

# Council for Scientific and Industrial Research: ABS Case Studies

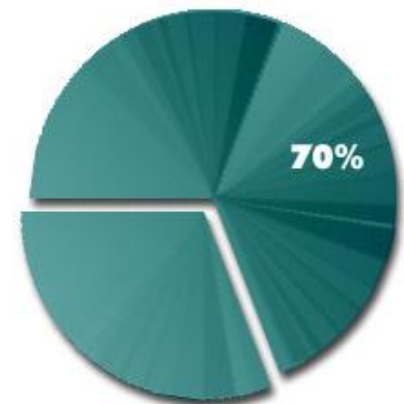
## Community-to-Community Exchange on ABS and Traditional Knowledge

Dr Sechaba Bareetseng  
03 September 2018  
Farm Inn, Pretoria, South Africa

# Context

- ❖ SA is the 3<sup>rd</sup> biologically diverse country in the world
  - ❖ 24 000 indigenous plant species
  - ❖ High endemism, 10% of world's plants
  - ❖ Number of new industries in based cosmetics, complementary medicines & natural based nutraceuticals
- 
- ❖ South Africa has a long tradition of medicinal use of indigenous plants
  - ❖ >500 000 THPs active throughout the country
  - ❖ At least 3 000 plants are used traditionally for ailments
  - ❖ 25% of prescription medicines at plant derived

SA has 10% of the world's plants



majority of South Africans consult a Traditional Healer



# South African plant genetic resources of commercial importance

*Agathosma betulina*, *Aloe ferox*,  
*Artemisia afra*, *Aspalathus linearis*,  
*Cyclopia genistoides*,  
*Harpagophytum procumbens*,  
*Hoodia gordonii*, *Hypoxis*  
*hemerocallidea*, *Lippia javanica*,  
*Mesembryanthemum tortuosum*,  
*Pelargonium sidoides*,  
*Siphonochilus aethiopicus*,  
*Sutherlandia frutescens*, *Warburgia*  
*salutaris* and *Xysmalobium*  
*undulatum*, *Schlerochiton ilicifolius*

B.-E. van Wyk (2008), Journal of Ethnopharmacology,  
pp 342–355





# Commercial products developed from South African TK



(B.-E. Van Wyk (2011))

# South African IKS Policy

- ❖ Dept. Science and Technology (custodian policy)
- ❖ NIKSO, Depart. Science and Technology (Policy implementation management)
- ❖ Affirms IKS as a sources of research and innovation (specific initiatives, not limited to)
  - infrastructure development (R&D) at universities
  - education and training (e.g. IKS Bachelor degree UKZN and UNW-Mahikeng Campus)
  - IKS Research Chairs (NRF)
  - IKS Call for proposals funding (NRF)
  - accreditation & certification of Knowledge Holders
  - documentation of IKS (National Recordal System – 2013)
  - IKS expo's including international conferences
  - digital database (pharmacopoeia)
- ❖ Framework protection of the rights of IK Holders, e.g. IKS Bill

*Indigenous Knowledge Systems*



science and technology

Department:  
Science and Technology  
REPUBLIC OF SOUTH AFRICA



# South African ABS legislation: Biodiversity Act, 2004



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AIDS HELPLINE: 0800-0123-22 Prevention is the cure

- ❖ Bioprospecting activities
  - ❖ Export of biological activities for R&D
  - ❖ Biotrade activities
  - ❖ Requirements for compliance:
    - Prior informed consent
    - Material Transfer
    - Benefit sharing agreements with, indigenous communities which contribute to research and agro-processing
    - bioprospecting permit application with the intension to do basic research and commercialise.
- 
- ❖ The Act was amended in 2010:
    - Distinction: Bioprospecting discovery phase v/s Commercial phase
    - Recognition of the practitioners as owners of indigenous knowledge

