



REPUBLIC OF SOUTH AFRICA



Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities

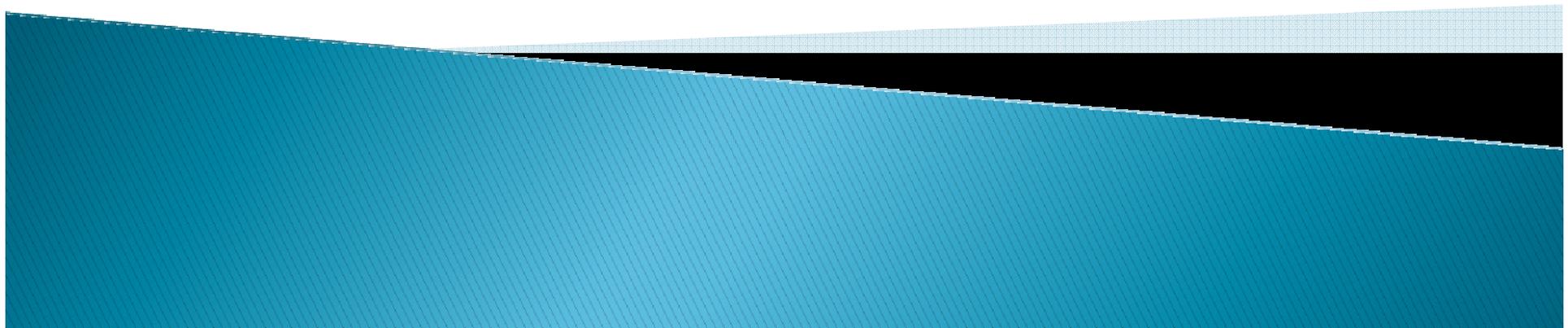
***Topic 5: Overview of the Use of Patent-Related Flexibilities
and the Main Constraints thereon within the Region***

**Durban, South Africa
January 29 to 31, 2013**

Regional Seminar for Certain African Countries on the
implementation and use of several patent-related flexibilities
Organized by the World Intellectual Property
Organization(WIPO)
in collaboration with Department of Trade and Industry
South Africa

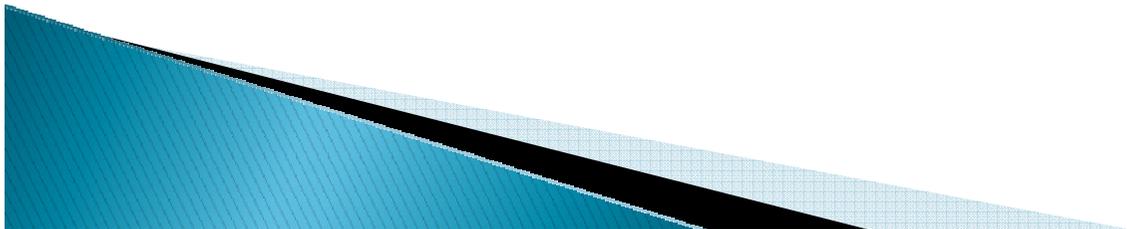
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Topic 5: Overview of the use of Patent Related flexibilities
and main constraints thereon within the Region.
Presented by Timothy Leatile Moalusi



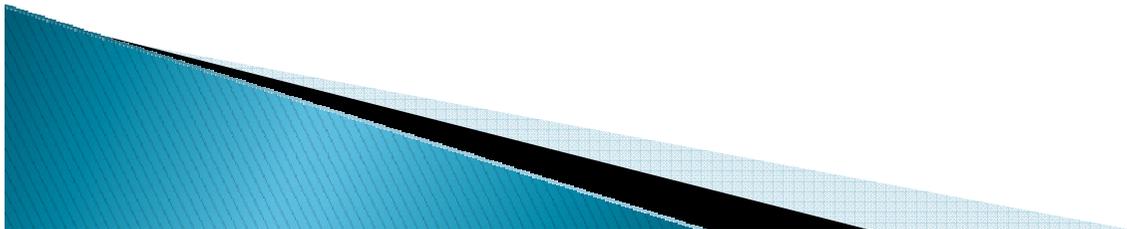
OUTLINE

- ▶ Introduction
- ▶ Strategies to finance the National Anti-retroviral Therapy Programme.
- ▶ Challenges
- ▶ Solutions
- ▶ Conclusion



