Challenges for PDPs in Facilitating Equitable Access to New Health Products in Low Income Countries

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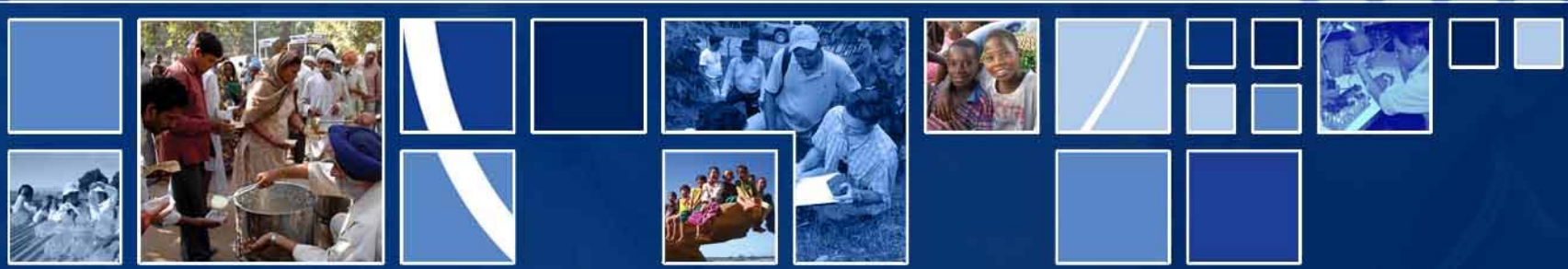


ACCESS TO MEDICINES IN LMICs

Definition :

For PDPs, access refers to a set of coordinated activities needed to ensure that the products developed will ultimately have an equitable public health impact (1)

Definition of success in access critical

Countries must select the appropriate mix of interventions and strategies relevant for their situation (2)

How are access strategies developed and communicated?

(1) Brooks et.al., “The Role of PDPs in Ensuring Access by Developing Countries to New Healthcare Products” 2008)
(2) Herman L, Oudin A, Gardiner E, Camus-Bablon F, Douglas D, on behalf of the PDP Access Steering Committee

PDPs and ACCESS TO MEDICINES

- lack clear definitions of success
- Few accompanying metrics to track progress
- Define PDP's role in supporting post-licensure issues
- Global and country-level advocacy as important for building support for new products
- South Africa – TMC207 phase IIa trial
  - tenofovir based microbicide phase IIb trial
- Co-marketing shared portofolio issues v product specific
- Share experience

ACCESS TO MEDICINES IN LMICs

How are access concerns such as :

- Financing
- Pricing
- Regulatory issues
- Decision-making

integrated in a country context?

SOUTH AFRICA

Ministry of Health – African National Congress

49 million – 7 million private health insurance : US$ 9 billion

- 42 million public health system : US$ 10 billion

Pharmaceutical industry – US$ 2 billion in sales

20% local manufacture

Clinical trials industry – US$ 200 million +

PDPs – Biovac

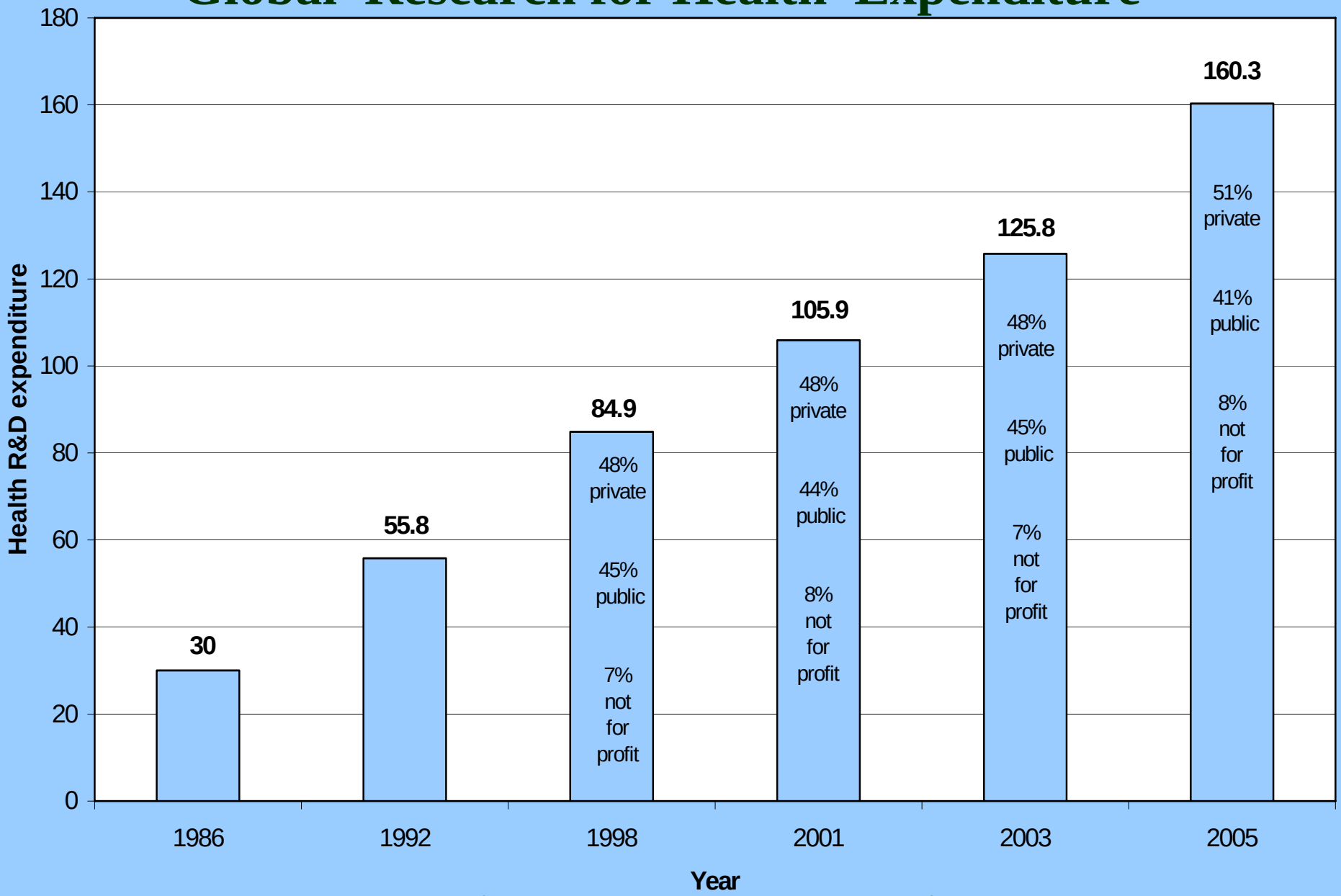
ACRO

GATB

Aeras

Medicines Control Council

Global Research for Health Expenditure



Monitoring Financial Flows for Health Research 2008 Global Forum for Health Research, Geneva

PERSPECTIVE

- Medicines Control Council of South Africa (Vice Chair of Clinical Trials Committee) 2000 – 2003
- Chair of the Taskteam preparing the Operational Plan for Comprehensive Treatment and Care of HIV and AIDS in South Africa, Oct 2003
- Expert Economic Group on Advanced Market Commitments, 2008
- Technical report on ARV API production for cabinet February 2010

