



# WIPO CONFERENCE GENEVA

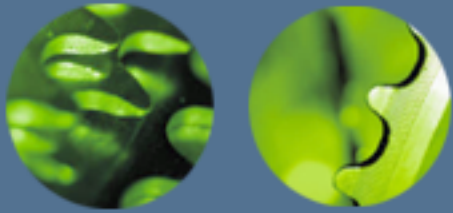
## Promoting Access to Traditional African Medicine, Managing the IPR: The Case of South Africa

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## Scope of the Presentation

1. The problem Statement
2. South African Policy Landscape
3. Institutionalization of ATM
4. Defensive Protection of ATM
  - a. Legislative
5. Positive protection of ATM
  - a. “Farmer to Pharma Grand Challenge”
6. Challenges and opportunities

# 1 Problem Statement: Gaps in the IP system to protect ATM

- There is concern that traditional knowledge is at times appropriated, adapted and patented by scientists and industry, with little or no compensation to the custodians of this knowledge and without their prior informed consent.
- A cursory observation of our national legislation reflects an inability and deficiency of current intellectual property rights regimes to fully accommodate and protect indigenous knowledge. Many legal and practical problems relating to protection of IPR remain yet to be fully understood and addressed: the collective ownership/ custodianship of traditional medicine; the problem of ownership and exercise of rights in traditional medicinal knowledge which exists across different countries in a region; practical means for the exercise and management of rights; mechanisms for application of customary law to protection of traditional medicine; and the need for comprehensive documentation standards, for traditional medicine.
- The most fundamental reason for the inappropriateness of current IP regimes to protect TM is the they were drafted during the industrial era of the 18<sup>th</sup> century.
- The marginalization of IKS in the Knowledge Economy



# 1 Problem Statement: Mechanism to address IP gaps- SA experience

- Development of national policy on traditional medicine as part of the national health policy and countries should develop and utilize traditional medicine in a meaningful manner in the national health care system
- Development of alternate legislation (sui generis) to provide for the protection of community intellectual rights
- Development of guidelines or regulations to ensure benefit sharing with the community for commercial use of indigenous knowledge
- Setting up of a documentation and registration system for informal innovations
- Mainstreaming IKS/ ATM in the National system of Innovation
- The Development of a Pharmaceutical Industry based on ATM



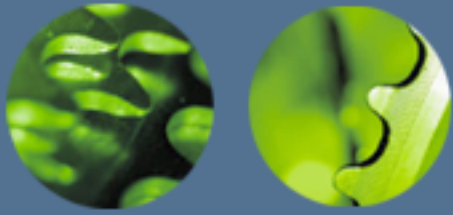
## SA Policy landscape on ATM

- The policy on ATM comes at a time when the public health care system is in a dire need to reflect the diverse health disciplines which the citizen utilize for their healthcare needs in South Africa.
- It provides a transformational process for formal recognition of the ATM system to acknowledgement our heritage as a country and to address issues of:
  - (a) building capacity of and protecting Traditional Health Practitioners and the users of ATM,
  - (b) protecting Indigenous Knowledge, and
  - (c) strengthening the National Health System



## 2. South African Policy landscape (2)

- Four Government Departments have played key and strategic roles vis visa ATM:
  - DST
  - DEA
  - DOH
  - DTI



# DST Policy Background (3)

White Paper on S & T (1996)

SA National R&D Strategy (2002)

National Biotechnology Strategy (2001)

Indigenous Knowledge System Policy (2004)

Ten Year Innovation Plan  
2007

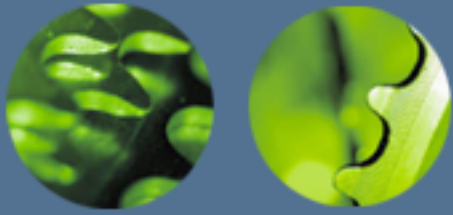
Farmer to Pharma

Space Science

Energy Security

Climate Change

H&S Dynamics



# F2P Grand Challenge

## Pillars of a knowledge based economy:

- Human capital development (education)
- Knowledge generation and exploitation  
(R&D, technology development and innovation)
- Infrastructure
- Bridging the innovation chasm  
(technology transfer and commercialization of  
R&D for socio-economic outcomes)



