REPUBLIC OF SOUTH AFRICA

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ORGANIZATION

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

Topic 11: The Pharmaceutical Industry Perspective

Durban, South Africa
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innovative medicines South Africa

The Pharmaceutical Industry perspective

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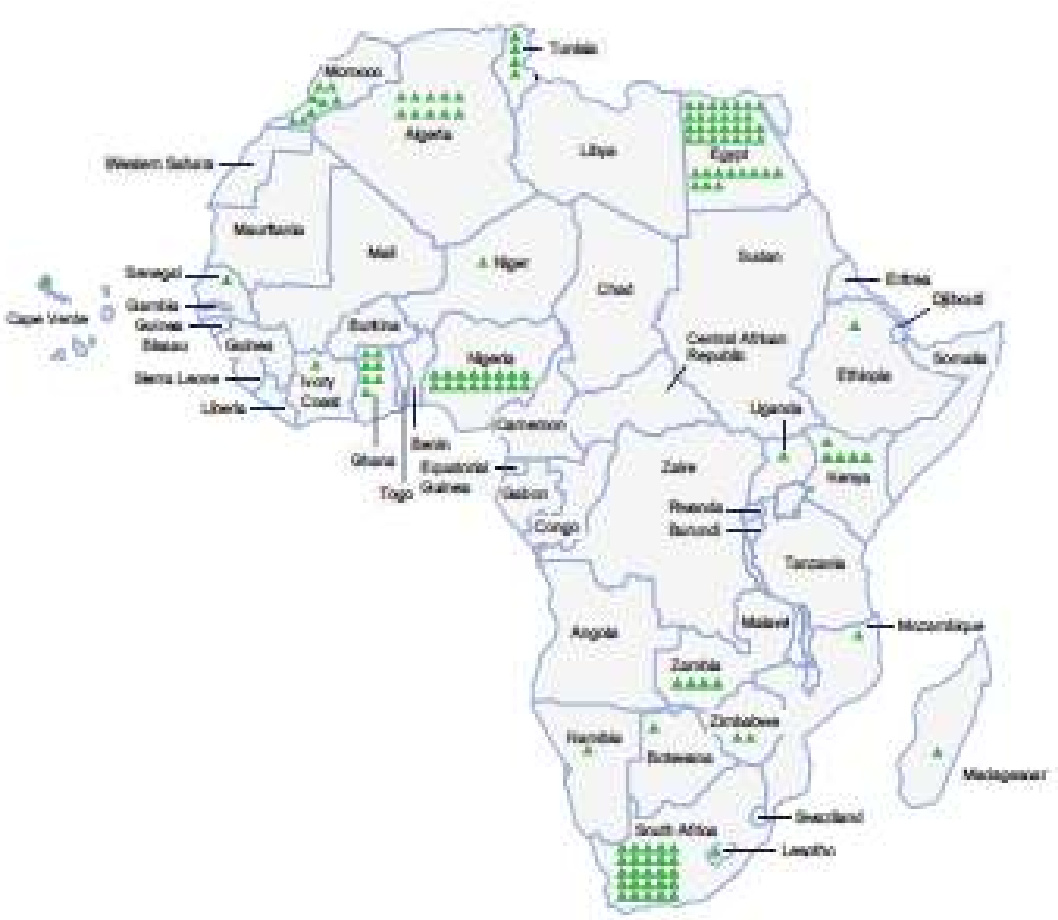
Mapping of pharmaceutical manufacturing capacity in Africa



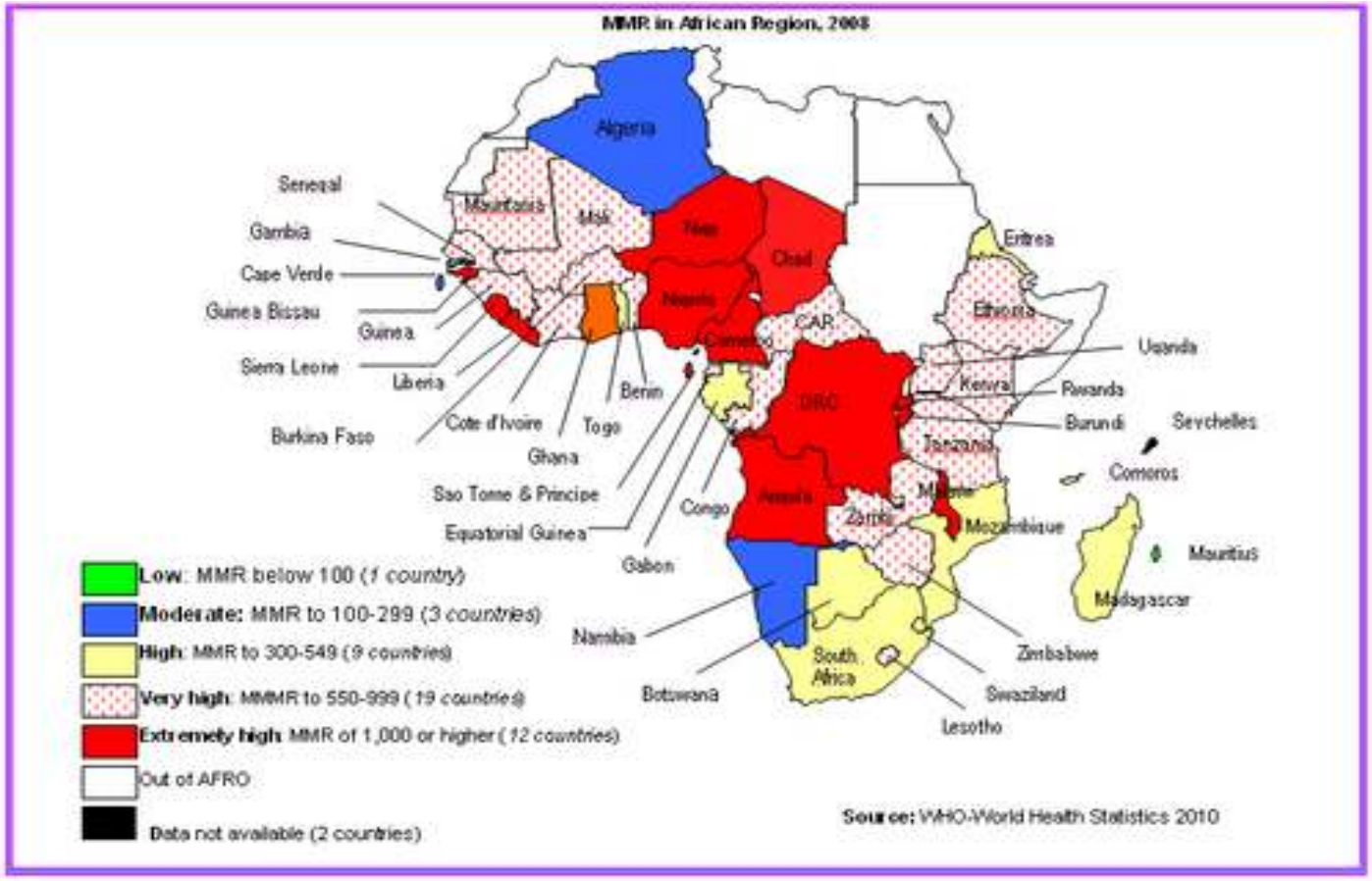
- Total of 129 companies identified
- Most companies locate to Egypt, SA, Nigeria, Morocco and Algeria
- Estimated average sales for identified companies of ~USD 90 million/year