- Vice Chair Board of TB Alliance
- Former President of the South African Medical Research Council 2005 – 2010
- Executive Director Global Forum for Health Research
- Trustee of Bioventures (Biotechnology Venture Capital Fund)
- Board of ACRO : African Clinical Trials Research Organisation
- Strategic Working Group of the NIAID for HIV/AIDS clinical trials

FINANCING

- Antiretroviral coverage in adults has risen from 4.9% in 2004 to 40.2% in 2008 (Muhammad A, Johnson L. south African Medical Journal in September 2009 Vol. 99, No. 9 SAMJ
- Procurement of ARVs in South Africa :
  - public tender (79%)
  - private sector
  - disease management programmes
  - work-place treatment programmes
  - non-governmental organisation
- Target 80% of those who need ARVs by 2011 (1.89 million)
- US$ 800 million on HIV/AIDS yet US$ 300 million short

PRICING

- Globalisation has reduced opportunities to maximise profits through market segmentation and differential pricing
- External price referencing,
- South African public sector (over 1 million initiated on ARVs in 5 years) :
  - 26 formulated products based on 10 active pharmaceutical ingredients (APIs) (efavirenz (40.1%), tenofovir (7.8%), lamivudine (11.3%) and zidovudine (5.6%) by value.
  - value of the tender is US$ 560 million over the 2 years
  - 2003 with Aspen-Pharmacare negotiating a voluntary licence from Bristol-Myers-Squibb (BMS) for the manufacture of stavudine (d4T),

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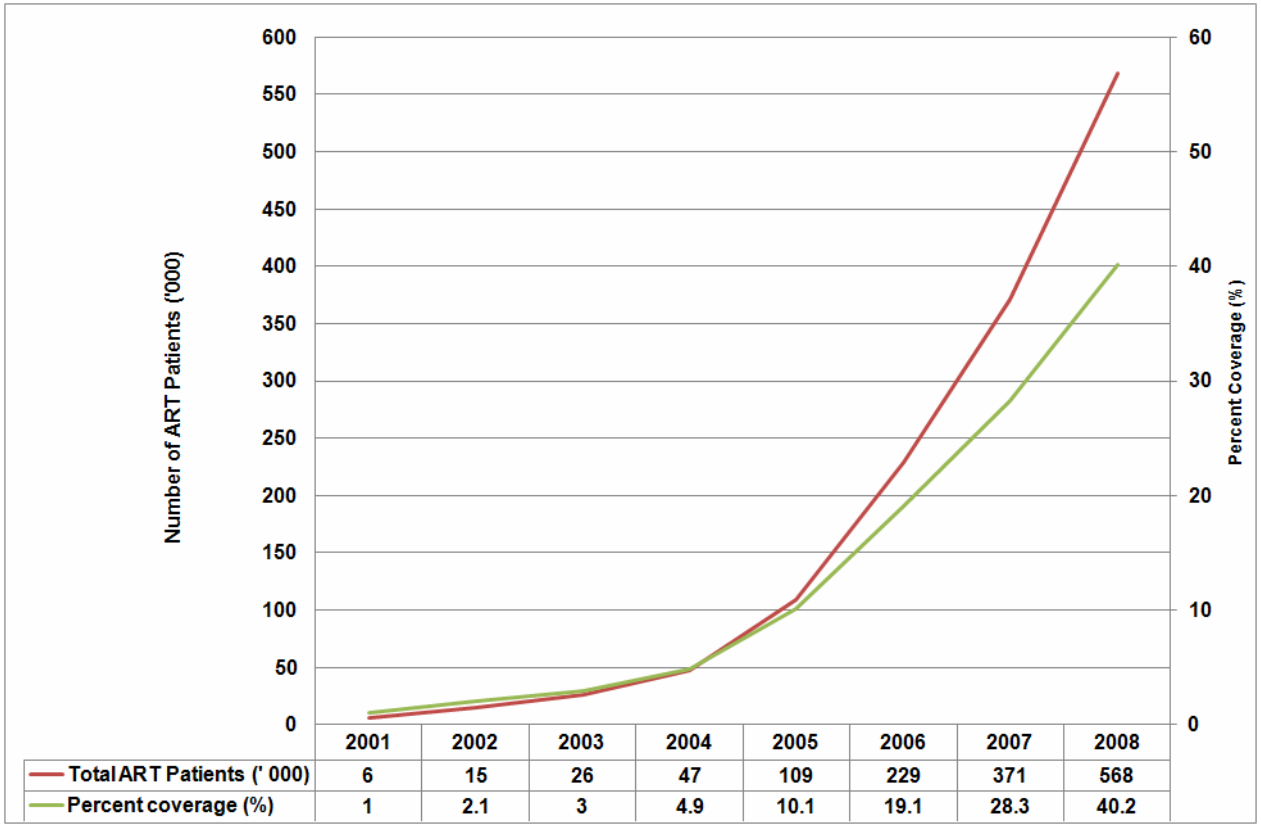
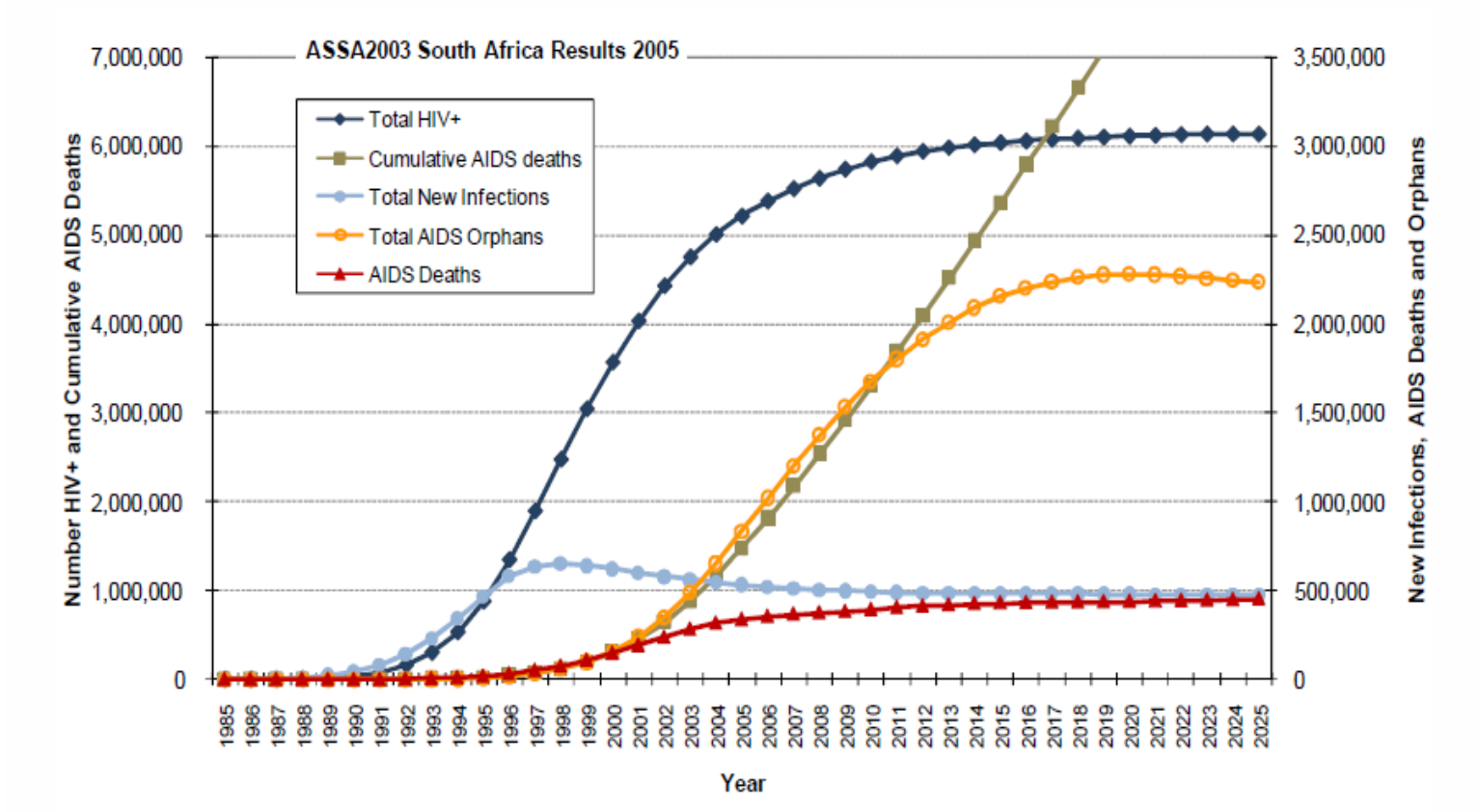
Antiretroviral Therapy in South Africa, 2001 – 2008