## 2. DoH Policy Initiatives: Institutionalisation of ATM in South Africa (1)




- Official support for acceptance and recognition of traditional medicine in the formal healthcare sector often through a national focal point such as an institute.
- Establishment of a system to regulate, register and license Traditional Health Practitioners and the provision of formal training of such practitioners;
- The establishment of a system to develop, regulate and register Traditional Medicine to ensure safety, quality and efficacy, including scientific research;
- The development of a national Pharmacopoeia or the updating of existing ones as part of the regulatory system;
- collaboration with other countries and the World Health Organisation in order to exchange information and promote policies and regulation according to international standards



# DoH Regulations of ATM (2)

- **It is recommended that legislation on African Traditional Medicine be enacted to provide an enabling environment for African Traditional Medicine in its entirety and scope, covering but not limited to:**
- the regulation of African Traditional Medicine in South Africa;
- Registration and regulation of African Traditional Medicines and Medicinal Products in South Africa;
- Protection of African Traditional Medicine knowledge and Intellectual Property rights; and
- The protection of the rights of persons involved in the discipline of African Traditional Medicine in South Africa.



## DoH: National Institute of African Traditional Medicine (NIATM) (3)

### **The five components of NIATM are:**

- A school or faculty, as it is done in sports, where education and training in aspects of traditional medicine and primary health care is provided to traditional practitioners, students of medicine and pharmacy and also allopathic doctors who wish to use TM in their practices.
- A research institute for the research and development of high quality, safe and evidence-based traditional medicines.
- A hospital and other facilities where traditional practitioners (alone or in collaboration with allopathic doctors) provide health care. There should be a separate pharmacy where traditional remedies are dispensed (as is the case in China, for example).
- An experimental garden or botanical garden where medicinal plants are grown on an experimental or semi-commercial scale for research and development, as well as for display and educational purposes.
- A museum, library and documentation centre, where collections of historical artefacts, traditional medicines, books, documents and other resources are displayed and maintained under proper curation (as experienced in China).

## 2 SA Policy Landscape 3: DoEA- ABS regulations (1)

- The need for internationally agreed methodologies for giving effect to the equity provisions of the Convention on Biological Diversity (CBD) is now widely recognized.
- However, certain critical issues remain unresolved under the CBD, particularly in relation to how to go about legalizing and formalizing the bio-prospecting process in a way which ensures that there is full and prior informed consent of fair and equitable benefit sharing with the originator of the knowledge and resource that enable the bio-prospecting.
- Appropriate strategies to increase awareness about the need for sustainable use and conservation medicinal plants and traditional medicine, can complement research efforts aimed to achieve this objective.
- In 2008 the Department of Environmental Affairs enacted regulations to ensure ABS and PIC in so far it relates to bioprospecting



## 2 SA Policy Landscape: DTI Initiatives:

- **Disclosure issues included in SA Patent Act**
- The Department of Trade and Industry introduced into the South African Patents Act provisions, in the first place, compels applicants for patents in those cases where an invention entails the use of genetic or biological resources, or where an invention is based on indigenous or traditional knowledge, to disclose this fact in the patent application; and, in the second place, to compel applicants for patents in those cases where a patent aims to protect an element of indigenous or traditional knowledge or of "heritage", to obtain the prior and informed consent of the owners of the traditional knowledge for the sharing of the ownership, control, use and benefits of such knowledge; and, in the third place, to provide for sanctions in cases of non-compliance with these provisions. These include but not limited to the revocation of the patent application.
- Amendment to the Conventional IP Regime to include the Protection of IKS- Bill is before Parliament



# 3. Institutionalisation of ATM

Much of these developments have been underpinned by the strengthening of our capacity as a nation to undertake ATM research and development through several government-funded innovative enterprises including the creation of the:

- MRC Traditional Medicines research unit at UWC and UCT, which has completed its work
- National Drug Development From Plants Platform Consortium
- MRC IKS Lead Programme
- SA Herbal Science and Medicine Institute at UWC, with its disruptive innovative technology called Reverse Pharmacology for unlocking the value of traditional medicine
- National Reference Centre on African Traditional Medicine
- PEPFAR-funded UKZ-N Traditional Health Practitioners and Biomedical Scientist Programme, headed by the DST/NRF Chair in IKS Healthcare Systems
- NIH-funded International Centre for Indigenous Phytotherapy Studies led in SA by the UWC SA Herbal Science and Medicine Institute, with its consortium partners at the UKZN, UCT and MRC
- Biotechnology Regional Innovation Centres
- CSIR Bioprospecting Programme.
- MRC National Collaborative Programme: Traditional Medicine, Drug Discovery & Development.