HEALTH MDGS – 1990-2015

4: Reducing child mortality: Reduce by two-thirds the under-five mortality rate, (4.3%)

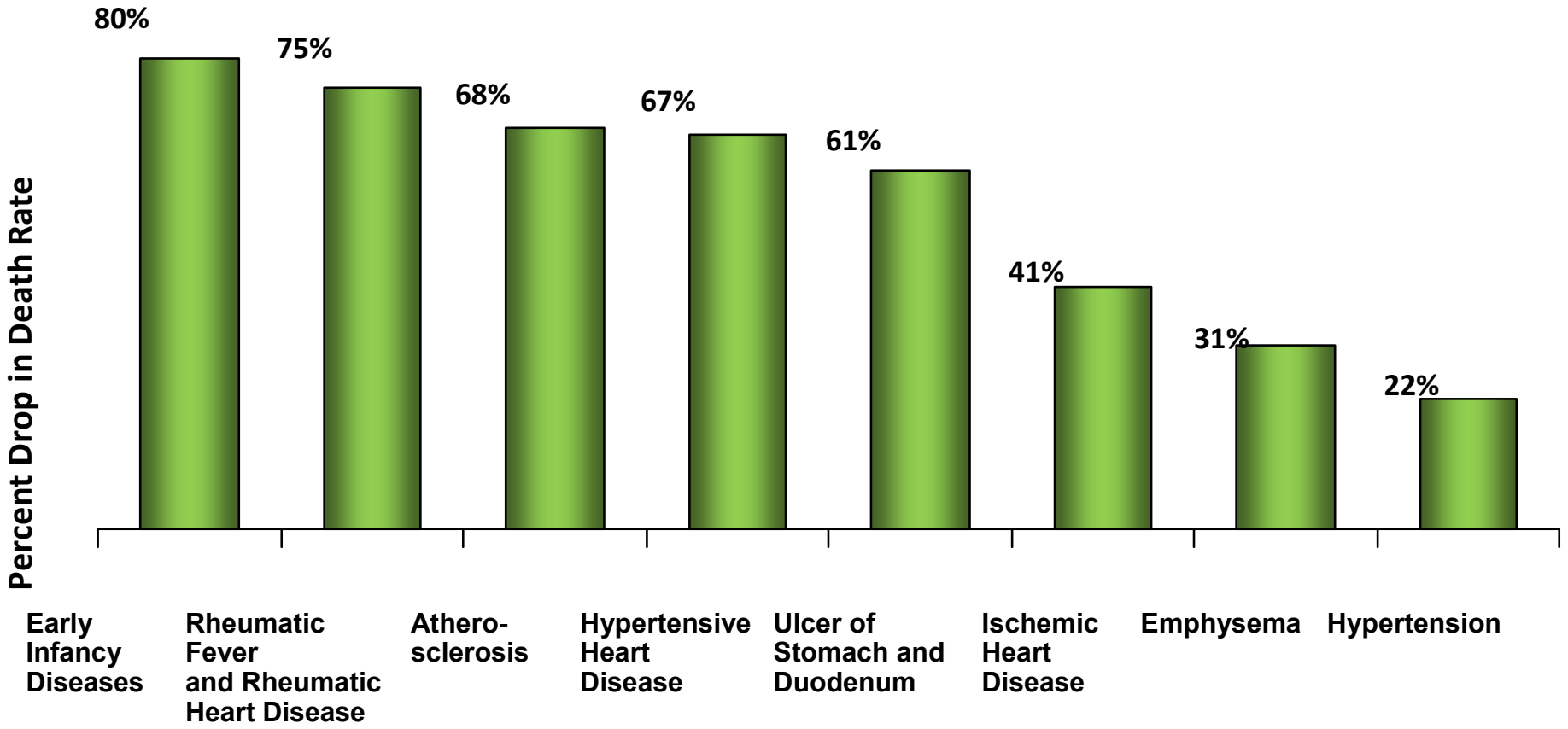
5: Improving maternal health: reduce by ¾ maternal mortality ratio, (5.4%).

6: *Combating HIV/AIDS, malaria and other diseases*. Halt and begin to reverse the spread of the diseases by 2015



NEW MEDICINES HAVE PROLONGED LIFE

Drop in Death Rate for Diseases Treated with Pharmaceuticals, 1965–1995



Source: PhRMA, Based on Boston Consulting Group, 1993; and US National Center for Health Statistics, 1998

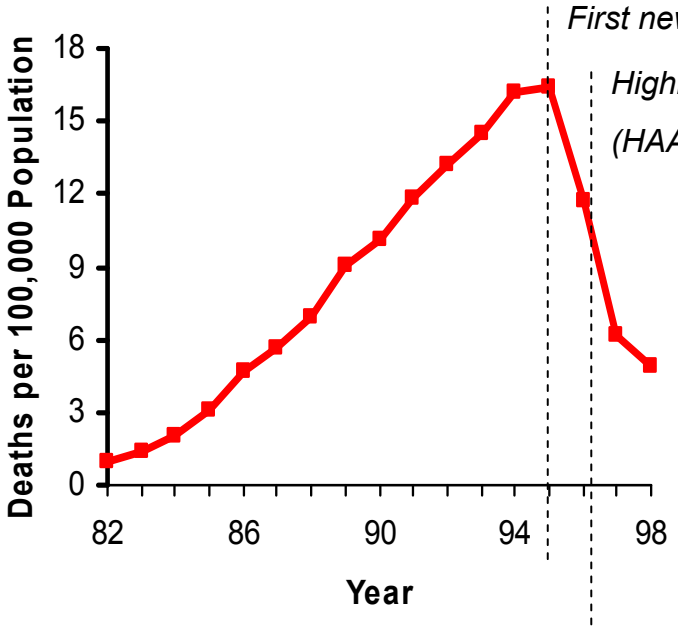
NEW SCIENCE IS CHANGING HEALTHCARE

Structural Biology	Rational design of new medicines
Genetics, genomics and proteomics	Better targeting of medicines
Metabonomics	Better diagnosis and monitoring
Vaccines and immunomodulation	Prevention and monitoring of infectious diseases
Point of care diagnostics	Faster diagnosis and enhanced involvement of the patient
Bionics	Organ replacement and enhancement
Cell and tissue engineering	Regenerative medicine
Imaging	Better diagnosis and precision treatment
Micro-electronic devices	Sensing and monitoring; increased independence for individuals
Minimally invasive and robotic surgery	Enhanced precision and reduction in unwanted drama