# South African ABS Regulations, 2008: Basic research

## Basic research:

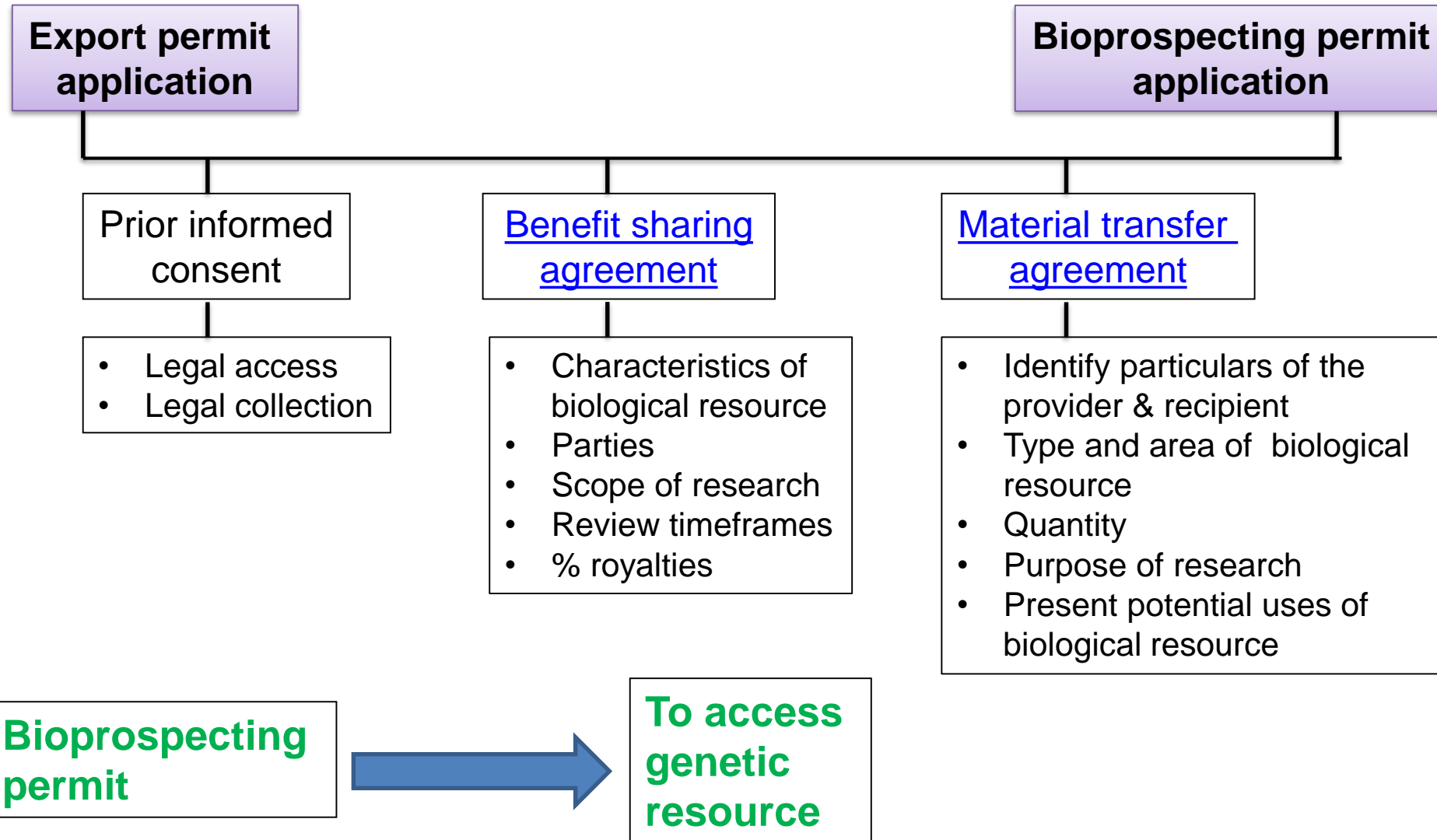
- ❖ Exploratory phase and ultimate findings of the scientific research are often unknown
- ❖ Prior informed consent
- ❖ Researchers are required by the Biodiversity Act to notify the Minister of Environmental Affairs about the research. But how?
- ❖ Fill in the [notification form](#) (available: [www.dea.gov.za](http://www.dea.gov.za))
- ❖ Submit to the DEA electronic version and hard copy
- ❖ Mrs. Lactitia Tshitwamulomoni  
Fax: 086 530 9607  
Email: [Lmabadahane@environment.gov.za](mailto:Lmabadahane@environment.gov.za)

# South African ABS Regulations, 2008: commercialization

- ❖ Definition of commercialisation
  - filing of intellectual property (IP) / patent application in South Africa or elsewhere
  - Obtaining or transfer of IP and other rights
  - commencement of clinical trials and product development, including market research
  - multiplication of genetic resources through cultivation, propagation, or cloning to develop and produce medicines, industrial enzymes, food flavours, fragrances, cosmetics, emulsifiers, oleoresins, colours and extracts
- ❖ Researchers and private companies (including SMMEs) are required to apply for the bioprospecting permit
- ❖ Fill in the [bioprospecting permit application form](http://www.dea.gov.za) (available: [www.dea.gov.za](http://www.dea.gov.za)) together with BSA and MTA and project plan
- ❖ Submit both electronic and hard copies to the DEA



