

COMMUNICATION TO STAKEHOLDERS

Issue No.: PV02-2025/26

06 October 2025

Amendment of the training dates for the 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. This communication supersedes Issue No: PV01-2025/2026.

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 dates for industry has been postponed to 3rd – 5th December 2025 as follows:

- Day 1 (3rd December 2025) – General overview/Getting started on MedDRA
- Day 2 (4th December 2025) - Coding with MedDRA
- Day 3 (5th December 2025) - MedDRA Data Analysis and Standardised MedDRA Queries (SMQs)

Day-1 'Getting Started' will be open to anyone who is interested in MedDRA, both **subscribers** (new and old) and **non-subscribers** who have no experience and may require information about MedDRA.

Day 2 and 3 will be open to **subscribers only**, as per Maintenance and Support Services Organisation policy.

We would therefore like to encourage HCRs/applicants to subscribe to MedDRA prior to the training and have a MedDRA ID, which will then enable them to register for day 2 and 3 trainings. Here is a guide on how to subscribe to MedDRA – <https://bit.ly/4pfNHzs>.

To be able to attend this MedDRA training, it is important for attendees to register for logistics purposes. Please complete the attached registration form: <https://forms.cloud.microsoft/r/96QAZNPYPT> by **31 October 2025**.

- Names listed after 31 October 2025 may not be accommodated in the training.
- Please note that up to **three** representatives per company will be permitted to attend the training. Should the number of attendees be exceedingly high, preference will be given to key individuals in each company, e.g. Qualified Person Responsible for Pharmacovigilance.

Those who have registered based on the initial communication, please do not register again unless there is some changes related to attendance days. Details about the venue and any other logistics will be communicated once finalised.

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