Health products regulation in 2020

Professor Helen Rees
SAHPRA chairman of the board

It's been exactly two years since the South African Health Products Regulatory Authority (SAHPRA) was established to replace the Medicines Control Council (MCC) and the Directorate of Radiation Control (DRC).

By Nicky Belseck, medical journalist

TO SAY SAHPRA inherited a disaster from the overwhelmed MCC is an understatement. With a massive backlog of around 16 000 medicine regulatory applications, the organisation had a steep hill to climb.

But the backlog was just one of many obstacles SAHPRA had to face. *Medical Chronicle* spoke to the chairman of the board, Professor Helen Rees, and new CEO Dr Boitumelo Semete-Makokotlela about the road so far, and SAHPRA's plans for 2020.

"We started in the negative zone in February 2018 and are about 60% on track to be a well-functioning authority," said Prof Rees. "To be 100% we will have to get rid of the backlog so I would say another 18 months."

TRANSPARENCY

"True transparency is around communication, and I don't think we do that at all," said Dr Semete-Makokotlela. Prof Rees agreed: "What we recognised is that we have to completely overhaul the way we receive and send out information to applicants, and the way we share information with the broader public. In order to do so and ensure transparency we need to develop an appropriate website and completely overhaul our IT system."

"Communication is required with a much broader stakeholder – public, business, etc in terms of our position on certain matters," said Dr Semete-Makokotlela. "For example, codeine, and there's also transparency around what we're doing with emerging topical areas like cannabis.

"But there also needs to be transparency with our customers," said Dr Semete-Makokotlela. "When they apply for a permit to be registered, our clients need to know how long it's going to take, and where their application is in the process, and we're not there yet. But we need to be transparent about our processes, timelines, and any changes we're going through."

Prof Rees insists this will all be addressed with the new IT system that's being developed. "We're going to be launching it in the first or second quarter when we move into our new buildings and it will make a profound difference."

CLEARING THE BACKLOG

In November 2018, SAHPRA's board committed to a very ambitious timeline to clear the backlog within two years – 10 months from now. However, they have encountered a number of hurdles since then, the biggest of which is funding.

"So far we've been fixing the backlog with a parallel budget where the money has been raised from non-profit foundations and philanthropic sources, primarily the Gates Foundation," said Prof Rees. "We've raised over half of the estimated budget for the backlog, but we have a shortfall. Because I don't think it's going to be possible for us to raise the balance through those same kinds of philanthropic and bilateral funding sources we are in dialogue with treasury. Promisingly we have found with government there's a lot of support coming to us from the job summit National Economic Development and Labour Council (NEDLAC) process. But in terms of clearing the backlog in two years, finding the balance of funds is critical."

The second hurdle is staff capacity. "Getting sufficient skilled evaluators is crucial," said Prof Rees. "The medium to longer-term aim will be to capacitate skilled evaluation more and more from within SAHPRA so that we'd only need to get external expertise in for things like new chemical entities and things that are more challenging. We've got some of that skill, but we need more. In order to train we need mentors and unfortunately mentors are currently limited within SA. So, as well as looking at all our local evaluators who can assist with mentorship, and helping with the backlog, and business as usual, we are having to go and recruit international expertise.

"If we can find the money then we can find evaluators and then our two years is on track. If we can't find the money, we will have another discussion with industry who are very keen to support us."

FINDING THE NEW CEO

"We did advertise the position twice," said Prof Rees. "But then we realised we were asking for too much in just one person. If you wanted somebody who was an exceptional

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regulator with extensive experience, who could also lead the big organisation as well as be strategic thinking, well, to get all of that in one package from SA, was going to be impossible.

As acting CEO, Portia Nkambule was doing everything, which was really impossible," said Prof Rees. We realised we needed somebody who is senior, to oversee all of the technical aspects and backs up all the different divisions, and is there to assist not with the routine work, but with the many problems that will always come up with a regulatory authority, as well as the discussions that need to be had with stakeholders. So that's why we decided to separate the roles and established the position of Chief Regulatory Officer (CRO).

"We wanted a CRO who is a knowledgeable regulator, who is close to health, and will pick up regulations and the legislation really quickly. To be a knowledgeable, in-depth regulator you really need to have your feet under the table for probably at least 10 years, and Nkambule fits that bill.

"When headhunting for the position of CEO, we realised Dr Semete-Makokotlela was really good at what she does. She comes from a broadly speaking health background. She's headed institutions and done turnaround of institutions within the Council for Scientific and Industrial Research (CSIR). She's highly qualified both from a scientific point of view but also from an MBA and business management point as well. She's young. She had a very strong vision that she was able to articulate to all of us about how she sees SAHPRA evolving – so she really got her head around this very quickly. And she's ambitious for the organisation," said Prof Rees. "With her track record, health-aligned management, and leadership, she ticked all of the boxes, and we're extremely excited."

CEO vs CRO

"The CEO has strategic vision and oversight, and ultimately all responsibility lies with her," said Prof Rees. "In order to achieve that, particularly noting how much work needs to be done to get SAHPRA on its feet – from taking over from the MCC – the CEO needs to fill that leadership and strategic role."

Dr Semete-Makokotlela agreed: "With the CEO role, there's an overall accountability for whole the organisation. From a regulatory function, if we for example make a wrong decision about how we schedule something the buck stops with me. As the CEO I must be able to have the ability to check and ask the right questions. The CEO also has a very important role in ensuring that the capacity, the skills, and everything we do, is on par with global norms and standards. As such, I must put in place the mechanisms to ensure that the CRO has the right skills, capacity, etc to do her job.

"Nkambule's key responsibility as CRO is the regulatory, the routine day-to-day work," said Dr Semete-Makokotlela. "She has great experience in regulation and is responsible for ensuring we implement the right types of regulation and we don't make decisions that are not aligned with our mandate, are not aligned with global standards. For example, the matter of us wanting to up schedule codeine."

CEO'S TOP 3 IMMEDIATE PRIORITIES FOR SAHPRA

1. Operational environment

"We haven't completed the process of moving over from MCC to a Section 3A public entity, and for me it's important that we do," said Dr Semete-Makokotlela. "We need to complete the process from a people perspective, workflow perspective, culture perspective, even our look and feel. That part for me is critical because the sooner we finish, the quicker we can start operating in a mechanism which ensures we are able to efficiently deliver. That speaks to ensuring we have the right processes so that we never have a backlog."

2. Stakeholders

"One of the things you hear a lot is that regulations in the country are a barrier to growth and to access. Regulations always lag innovation and technology, that's just the nature of things. But they should not be a barrier. So, for me, in the next five years I want to change the narrative."

3. Enabling innovation

Being a scientist is important to me, and along with it, enabling innovation. There's a lot happening in terms of product development and innovation, new approaches of doing things, and I want us to be able to enable that," said Dr Semete-Makokotlela. "I want to be in a position where if there's a professor at the University of Limpopo who has developed the newest type of medical device that no one else has in the world, we should be able to say, actually, this is how we can guide you, and then walk the journey with them to having the device registered and go global. So really enabling innovation is a big thing." MC