	2001	2002	2003	2004	2005	2006	2007	2008
Total ART Patients (' 000)	6	15	26	47	109	229	371	568
Percent coverage (%)	1	2.1	3	4.9	10.1	19.1	28.3	40.2

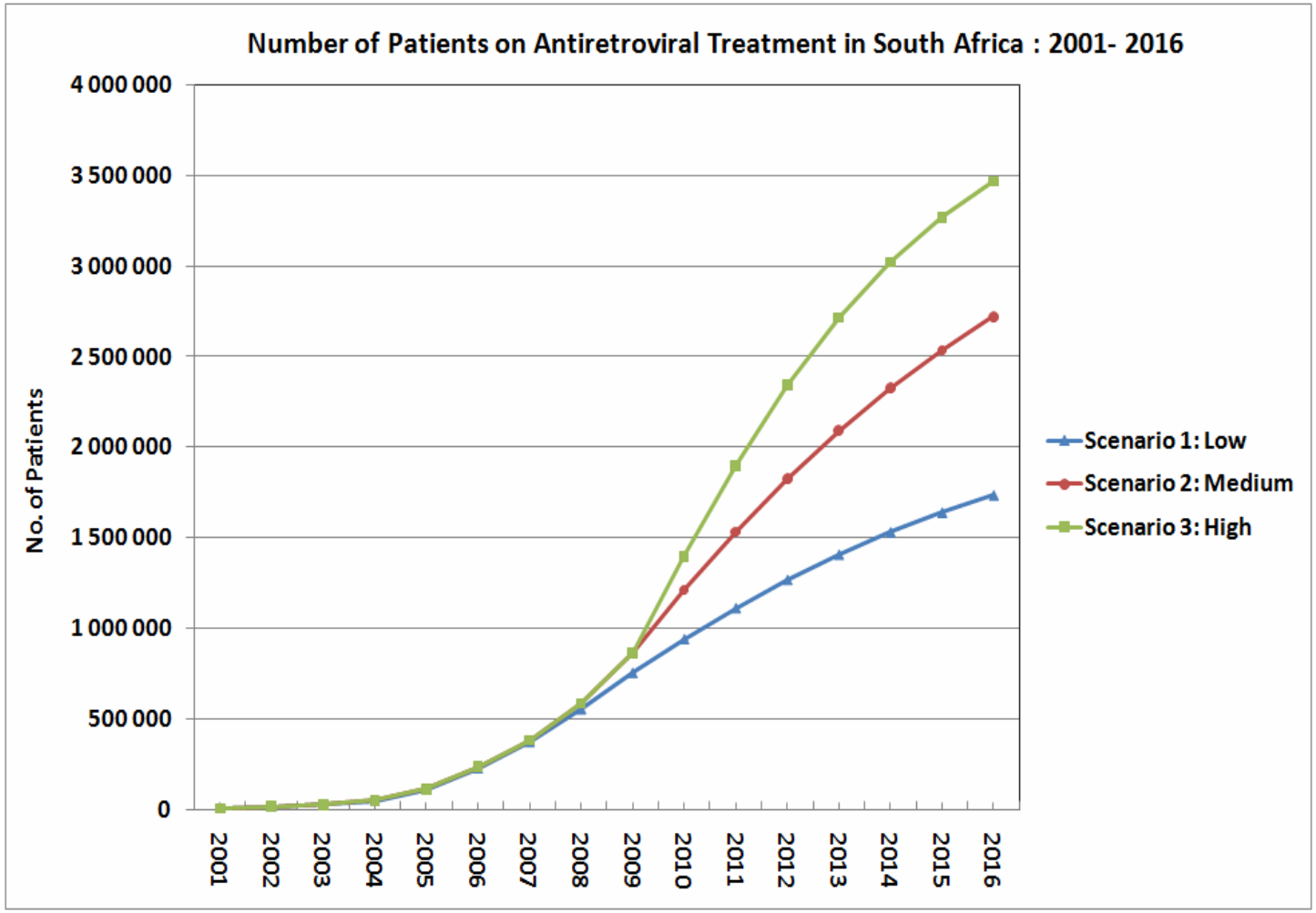
Muhammad A, Johnson L. 2009, Vol. 99, No. 9 SAMJ: Estimation of adult antiretroviral treatment coverage in South Africa