## 4. Defensive protection of ATM

- **Concerns:**

- Current intellectual property legislation vests ownership in the inventor
- The foundations of our present scientific development were created under the explicit assumption that knowledge was a common good created for the common good.
- The nature of traditional medicine is such that more of it is transmitted orally than written down.



## 4. Defensive protection of ATM

- Concerns continued:
  - The period of protection is problematic to indigenous and local communities.
  - Lastly, on an operational level, the cost of filing in registration of IPR is prohibitive, as are the costs of enforcement and infringement proceedings.





## *sui generis*

### Why a Sui Generis regime?

- Recognition that indigenous and local communities are the guardians of their indigenous knowledge and have the right to protect and control the dissemination of that knowledge;
- That existing protection mechanisms are insufficient for the protection of indigenous cultural and intellectual property rights;
- That the cultural and intellectual property rights of indigenous and local communities are vested with those who created them;



## 4. Defensive protection of ATM

What are the elements of a sui generis system?

- Definitions of IK and indigenous and local communities in accordance with indigenous customary law;
- Collective (as well as individual) ownership and origin;
- Coverage of historical as well as contemporary works;
- Protection against debasement, misappropriation, misuse of culturally significant items
- Co-operative rather than a competitive framework;
- Beneficiaries of that knowledge;
- Cross-generational coverage span;



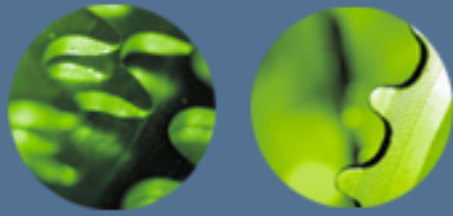
## 4. Defensive protection of ATM

- Exemptions from the requirements of inventive step and non obviousness;
- Duration of protection in perpetuity;
- Evidence of prior informed consent and benefit sharing to the community from where the knowledge has been accessed;
- Establishment of agencies/institution to allow indigenous and local communities to charge fees; and
- Requirements for disclosure of the geographical source or community from which indigenous knowledge has been derived and sanctions for deliberate concealment or misrepresentation of the knowledge.



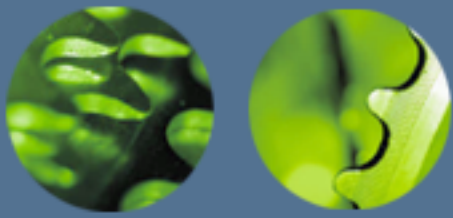
## 5. Positive Development of ATM

- The DST 10-year Innovation Strategy and the Farmer to Pharma Grand Challenge, which focuses on unlocking the value of our biodiversity, indigenous knowledge and traditional medicine
- The DoH as primary leader on regulations, product registrations and THP services in the country, together with
- The DTI as the main enabler of industrialization and commercialization for the nation.
- The WHO Plan of Action on IPR from Research and Development for Public Health as well as
- The SA National Industrial Policy Framework (NIPF) and Industrial Policy Action Plan (IPAP).
- The SADC Pharmaceutical Business Plan (2007-2013),

