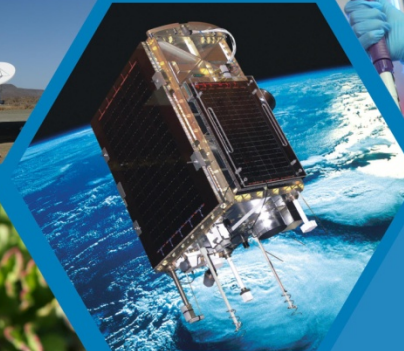


# Building API manufacturing in South Africa



science  
& technology

Department:  
Science and Technology  
REPUBLIC OF SOUTH AFRICA



# Problem

- Rise of low price generic manufacturers in the Asia Pacific regions
  - China dominating the fine chemicals sector - critical intermediates, reagents, high quality solvents and packaging
  - Indian dominate the API side
- Since 2006 SA government concerned about the security of supply of ARV APIs & high cost to the fiscus.
- Initiated concerted effort to attract global API to establish operations in the country.
- Despite incentives such as grants, tax rebates, co-funding and preferential offtake agreements -- little success was achieved
- Some API capacity: Fine Chemicals Corporation and emerging new API manufactures: Chemical Process Technology Pharma and Inicio.





# Challenges

- **High cost of local manufacturing**
  - High cost of equipment (glass lined vessels, valves, instruments, purification units, etc) due to lack of local engineering and manufacturing capabilities
  - dire shortage of process and project engineers & construction companies experienced in API (cGMP) plant
  - Waste regulations in South Africa contribute to both high capital and manufacturing (waste mitigation) costs.
  - nearly all reagents, intermediates and specialized solvents would have to be imported from far off regions at high logistics costs.
- **Lack of national API focus**
  - needs to demonstrate capability in either producing new/modern APIs cost competitively or achieves radical innovation in existing high demand APIs
  - silo approach by researchers (own publications, patents or pet projects)





# Challenges

- **Lack of relevant skills**
  - process chemistry, process engineering (cGMP standards), project engineering, project management, process operations, maintenance and process quality control and assurance.
  - platform for skills development - to enable a sustained pipeline of multidisciplinary skills for the envisaged API industry expansion.
  - entrepreneurial thinking
  - attract young talent in establishing niche businesses within the API manufacturing sector.
- **Small local market size**





# Options

**Strategy A:** Attract large API manufacturers to establish manufacturing capabilities in South Africa.

- Tried with little success
- main hurdles: high cost of investment, manufacturing costs and lack of skills
- IF want to pursue: much attractive incentive basket that address key investment decision drivers, e.g.
  - dedicated API and fine chemicals industrial park with pre-approved environmental license,
  - established infrastructure -- central waste processing facilities,
  - competitively priced and secure utilities supply,
  - fast tracked licenses and approval processes,
  - skills incentives and expat support,
  - capital incentives, manufacturing rebates, export incentives and other tax incentives
- However will need additional support: operational cost subsidies or rebates, price premiums and/or preferential procurement





