



science & innovation

Department:
Science and Innovation
REPUBLIC OF SOUTH AFRICA



Request for Applications (RFA):

**Using new, improved technologies to manufacture APIs of
need for Africa**

APIC-RFA-1

Release Date: 14 August 2020

Closing Date: 5pm CAT 30 September 2020

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1. Introduction

The local manufacturing of active pharmaceutical ingredients (APIs) has been a priority of the South African government since the large-scale roll-out of government sponsored anti-retroviral (ARV) treatments for HIV/AIDS infected patients. Reliance on the importation of finished drugs or the API itself not only places the country with a security of supply risk, but also results in a significant trade deficit for the pharmaceutical sector.

Attempts to establish local API manufacturing by attracting multinationals with these capabilities have not been successful due to South Africa. To drive technology development and commercialization of API manufacturing in South Africa, an API Technology Innovation Cluster Program (API-TICP) has been established to stimulate industry competitiveness through leveraging the strengths of South African academic research labs and to integrate forward to develop manufacturing capabilities in South Africa to address the supply of strategic molecules.

Hosted by North West University (NWU) and residing under the Technology Innovation Agency (TIA), the Technology Innovation Cluster Program will focus on aligning current capabilities residing at various Higher Education Institutions, Science Councils and commercial companies towards establishing a National Programme focused on small molecule APIs for human health using modern manufacturing technologies.

The goal of this call is to make several awards to researchers who seek to develop and employ technologies to improve the manufacturing process for drugs of need for Africa by demonstrating synthesis of the selected small molecule API at laboratory scale (Technology Readiness level 4).

2. Funding opportunity description

The API-TICP cluster is providing seed funding of up to R2M for this RFA to support several projects specifically seeking to generate synthetic process improvements for APIs of need to develop technology competitiveness.

These improvements may include:

- New API synthesis routes – shorter reaction steps, improving yields, etc. – better than existing processes,
- An alternative route using a strategically inexpensive starting material; using an intermediate from an existing process is ideal.
- Telescoping stages for maximum efficiency to improve the robustness and purification of the process.
- Offering high “atom economy,” creating minimal waste or potential for waste recycling *via* a greener process.
- Utilisation of less hazardous and toxic solvents

In terms of drug molecules, we are interested in receiving proposals for:

- Molecules on the essential drugs lists of South Africa whose patents may have expired and where there is a **CLEAR MARKET NEED**
- Molecules for potential scaling for applications in COVID-19 response.
- Drugs of demand for Africa – such as anti-bacterials, anti-retrovirals, new anti-malarial drugs etc.

These may be extensions of existing projects funded by TIA, the Department of Science and Innovation (DSI) as well as other funders - if there is demonstrated proof of concept.

3. Eligibility

This is an open call for proposals from researchers, universities, science councils and other public research organisations, including:

- Any institution approved by the Minister of Science and Innovation for NRF funding
- Locally registered not-for profit research organisations whose primary purpose is to conduct research and/or product development, and are working with a local university of science council – such entities should preferably have at least one local university or science council collaborator and may be subject to due diligence before the award of funds
- Local private sector partners can apply as subcontractors on applications received from academic PIs if the University is not able to conduct all of the research in-house

Applicants / principal investigators (PI) must be South African citizens or permanent residence holders. While there is no limit to the number of applications submitted per institution, principal investigators may only submit one application each as the principal investigator but may be involved in more than one application if listed as a co-investigator.

4. Application Process and Timeline

It is critical that applicants follow the instructions in this RFA. **Applications will not be processed further or considered for funding if they:**

- Are deemed non-responsive to the specific topics included in this RFA
- Are received after the deadline for submission
- Are incomplete, i.e. do not have **all** sections of the proposal and budget templates completed and all requested supporting documents attached
- Are from non-eligible organizations

All applications must be submitted using the API-TICP Proposal template available. The submission must include the following:

- the fully completed Proposal Template signed by the relevant authority at the institution and the PI – the proposal may be submitted as a Word document with a separate scanned pdf with signatures or a converted pdf document with signatures
- CV of the principal investigator

The full set of application documents must be emailed to Liezl-Marie Scholtz (API-RFA@nwu.ac.za) by 5 pm SA time on 30 September 2020. Any applications received after this date and time will not be accepted.

The timelines for the application process are shown in Table 1.

Table 1 Application timelines:

RFA Release Date	14 August 2020
Application Due Date	30 September 2020, 5pm SAST
Peer Review of Applications	October-November 2020
Internal Approvals	November 2020
Notification of Awards	December 2020

5. Review and Evaluation of Proposals

There will be a two-step review and evaluation process:

1. Internal API-TICP members will screen applications for responsiveness to all the specified administrative and procedural provisions required in the RFA.
2. National and international peer review to assess the scientific merit (and other review criteria as specified below) of applications found to be responsive to the RFA.

Peer review

Each responsive and complete application received by the due date will be reviewed by local and international reviewers who are experts in the RFA priority areas. Reviewers will consider each of the review criteria below in determining scientific and technical merit and provide an overall score for the proposal.

Significance

Does the proposal fit well within the objectives and scientific remit set out in the RFA? Is the technology improvement measurable and scalable? Is the chosen API of importance to (South) Africa? What is the market size? What is the IP status of the molecule? Is the molecule on the priority drug list?

Investigator(s) and research team

Are the PIs, collaborators, and other researchers well suited to and qualified to undertake the project? Do they have international scientific standing in the field, including publications and citations? Is the PI experienced in the area?

Environment

Will the scientific environment in which the research will be conducted contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the proposed project? Will the project benefit from unique features of the scientific environment, existing research programmes collaborative arrangements or other resources?

Methodology and Approach.

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are the milestones and deliverables clearly thought through and articulated? Are potential problems, alternative strategies, and benchmarks for success presented? Has any preliminary or pilot work been done to inform the design and feasibility of the study? Are the plans feasible, with a realistic timeline? Is there credible supporting data on which the study is based (applicants must supply this). Are all of the necessary components for product development in place and/or available to the investigators?

Funding:

Is there any co-funding that can be leveraged for projects?

6. Selection of Awardees

The award of grants emanating from this call will be determined by the TICP Steering Committee and the taking into account the results of the peer review process as well as national strategic imperatives which may also consider additional factors, such as geographical and institutional diversity and transformation in making its final determinations.

Based on the scientific merit of the applications and/or budget limitations, the TICP may award fewer or more grants than expected and may elect not to allocate all of the available funds to awards from this RFA.

7. Important Information

- The TICP may seek to verify any information provided by applicants through independent research or by third parties approved by the TICP.
- The TICP assumes no responsibility for costs incurred in responding to this RFA or any further invitations or communications.
- The TICP reserves the right to amend or withdraw the RFA at any time.
- Successful awards may be subject to addressing reviewer comments and/or negotiation of project plans and budget.
- Grants will be paid to the institution where the principal investigator is employed, as set out in a funding agreement to be concluded between the parties.
- No grant funds will be paid over until proof of the necessary ethics and regulatory approvals for the project have been provided to the TICP. Should the investigators fail to obtain the necessary approvals within a reasonable time period, the TICP reserves the right to withdraw the award.
- The TICP may use text, video or other visual representation submitted by successful applicants on the NWU website or on materials for publicity and/or public awareness.

8. Contact Details

Please direct any requests for information and questions/queries on this RFA **by email** to Liezl-Marie Scholtz at API-RFA@nwu.ac.za