# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 1249**

**DATE OF PUBLICATION IN INTERNAL QUESTION PAPER: 14 MAY 2021**

**(INTERNAL QUESTION PAPER NO. 13)**

**Inkosi R N Cebekhulu (IFP) to ask the Minister of Health:**

(1) Given the reality brought to us by the COVID-19 pandemic about the importance of investing in scientific research capacity for pharmaceutical production, what strategies has the Government adopted to boost local research capacity in pharmaceuticals;

(2) whether the Government intends to intervene in the pharmaceutical sector to ensure self-reliance in pharmaceuticals; if not, why not; if so, what (a) are the relevant details of the strategy and (b) is the projected timeline?

###### NW1440E

**REPLY:**

1. The SAMRC has a variety of grant programs (both internal and through strategic partnerships) that are supporting drug discovery research and development in key health priority areas. These projects are leading to novel drug targets and candidate molecules and include plant-based medicines as well as biologicals such as vaccines and monoclonal antibodies.

 The Technology Innovation Agency, with funding from the Department of Science and Innovation has established an API Cluster aimed at increasing the capacity of the country to develop the processes and manufacturing capability for the manufacture of active pharmaceutical ingredients. This cluster links innovators at the universities and science councils with industry, including development partners and pilot production facilities. This provides a mechanism to advance new drugs in development by local innovators towards testing and approval. One of the objectives is to synthesise molecules that may have efficacy against Covid to ensure continuity of supply. We are in discussions with international partners round this.

 Government, through the Department of Science and Innovation, is a shareholder in The Biovac Institute, which has embarked on an ambitious journey to bring manufacture of vaccine APIs to the country. Biovac has been pursuing a backward integration strategy and has undertaken technology transfers with major pharmaceutical companies to establish the capacity for formulation, fill and finish of vaccines. It is raising funding to expand this capacity and to add a production suite for antigens/immunogens/biologicals. The same applies for Afrigen Biologics. Biovac and Afrigen are, further, developing its own vaccine candidates. Government has also been supporting the CSIR’s efforts to establish GMP manufacture of biologicals using plant production systems. The team are actively working on a concerted strategy to leverage off South Africa’s scientific investments to see if these can translate into products.

 There are a number of pockets of excellence in drug discovery and vaccine development research in South Africa, situated predominantly at the universities and science councils. A key bottleneck, however, is the pilot scale manufacture of these under GMP conditions for clinical trials and later commercial manufacture at scale. This is where further investment is required to ensure that the full pharmaceutical and vaccine development value chain is in place in the country.

1. On 2 October 2020, India and South Africa proposed the TRIPS Waiver”, a proposal to suspend intellectual property protections for products and technologies needed for the fight against COVID-19, including vaccines, for the duration of the pandemic. This would involve a temporary suspension of certain rules set out in the Trips agreement, the intellectual property treaty of the World Trade Organization (WTO). The waiver proposal by India and South Africa presents an important opportunity for all governments to unite and stand up for public health, global solidarity, and equitable access through a concrete step at the international level that can provide an automatic and expedited solution to address IP and technology challenges collectively.   The TRIPS Waiver proposal is now gaining support from major drug manufacturing countries.

The Department of Science and Innovation, and Trade, Industry and Competition are developing strategies for the local production of pharmaceuticals, especially the production of the active pharmaceutical ingredients.

Inter-Ministerial Committee on Covid-19 vaccines has a DPME lead Technical Working Group tasked with mobilizing local capacity to deliver the dosages required and building a long-term capability step by step using current capacity from upstream to downstream to prepare for the next pandemic. They are starting by looking at the vaccines already developed and approved and those in the pipeline to determine what they can do locally in ensuring dosages by using a fill/finish strategy and then move to how to build capabilities to enable future pandemic response.

The following are key milestones that have been achieved to date:

1. Several partnerships established with current and under development Covid-19 vaccines developers (Biological E partnership; ImmunityBio**;** Centre for Genetic Engineering and Biotechnology of Cuba; Greenlight BioSciencefor technology transfer of mRNA technology; Kentucky Bio-Products; and J&J – already manufacturing locally through Aspen)
2. South Africa have the following competitive advantages which can be used to build permanent State Infrastructure to enable future pandemic response
	1. South Africa has experienced principal investigators who are employees of universities and Science Councils which is an advantage.
	2. Bioanalytical laboratories e.g. North-West University/DSI – Preclinical Drug Development Platform facility has been developed for this purpose
	3. Ethics related expertise including individuals for the data safety and management board
	4. Existing capabilities locally: CAPRISA, SAMRC, AURUM, DESMOND TUTU, WITS HEALTH, AHRI, and others on the clinical research side

END.