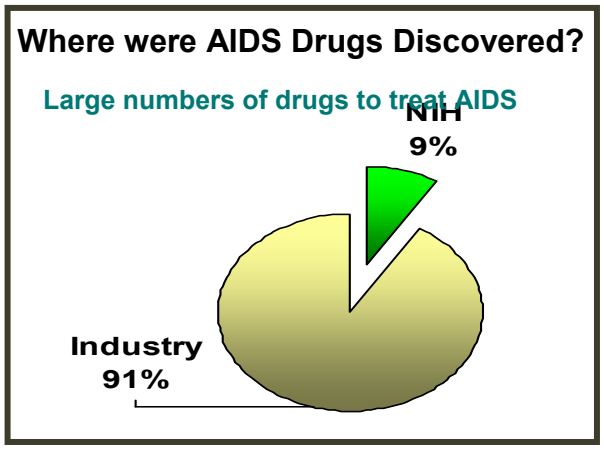
Source: Sir Richard Sykes, Imperial College London

PRESCRIPTION DRUGS SAVE LIVES & MONEY

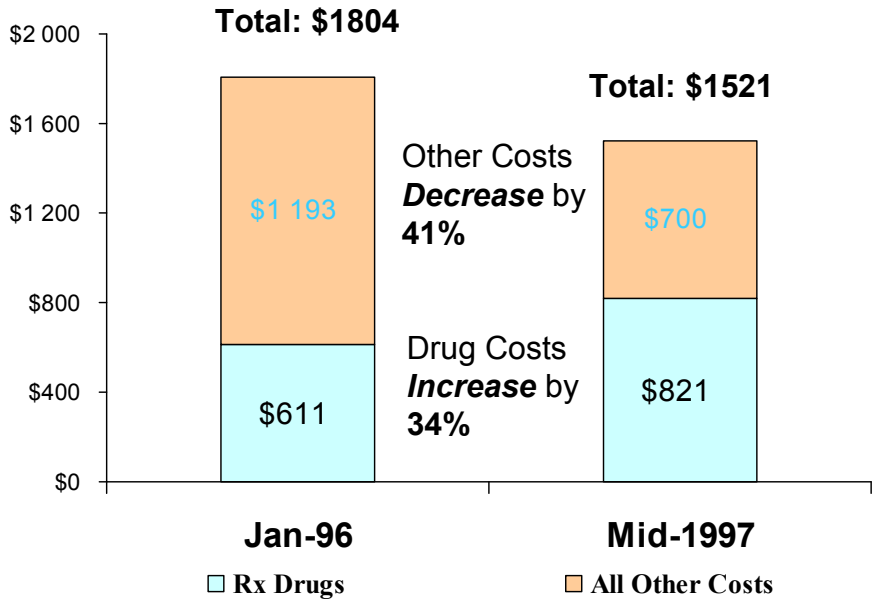
HIV Mortality Declined Dramatically After Introduction of First "Expensive" Antiretrovirals…



Source: Costs - Bozette et al.,*New England Journal of Medicine* Vol. 344, No. 11, March 15, 2001; Mortality - Centers for Disease Control; data on drug development from PhRMA and the NIH Office of Technology transfer



…While Monthly Costs for AIDS Patients Decreased by 16% After HAART Introduced



INNOVATIVE MEDICINES ADD VALUE

- Patients care about:
  - Increased longevity
  - Increased quality of life
  - Prevention of disability
  - Maintaining autonomy and independence
- Employers care about:
  - Potential for direct offset to other health care costs
  - Increased workplace productivity
  - Decrease in absenteeism
- Doctors care about:
  - Ability to replace costly surgery

Innovative medicines have been shown to add value across the spectrum – there are many examples

THE ARGUMENT FOR ACCESS TO INNOVATIVE PHARMACEUTICALS

Drugs and vaccines – eliminated/control many diseases and conditions that once had high mortality rates (e.g., influenza, polio, pneumonia, and diptheria).

Dramatically reduce mortality rates for other diseases and conditions (e.g., AIDS, asthma, heart attacks, strokes, and ulcers).

Trend will continue with new medicines significantly reducing mortality from disease

Newer drugs have improved side effect profiles with better compliance

PATIENT PERSPECTIVES

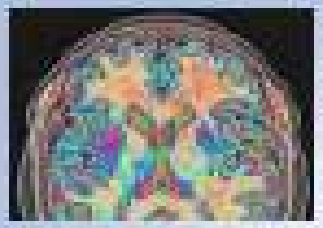
Schizophrenia

Then

Between the 1950s and the 1980s, the antipsychotic medications available to treat schizophrenia—a devastating mental illness affecting approximately 1 percent of the population—were a double-edged sword. On the one hand, they helped control symptoms like hallucinations and paranoid thoughts. But they also had unpleasant side effects, like muscle stiffness, tremors, and abnormal movements that grew worse over time.

Control with unpleasant side effects

Now



Thanks to new medicines introduced in the 1990s, people living with schizophrenia can now manage their condition more effectively than ever, and with fewer side effects. These medicines—dubbed "atypical antipsychotics" to distinguish them from earlier, "typical" drugs—also help people whose schizophrenia had not previously responded to treatment, making it possible for them to leave institu-

Less side –effects and greater response rate

Leukemia

Then

If you had been diagnosed with chronic myeloid leukemia (CML) in 1999, chances were that you would not be alive today. Just 3 out of 10 patients survived for even five years. In the meantime, you had two daunting treatment options: a high-risk bone marrow transplant or daily injections of interferon, the side effects of which have been compared to "having a bad case of the flu every day of your life."

3/5 survived - options
Bone marrow transplant or Interferon

Now

You can take a daily pill that has a good chance of driving your cancer into remission—normalizing your blood count with few, if any, side effects. The new medicine targets CML on a molecular level, so it affects only the enzyme responsible for the disease. The tremendous effectiveness and precision of the approach is heralded as the "wave of the future."

New pill targets CML at cellular level –
remission possible with fewer side effects

Life expectancy 26 months
Treatment regime problematic

HIV/AIDS

Then

If you were diagnosed with AIDS in 1990, you might expect to live for only 26 months. During that time, you would be likely to contract a number of opportunistic infections that would make your remaining days unpleasant and painful. The only treatment available had to be taken every four hours—around the clock—and had serious side effects.

Now

Symptom free for a number of years – many treatment options

Thanks to the approval in 1995 of protease inhibitors—and further advancements in new medicines and combination therapies in the decade since—the AIDS death rate in the United States has fallen by 70 percent. If diagnosed today, a range of treatment options (including different combinations of drugs) might be able to keep you symptom-free for years

Ulcers

Then

Thirty-five years ago, treating an ulcer meant painful surgery that brought with it the risk of life-threatening infection and more ulcers in the future. Along with surgery, doctors often recommended weeks of bed rest, a mild fatty diet including boiled milk, and increased tobacco use, in an effort to stop the suspected culprits: a stressful lifestyle and spicy food. But none of these remedies made much difference to ulcer sufferers.