# Requirements for obtaining the bioprospecting permit in South Africa



# Prior informed consent: South African perspective

- ❖ Full disclosure of the intent/purpose and scope of activities, and of information about corporate and institutional stakeholders of research
- ❖ The persons in charge or personnel likely to be involved in the execution of the proposed research project
- ❖ Potential benefits and possible problems associated with the research for the community and environment
- ❖ Research methodology including duration of the research
- ❖ Complete disclosure of the risks and benefits to individuals and to the community of participation in the research
- ❖ The conditions for collection and use of indigenous knowledge and disclosure of data
- ❖ Source of project funding and support, as well as obligations to the sources

# Patent Amendment Act, 2007

- ❖ Integrates protection for indigenous biological resource and indigenous knowledge into existing patent legislation
- ❖ Requires applicants for patents to disclose if the patent is based on indigenous knowledge or the use of the biological resource
- ❖ Proper access to biological resource and / or indigenous knowledge
- ❖ Prior informed consent, Material Transfer Agreement and Benefit Sharing Agreement
- ❖ Actual permit granted by the Department of Environmental Affairs
- ❖ Evidence of compliance with the Bioprospecting, Access and Benefit Sharing Regulations of 2008



# South African IKS (Protection, Promotion, Development and Management) Bill

South African Protection, Promotion, Development and Management of Indigenous Knowledge Bill defines indigenous knowledge as “knowledge which has been developed within an indigenous community and has been assimilated into the cultural and social identity of that community, and includes knowledge of a functional nature; knowledge of natural resources; and indigenous cultural expressions.”

# Implications of the ABS legislation

- ❖ Compliance with the law
- ❖ Apply bioprospecting permit
- ❖ Obtain prior informed consent from the TK Holders for research purposes
- ❖ Document where resources are found
- ❖ Document the provider of TK Holders community
- ❖ Use contracts to protect both the CSIR and the TK Holders
- ❖ Share benefits with TK Holders derived from application of their knowledge and genetic resource
- ❖ Ensure sustainable cultivation of genetic resource
- ❖ Provide feedback to the community on the research (build trust)

