT GUIDELINES



SUPPORTING INDUSTRY...OPPORTUNITIES

- **THERE ARE NO OR VERY FEW RELATED AND SUPPORTING INDUSTRIES**
- **CONSEQUENTLY THERE IS NO READY AVAILABILITY OF RAW AND**

PACKAGING MATERIALS:

- **NO RAW MATERIALS ARE LOCALLY AVAILABLE EXCEPT FOR VERY FEW LIKE SUGARS; AND SPECIALIZED PACKAGING MATERIALS SUCH AS**
- **PRINTED POLY COATED PAPER FOR STRIP PACKING, PRINTED BLISTER ALUMINIUM FOIL, RIGID PVC FILM FOR BLISTER PACKING, PRINTED ALUMINIUM LAMINATE FOIL, ETC. ARE ALL IMPORTED AS THERE ARE NO LOCAL MANUFACTURERS FOR SUCH ITEMS**

PHARMACEUTICAL INDUSTRY – HARMONISED REGULATION

IN ADDITION TO HAVING A FREE TRADE SPACE, SADC ALSO BOASTS A HARMONISED REGULATORY ENVIRONMENT – ZAZIBONA.

CURRENT ACTIVE PARTICIPANTS ARE: ZAMBIA, ZIMBABWE, BOTSWANA, NAMIBIA (INITIALLY GAVE THE ACRONYM ZAZIBONA) AND SOUTH AFRICA. UP TO 11 COUNTRIES ARE PARTICIPATING IN MEETINGS, IN PREPARATION FOR FULL PARTICIPATION IN ASSESSMENT AND INSPECTIONS.



HARMONISED REGULATION

BENEFITS FOR APPLICANTS:

1 PRIMARY ASSESSMENT – FOR 5 COUNTRIES

**WITH TIME LINES: FROM SUBMISSION TO FINAL RECOMMENDATION –
TARGET IS 9 MONTHS.**



POTENTIAL GROWTH

SAGMA IS A MEMBER OF FAPMA, THE FEDERATION OF AFRICAN PHARMACEUTICAL MANUFACTURERS' ASSOCIATION. THUS SOME OF ITS MEMBERS ARE PARTICIPATING IN THE FAPMA-GLOBAL FUND INITIATIVE TO SUPPLY AFRICA WITH MEDICINES FOR NON-PANDEMIC DISEASES.

THIS PRESENTS A HUGE POTENTIAL FOR GROWTH AND CONSEQUENTLY INVESTMENT.



VOICES TO ADDRESS OPPORTUNITIES FOR INVESTMENT

**AMONG THE SADC MEMBER STATES, DEVELOPMENT OF THE VOICE FOR
PRIVATE SECTOR PHARMACEUTICAL MANUFACTURE, IS ALMOST
PROPORTIONAL TO THE LEVEL OF DEVELOPMENT OF THE
MANUFACTURING SECTOR.**

INDUSTRY ASSOCIATIONS IN SADC



INDUSTRY SECTOR VOICES

SOUTH AFRICA HAS 3 INDUSTRY ASSOCIATIONS:

**IPASA (Innovative Pharmaceutical Association of South Africa)–
RESEARCH BASED AND INCLUDING 27 COMPANIES MAINLY
REPRESENTATIVES OF BIG PHARMA;**

**GBMSA (Generic and Biosimilar Medicines of Southern Africa)
COMPRISING 22 COMPANIES FOCUSSED ON BIOSIMILAR MEDICINES;**

**PIASA (Pharmaceutical Industry Association of South Africa)– WITH 18
MEMBERS MANUFACTURING AND MARKETING PRESCRIPTION DRUGS.**

INDUSTRY SECTOR VOICES

ZIMBABWE:

- The PHARMACEUTICAL MANUFACTURERS ASSOCIATION (PMA),
COMPRISES 9 MEMBERS WHO ARE THE MAIN GENERIC
MANUFACTURERS.

ZAMBIA:

- THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION (PMA)
COMPRISES 7 GENERIC MANUFACTURERS.

MALAWI:

- 4 MANUFACTURERS NOT YET ORGANISED INTO AN INDUSTRIAL
ASSOCIATION



CONCLUSION

SOUTHERN AFRICA IS READY FOR INVESTORS!

THANK YOU