35 yrs ago surgery

Now

In the late 1970s, new medicines were developed to heal the lining in the stomach or duodenum, making it possible for the first time to treat ulcers effectively without surgery. With the discovery that the bacterium H. pylori causes the vast majority of ulcers in 1982, doctors are now able to treat ulcers both quickly and permanently by targeting the real root of the problem—bacteria.

Treatable permanently without surgery

THE PATIENT PERSPECTIVE

Organ Transplant

Then

In the 1950s and early 1960s, patients needing an organ transplant were in a tragic bind. Transplants were surgically possible, but the body's immune response rapidly rejected organs donated by unrelated individuals. People either died or led greatly diminished lives.

Until early 60s rejection an issue

Now

Thanks to anti-rejection medicines that were developed in the 1960s and 1980s, tens of thousands of Americans have received transplants of a wide variety of organs and are able to prolong their lives, regain their health, and maintain their independence.

Transplants now common place

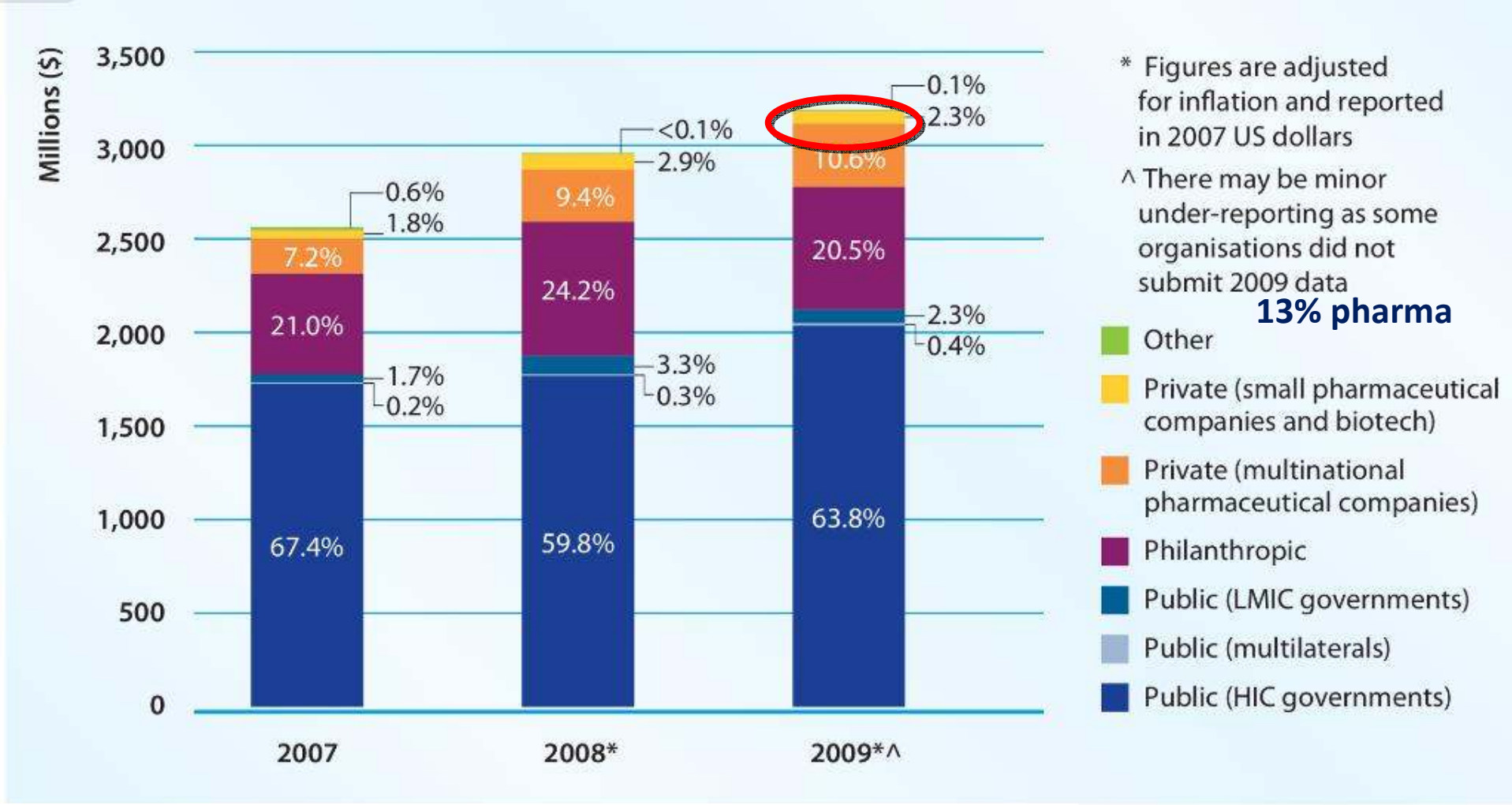
Healthcare is a dynamic good:

Patients and society have reaped exceptional returns from medical innovation and have an enormous stake in its continued progress. Innovative medicines of the past are the commonly used generics of today.

