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SAHPRA issues guidance on of Artificial Intelligence and Machine Learning-enabled medical devices

In September this year, the South African Health Products Regulatory Authority (SAHPRA) issued a communiqué to provide its stakeholders with the regulatory requirements of Artificial Intelligence and Machine Learning (AI/ML)-enabled medical devices in South Africa. The communiqué outlines SAHPRA's position and regulatory expectations for AI/ML-enabled medical devices.

SAHPRA recognises the transformative potential of AI/ML enabled medical devices and in vitro diagnostics (IVDs) in healthcare and notes that, although it has not yet commenced with the registration of medical devices and IVDs as required by regulations published in 2016, proactive engagement with the medical device industry to promote patient safety, compliance, and responsible innovation has become necessary in light of the rapid advancement and adoption of these technologies. For AI to be safely and effectively integrated into South Africa's healthcare system, regulatory frameworks will need to be amended. The guidance provided in the communiqué draws on emerging frameworks from leading global regulators and expert bodies, enabling SAHPRA to harmonise its approach with international trends. However, it also emphasises that South Africa's unique healthcare and data governance context must be addressed simultaneously to ensure the safe development, effective performance, and ethical oversight of AI/ML medical technologies available for use in South Africa.

A medical device is defined as "any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973)—intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following: (i) diagnosis, prevention, monitoring, treatment, or alleviation of disease; (ii) diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; (iii) investigation, replacement, modification, or support of the anatomy or of a physiological process; (iv) supporting or sustaining life; (v) control of conception; (vi) disinfection of medical devices; or (vii) providing information for medical or diagnostic purposes by means of in vitro examination of specimens derived from the human body; and which does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means."

Artificial intelligence (AI) is defined as "a branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions and making predictions. AI-based systems demonstrate various degrees of autonomy (the level of capacity to perform tasks in a complex environment without constant guidance/input from a user) and capacity for adaptability (extent of the ability to learn from experience and thereby change performance)." ML it states, is a subset of AI, which "involves a computer implementing an ML training algorithm to learn patterns from data, including classification, inference, matching previous patterns, predicting future outputs, etc., which results in an ML model to be applied to new data." An AI/ML-enabled medical device is therefore defined as "a product that conforms to the definition of a medical device and utilises one or more AI or machine-learning algorithms to perform, in part or in whole, its intended medical purpose." Some examples are medical imaging analysis (e.g., software using AI to detect tumours or fractures in radiological images); predictive algorithms (e.g., an ML model that forecasts risk of patient deterioration); clinical decision support systems (e.g. AI-driven diagnostic aids or treatment recommendation systems for healthcare professionals); and wearable health monitoring technologies (e.g., wearables that analyse biosignals and alert to abnormalities). It is highlighted that all AI/ML-enabled medical devices must comply with the same fundamental safety and performance requirements as conventional medical devices.

SAHPRA's Essential Principles of Safety and Performance provides a regulatory framework to ensure that devices are safe and effective. These principles cover general requirements such as device design and manufacturing quality, risk management, clinical evaluation, usability, and labelling, and specific considerations like electrical safety and cybersecurity. A robust quality management system covering software development and maintenance lifecycle will need to be implemented. In addition, thorough risk management to identify and mitigate risks associated with the device's hardware and software, including risks unique to AI, such as algorithm errors and data drift will have to be conducted. Also required are that clinical performance and benefit through appropriate validation studies are demonstrated and that AI/ML devices should undergo clinical evaluation to confirm they fulfil their intended medical purpose and improve patient outcomes under real-world conditions. Usability must be ensured and human factors considered. Healthcare professionals or users should understand and appropriately respond to the device outputs. Cybersecurity controls need to be incorporated to protect data integrity and device function from unauthorised access or alterations. Importantly, the use of AI/ML does not exempt a device from any existing safety or performance obligation as additional considerations arise that manufacturers need to address within the established framework of essential requirements. Fundamentally, an AI/ML-enabled medical device must be as safe and effective as a traditional device intended for the same purpose. The manufacturer is accountable for any new risks introduced by the AI/ML functionality.

SAHPRA states that although formal regulatory pathways for AI/ML-enabled medical devices have yet to be developed, developers and manufacturers are expected to adhere to key guiding principles informed by internationally recognised best practices to ensure the responsible development and use of these products. Paramount among these principles is the protection of patients' well-being. The guidance provided in the communiqué is comprehensive, and full details are available at: https://www.sahpra.org.za/wp-content/uploads/2025/09/MD08-20252026_-SAHPRA-Communication-to-Industry-AI-Medical-devices_Acknowledgements.pdf

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