Progression of the HIV/AIDS Epidemic in South Africa using the ASSA2003 Model



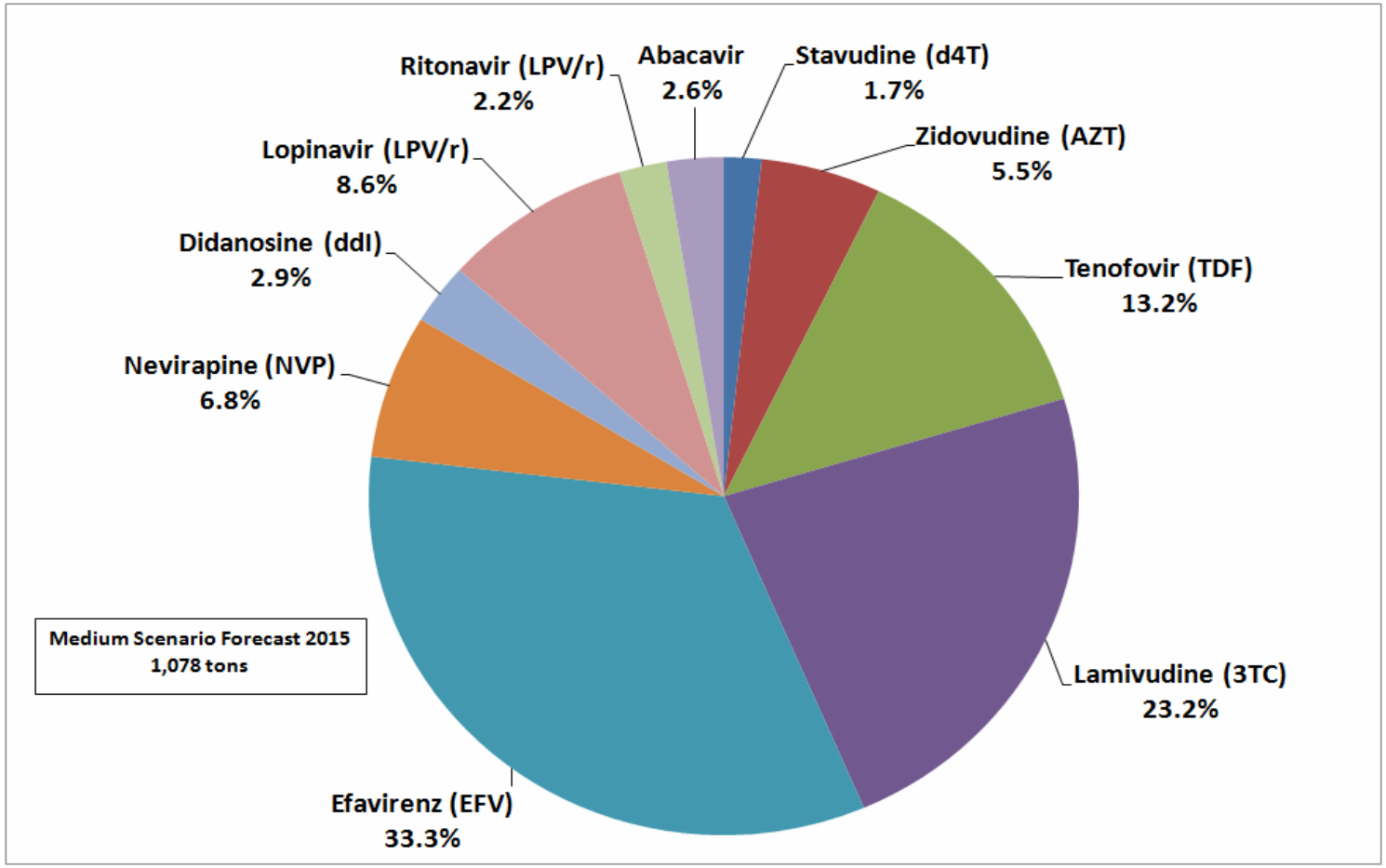
(Dorrington, Bradshaw et al) ASSA2003 model: http://www.actuarialsociety.org.za/Models-274.aspx

ART estimates: 2001 – 2016



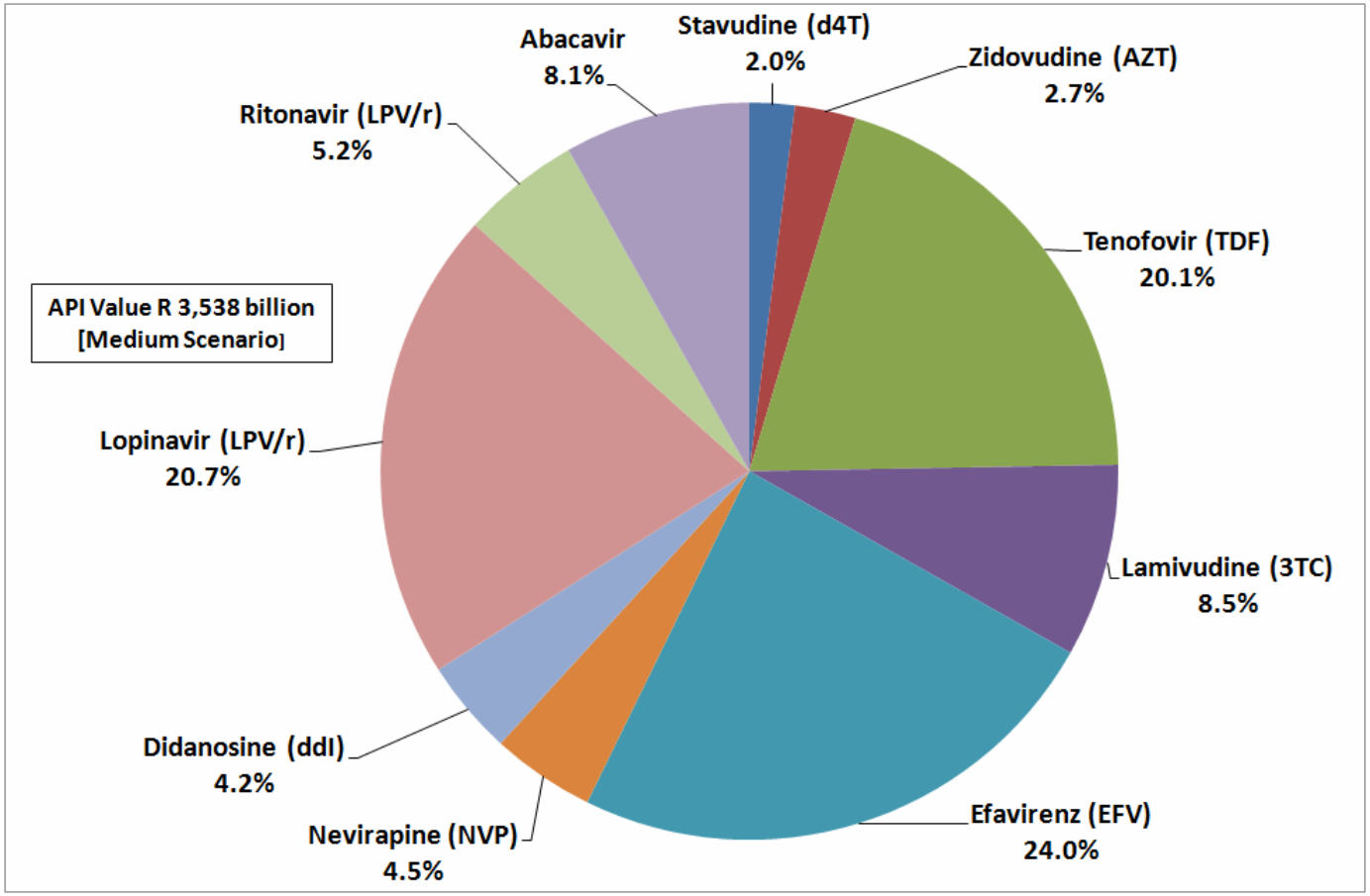
Modelling performed by Dr Leigh Johnson for DST