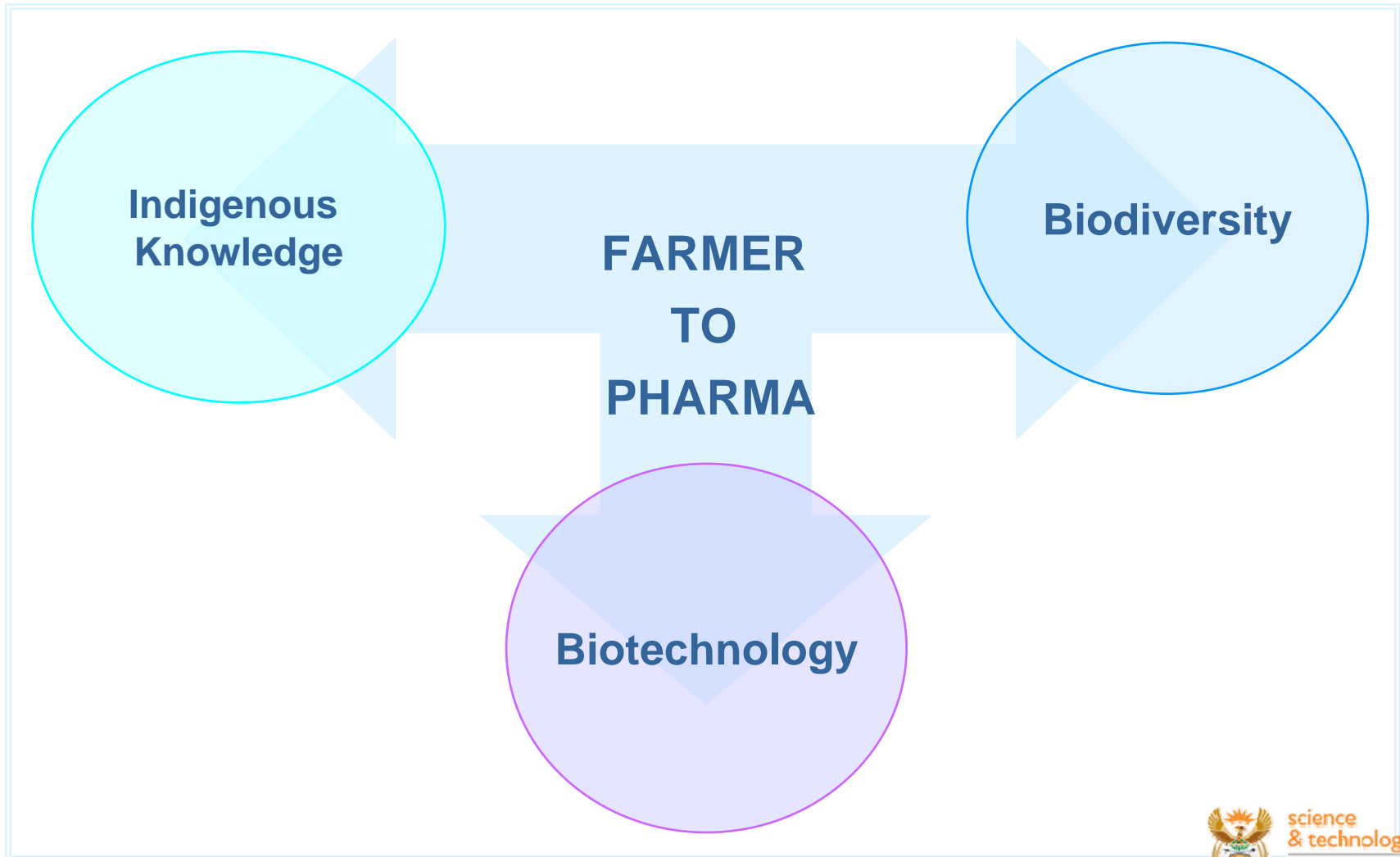


## Deliverable Outcomes

- Be one of the top three emerging economies in the global Pharmaceutical industry, based on an expansive innovation system using the nation's indigenous knowledge and rich biodiversity
- Designed and created the appropriate technology platforms, and R&D and innovation infrastructure that facilitate diagnostic and medical solutions
- Created and funded five theme-specific consortium-based centres of competence that focus on the five top national health priorities, linked to the growth of the local Pharmaceutical industry
- Increased foreign investment in South African health-related R&D through reinvigorated health research, with particular emphasis on pharmaceutical R&D;