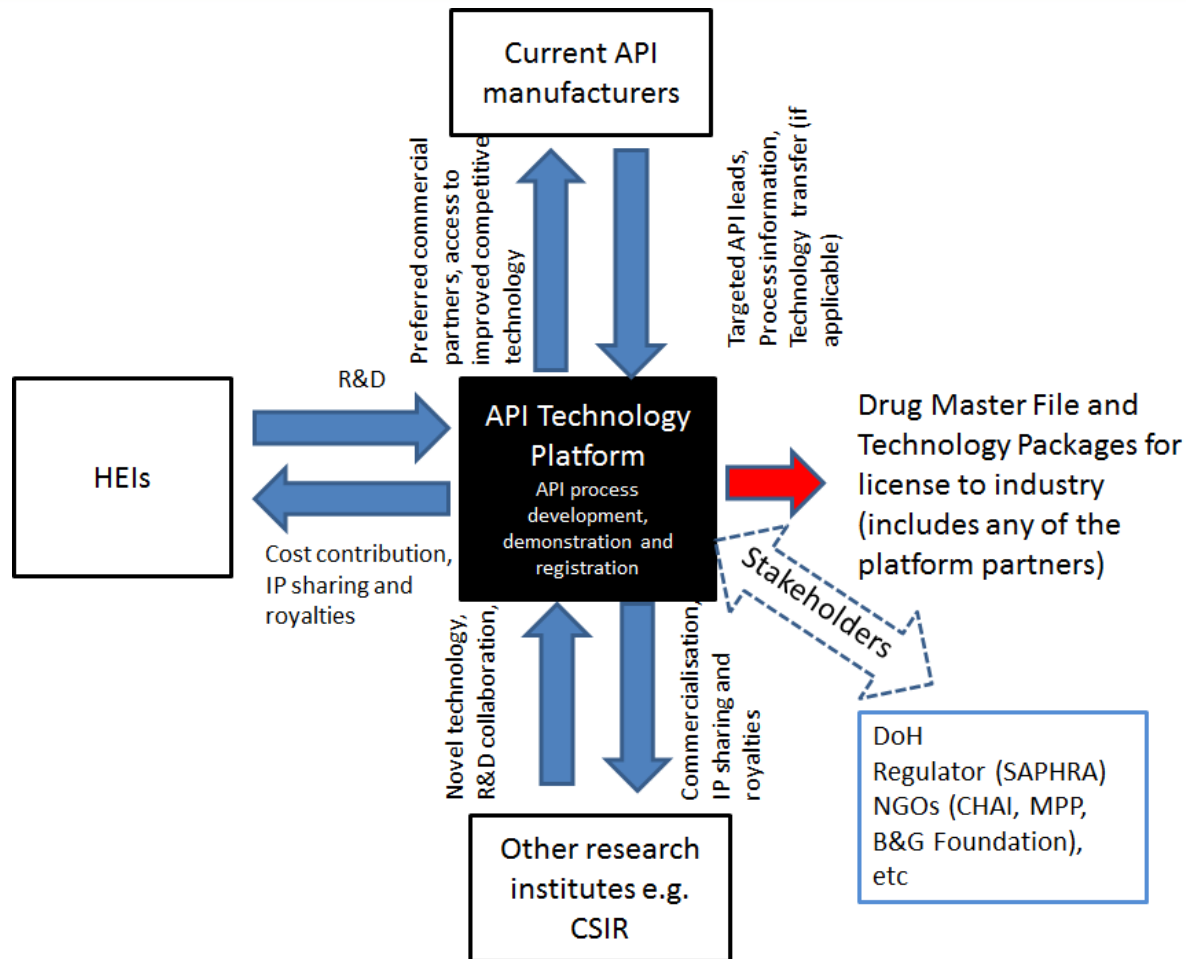
# Options

**Strategy B:** Adopt an aggressive home developed technology strategy which can be used to lever collaboration and partnership with large multinational API producers.

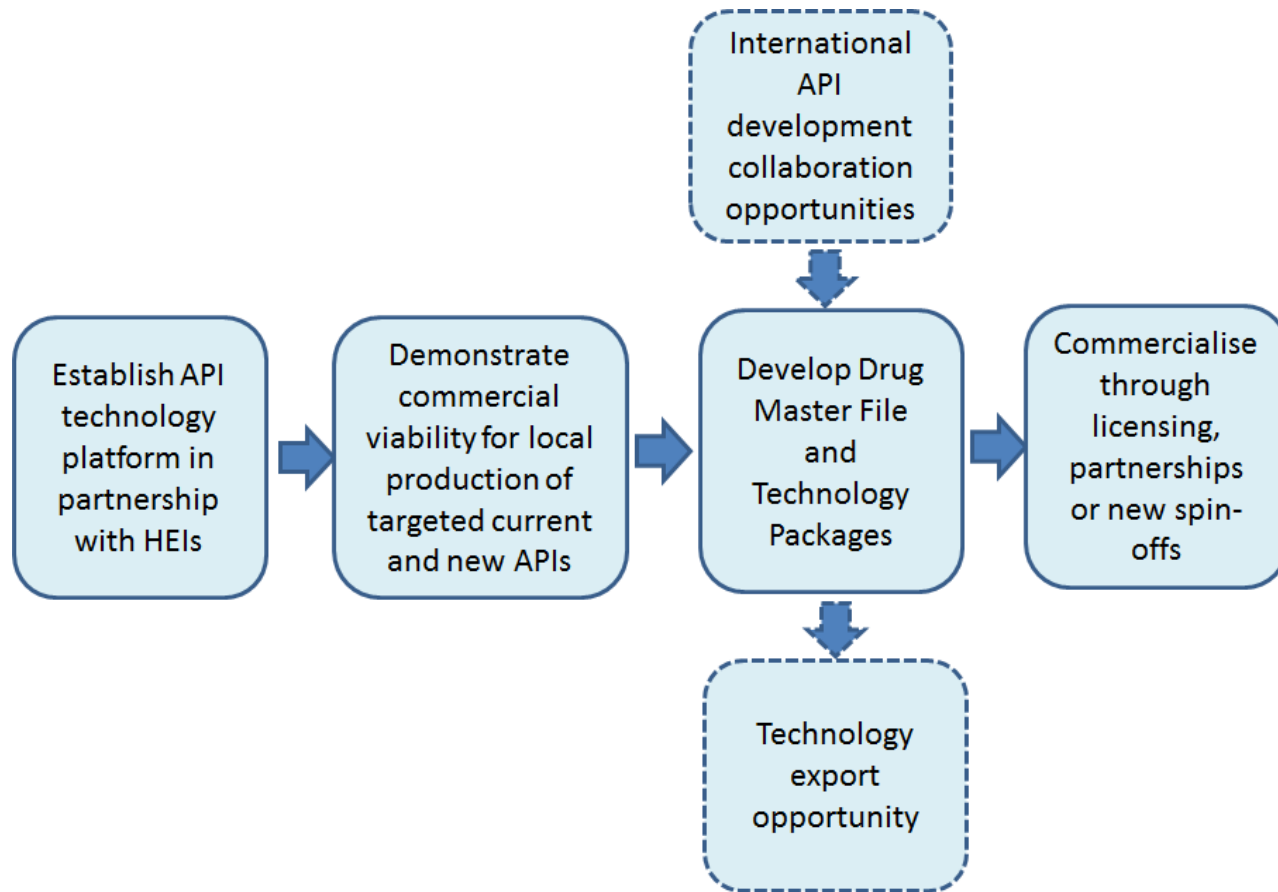
- realigning current capabilities residing at various HEI and other research institutes towards a focused API process synthesis and engineering platform,
- developing drug master file for competitive manufacturing of targeted APIs
- leveraging this to set-up a commercial pipeline for local API manufacturing