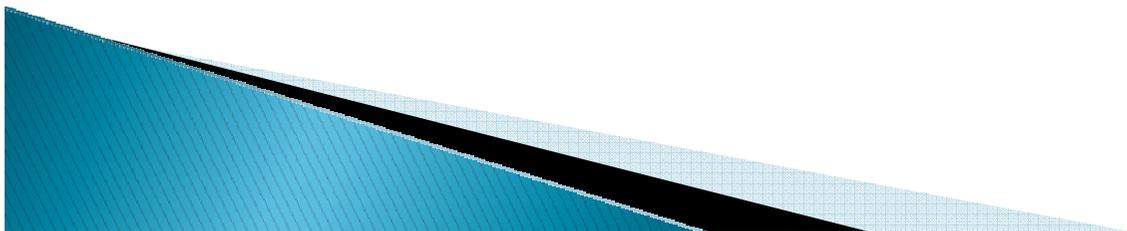
INTRODUCTION

- ▶ HIV/AIDS continues to have a major impact on health, poverty reduction and development objectives across sub-Saharan Africa, and particularly in Botswana.
- ▶ In 2000, the Botswana Cabinet declared HIV/ AIDS a national emergency.



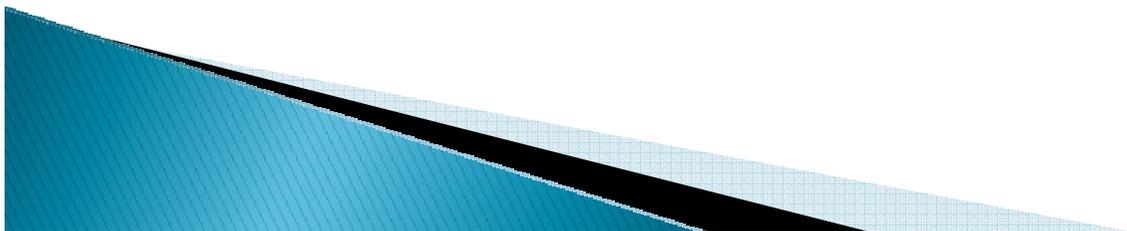
INTRODUCTION

- ▶ Great efforts focused on the technical and financial challenges of providing HIV treatment, based on antiretroviral therapy, as part of the comprehensive response to HIV/AIDS.
- ▶ Considerable extra resources were put into HIV/AIDS-prevention-and-care activities, The President subsequently declared his intention of making antiretroviral drugs available to every HIV-infected person who needed them.



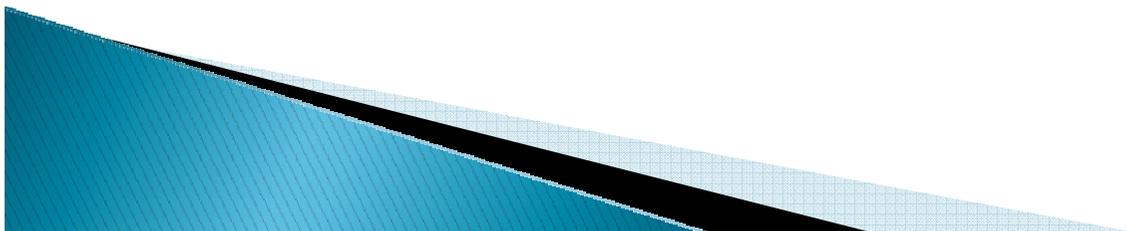
INTRODUCTION

- ▶ In January 2002, Botswana was the first African country to launch a national, public sector Antiretroviral Therapy(ART) programme, and has the greatest number of public sector patients benefiting from free treatment.
- ▶ This programme offers the total package of comprehensive care through the public health system, which includes the provision not only of drugs for opportunistic infections, but also treatment with antiretroviral drugs.