# Interface

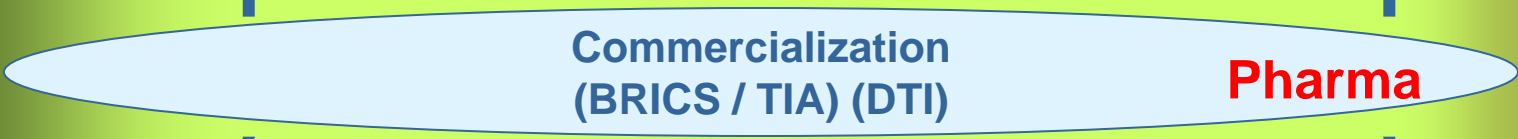
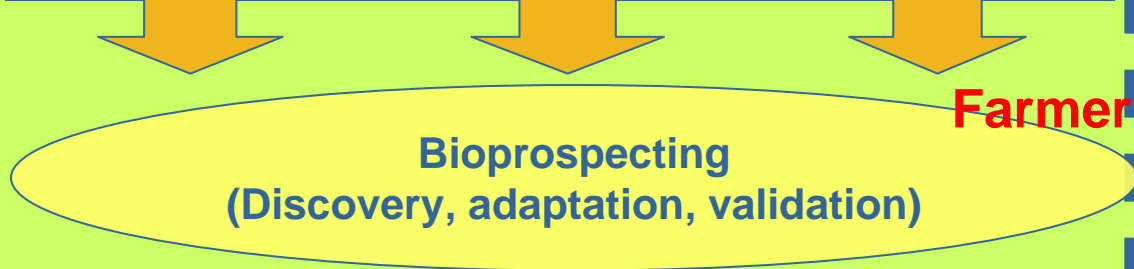


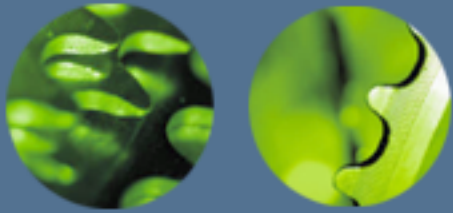


Biotech

# Farmer to Pharma

IKS





# Supporting Platforms

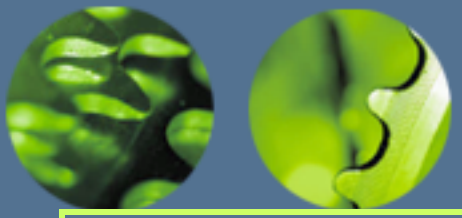
Preclinical drug development platform – toxicology, ADME

Bioprospecting platform (IKS and non-IKS)

