

Equipment / Infrastructure Support for the Research, Development, Testing, Pilot Scale Production and Regulation of Vaccines in South Africa



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Non-compulsory Briefing Session
26 June 2024

BACKGROUND

- The German development cooperation with South Africa has a long-standing relationship in the health sector, which has included substantial financing support during COVID.
- In 2021, a feasibility study and an appraisal mission to South Africa was conducted by KfW and its consultants, management4health, on “*How to fill gaps of vaccine production?*”
- At government negotiations between the German Federal Ministry for Economic Cooperation and Development (BMZ) and the South African Government in October 2022, pledges were made for bilateral development cooperation in the health sector in the area of **vaccine production**.
- Consequently, the German government is committed to supporting vaccine production in South Africa.



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PROGRAM OVERVIEW

The purpose of the Program is to address the gaps and strengthen the infrastructure for vaccine research, development, pre-clinical testing, pilot-scale production and regulation in South Africa. This will contribute to the sustainable production of vaccines (beyond Covid-19) and will manifest South Africa's leading role as a researcher and manufacturer of vaccines on and for the African continent.

Funder: Government of the Federal Republic of Germany through KfW Development Bank

Recipient of the Funding: South African Government via Department of Science and Innovation (DSI)

Project Executing Agency: South African Medical Research Council (SAMRC)



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AREAS TO BE SUPPORTED THROUGH THE PROGRAM

No.	Support Area	Outcome	
1.	Pilot Vaccine Production	(a)	Procurement and installation of equipment at a pilot plant for active pharmaceutical ingredients (APIs) using mRNA technology.
		(b)	Procurement and installation of equipment at a pilot plant for vaccine APIs with other than mRNA technology.
2.	Research and Laboratories	Procurement and installation of laboratory equipment and support infrastructure (including IT) for upgrading and modernizing research facilities (including animal facilities) and laboratories, including the National Control Laboratory.	
3.	Training	Procurement and installation of laboratory training equipment potentially attached to a pilot plant or equivalent facility.	
4.	Regulation	Procurement and installation of equipment supporting the digitalization as well as the regulation capacities at SAHPRA.	

Total investment of up to €17M = ~ R300M for components 1-3



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TARGETED ACTIVITIES

- Genetic sequencing for immunogen identification
- Immunogen design
- Development of vaccine platforms / technologies
- Development of vaccine candidates
- Development of vaccine delivery mechanisms and carrier molecules
- Formulation of vaccines
- Preclinical testing of vaccine candidates
- Immunogenicity assessment of vaccine candidates
- Data management for the above activities
- Pilot-scale manufacture of mRNA-based vaccines under Good Manufacturing Practice (GMP)
- Pilot-scale manufacture of non-mRNA-based vaccines under GMP
- Quality testing of vaccines
- Production of reagents for vaccine manufacture
- Laboratory training on vaccine technology (potentially linked to a pilot plant or equivalent facility)
- Regulation of clinical trials and vaccines (limited to the national regulator)
- Other vaccine-related research and/or development activities not listed above may be considered

REQUEST FOR APPLICATIONS

- This RFA is seeking program **Implementing Partners** to receive support for the procurement and installation of equipment/infrastructure specifically required for one or more of the targeted activities listed on the previous slide
- The program will cover the direct costs of the equipment and, where applicable, infrastructure upgrades
- The program is being implemented through this open competitive call – there will be no invitations to specific organisations to submit applications, with the exception of SAHPRA for component 4



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ELIGIBILITY CRITERIA

Eligible Entities:

South African public and private entities involved in the areas of vaccine research, development, preclinical testing and pilot production listed previously

Must be registered in SA or established by legislation in SA

The RFA is aimed primarily at South African Public Universities and South African Public Research Entities, namely Science Councils, National Facilities, and other recognized research institutions as declared by the DSI and national laboratories involved in the testing of vaccines and other biologicals

Pilot production facilities that are not GMP-accredited must submit plans and a timeline for obtaining GMP accreditation



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ELIGIBILITY CRITERIA

Eligible Applicants:

Minimum criteria

- Must be employed at an eligible entity for at least 3 years from the time of submission of the application – if not, a co-applicant must be included as a potential successor to take over the management of the equipment
- Must have a demonstrated track record in research and/or training and/or production (as applicable) relevant to the proposed use of the equipment and infrastructure
- Must be actively involved in the utilization and management of the equipment in line with the objectives of the project
- For **research** equipment and infrastructure applications (component 2) - must have held a doctoral degree for at least 5 years prior to the application

Co-applicants with demonstrated applicable track record and who will co-support the utilization and management of the equipment in line with the objectives of the Project may be included

WHAT CAN BE REQUESTED

- One or more single instruments or multiple complementary instruments that are collectively required to achieve a research, development, testing or production purpose
- Significant information technology (IT) infrastructure (e.g. software systems) required to operate such instruments
- In the case of public research institutions and national testing laboratories, upgrading or modernizing of building infrastructure (construction / renovations)
- The **total cost** of acquisition may include a full 5-year maintenance plan and costs associated with the delivery, installation and commissioning of the equipment
- Applicants may submit applications in different areas of support, i.e. 1(a); 1(b); 2; or 3 but must submit a separate application for each area
- There is no limit to the number of applications submitted by a single entity; however, applications from the same entity must be coordinated to ensure that there is no duplication between applications
- Applicants must ensure that the equipment requested is not already available within their departments or institutions and/or between regional institutions

