

COMMUNICATION TO STAKEHOLDERS

Issue No.: PV01-2025/26

09 September 2025

Invitation to participate in MedDRA Training

The South African Health Products Regulatory Authority (SAHPRA) would like to invite you to a Medical Dictionary for Regulatory Activities (MedDRA) training. MedDRA is an international standardised medical terminology developed to facilitate the sharing of regulatory information for medical products used by humans.

SAHPRA is embarking on a process of ensuring that all adverse event reports received from the holders of certificates of registration (HCRs)/applicants are submitted electronically. In preparation for the roll-out of electronic reporting by industry, SAHPRA has organised the MedDRA training to ensure that all reports from HCRs/applicants submitted electronically are coded. MedDRA enables the process of coding of adverse events, which is a crucial step in pharmacovigilance that **ensures that data is clear, comparable, and useful for identifying safety signals**.

The training for industry is planned for the 15th – 17th October 2025 as follows:

- Day 1 – General overview/Getting started on MedDRA
- Day 2 - Coding with MedDRA
- Day 3 - MedDRA Data Analysis and Standardised MedDRA Queries (SMQs)

• Chairperson: Dr Thapelo Motshudi • Vice-Chairperson: Prof Glenda Gray
• Dr Alfred Kgasi • Dr Chevon Clark • Dr Johanna Gouws • Dr Tobeka Boltina
• Ms Mmatebogo Nkoenyane • Mr Anthony Ngcezula • Mr Rajesh Mahabeer
• Mr Nkosenhle Ngongoma • Mr Moses Moselekwa
CEO: Dr Boitumelo Semete-Makokotlela

The first day, 'Getting Started' will be open to anyone who is interested in MedDRA, both new subscribers and non-subscribers, who have no experience.

The following two days of training will be **open to subscribers only**, as per Maintenance and Support Services Organisation policy.

We would therefore like to encourage HCRs/applicants to please subscribe to MedDRA prior to the training event and have a MedDRA ID. Here is a guide on how to subscribe to MedDRA – <https://bit.ly/4pfNHzs>.

Please complete this registration form: <https://forms.cloud.microsoft/r/96QAZNPYPT> by 19 September 2025.

- Names listed after 19 September 2025 will not be accommodated in the training.
- **Please note** that should the number of attendees be exceedingly high, preference will be given to new MedDRA users, Qualified Person Responsible for Pharmacovigilance, and local generic companies.

Details about the venue and any other logistics will be communicated once finalised.

To ensure that all HCRs/applicants benefit from this training, **only one key individual per company will be permitted, unless otherwise motivated.**

Boitumelo Semete-Makokotlela

SIGNIFLOW

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer (CEO)
SAHPRA