# Envisaged platform and main role-players



# Proposed API development model for South Africa







NRF,  
DST special  
project.  
Company  
sponsored

**Current academic program (Universities)** **A**

- Basic synthetic chemistry
- Drug discovery
- Drug delivery
- Therapeutic drug monitoring for treatment design
- QA development ?

SPII  
TIA  
NIPP (investment and subcontracting, tech transfer)  
Revenue through contract manufacturing and niche sales

Black Industrialist Program,  
IDC, NEF  
NIPP, dti grants and IPAP instruments,  
SADC Pharma Development priority

TIA,  
Provincial funding instruments e.g. EDTEA (KZN),  
Focused DST project

**API technology development platform** **B**

- 50/50 eng/Sci driven **process** development program
- Target new APIs or ones with supply risks
- Demonstrate current commercial patented route.
- Develop new optimised routes – competitive advantage
- New technologies (flow chemistry) – competitive advantage
- Waste elimination, recycling, re-use
- Contract research and process development
- Engineering and commercial focused

**National cGMP Pilot Plant (CoC)** **C**

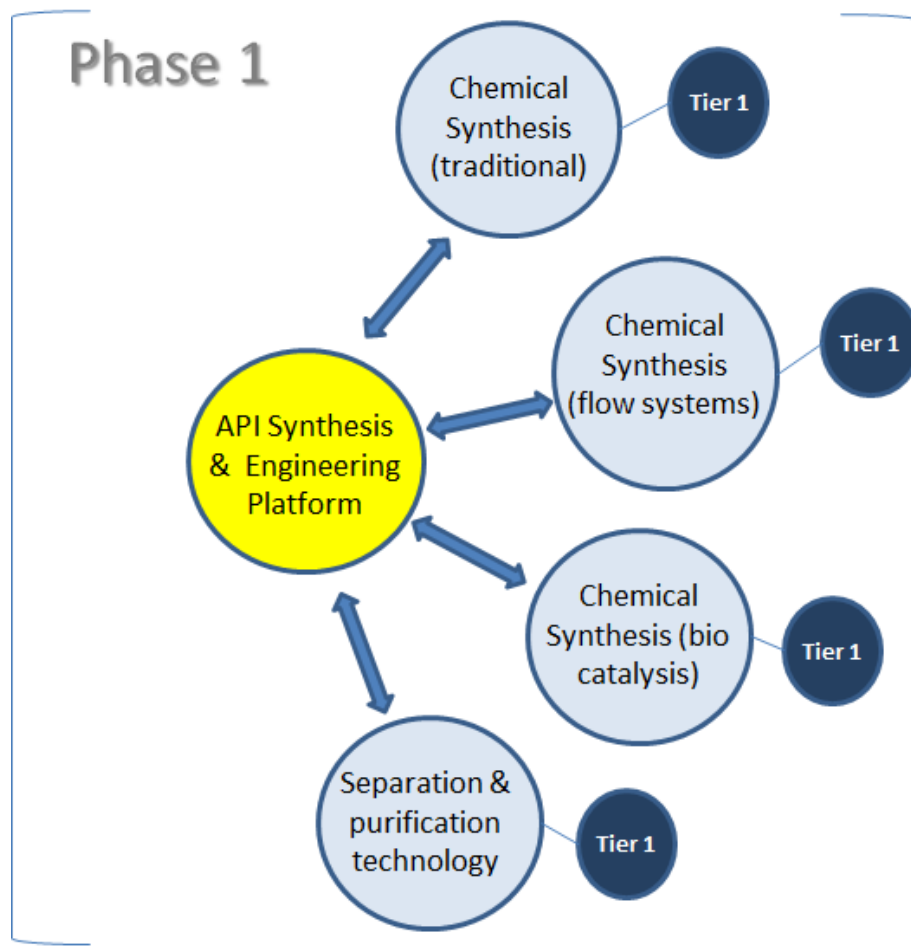
- Technology demonstration
- Tech transfer for tech licensing
- Post tech acquisition development
- Product and process registration
- Small scale production for clinical trials and niche sales
- Niche contract manufacturing – APIs and intermediates
- Contract process scale-up work