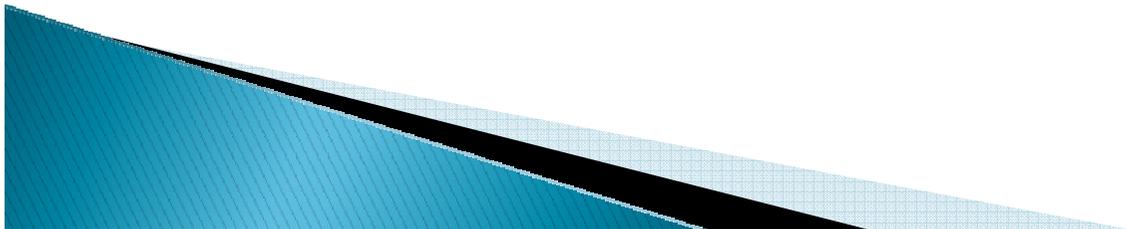
STRATEGIES TO FUND THE NATIONAL ANTI-RETROVIRAL THERAPY PROGRAMME

- ▶ Several of the major research-based pharmaceutical companies initiated donation and discounted drug access programmes with the overall aim of making high value branded drugs more affordable and accessible to selected health care purchasers in developing countries with high HIV burdens.
- ▶ As a result Botswana entered into partnerships with several pharmaceutical companies to provide drugs for the National ARV programmes.



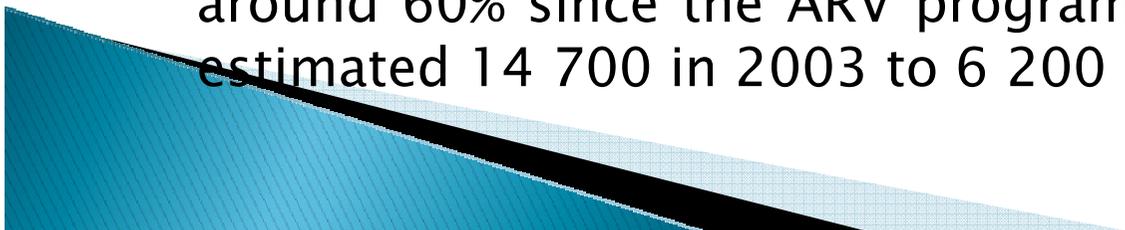
STRATEGIES TO FUND THE NATIONAL ANTI-RETROVIRAL THERAPY PROGRAMME

- ▶ A five-year agreement with Boehringer-Ingelheim to donate Viramune® (nevirapine) for prevention of mother to-child transmission;
- ▶ An indefinite memorandum of understanding (MOU) with Pfizer to provide Diflucan® (fluconazole) for treatment of two indicated opportunistic fungal infections (cryptococcal meningitis and oesophageal candidiasis);
- ▶ The Government of Botswana also has a very significant partnership to address HIV/AIDS in the form of the African Comprehensive HIV/AIDS Partnerships (ACHAP). This was initiated by Merck & Co, Inc., and the Bill & Melinda Gates Foundation with the Government of Botswana in 2000. The offer of donation of, two anti-retroviral (ARV) drugs Stocrin®/efavirenz and Crixivan®/indinavir sulfate.



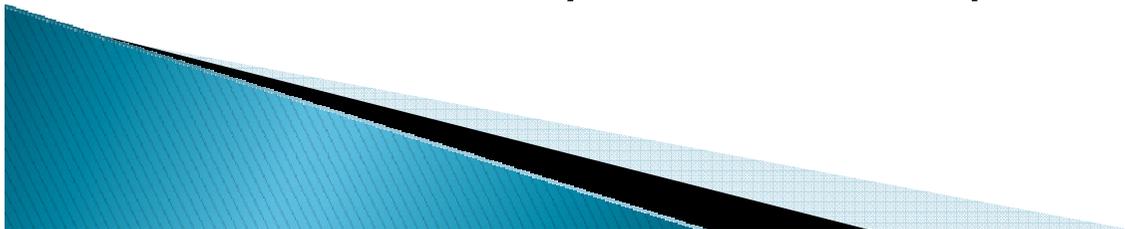
SUCCESSSES IN THE ARV PROGRAMME

- ▶ The transformation of the HIV from almost certain death to a chronic condition for many people living with HIV in Botswana through the MASA National ARV Programme has been a significant public health achievement. Access to antiretroviral treatment stood at 95% of those eligible for treatment. A total of 194 clinics are now dispensing antiretroviral medicines. This has ensured that more HIV infected Botswana can live longer and healthier lives, with life expectancy of people living with the virus having improved from 45 years in 2001 to 65 years in 2010 (State of Nation Address, 2011).
- ▶ According to the World AIDS Day Speech of 2011, the national estimates and projections, AIDS deaths have reduced by around 60% since the ARV program was introduced, from an estimated 14 700 in 2003 to 6 200 by the end of 2010.