R&D – VALUE TO AFRICA

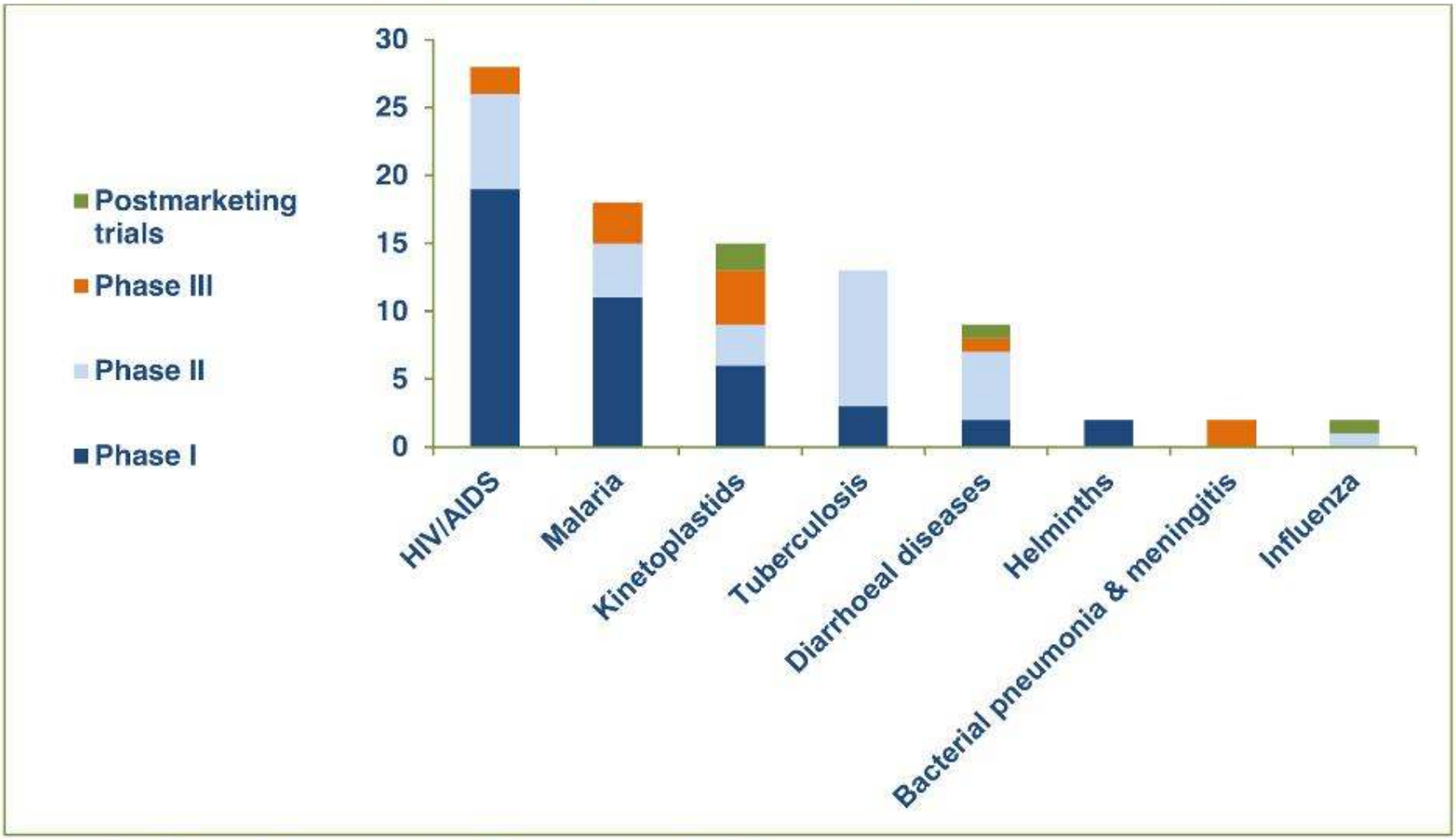
- Multiple simultaneous epidemiological crises
- Parasitic diseases
- High levels of communicable diseases
- Chronic conditions escalating – Africa's biggest health challenge by 2030 (Source: Economist Intelligence Unit 2012)
- Burden of "neglected" diseases

WHO IS FUNDING NEGLECTED DISEASE RESEARCH?



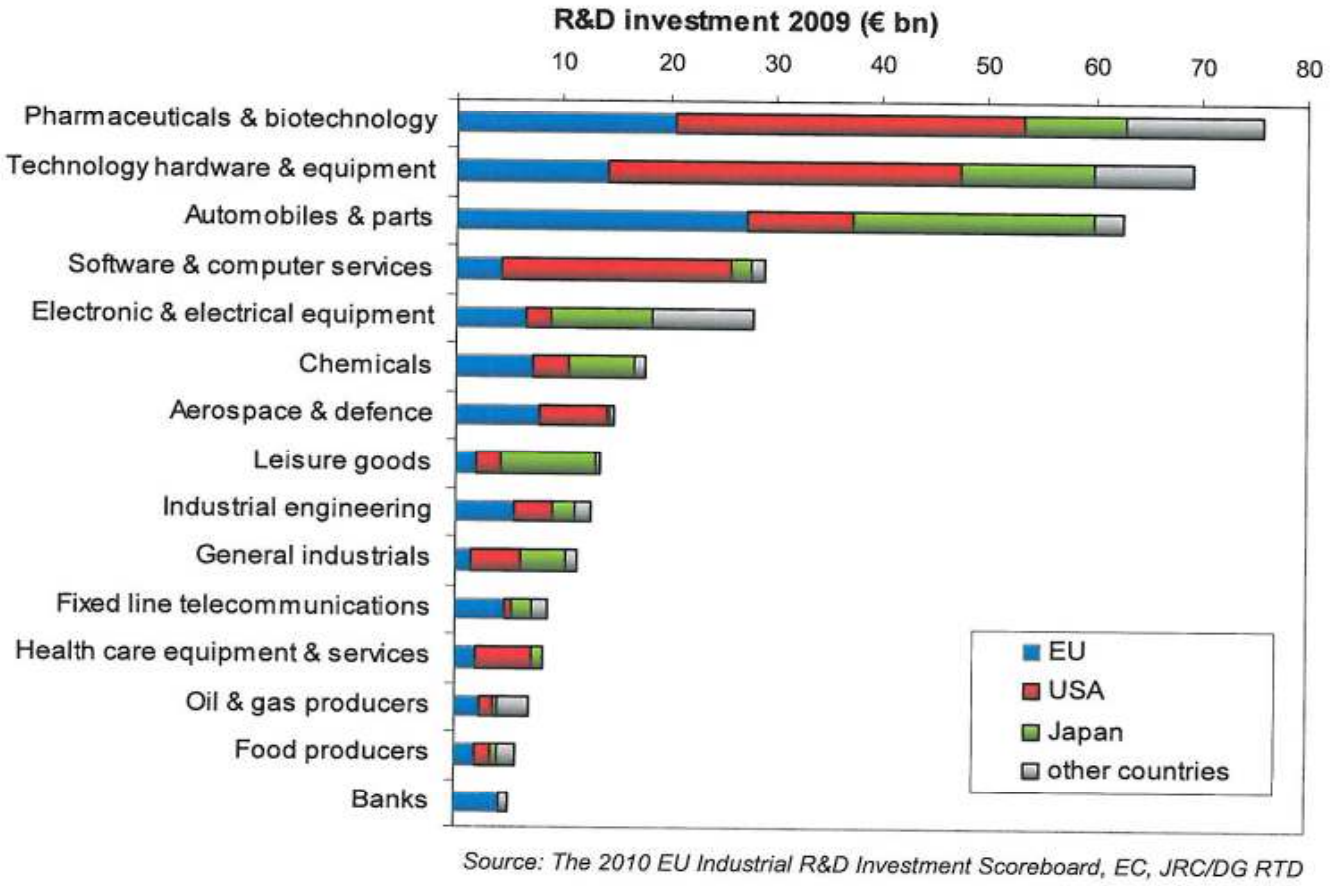
WHERE IS RESEARCH FOCUSED?