Supporting Platforms and CoCs within Biotechnology

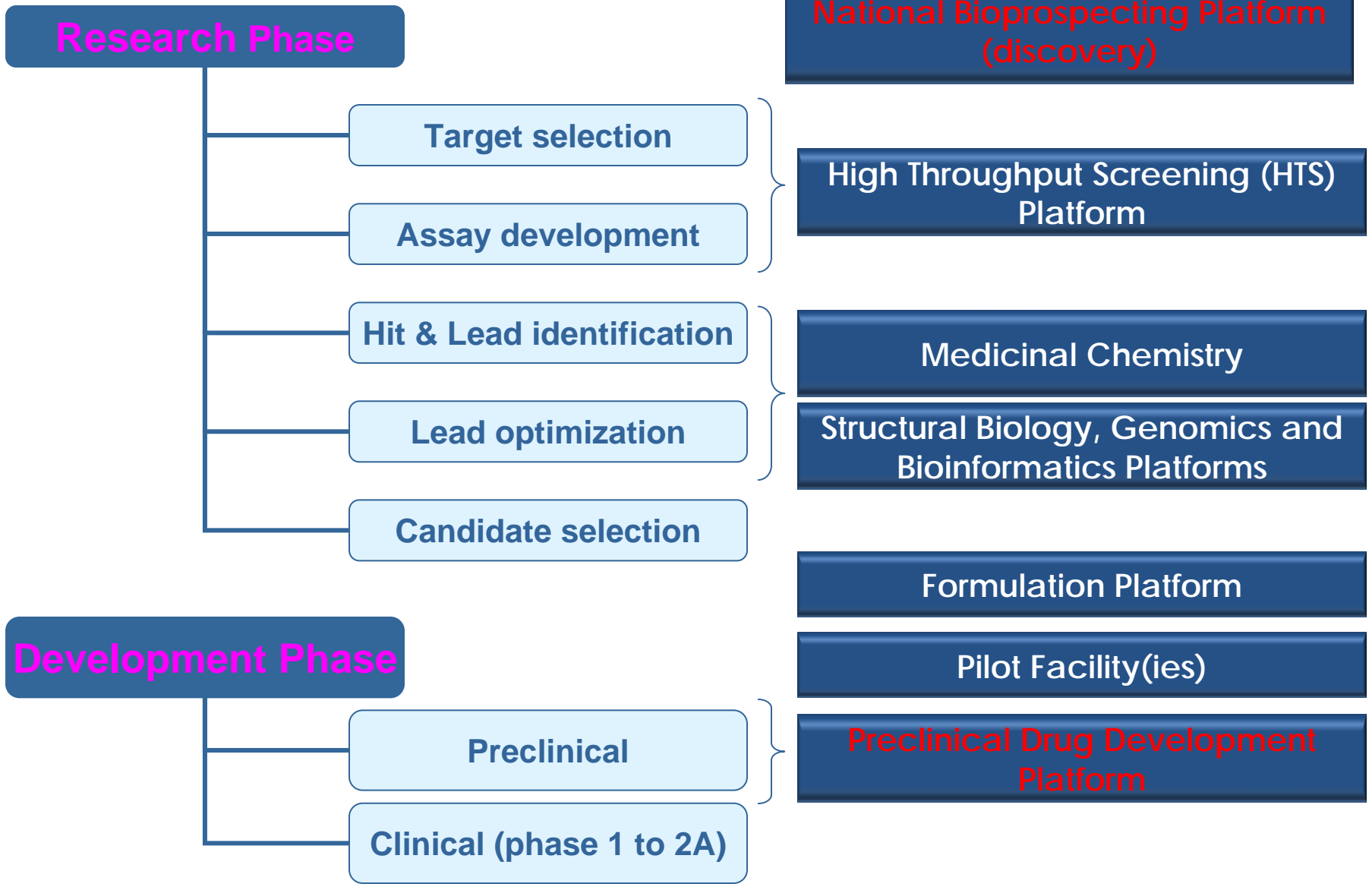
- Functional Genomics & Bioinformatics Platform
- Structural Biology Platform
- TB CoC
- HIV Prevention and Treatment Platform
- SAMI
- Pilot plants and Manufacturing Platforms
- Cancer CoC
- Diabetes CoC
- Human and Animal Vaccine Initiative