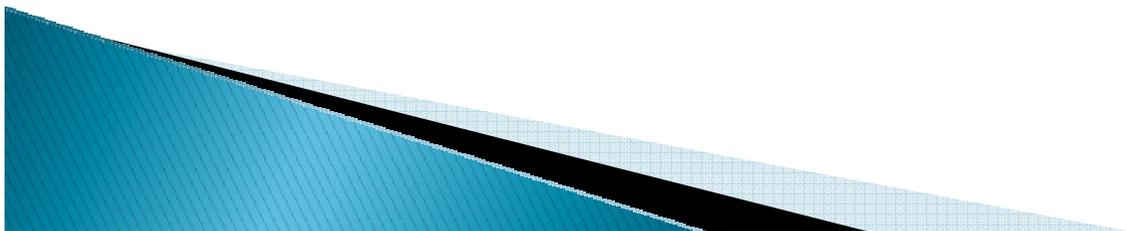
CHALLENGES

- ▶ The current world economic crisis reduced AIDS financing. This has led to sustainability issues of the National ARV programme.
- ▶ Short-term gains of donation agreements, need to be weighed against the longer term risks in terms of sustainability and drug choice if the donation were to cease in the future.
- ▶ In 2007 Botswana started looking at alternative generic market for drugs because in the medium and longer term, generics could contribute to greater coverage and adherence in the ARV Programme. This led to withdrawal by some of the pharmaceutical companies.



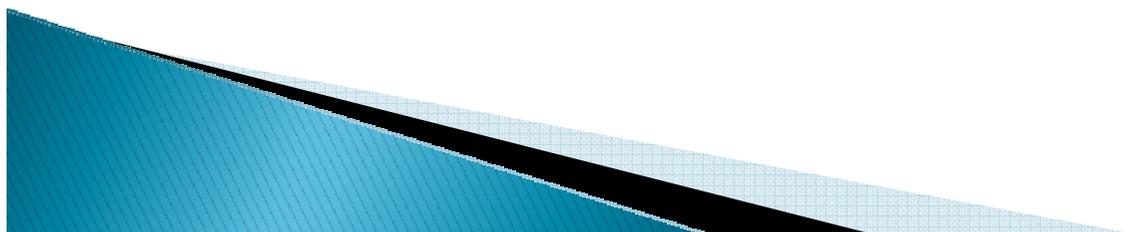
SOLUTIONS

- ▶ Botswana now has made a decision to use generic drugs and through the Government Central Medical Stores procures drugs from generic manufactures internationally through a tendering process.
- ▶ Botswana still maintains some of the partnerships with pharmaceutical companies to get discounted pricing on some drugs.



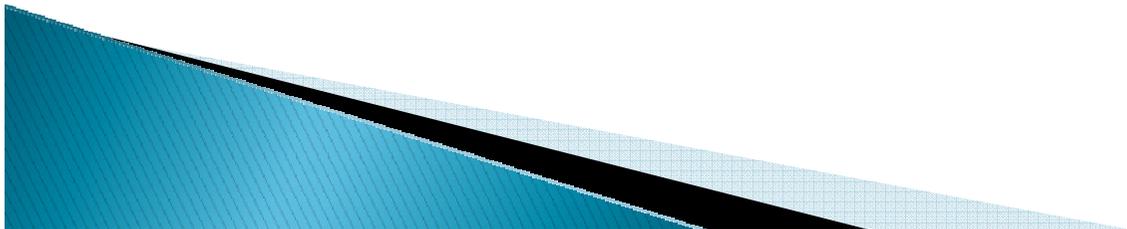
SOLUTIONS

- ▶ The Ministry of Health through the National Coordinating Agency (NACA) is leading national efforts within the Government of Botswana – United Nations Programme Operational Plan (GoB–UN POP – 2010 to 2014), to indentify strategies to ensure the sustainability of the National HIV Response, particularly the Anti–retroviral Therapy Programme.
- ▶ Under this process a tender has been issued for assessment of Botswana’s intellectual property laws, relevant policy and regulations relating to the utilisation of the TRIPS flexibilities for improved access to essential medicines for the National ARV programme



CONCLUSION

- ▶ Botswana has up to this point not utilized the TRIPS flexibilities as a mechanism for ensuring adequate access to essential medicines.
- ▶ The Industrial Property Act has been reviewed to incorporate the TRIPS Flexibilities.
- ▶ Due to sustainability issues Botswana intends in the medium to long-term to fully utilise the flexibilities in order to promote access to affordable HIV/AIDS medicines and other medicines essential for public health, nutrition and development.



THANK YOU

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