NON-FUNDABLE ACTIVITIES / NON-ELIGIBLE COSTS

- Import duties and other taxes
- Equipment maintenance, warranty, servicing, and insurance (unless provided for by the supplier as part of the procurement of the equipment)
- Back-up systems for the equipment
- Operational costs for the equipment
- Consumables, except as supplied on purchase of the equipment for training and commissioning purposes
- Research activities/projects
- Salary contributions
- Working capital
- Travel
- Other operational costs such as rent, administration, grant management, etc.
- Overheads

**** Research projects will not be funded through this RFA ****

APPLICATION PROCESS AND TIMELINES

Process Stage	Due Date
RFA Release Date	14 June 2024
Non-compulsory briefing session	26 June 2024
Application Due Date	26 July 2024
Review of Applications	August 2024
Approvals	August – September 2024
Notification of Awards	September 2024

Procurement from October/November 2024

HOW TO APPLY

- All applications must be approved by the relevant authorized representative of the entity (Deputy Vice Chancellor, Chief Executive Officer, Chief Financial Officer or equivalent) through a signed Declaration and Letter of Commitment uploaded on the system
- Applications with all supporting documents must be submitted online – no emailed applications will be accepted
- The online system will close at midnight on 26 July 2024 – **no late submissions will be accepted**
- Do not leave it to the last minute to submit – power failures, IT challenges, etc. will not be accepted as justification for late submission
- Please find out now what your internal cut-off date is for institutional review and approval
- Applications must include the following supporting documents:
 - CVs of the applicant and any co-applicants – CVs must be up to date and demonstrate experience and a track record relevant to the application;
 - Proof of registration and/or establishment of the entity in terms of legislation;
 - For non-public entities, an organizational profile, including ownership and governance structure;
 - Detailed quotes for the proposed equipment / infrastructure upgrades and pictures, where available;
 - Completed Summary Spreadsheet summarizing the items requested and estimated costs; and
 - Declaration and Letter of Commitment signed by the DVC, CEO, CFO or equivalent

IMPORTANT CONSIDERATIONS WHEN COMPLETING APPLICATIONS

- If applying for more than 1 component (1(a), 1(b), 2 or 3), complete a separate application form for each
- Ensure all that sections of the application form are completed in full, accurately and comprehensively
- We can only evaluate the applications based on the information provided
- Complete a new table for each item of equipment requested unless requesting a multi-component system
- Fully motivate for the need for the equipment and how it will contribute to the objectives of this Program
- Motivate if a particular brand or supplier of equipment is required
- Only public research institutions and national testing laboratories may apply for infrastructure upgrades
- **There is no maximum value for each application submitted or each item of equipment applied for**
- **The minimum value of an individual item of equipment should be R1,000,000 including VAT**

POST-AWARD



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PROCUREMENT

Procurement will be initiated following the approval of an implementation plan and procurement plan by KfW and the SAMRC Board

Procurement will be done by SAMRC through:

- Open tenders (PFMA-compliant)
- Sole- and/or single-source supplier route (where a specific supplier is required)

Suppliers will be paid directly by KfW or the SAMRC - **no funding will be transferred to the Implementing Partner**

Implementing partners will be involved in the development of the specifications

SAMRC will enter into agreements with the Implementing Partners to place the equipment

- For public entities – ownership of the asset will be transferred to the entity
- For private entities - ownership of the asset will remain with the SAMRC
- Placement arrangements for equipment at private entities will be for an initial period of 5 years (post commissioning), whereafter the Project Steering Committee will decide on further arrangements to meet the objectives of the Program

OBLIGATIONS OF THE IMPLEMENTING PARTNERS

- Sign a contract with the SAMRC and DSI to manage the equipment and infrastructure (where applicable).
- Pay any import duties, taxes and other costs that are not covered by the Program
- Provide for all maintenance, servicing, insurance, and backup systems related to the equipment
- Develop a financial model for the maintenance, upgrade and other related operational costs for the sustainable management of the equipment
- Provide appropriate building infrastructure to house the equipment in accordance with the supplier specifications
- Ensure that the equipment is fully commissioned within two (2) years of the award having been made
- Provide appropriately qualified personnel to operate and maintain the equipment
- Provide training on the use of the equipment
- Submit progress reports to the SAMRC from the date of award for a period of five (5) years post the year of commissioning of the infrastructure and equipment

GENERAL

- This is a competitive call for applications and only those demonstrating a clear need for the listed equipment and/or infrastructure and with demonstrable contribution and benefit to the South African vaccine innovation and manufacturing ecosystem may be selected for funding
- ***The SAMRC reserves the right to make no awards and re-advertise a Request for Applications if it so wishes or to cancel the Program altogether***
- Applicants must fully familiarize themselves with the content of the RFA document
- Applying entities must be specifically aware of their obligations if awarded
- Email us with any queries at vaccine.equipmentdfa@mrc.ac.za (please note the corrected email address).

Thank you for attending

Questions?



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Questions and Answers document to follow



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