Figure 5: Clinical activity by disease (with PDPs as lead sponsors, 2007-2012)



Pugatch MP et al. Assembling the pharmaceutical R&D puzzle for needs in the developing world

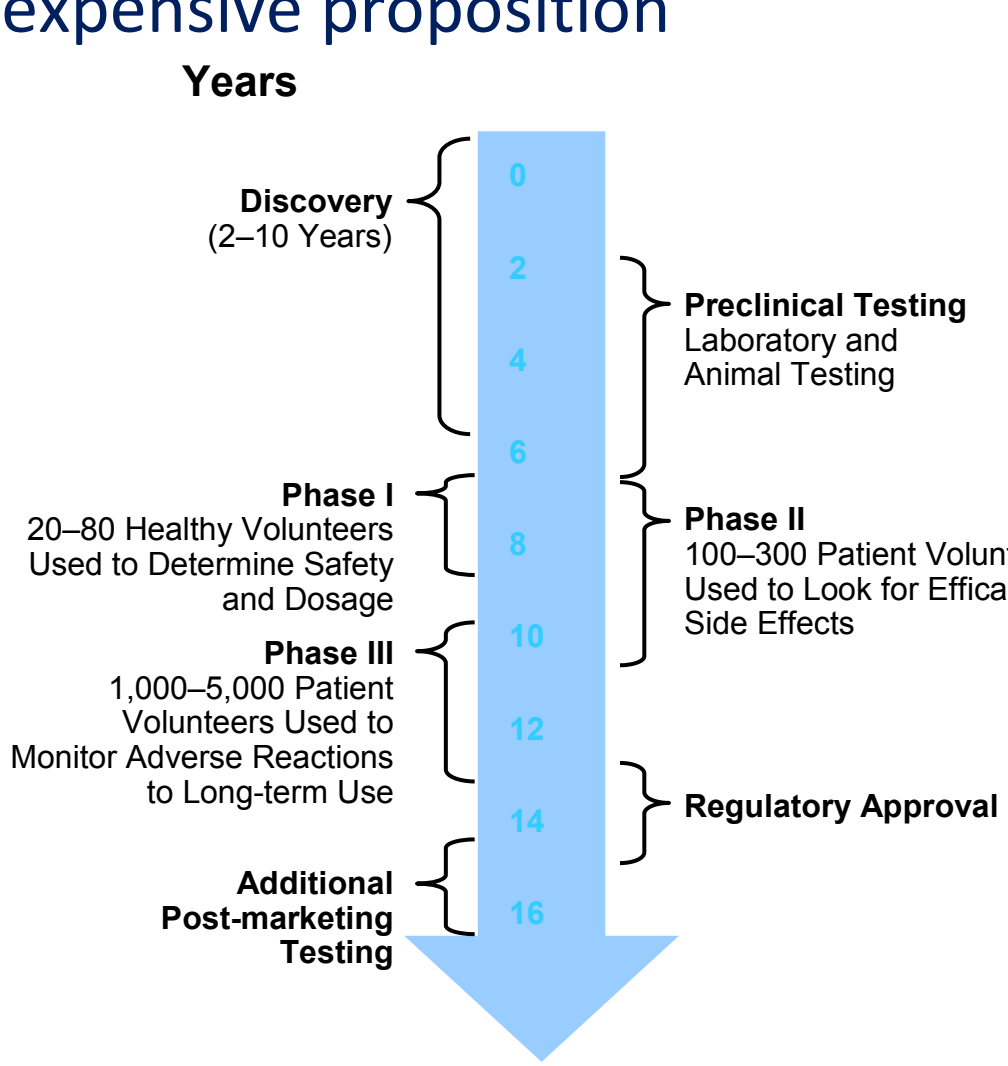
R&D INVESTMENT BY SECTOR



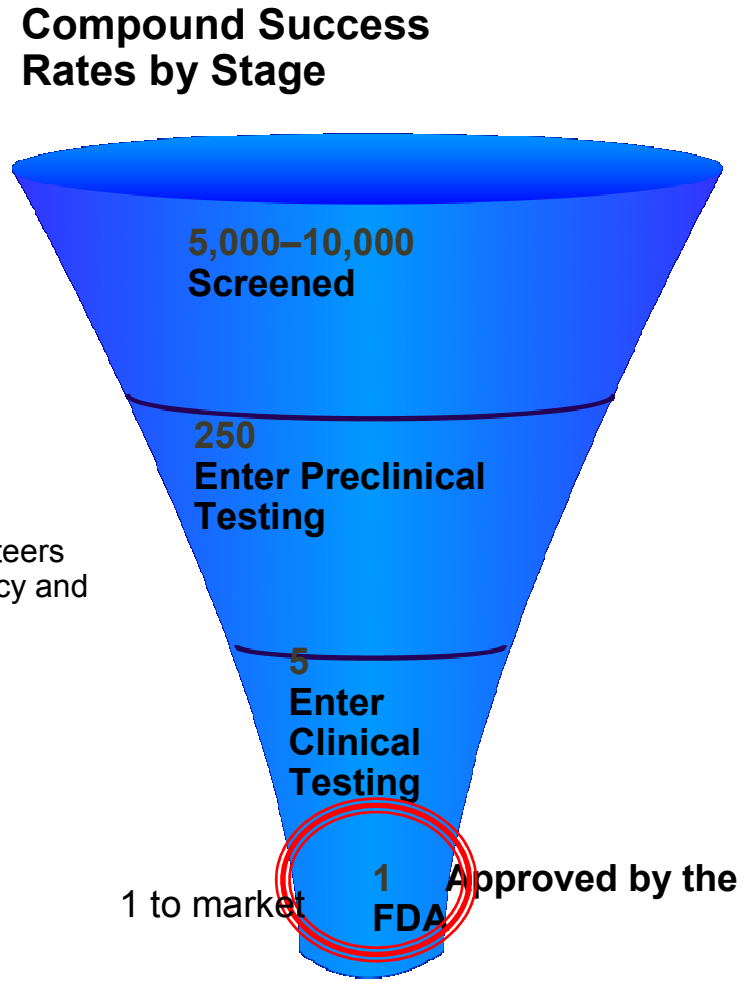
Source: The 2010 EU Industrial R&D Investment Scoreboard, EC, JRC/DG RTD

Pharma & biotech sector reinforces its position as top R&D investor worldwide

NEW PRODUCT DEVELOPMENT - A risky & expensive proposition



Up to 15 yrs to market



High Pharma R&D vs other sectors

Source: Tufts Center for the Study of Drug Development

PHARMA R&D IN SA

R1.75 billion – total industry R&D (2008)

R397 million – local subsidiaries

R1.35 billion – international HQs

Source: Deloitte Report, 2010. In sights into the high level contribution of the Pharmaceutical Industry in South Africa

EMBRACING INNOVATION – SA GOVERNMENT

An enabling IP framework in place predating TRIPS.