# The CSIR Mandate

## CSIR MANDATE

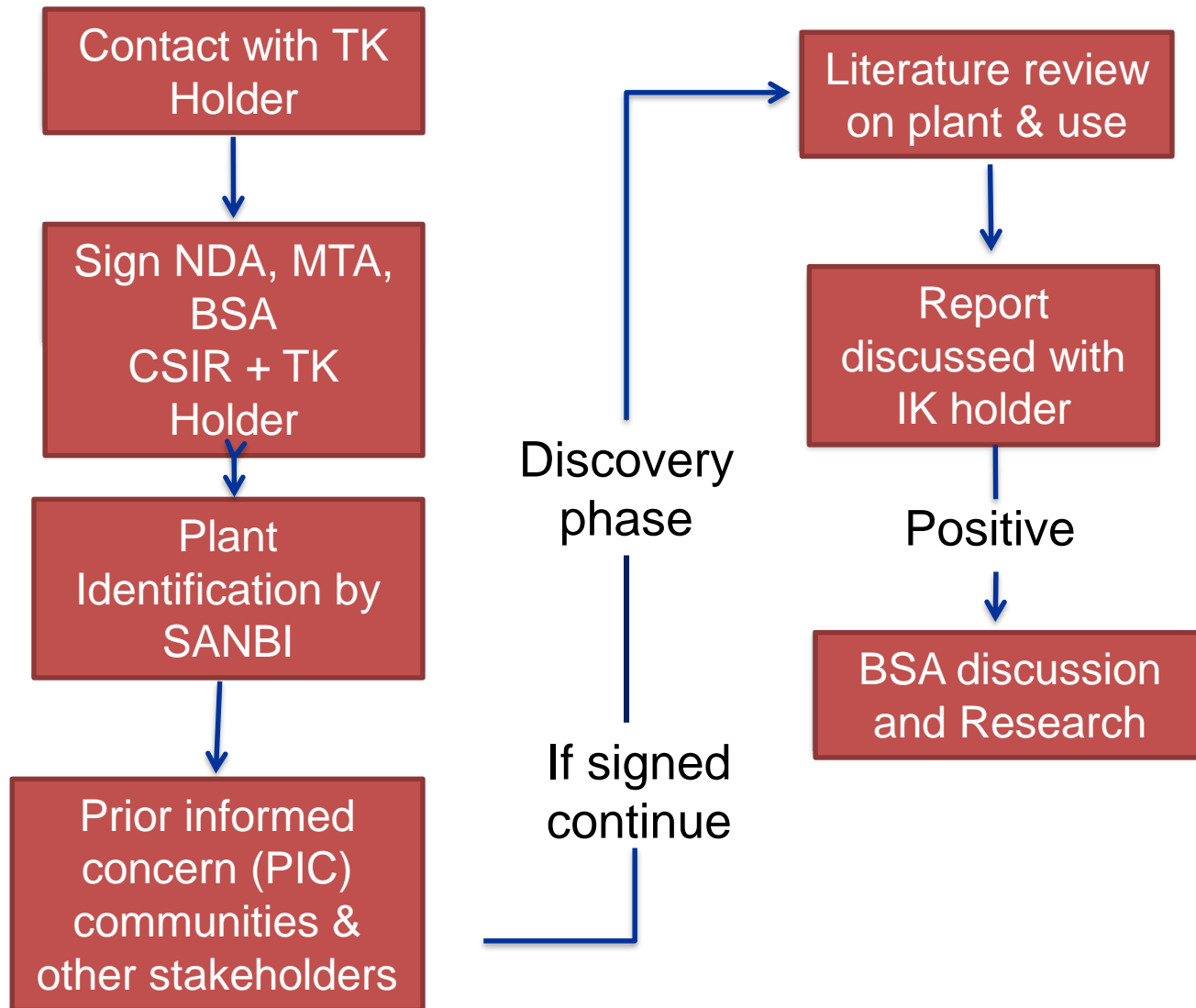
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“The objects of the CSIR are, through directed and particularly multi-disciplinary research and technological innovation, to foster, in the national interest and in fields which in its opinion should receive preference, industrial and scientific development, either by itself or in co-operation with principals from the private or public sectors, and thereby to contribute to the improvement of the quality of life of the people of the Republic, and to perform any other functions that may be assigned to the CSIR by or under this Act.”

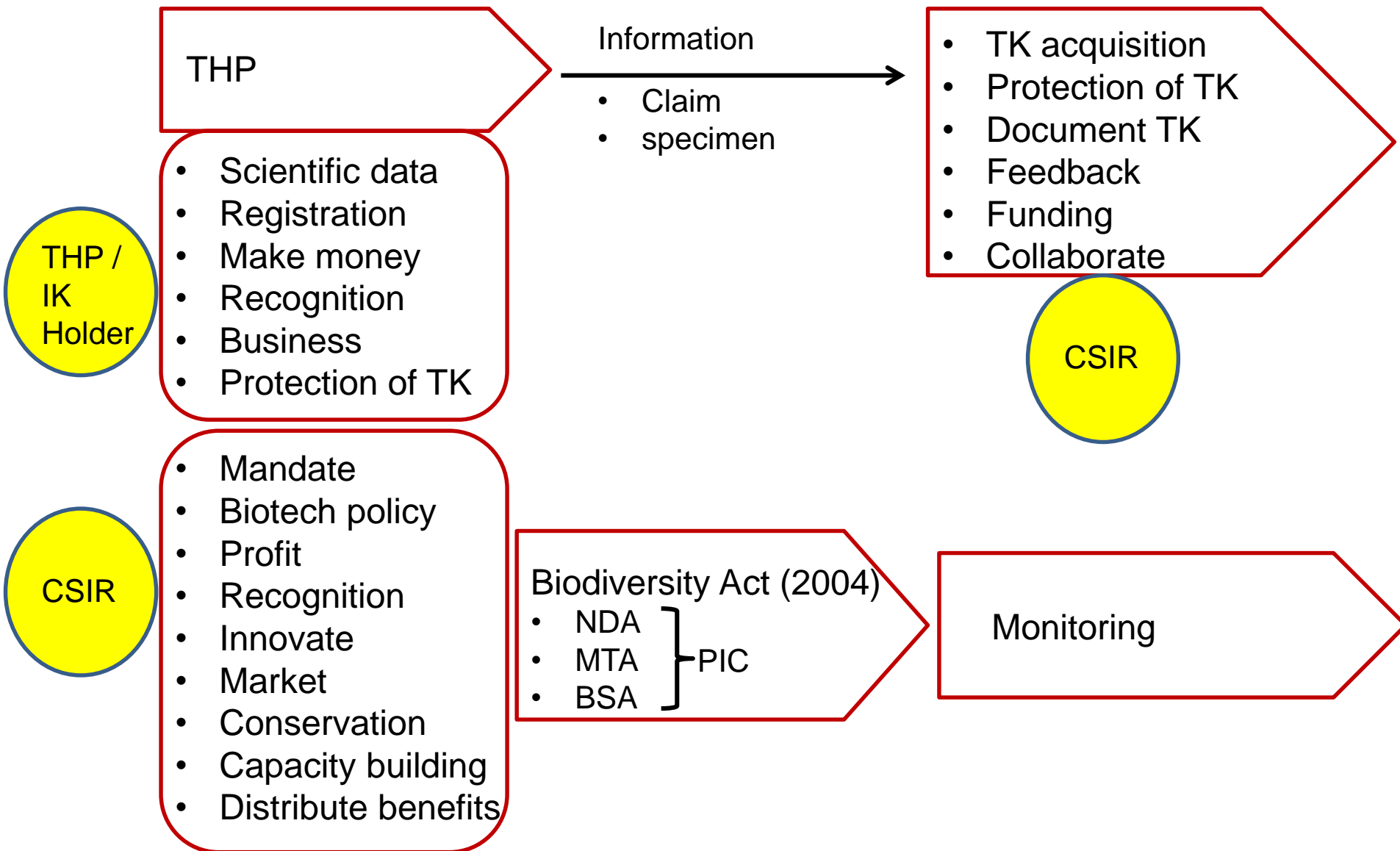
(Scientific Research Council Act 46 of 1988, amended by Act 71 of 1990)