Percentage Contribution by ARV API by Volume in 2015 -

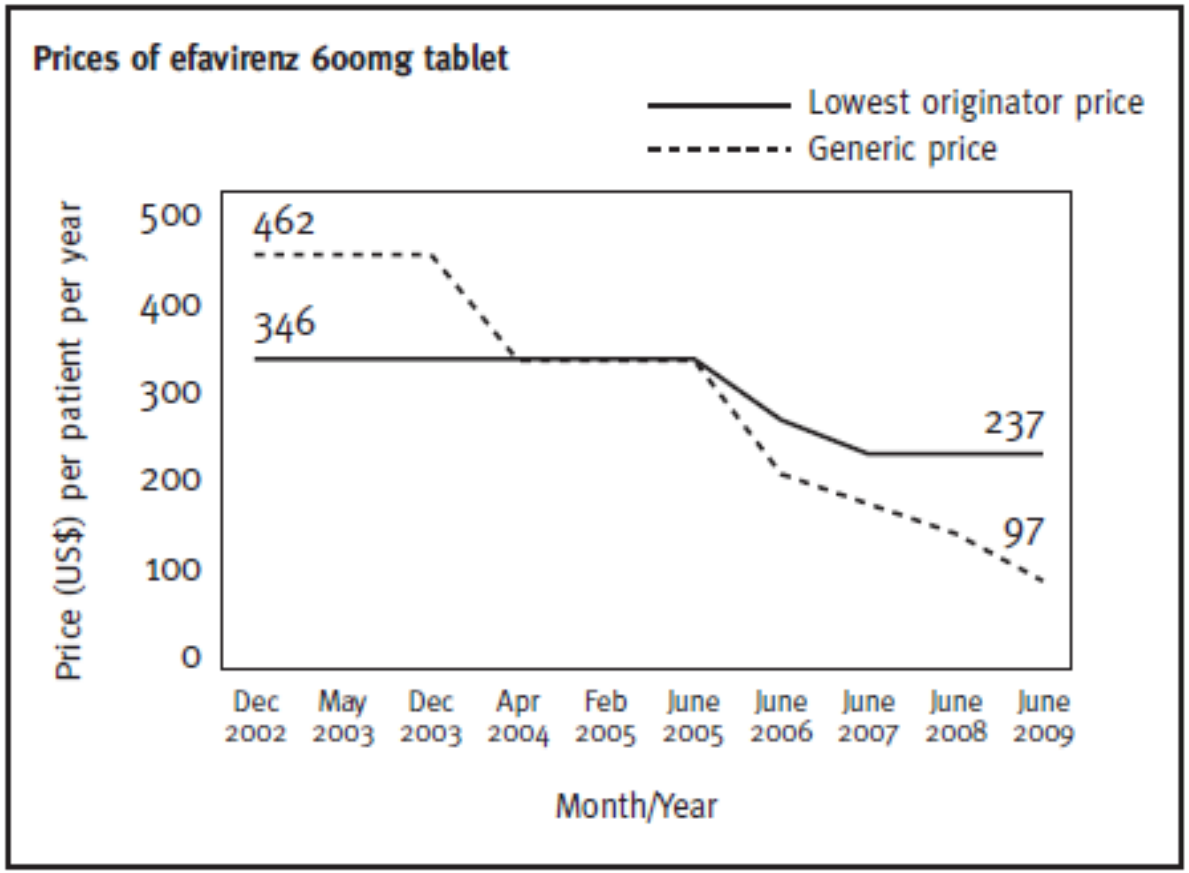


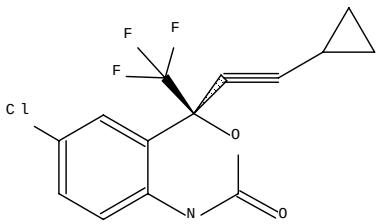
Pinheiro E dos S, Antunes OA, Fortunak JM. A survey of the syntheses of active pharmaceutical ingredients for antiretroviral drug combinations critical to access in emerging nations. Antiviral Res. 2008 Sep;79(3):143-65.

Estimated Cost for the ARV APIs by Value in 2015



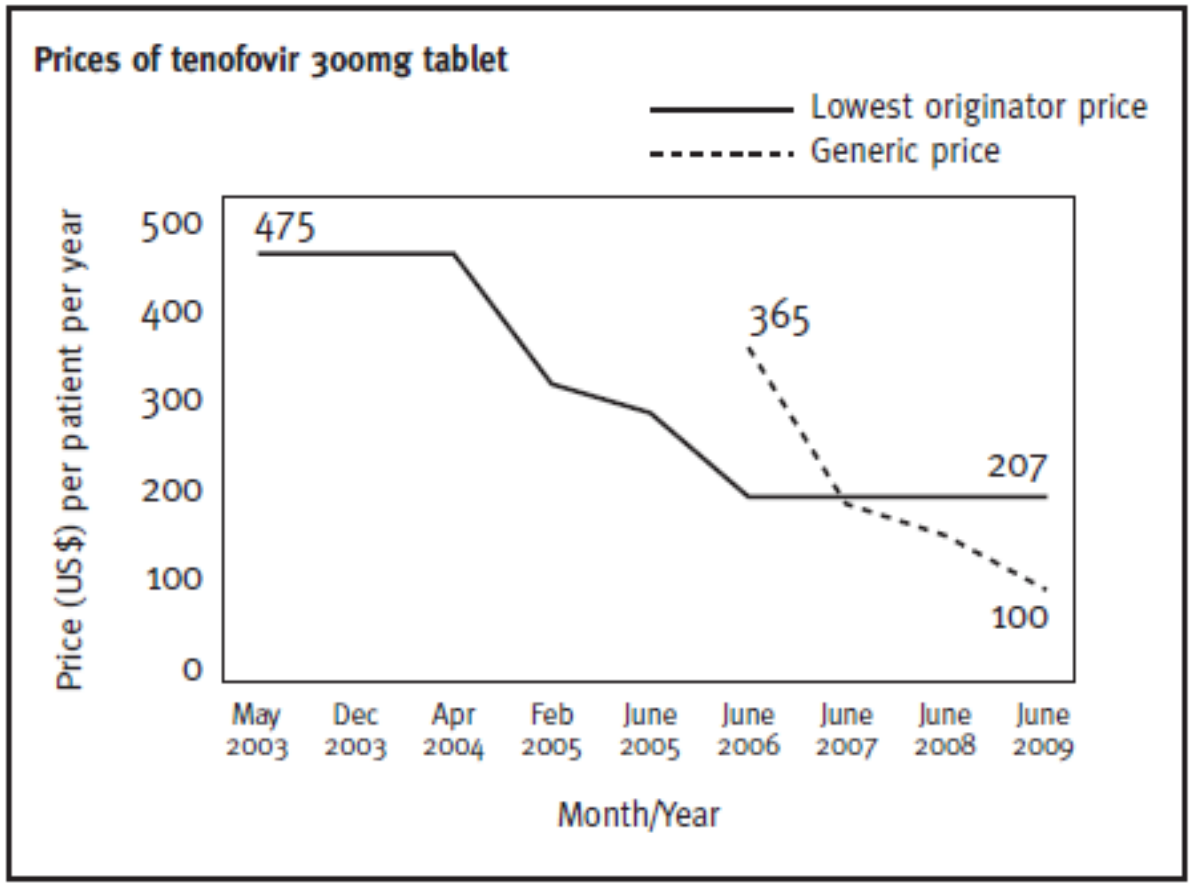
Price Trend for Efavirenz (600 mg) 2002 – 2009

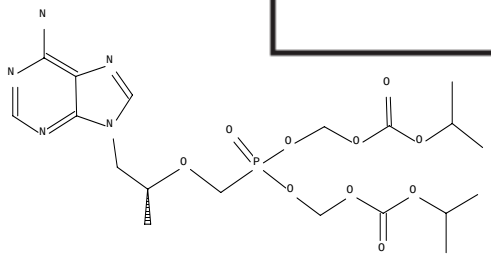




(Médecins Sans Frontières)

