Writer: More Matshediso

Removing barriers and promoting access to **health products**

The COVID-19 pandemic turned the spotlight on the South African Health Products Regulator (SAHPRA), with many people expecting the regulator to approve medication that would see the end to the virus, but more often with limited understanding of the processes involved in reaching such a decision. Like many other organisations around the globe, the regulator had never been in a situation where it needed to urgently react to a pandemic of such magnitude.

Dr Boitumelo Semete-Makokotlela led the country's health products regulator through the pandemic and did so with excellence, stringency and integrity.

As the Chief Executive Officer (CEO) of the SAHPRA, Semete-Makokotlela says the COVID-19 pandemic demonstrated that while her organisation is stringent in executing its work, it must also be responsive and agile so that it does not become a barrier for companies that manufacture health products.

The SAHPRA, an entity of the National Department of Health, has at the core of its mandate, the well-being of human and animal health.

"Our mandate is to provide regulatory oversight for health products, including therapeutics, vaccines, medical devices, and In Vitro Diagnostics (IVDs). In essence, our job as a regulator is to ensure that we evaluate, monitor and regulate these products. We also conduct inspections of the facilities, where these products are manufactured, we look at the control of these products," she explains.

Furthermore, the SAHPRA provides regulatory oversight for clinical trials that are conducted in the country. It also issues licences to companies that manufacture health products and ensures that they are compliant.

"When companies are compliant, it shows that [the] SAHPRA is part of a well-functioning sector and that patients are protected," she says.

Her key role is to ensure that the regulator delivers on its functions, has adequate capacity to deliver, complies with good governance practices, and that it is compliant with the Public Finance Management Act, 1999 (Act 1 of 1999) while executing its role.

Leading during a pandemic

As CEO of the SAHPRA, Semete-Makokotlela contributes to access to health products, including medical devices, IVDs, medicines and vaccines.

She joined the institution at the beginning of 2020, shortly before COVID-19 hit South Africa, and her extraordinary leadership is already being recognised.

In 2022, she won a management award at the 24th National Science and Technology Forum Awards for successfully leading the authorisation of a number of COVID-19 diagnostic tests, vaccines and therapies during the pandemic.

"This is really a great achievement, not only for myself but for the team because it was in recognition of the work done by the SAHPRA under my leadership. The team really worked hard to ensure that we are responsive and support the country during the COVID-19 pandemic," she enthused.

"It was good for the organisation to be recognised in this manner. I was quite thrilled personally because it then speaks to my ability to lead a team during very tough times and to ensure that we come out successful," she assented.

Among other achievements, she has also received an award from the Charlotte Mannya Maxeke Institute for the leadership

role that she exemplified during the COVID-19 period.

Semete-Makokotlela's advice to other leaders in the public sector is "ensure that you are able to pull your team together so that you are able to deliver during very difficult periods, as we saw with the pandemic."

She admits that it is not always easy but reckons that leaders have to find tools to enable them to get the buy-in.

Ground-breaking medication

In January 2023, the authority registered Paxlovid, an anti-viral medicine manufactured by Pfizer, to treat mild to moderate COVID-19 in adults who do not require supplemental oxygen and who are at increased risk for progression to severe COVID-19.

She says the regulator is committed to fast-tracking the registration of all health products that are of an urgent nature such as HIV and AIDS, cancer and COVID-19.

As COVID-19 is still a looming threat, she says the registration of Paxlovid heralds a welcome signal in the fight against the pandemic.

She adds that some of the lessons learnt from COVID-19 are around the efficiency and the urgency required in authorising health products, particularly for public health emergency.

"This period showed that we are able to execute our mandate with urgency, although it was a tough process because we had limited resources. Our team had to work lengthy hours, and we had to deploy teams into other areas, which is understandably a public health emergency," she explains.

In December 2022, the authority achieved another milestone when it registered Cabotegravir (Apretude 600 mg/3ml injection),

> "She views being a public servant as an opportunity to shape the country and how it is run."

a long-acting HIV pre-exposure prophylactic. The treatment is expected to be accessible to the public from 2023.

In another win towards the fight against HIV and AIDS, the regulator also approved the use of the monthly dapivirine vaginal ring by adult women in March 2022.

"Our role was to review the product, the basis of its quality, safety and efficacy. As a regulator, we do not get involved in the roll-out of products. We ensure that the product complies with safety, quality and efficacy, and we monitor it through pharmacovigilance processes once it is being rolled out," she says.

Through monitoring, the authority takes note of any adverse events that are being reported by patients who are consuming the product.

"There are many other products for HIV that we continue to look at, and these forms part of our priority review pipeline," she says.

The more the ranges of products that the authority approves, the more options for citizens as far as combating the spread of HIV and AIDS is concerned.

For example, "the dapivirine vaginal ring gives women a mechanism, therapy and a tool that they can utilise to protect themselves," she says.

Accolades from the WHO

The SAHPRA has recently received the World Health Organisation maturity Level 3 status, which means that the regulator is well functioning and has integrated systems.

"This means that people can rely on the decisions that we make. It also means that any product that has been authorised by [the] SAHPRA is compliant with the required legislation and authorisation, it can be exported to other countries, and there can be confidence that the product has been reviewed by a stringent regulator," explains the CEO.

Semete-Makokotlela emphasised that as the regulator works towards building efficiency, it cannot compromise on making evidence-based decisions. Where the regulator is not satisfied with the information that has been provided, the product will not be authorised.

She views being a public servant as an opportunity to shape the country and how it is run and urges others to ensure that they operate with the required stringency, uphold the mandate of their respective institutions and focus on serving the public with excellence, integrity and principles of Ubuntu.

Semete-Makokotlela's wish is to leave behind a legacy of a company that is responsive and agile.

Career journey

Semete-Makokotlela holds a Master of Science in Management Finance and Investment from the University of the Witwatersrand Business School and a PhD in Biochemistry from North-West University.

Her career journey includes working the Council for Scientific and Industrial Research as a researcher before taking up a postdoctoral research fellowship with the University of Nottingham in the United Kingdom and Ecole Polytechnique Fédérale de Lausanne in Switzerland.