# The CSIR interaction with the TK Holders



# The TK Holders approach CSIR



# TK protection at CSIR



**Bioprospecting**  
 **CSIR**  
BIO/CHEMTEK

[home](#) | [despatch](#)

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**ethnobotanical claim**

**source:** 

**claim number:** THC04129

**received:** 29/09/2004

**address:**

**phone:**

**components:** Rhizomes brought (creeper)

**uses:** Memory loss;depression;symptoms of HIV disease (depression;memory loss)

**preparation:** Ground to powder;1/4 teaspoon to 1L of water;boil 45min to 1 hour;1/2 cup a day;serve 1 teaspoon/1 hour;same preparation;also as snuff; also for steaming;can also burn and inhale the smoke.

**additives:** no additives

**dosage:** Also used for children not the same dosage.

**side effects:** none,plant scarce

**toxicity:** not toxic

**notes:**

**Authentication between botany and TK on use of medicinal plants as well as public information of medicinal plants**



# The CSIR bioprospecting permits

## ❖ *Lippia javanica*

- cultivation and product commercialisation
- patent granted and licensed to a commercial partner

## ❖ *Siphonochilus aethiopicus* (African ginger)

- cultivation and clinical research studies
- patent granted

## ❖ *Monsonia angustifolia*

- cultivation and clinical studies
- patent granted

## ❖ Monatin

- pre-clinical studies (safety)

# CSIR ABS case: *Lippia javanica*

South African regulatory authority: Department of Environmental Affairs  
Bioprospecting, Access and Benefit Sharing Regulations of 2008

Traditional Healers  
Committee

TK & list of medicinal plant species  
(Heads of Agreement 1998)

Royalty payment  
(Benefit Sharing Agreement  
2003)

CSIR  
Biosciences – R&D

Royalties

Non exclusive license

Zollhaus International  
(Pty) Ltd

Hi-Hanyile / Dzundze Trust  
(landowners; labour force)

