25 May 2020

**Making HealthCare affordable by strengthening the South African Pharmaceutical Value Chain**

**The Technology Innovation Agency (TIA) in collaboration with the Department of Science and Innovation (DSI) and the North-West University (NWU) announce the establishment of a Local Manufacturing Active Pharmaceutical Ingredient (API) Technology Innovation Cluster, that aims to:**

**“Enable a dynamic South African pharmaceutical manufacturing industry with access to critical and modern drugs through innovative and world-class processing technology”**

The Active Pharmaceutical Ingredient (API) cluster could be what South Africa needs to save on the billions of Rands it currently spends importing APIs for medicines. The cost of pharmaceuticals is contributing to the high cost of healthcare in South Africa, with the country spending approximately R15 billion a year on imported APIs.

The API cluster represents TIA’s approach to assessing value chains and stimulating the development of activities and interventions to facilitate sector or industry-level engagement through the crosscutting approach adopted in the Technology Innovation Cluster model. This approach is intended to address systemic weaknesses that hamper innovation and commercialisation beyond just the provision of funding to individual projects.

The joint R13 million investment to establish the API Technology Innovation Cluster aims to drive technology development and commercialisation of API manufacturing in South Africa by focusing on the synthesis of small molecule APIs for human health using modern manufacturing technology. Emerging trends and competitiveness of the industry are strong motivators to enhance the security of supply of critical drugs and address the imbalance of imports versus exports in this sector, positioning the country as a strategic regional API manufacturing hub.

The cluster will stimulate industry competitiveness and world class API manufacturing in South Africa through leveraging existing skills, technologies and facilities available in South Africa. The foundation of the cluster will be an aggressive locally developed technology strategy which can be used to lever collaboration and partnerships within the pharmaceutical sector. The strategy will be underpinned by realigning current capabilities residing at various Higher Education Institutions, Science Councils and commercial companies towards a focused API process synthesis and engineering programme. The goal is the development of Drug Master Files for competitive manufacturing of targeted APIs and leveraging this to set-up a commercial pipeline for local API manufacturing. The intention is thereby to successfully demonstrate South Africa’s potential self-reliance on establishing API manufacturing capabilities.

With support from actors across the value chain such as the National Department of Health, the Department of Trade, Industry and Competition, the Industrial Development Corporation and the various Industry Associations, the cluster aims to establish a cohesive approach to the development of the pharmaceutical sector’s value chain, by localising production of this primary input material which is otherwise imported, thereby creating further economic value within the country. The collaborative approach supports not only technology development but joint advocacy and lobbying in unlocking constraints within the policy and regulatory environments, as well as challenges within the local procurement value chain to ensure market uptake of the APIs.

Provision of pharmaceuticals is governed by procurement policy, with several routes for delivery of the products to patients.[[1]](#footnote-1) The complexity of the sector is compounded by a pathway that runs from drug discovery through to manufacture and then retail, with various points of integration. Strengthening the ecosystem will enhance linkages in the already fragmented value chain that has several channels within its distribution network for both the private medical and public sectors by retaining the economic value created between API suppliers, final product manufacturers, drug procurers and the end user. Molecules to be synthesized will be carefully selected amongst the key role players and decision makers within the cluster and will be considered across various disease burdens and based on technical viability and commercial potential.

The investment in establishing local API manufacturing capabilities will have a number of direct and indirect benefits on the South African economy, such as:

* Reduction of the high reliance on imported APIs and contribution towards reducing the national trade deficit in the pharmaceutical sector;
* Leveraging funding from local and international funding sources;
* Job creation through the establishment of new manufacturing facilities; small, medium and micro-sized enterprise development and supporting the advancement of black entrepreneurship in the pharmaceutical manufacturing sector;
* Improved productivity of the industry;
* Training and capacity building for the pharmaceutical sector across the value chain; and
* Development and diversification of the chemicals sector, export of APIs to the SADC region and human capital development.

In ensuring the commercial translation of the API molecules synthesised toward full scale production, the cluster is also establishing a dedicated pilot scale regulatory compliant API chemical laboratory which will support the analytical testing required during the synthetic process of API molecule development. This laboratory will serve the analytical needs within the API cluster and be accessible to all industry parties. The laboratory is intended to be hosted by an industry facing partner and will play a critical role in technology translation between the Higher Education Institutions and manufacturing scale-up.

In the wake of the current global Covid-19 pandemic, the negative effects of limitations on international trade currently directly impact ability to import APIs from countries such as China and India and hence affects the provision of drug products within the South African healthcare system. South Africa’s current dependency on these countries for API raw material is further motivation for the investment in promoting local API manufacturing thereby ensuring security of supply of essential drugs.

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1. SADC, SADC industrialization strategy and roadmap 2015-2020, 2015 [↑](#footnote-ref-1)