NEWS ITEM

SAHPRA CEO delivers keynote address at 2024 SAAPI Conference

The South African Association of Pharmacists in Industry (SAAPI) held its 2024 conference at the Council for Scientific and Industrial Research (CSIR) International Convention Centre on 5-7 June 2024 under the theme “Engage and empower: Pushing the frontiers of the Pharma Industry”.

South African Health Products Regulatory Authority (SAHPRA) Chief Executive Officer, Dr Boitumelo Semete-Makokotlela, delivered the keynote address focusing on SAHPRA’s mission and vision for delivering safe, efficacious and quality medicines and other health products on the opening day of the conference. “Our mandate is to ensure that in all of the developments and new innovations at the heart of what it is that we do, we keep patient safety and matters of access core. At the heart of us being agile and responsive, we will make sure that we do not compromise on safety, quality and the efficacy of products that we regulate,” expressed Dr Semete-Makokotlela.

Dr Semete-Makokotlela also emphasised that SAHPRA is open to engagement so that the Regulator works in shifting the needle through cooperation with the overall goal of access to safe, effective, and quality medicines and other health products to meet South Africa’s healthcare needs.

The SAAPI conference programme also featured presentations from various SAHPRA officials. Colleagues from various units presented invaluable information to SAAPI conference delegates.

In explaining an overview of SAHPRA’s reliance approach to medicines registration, Senior Manager: Inspectorate and Regulatory Compliance, Deon Poovan said: “When you are doing a review of a dossier, it takes time, and when you can rely on somebody else that has actually done the work, we can reduce that time that we take to review a dossier. So, we have adopted the reliance review process as a pathway for registration and this approach then allows us (the Regulator) to leverage on what a recognised regulatory authority (that we recognise) has done so that we can then rely on its evaluation process and ensure better market access so that we can get drugs that we need onto the market and then obviously Industry can then market the product”.

Sasani Chauke, a Medicine Registration Officer in the Pharmacovigilance Unit, spoke to safety signal management within the Regulator. One has to have a clear idea of what a safety signal is. “A safety signal is any information on any new known adverse event that is potentially caused by a medicine and requires further investigation to determine whether there is a real risk or if there is a regulatory action that is required,” explains Chauke.

Tshepiso Bokaba, Manager: Information and Communication Technology, shared perspectives on new specifications for eSubmissions across various areas.

Mokgadi Daphney Fafudi, Manager: Regulatory Compliance, explained how the Regulator is using E-signatures to allow for a more seamless signing process that also ensures the authenticity and integrity of documents. She emphasised the importance of industry ensuring compliance with the ALCOA+ data integrity principles in their submissions to SAHPRA, thus guaranteeing the authenticity, legibility, contemporaneity, originality, and accuracy of data within submissions. She also alluded to the fact that SAHPRA is reviewing the *General information guideline* in order to provide guidance on acceptable minimum requirements concerning e-signatures.

Dr Alice Sigobodhla, Manager: Veterinary Medicines, shared the latest developments and status of veterinary medicine registration within SAHPRA. Dr Sigobodhla was also part of a robust panel discussion around veterinary medical devices.

Lydia Motlogelwa, Manager: Medical Device Registration and Clinical Trials, provided an update on the latest developments on medical device regulation.

The many speakers during the course of the conference embodied their theme *of Engage, Empower – Pushing the frontiers of the Pharma Industry*.