Manufacturing capacity

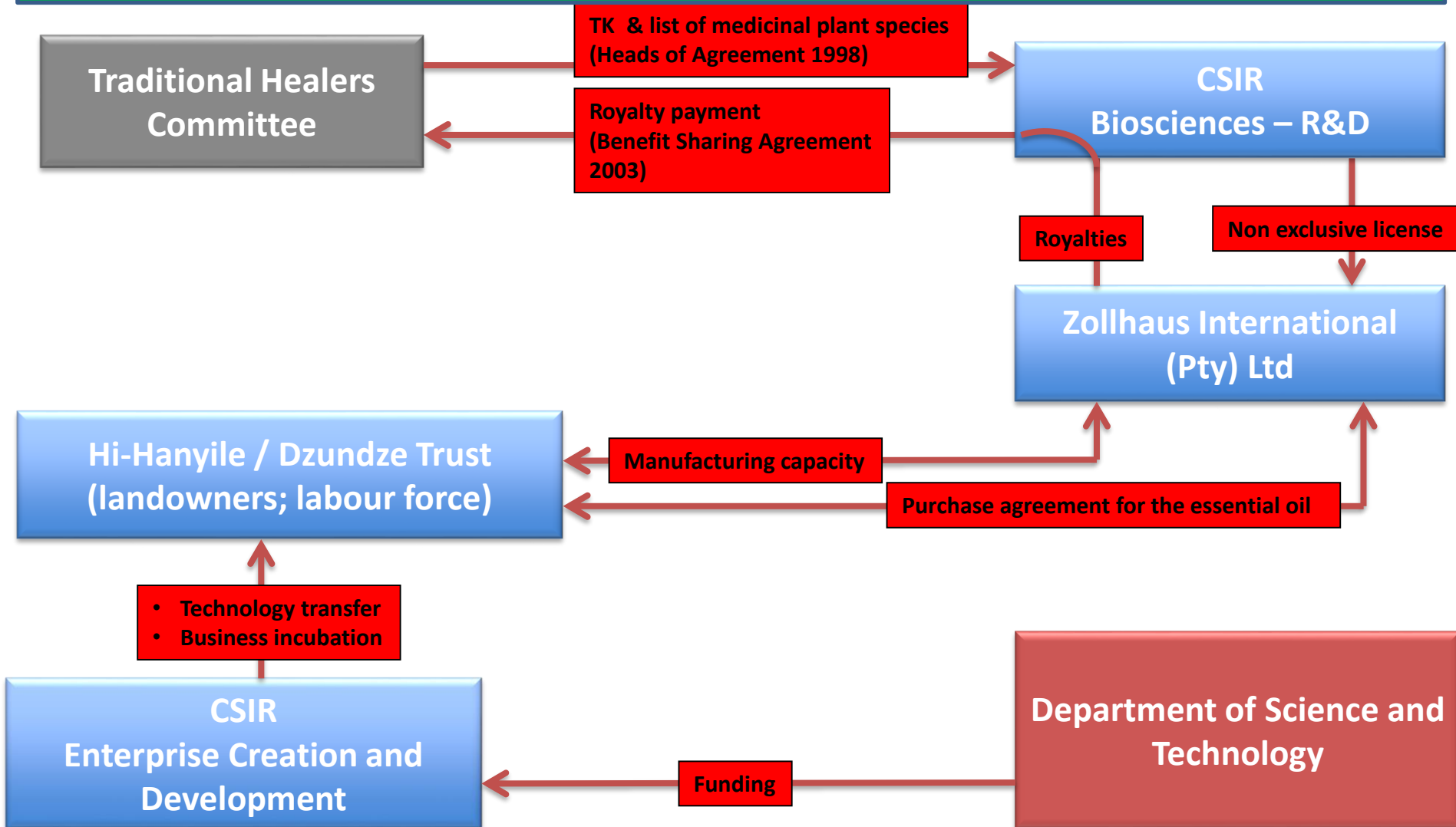
Purchase agreement for the essential oil

- Technology transfer
- Business incubation

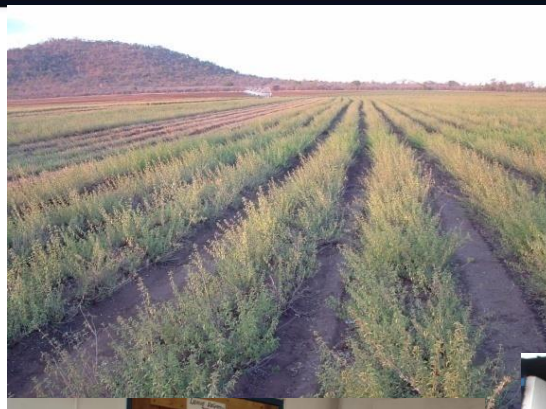
CSIR  
Enterprise Creation and  
Development

