MEDIA RELEASE

SAHPRA celebrates the conclusion of the backlog clearance project

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Pretoria, 2 December 2022 – With the establishment of the South African Health Products Regulatory Authority (SAHPRA) in February 2018, the regulatory authority inherited a backlog of approximately 16 000 new product and variation applications from its predecessor, the Medicines Control Council (MCC).

As is generally the norm for low middle income countries with the majority of its citizens stratified across lower socio-economic classes, more than 95% of these applications were generic medicines. Thus, this backlog had an impact on access to safe, cost-effective medicines. Some of the pioneering therapies, especially those that were New Chemical Entities held up in the pipeline, were offering hope to terminally ill patients, yet access was delayed by the previous inefficient review practices.

After intensive consultation with both internal and external stakeholders, a project timeframe of two years for the clearance of the application backlog was agreed upon. SAHPRA, with the assistance of the National Department of Health, National Treasury and various funders, set up a dedicated Backlog Clearance Project unit with sufficient staff and resources to clear the application backlog. This project went live in August 2019.

In order to achieve the ambitious timeframe, mechanisms such as reliance review (most notably abridged review for applications where unredacted assessment reports from Recognised Regulatory Authorities (RRAs) were available), as well as risk-based assessment, were implemented in the project. The new re-engineered regulatory processes contributed significantly to the clearance of the backlog of product registrations, and these have already been deployed in other core business areas within SAHPRA. The learnings from the Backlog Clearance Project have been shared not only within the South African regulatory agency, but further afield in Africa, where numerous National Regulatory Authorities (NRAs) are battling their own application backlogs. Expedited, streamlined regulatory processes and outcomes translate into improved access to quality, safe and effective medicines, which is ultimately the mandate of every Medicines Regulatory Authority.

SAHPRA hosted an event at its offices in Loftus Park, Arcadia, Pretoria on 2 December 2022 to celebrate the conclusion of the project, where the keynote address was delivered by Dr Nicholas Crisp, Deputy Director General: National Health Insurance (NHI) on behalf of the Health Minister, the honourable Dr Joe Phaahla. This was an opportunity to thank the myriad of stakeholders, without whom this achievement would not have been possible. SAHPRA's collaboration with both Industry and various stakeholders was pivotal in ensuring the success of the project.

"I am proud to have participated in migrating SAHPRA from the Medicines Control Council (MCC). Unfortunately, the MCC had a historical backlog of approximately 16 000 medicines applications. Initially, this seemed rather intimidating. However, it was sheer commitment, hard work, long hours and a dedicated Board and leadership that culminated in clearing this mammoth backlog in record time. The generosity of the funders must also be commended for their commitment. This is indeed a milestone for SAHPRA," indicates Dr Nicholas Crisp, Deputy Director-General, National Health Insurance.

"The Pharmaceutical Task Group (PTG) which represents over 80% of the South African pharmaceutical industry, welcomes this development and congratulates the SAHPRA Board and management in achieving the significant clearing of the registration backlog that historically hampered the MCC – the predecessor to SAHPRA – and hindered access to new

medicines for patients. The pharmaceutical industry, along with other key stakeholders has worked together with SAHPRA on an independent basis, in supporting SAHPRA's efforts in eliminating the backlog and in collaborating to make medicines accessible to patients, whilst ensuring that the quality, safety and efficacy of medicines is not compromised. We wish to thank and congratulate all SAHPRA personnel on achieving this important milestone and look forward to our ongoing collaboration in achieving greater efficiency in the medicines regulatory pathway," stated Stavros Nicolaou, Chairman of the PTG.

Professor Helen Rees, the SAHPRA Board Chairperson, applauded the SAHPRA team and its expert advisers, the donors who supported the backlog project, and industry who worked with SAHPRA to develop an innovative strategy. "When the SAHPRA Board was appointed in 2018, we knew there was backlog but didn't know its size or the nature of the applications. Having established that there were 16 000 applications stuck in the system for years, the Board and acting CEO prioritised backlog clearance using a dedicated internal and external team, supported by funds and advise from donor agencies. Our ambition to be a world class regulatory authority would not be realised without addressing the log jam created by outdated systems. Well done to Tumi and the team for their ongoing efforts to make SAHPRA a fit for purpose regulator."

"This is an achievement worth celebrating and it is indicative of the hard work and dedication of SAHPRA staff members, associates, funders, and industry role players. The SAHPRA Board, especially, the Board Chair, Prof Helen Rees must be applauded for their guidance and support in achieving this milestone," indicates SAHPRA CEO, Dr Boitumelo Semete-Makokotlela.

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About SAHPRA:

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and in-vitro diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973).

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of all who reside in South Africa:

- Safety
- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.