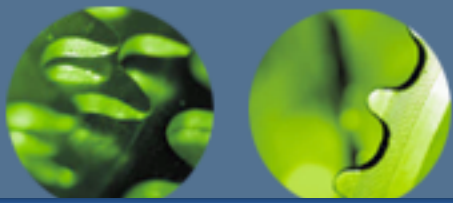


# Matrix

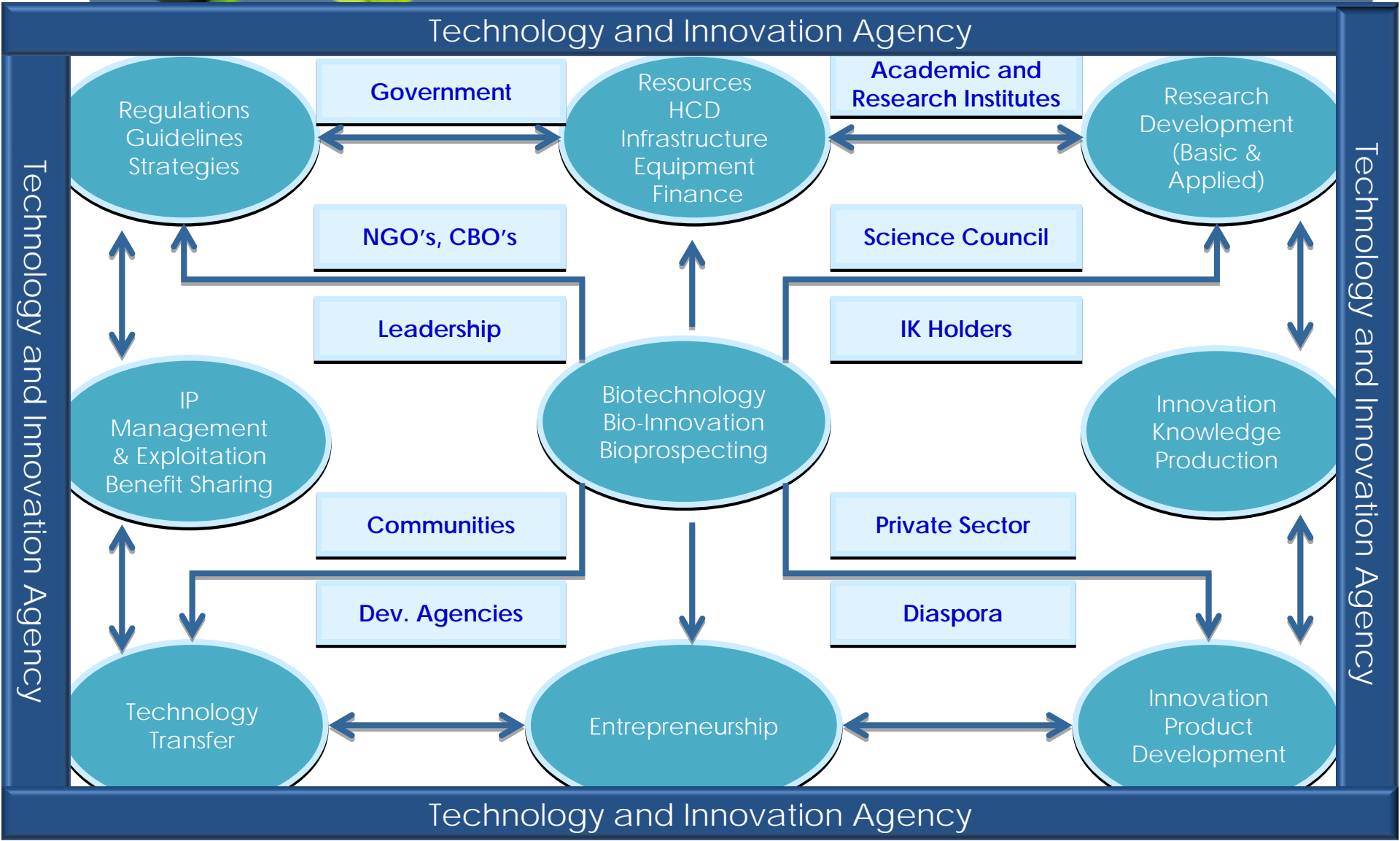
	Health	Agriculture	Industrial
Bioprospecting			
PCDDP			
Biosafety Platform			
Bioinformatics and Functional Genomics			
Structural Biology			
Pilot plant Manufacturing Facility			

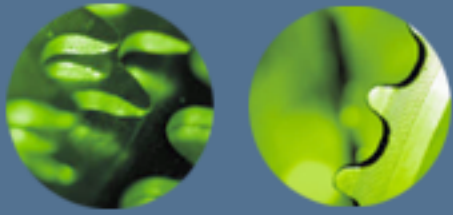


Role of various platforms in creating a value chain for a drug / therapeutic pipeline in SA



# Implementation Building Blocks

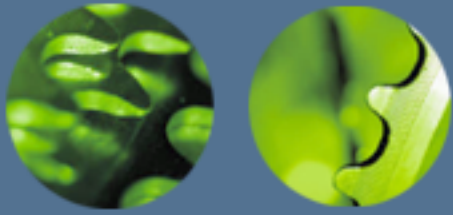




# Key Implementation Milestones

## Resources:

- Human capacity (critical mass, transfer of skills at community level, high level – to low level, etc)
- Infrastructure – facilities, equipment, manufacturing competence
- Funding
- Research, development, innovation and commercialization initiatives (CoE, CoC, platforms, pilot plants, value chains, socio-economic benefits, etc)



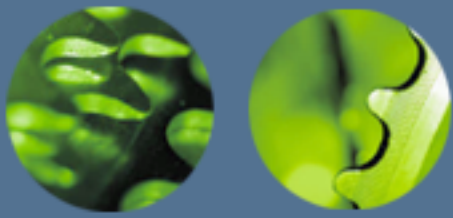
# Outcomes & Goals

## Outcomes

- Social benefits
- Economic benefits
- Environmental benefits

## Goals

- Address National Imperatives (HIV/AIDS, malaria and TB)
- Create Wealth
- Meet Millennium Development Goals



*Thank You*



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