Funding

Department of Science and  
Technology



# Hi-Hanyile / Dzundze Trust





# CSIR share royalties with the Traditional Healers Committee: *Lippia javanica*





# CSIR ABS case: African ginger



Transfer of TK from THC to CSIR & signing of PIC, MAT and BSA



BP4 rhizomes



Processing of plants in BSU



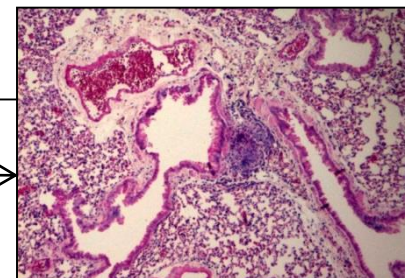
Product development



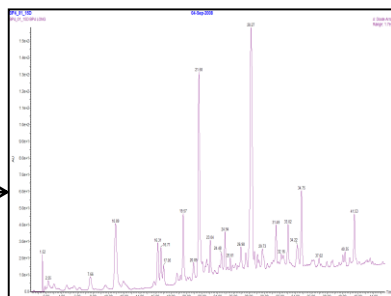
Cultivation



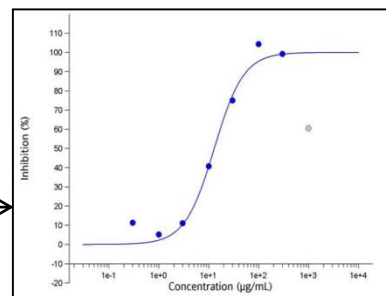
IP protection: International Patent (WO/2007/113698)



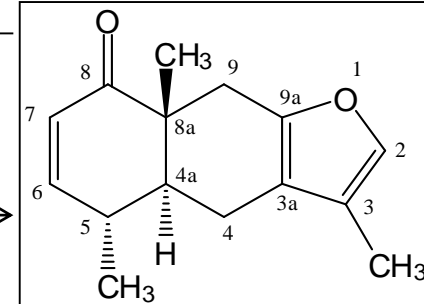
*In vivo* bioassaying – significant ↓ in lung inflammation (viz. IL8; cell infiltration; eosinophils + neutrophils in BAL), no toxicity



Chemical profiling + optimisation of herbal preparation



*In vitro* bioassaying – most potent activity at glucocorticoid receptors



Bioassay guided fractionation – active ID

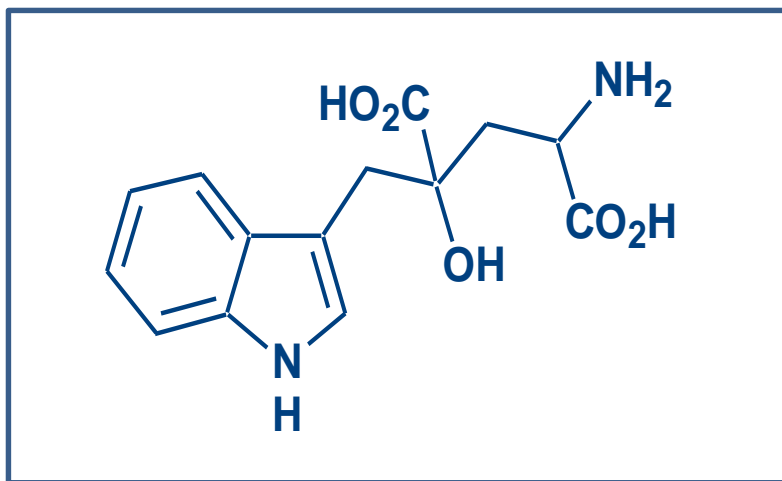


# African ginger programme – tissue culture



# CSIR ABS case: “Molomo monate”

- Molomo monate is found predominately in the Limpopo region
- Local communities including the Traditional Health Practitioners associate molomo monate with its traditional uses
- Molomo monate means, according to local communities and Traditional Health Practitioners, using the medicine makes one words “sweet” or convincing
- Local communities: Seleka and Shongoane in the Limpopo Province
- R&D: monatin compound





# CSIR-Seleka/Shongoane benefit sharing agreement process

- ❖ The process of negotiating benefits with the Seleka and Shongoane Communities took for almost a year to complete
- ❖ The process entailed visits and meetings with communities; introducing the project; explaining the project; and discussions until benefits were agreed
- ❖ The Seleka and Shongoane Traditional Leadership negotiated on behalf of communities, respectively
- ❖ The National Department of Environmental Affairs, which is the custodian of the National Environmental Management, Biodiversity Act of 2004, was involved in the entire process to ensure transparency and equitable sharing of benefits between the CSIR and these communities is fair