**Commercialisation** **D**

- New start-ups or spinoffs leveraging black industrialist and NEF programs
- Partnership with local and international industry players
- Optional state participation
- Toll manufacturing for originators based on new process engineering developed



# API technology platform phase 1 strategy



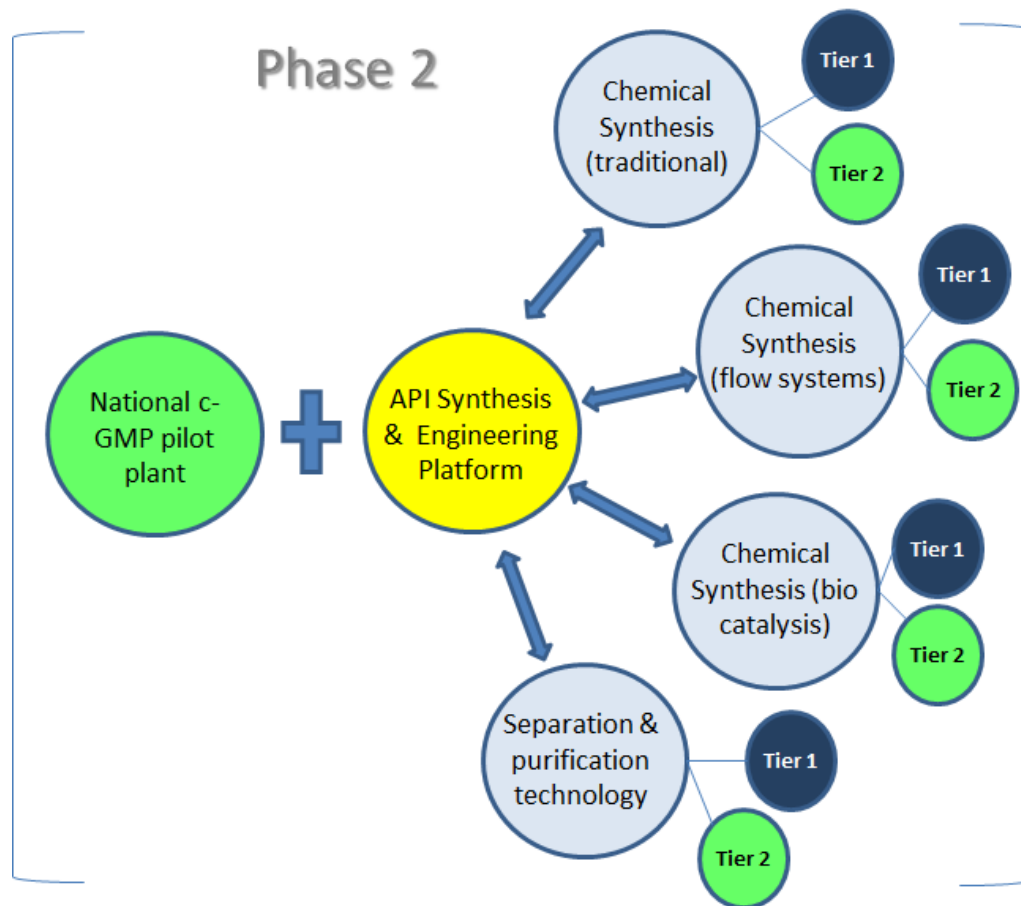
## Aims

- Establish the API tech platform
- Establish desired network with synthesis research groups (Tier 1) and develop tech development distribution model
- Test candidate API screening process

## Outputs

- Process synthesis technical report (TRL-3) of nominated APIs.
- Proposal on national pilot plant strategy.

# API technology platform phase 2 strategy



## Aims

- Incorporate Tier 2 players into the platform
- Establish national cGMP pilot plant
- Promote platform for collaboration with industry players
- Promote platform for collaboration with international API research groups

## Outputs

- Drug Master Files
- Process synthesis technical report (TRL-3) of at least 2 nominated APIs.
- Proposal on pilot plant strategy.



# Vaccines and Biologics



## South African Vaccines and Biologicals Value Chain and its Players