Price Trend for Tenofovir (600 mg) 2002 – 2009 (

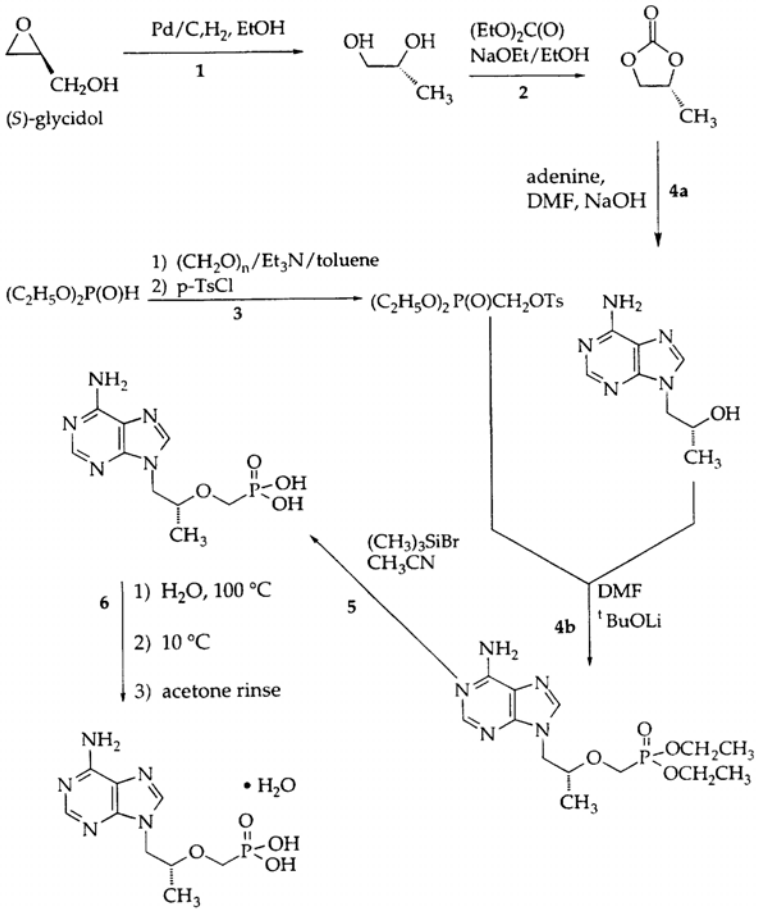




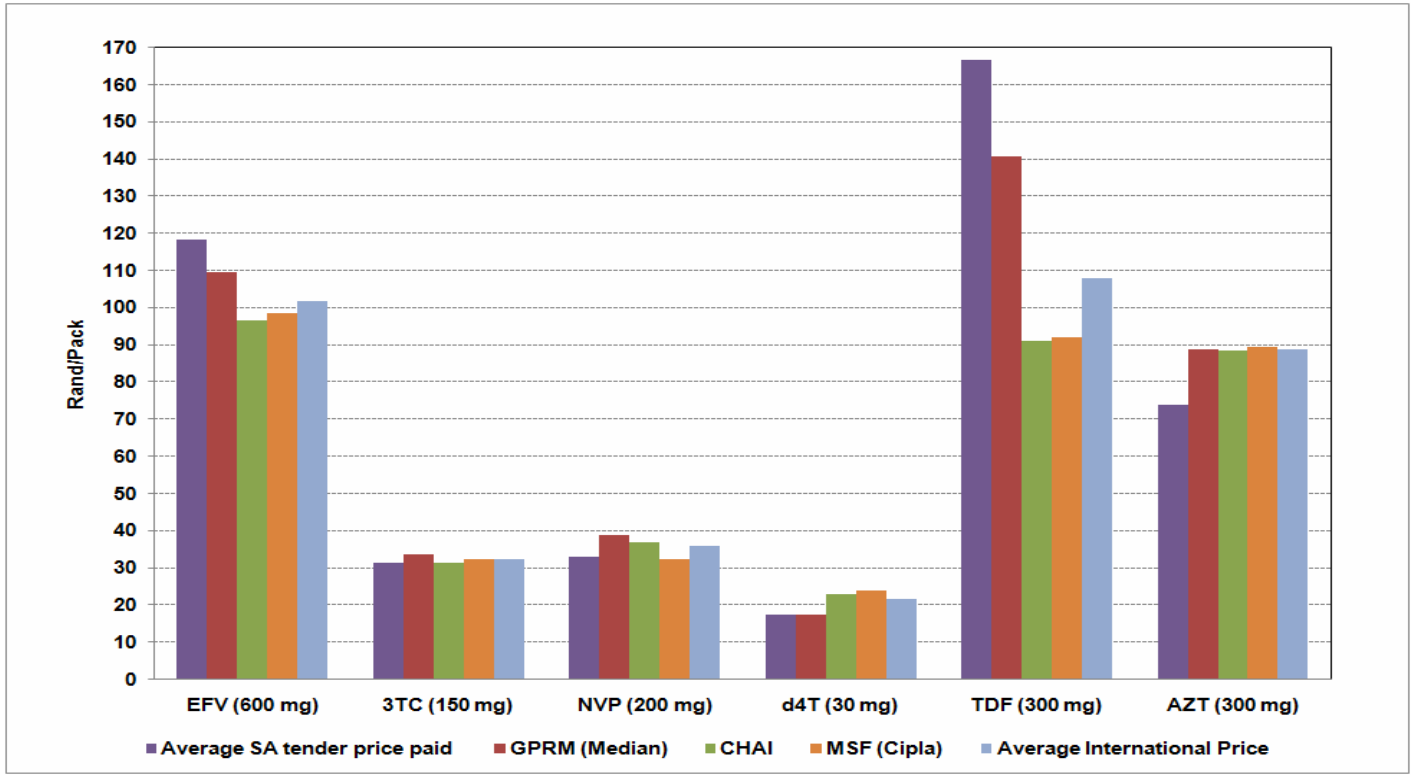
Tenofovir disoproxil fumarate(TDF)