# CSIR-Seleka/Shongoane benefit sharing agreement negotiation



**Seleka Traditional Leadership**

**Shongoane Traditional Leadership**



# Signed CSIR-Shongoane benefit sharing agreement

## BENEFIT SHARING AGREEMENT BETWEEN

### THE CSIR

a statutory council established  
in terms of Act No. 46 of 1988  
herein represented by Mr Chris Sturdy  
in his capacity as Chief Financial Officer and he being duly authorised thereto

(hereinafter referred to as "CSIR")

and

### SHONGOANE COMMUNITY

An indigenous community of Lephalale, Limpopo Province in the Republic of South  
Africa and herein represented by  
Mrs Shongoane in her capacity as  
Chief and she being duly authorised thereto

### SIGNATURES ON BEHALF OF THE CSIR:

Signed by Mr Chris Sturdy in his capacity as Chief Financial Officer of the CSIR and  
duly authorised to contract on behalf of the CSIR

.....  
Mr Chris Sturdy

### AS WITNESSES

1. ....
2. ....

### SIGNATURES ON BEHALF OF THE SHONGOANE COMMUNITY TRUST

Signed by Mrs Shongoane in her capacity as Chief of the Shongoane Community  
and duly authorised to contract on behalf of the Shongoane Community

.....  
Chief Shongoane

### AS WITNESSES

1. ....
2. ....

AS  
PS

**Benefit sharing agreement approved by the  
Minister of Environmental Affairs through the recommendations from the  
Bioprospecting Expert Group**

# Signed CSIR-Seleka benefit sharing agreement

## BENEFIT SHARING AGREEMENT BETWEEN

### THE CSIR

a statutory council established  
in terms of Act No. 46 of 1988  
herein represented by Mr Chris Sturdy  
in his capacity as Chief Financial Officer and he being duly authorised thereto

(hereinafter referred to as "CSIR")

and

### SELEKA COMMUNITY

An indigenous community of Lephalale, Limpopo Province in the Republic of South  
Africa and herein represented by  
Mr Seleka in his capacity as  
Chief and he being duly authorised thereto

M.H. A-S  
PBS. in 10  
M.H. M.V. Otsone

## 14. PERFORMANCE



The PARTIES shall do all acts and sign all such documents as may be required  
from time to time in order to implement and carry out the terms and conditions  
of this AGREEMENT.

### SIGNATURES ON BEHALF OF THE CSIR:

Signed by Mr Chris Sturdy in his capacity as Chief Financial Officer of the CSIR

  
Mr Chris Sturdy

### AS WITNESSES


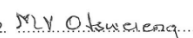
1. 
2. 

### SIGNATURES ON BEHALF OF THE SELEKA COMMUNITY TRUST

Signed by Mr Seleka in his capacity as Chief of the Seleka Community and duly  
authorised to contract on behalf of the Seleka Community

  
Chief Seleka

### AS WITNESSES

1. 
2. 

M.H. A-S  
PBS. in 10  
M.H. M.V. Otsone



# Monetary benefits

- ❖ R2.6 million milestone payment by CSIR into the National Bioprospecting Trust Fund as required by the Biodiversity Act of 2004 in 2016
- ❖ R1.3 million for Seleka and R1.3 million for Shongoane
- ❖ The National Bioprospecting Trust Fund is managed by the National Department of Environmental Affairs as required by the Biodiversity Act
- ❖ Monetary benefits were paid into the bank accounts of the Seleka and Shongoane Traditional Leadership, respectively by the National Department of Environmental Affairs
- ❖ Monetary benefits to be used towards community development projects

# Conclusions

- ❖ South African policy and legislative framework on TK and ABS
  - IKS Policy affirms the TK as part of the research and innovation processes
  - Biodiversity Act provides research institutions the framework to protect the rights of local communities: PIC, MAT and BSA
  - Patent Amendment Act
- ❖ TK protection and plant genetic resources management
- ❖ CSIR has a long history research based on TK and plant genetic resources
- ❖ Community enterprise development (CSIR Enterprise Creation for Development)
- ❖ Capacity building (local communities)

**Thank you**

**sbareetseng@csir.co.za**

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**Mobile: +27 82 332 8367**



**Strictly confidential**