DTI

- Industrial Policy Action Plan – pharmaceuticals
- Various initiatives such as Ketlaphela project

DST boast:

- 10 year innovation plan, 2008
- Strengthening of the bio-economy
- SA urged to become a world leader in biotechnology and pharmaceuticals based on indigenous resources
- Investment in research - NHRC

ESSENTIAL MEDICINES

- Most African countries utilise an EML
- Industry study conducted in SA reflects that no medicines on SA EDL patent-protected
- Despite pro-generic environment, Governments still need recourse to innovative medicines that are safe, of good quality and efficacious

ADDRESSING NATIONAL HEALTH EMERGENCIES

ADDRESSING NATIONAL HEALTH EMERGENCIES

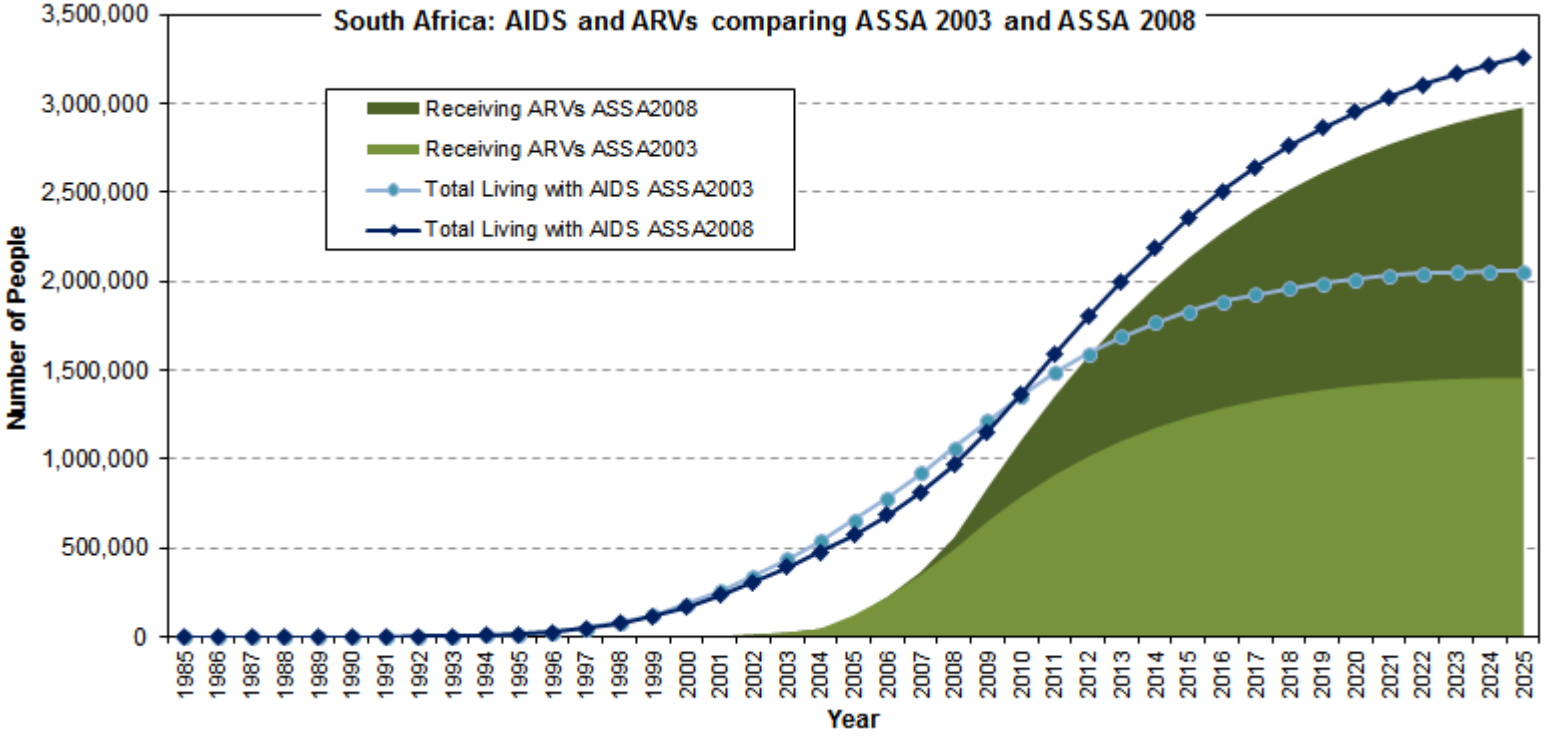
RESEARCH & DEVELOPMENT

MEDICINES INNOVATION BENEFITS PATIENTS

Direct benefits to patients through:

- Expanded number of treatments for complex diseases (HIV/AIDS, cancer etc);
- Improved treatments that more efficiently target diseases;
- Simplified medicine regimens that make patient's lives easier

ARV TREATMENT IMPROVED SURVIVAL TIMES



ASSA2008 projects a very much larger ARV programme. As a result, people live longer and hence the total living with AIDS increases substantially.