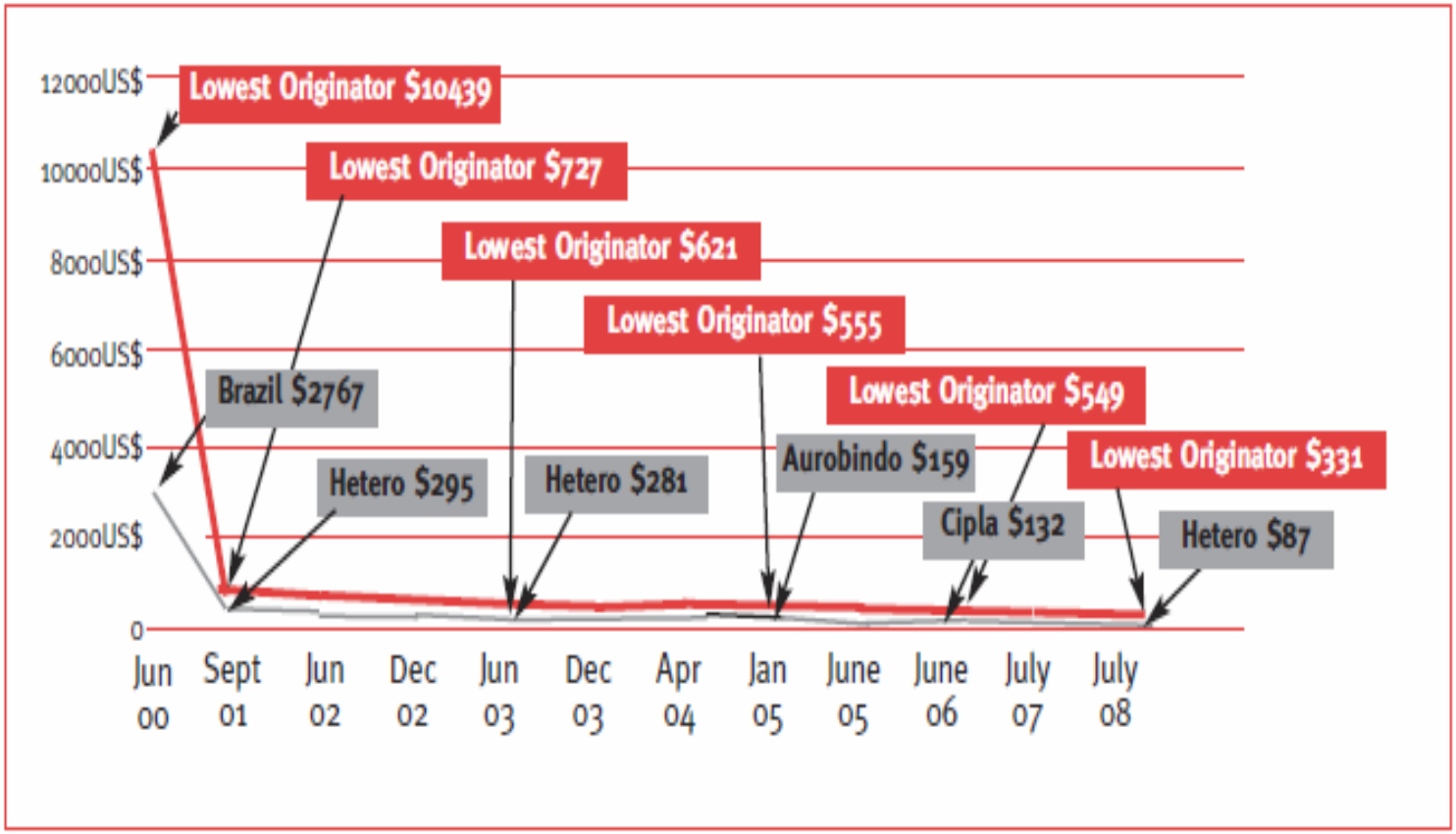
(Médecins Sans Frontières)

Tenofovir Process Routes



Comparison of ARV Prices: SA Tender 2008/10 vs International Prices 2009





(Médecins Sans Frontières (MSF) 2008 “Untangling the web of antiretroviral price reductions)

INTEGRATION

- South African Cabinet endorsed the HIV & AIDS and STI National Strategic Plan for South Africa (NSP), 2007-2011
- Provides the basic policy document for antiretroviral treatment in South Africa
- Broad consensus between Government and civil society on a comprehensive approach to HIV/AIDS
- The document reflects the sentiments originally expressed in the ANC Health Plan of 1994[5] of the need for a multi-sectoral approach. (http://www.doh.gov.za/docs/misc/stratplan/2007-2011/index.html)
- ART cannot be interrupted due to the development of resistance and possible death to the patient.
- Consequently, security of supply is essential; however global procurement maybe risky and prone to interruption.

- 88% of the 2008 / 2010 tender (excluding Lopinavir/Ritonavir - Kaletra®) locally formulated
- However, these companies rely entirely on imports of antiretroviral active pharmaceutical ingredients (ARV APIs).
- Local, selected API manufacture (Efavirenz , Tenofovir)
- Public private partnership rather than State Pharma
- Cost of APIs : 62 - 70% of the cost of manufacture of ARVs
- China and India are the only suppliers of generic ARV APIs, with four WHO-prequalified ARV API manufacturers in India and two in China
- The cost of importing the ARV APIs could increase to about US$ 600 million per annum, adding to an already huge negative trade balance of US$ 1.5 billion for the pharmaceuticals sector

DECISION MAKING

Political Will :

- The Department of Trade and Industry (DTI), in conjunction with the Department of Science and Technology (DST), the Department of Health (DoH) and the National Treasury (NT) embarked on a process to investigate the feasibility of developing a fully integrated local pharmaceutical production facility for essential medicines, including ARVs.
- The DTI's 2007 Industrial Policy Action identified the production of ARV pharmaceuticals as a strategic industry, through increased domestic production leveraging the ARV tender.

- **Technical Advisers**

  Comprehenisive Plan : Clinton Foundation (2003)

  API Plan : South Africa experts (2009)

  Biovac : South African and Cuban experts (1997)

- **National, intersectoral planning and coordination** :
  National Strategic Plan for HIV and AIDS

- **Public Private partnerships** :
  - ACRO : clinical trials
  - Biovac : vaccines including HIV vaccine manufacture
  - Microbicide (tenofovir) IIb clinical trails