Source: IMSA NHI Policy Brief 18: Projected Population and HIV/AIDS Update

INCREASE IN LIFE EXPECTANCY

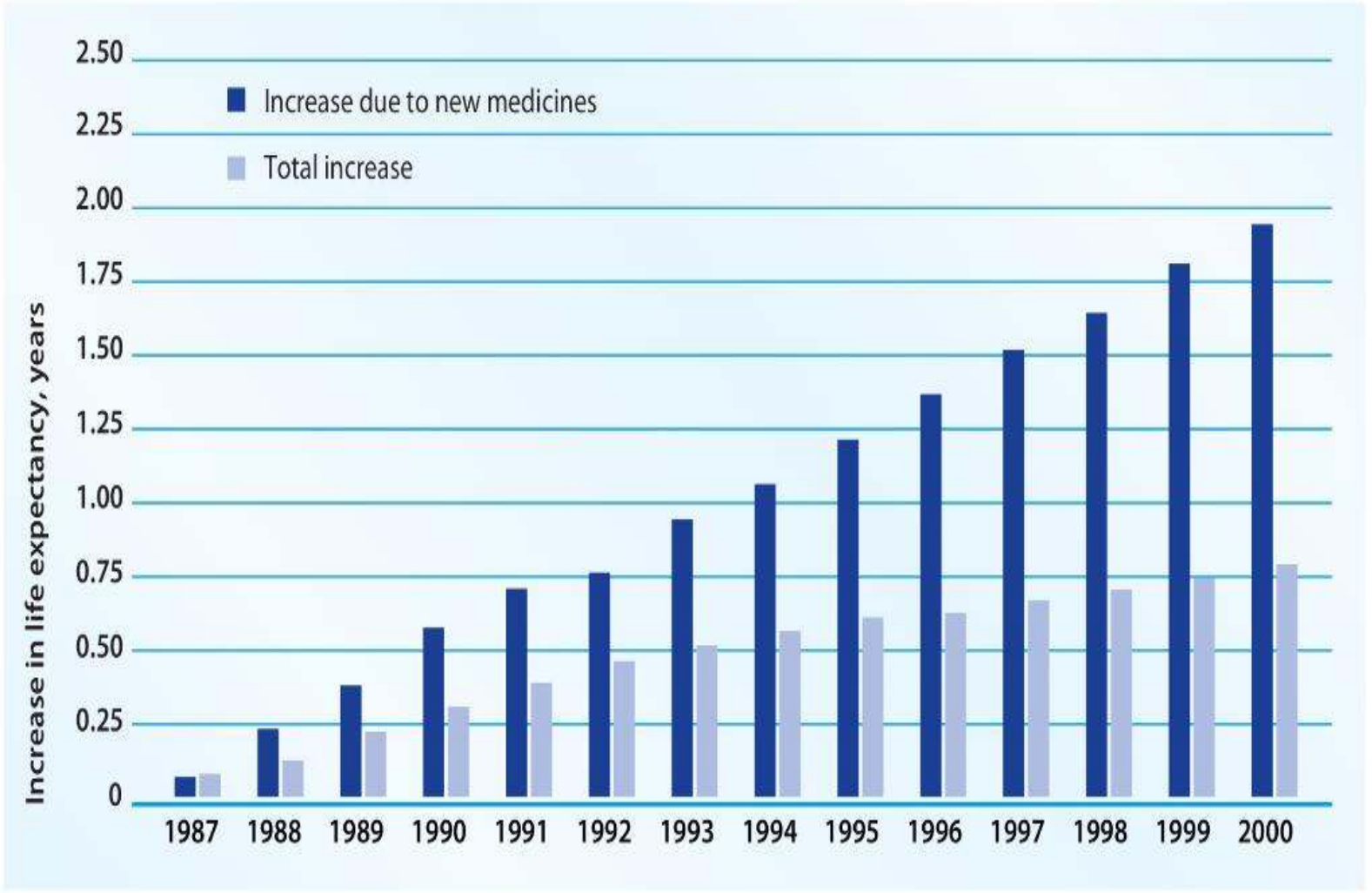
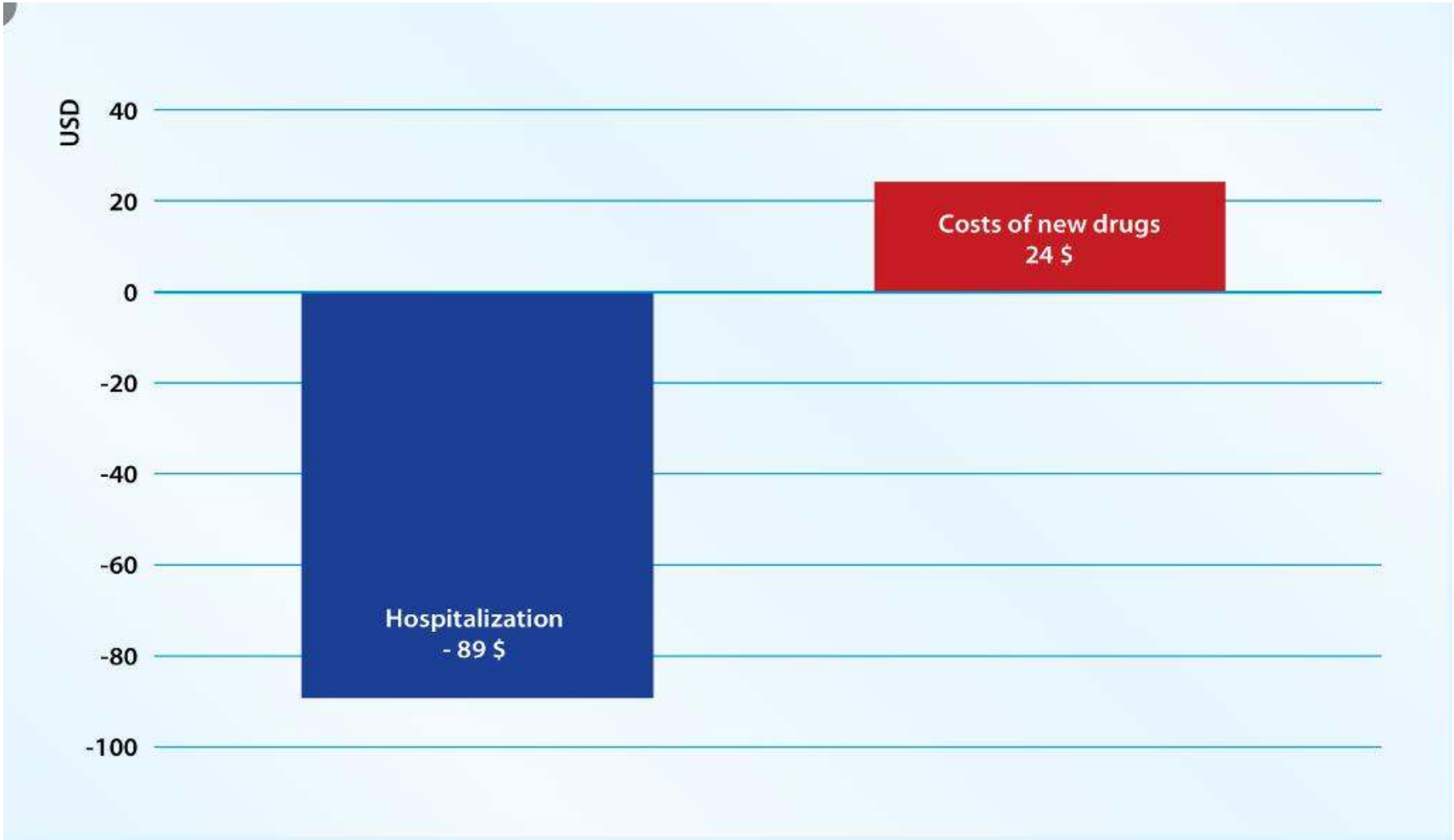


Figure 11: Increase in life expectancy due to new medicines[139]

DOWNSTREAM SAVINGS



Cost of newer cardiovascular drugs compared to savings in hospitalization in 20 OECD countries (1995–2003)[52]

	Actual hospitalizations avoided	Annual premature deaths avoided
Actual prevention: Based on current treatment rates	833,000	86,000
Potential additional prevention: If untreated patients received recommended medicines	420,000	89,000

Figure 12: Annual hospitalizations and deaths avoided through use of antihypersensitive medications[145]

MANUFACTURING CAPACITY

MANUFACTURING FOR AFRICA

- Currently we have only 129 plants in Africa Source: African Development Bank 2011
- India and China dominate generic and API production
- Donor funding sources imports directly from India
- Security of supply?
- CIPIH encourages manufacturing in developing countries – Cuban example

REGULATORY MECHANISMS

REGULATORY STANDARDS MUST COMPLY WITH GLOBAL BEST PRACTICE

MEDICINES, A FUNDAMENTAL LINK IN THE HEALTHCARE CHAIN *BUT, ONLY USEFUL IF…*

Quality guaranteed from manufacturer to patient

(Quality)

Available to patient when needed

(Availability)

Appropriate drug choice for patients need

(Drug Selection)

Dispensing: correct usage & patient compliance

ACCESS CHALLENGES ARE NOT IP RELATED

PATENTS OFFICE

MINIMUM REQUIREMENTS

- Respect for the standards of novelty, new inventive step and industrial applicability
- Patents to be granted within a reasonable period

CONCLUSION

- Many health challenges in Africa and developing world at large
- Challenges are not a constant - we need to keep abreast of their evolution
- Medicines will be needed to address these challenges
- Pharmaceuticals R&D is high investment with low success rate
- An enabling IP environment is critical to finding solutions to the health challenges of the present and future