VERTICALLY-INTEGRATED BIOPHARMA

science & technology

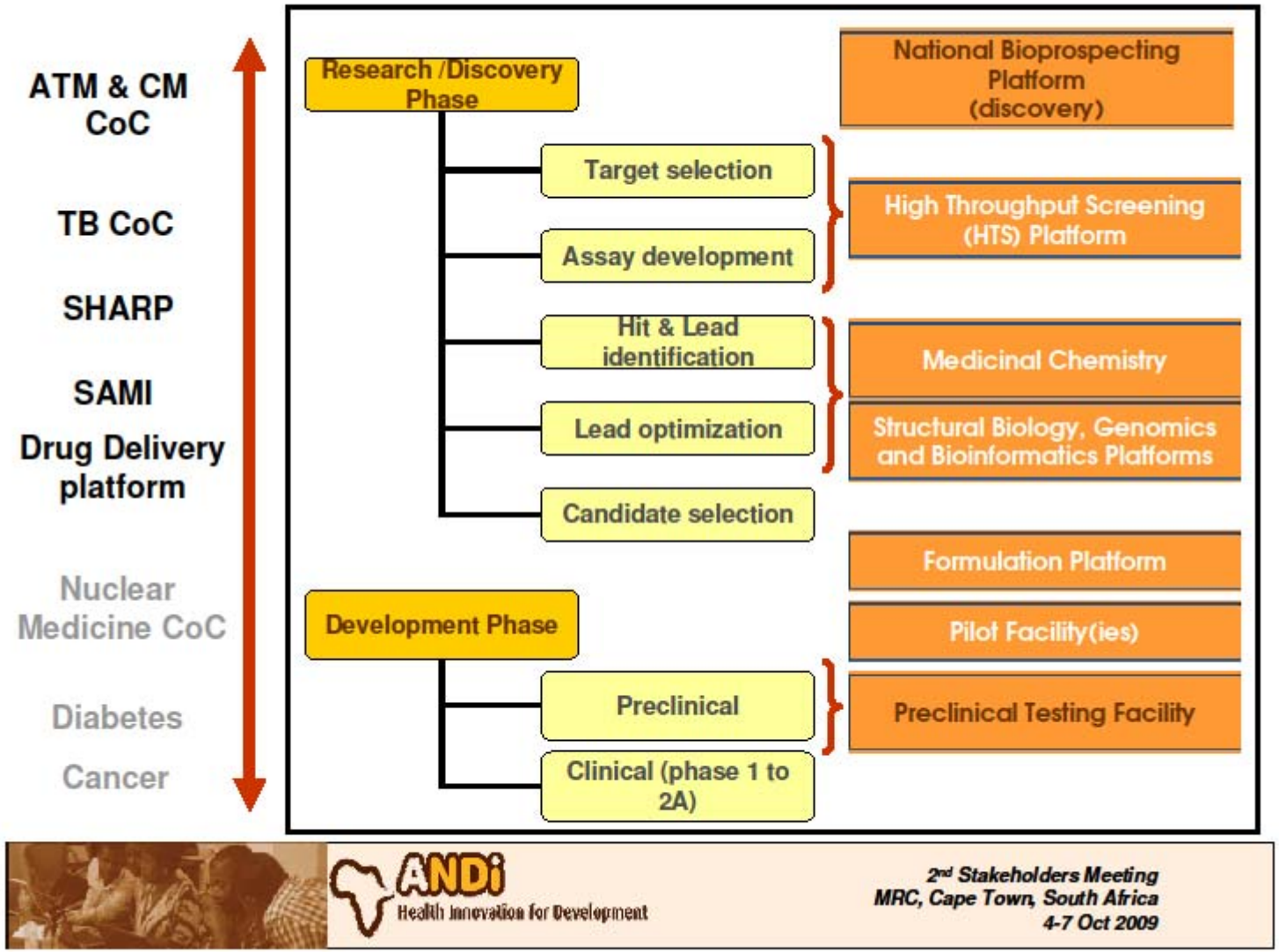
Platforms and CoCs within the BRICS

- Biosafety Platform
- Metabolomics Platform
- Metagenomics Platform
- Drug Delivery Platform
- Bioprocessing platform
- Algal platform
- Centre for Proteomics and Genomics Research (CPGR)
- Bioprospecting/beneficiation platforms
- IV plant propagation platform

ANDi
Health Innovation for Development

2nd Stakeholders Meeting
MRC, Cape Town, South Africa
4-7 Oct 2009

Global Forum for Health Research



Implementing the National Biotechnology Strategy 2001

2003

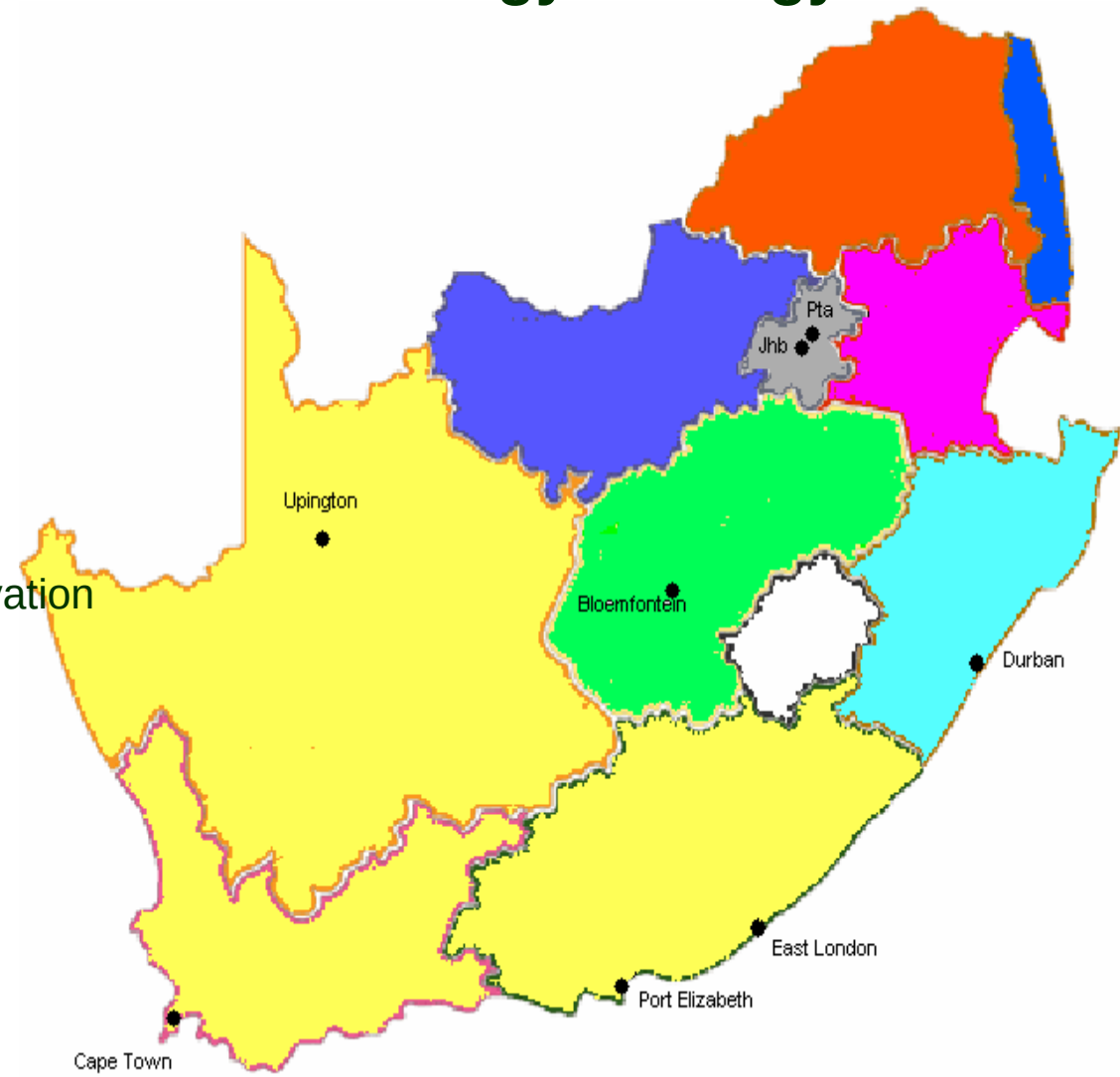
4 Innovation support centres
1 Bioinformatics Platform/Network
1 Public Understanding of Biotech programme

2007/8

16 technology platforms created
Approx 100 projects
38 companies created through innovation centres

2007 Audit

- 78 biotech companies
- 38 core biotech
- 1542 biotech products/services
- Revenues >R767 million
- 72 844 jobs



ACCESS TO MEDICINES IN LMICs
CONCLUSION

South Africa's attempts over the past 10 years to increase (affordable, sustainable) access to ARVs provides useful examples and learning points for access to medicines in general; including of integration in a country context of issues such as :

- Financing – government v private etc
  sustainability
  stockouts
  tier pricing – between LICs and MICs
  - within country (public v private)

CONCLUSIONS

- Pricing – country v global (external reference price)
  activists
  market power and leverage
  transparency
  regional tenders (9 SADC countries)

- Regulatory Issues –
  fast track
  discussions ab initio
  licensing agreements
  harmonisation (SADC, African Union)
  WHO prequalification

CONCLUSIONS

- Decision-making –
  - political will
  - cogent arguments
  - economic case and not just health impact
  - national security (e.g. pandemic flu vaccines)
  - integration (e.g. National Strategic Plan for HIV/AIDS and the South African National AIDS Council)