



Substandard and falsified medical products

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Substandard and falsified medical products (SFMPs) are identified as one of the urgent global challenges of this decade. The global threat and routes to the market of SFMPs have grown exponentially with the ever-increasing demand for medical products globally. The entry of SFMPs into the supply chain undermines efforts made towards ensuring access to quality, safe and efficacious medical products. Africa and South Africa import a lot of medical products; subsequently, a significant percentage of SF medical products circulating globally are found in Africa, and this presents a serious concern for public health, affecting the attainment of Sustainable Development Goal (SDG) 3, which aims to have universal health access for all. A common finding from the WHO Global Benchmarking Tool assessments is the need for strengthening the market surveillance and control function, which fights the SFMPs.

In 2024, the World Health Organisation (WHO) selected South Africa as the first country to pilot its draft handbook on the National Action Plan against Substandard and Falsified medical products (NAP), for a one-year pilot. Following the success of the RSA pilot, the WHO handbook will subsequently be rolled out globally to Member States for implementation. The NAP is a collaborative effort with key stakeholders to develop strategies for Prevention, Detection, and Response to Substandard and Falsified Medical Products (SFs/SFMPs). This project is led through the South African Health Products Regulatory Authority (SAHPRA) and the National Department of Health (NDOH). The pilot in South Africa seeks to adapt, test, and implement the handbook's framework. This serves both the objectives of strengthening the national health system and contributing to the WHO's global learning agenda. The handbook mentions that it takes political commitment, resources, and sustained, coordinated action to combat SF medical products and restore or maintain trust in health systems. The handbook also aimed to support national responses and encourage regional and global coordination engagement to reduce the threat to patients and consumers everywhere. In November 2024, the sensitisation workshop was conducted with all stakeholders.

SAHPRA's annual report, published on its website (SAHPRA, 2024:53)¹, includes the number of product quality complaints reported that resulted in investigations. In 2021/2022, 130 related investigations were recorded, which more than doubled to 297 in 2022/2023, increased to 430 in 2023/2024 and increased to 507 in 2024/2025 (not yet published). Raids by SAHPRA and law enforcement agencies

have confiscated numerous falsified products containing Glucagon-Like Peptide-1 (GLP-1) active components or a combination of Glucagon-Like Peptide-1 (GLP-1) and Gastric Inhibitory Polypeptide (GIP) agonists, which are claimed to be for weight loss, sexual enhancement (both male and female), skin-bleaching agents containing corticosteroids, anabolic steroids, headache sachets, etc. The aforementioned items are regulated under the Medicines Act and therefore require market authorisation.

SAHPRA, through its Regulatory Compliance Manager, Ms Fafudi, coordinated this initiative through an inclusive, collaborative process that involved a Steering Committee comprising key national stakeholders. The NAP Committee was established with four subcommittees: Education and Awareness, Enforcement, Infrastructure, and Supply Chain. Several meetings took place between February and August 2025.

The developed 5-year National Action Plan against SFs outlines a structured approach to address SF products in South Africa. As part of the NAP Committee's work, several presentations on its activities were made, including one at the WHO MSM meeting in Geneva (August 2025), the Permanent Forum on International Pharmaceutical Crime (PFIPC) in Vienna (September 2025), the WHO Regional Office for Africa (AFRO) meeting in Nairobi (June 2025), the African Working Group on SFs in Addis Ababa (July 2025) and the SADC SF Focal Points forum. In addition, presentations were made to the Parliamentary Portfolio Committee on Health, as well as during various NDoH/SAHPRA stakeholder workshops and multiple health and pharmaceutical industry conferences. On 30 September 2025, a significant milestone was achieved with the successful launch of Africa's first comprehensive National Action Plan, developed by the Committee.

Findings of the draft handbook pilot in the South African and general context:

- The document was sufficiently clear and accessible in terms of organisation, language and structure
- The document provided sufficient practical guidance in terms of what was needed to develop a national action plan
- The resources cited were sufficient to support the country in developing our national action plan

- The country implementing NAP will explore further components regarding Prevent, Detect and Respond strategies in the framework, as they are interlinked.
- Key considerations in assessing risk and prioritising national activities must be inclusive, factual, with a risk-based approach for practical implementation and investment justification
- The workplan templates and costing guidelines were helpful and tailored to our country's needs

Challenges that were identified include establishing formal Inter-Ministerial Committees (IMCs), as politicians are preoccupied with priorities at a macro level. The DGs in the department are accounting officers, equivalent to Chief Executive Officers, and thus, this structure was used for the IMC. The private sector responded swiftly to the establishment of the NAP, but the government's bureaucratic processes caused delays in responsiveness. Nonetheless, the development of the NAP was exceptionally embraced by focal point officials.

Focal points in both government and non-governmental sectors have been instrumental to the success of the project and the development of the NAP. Challenges also include departments prioritising their high-value areas when allocating human, financial, technological, and equipment resources. Therefore, when developing the operational plan, we needed to be practical in prioritising activities and roles. Generally, the country faces challenges such as tough economic conditions, including ongoing budget cuts, increased retrenchments and layoffs, and a high unemployment rate. The enforcement sector is overburdened, with a high volume of criminal cases to handle and a shortage of staff in relevant specialised units.

When developing and implementing a National Action Plan (NAP), it is important to consider the contextual factors and success conditions, including acknowledging that all participating stakeholders operate as independent entities. Their level of commitment is therefore influenced by their specific interests and the extent of their

participation in the process. Sustaining active participation requires scheduling regular meetings at intervals agreed upon by the majority to retain traction and continuity. All stakeholders need to feel valued and recognised, and for their contributions to be incorporated into action. Another factor is leveraging personal and professional relationships with members to further enhance collaboration and responsiveness, particularly since formal invitations sent through official channels often experience delays, leading to missed opportunities for timely meetings and actions.

The active NAP stakeholders include, but are not limited to: the National Department of Health, SAHPRA, South African Revenue Service, Department of Justice, National Prosecuting Authority, Department of International Relations and Cooperation, Border Management Authority, Department of Trade, Industry and Competition, CIPC, COGTA Traditional Affairs, South African Police Services, Department of Agriculture, all Health/Pharmaceutical Provincial Departments, Cooperative Governance Traditional Affairs, South African National AIDS Council, Department of Social Development, Central Drug Authority, Head of Pharmaceutical Services (HOPS), Government and private entities, Pharmaceutical Society of South Africa (PSSA), South African Pharmacy Council, Health Professions Council of South Africa, academia, and captains of the health industry supply chain/business.

The 5-year NAP development process included: situation analysis, data and risk analysis, goal setting, stakeholder mapping, dialogue with key stakeholders, potential barrier identification, establishment of governance and coordination mechanisms, development of structures nationally, resource allocation to implement NAP, prioritised activities identified, resource mobilisation, implementation model developed, monitoring and evaluation, and the sustainability of NAP implementation.

Reference

1. SAHPRA (South African Health Products Regulatory Authority). 2024. Annual Report 2023/24. Available at: <https://www.sahpra.org.za/document/annual-report-2023-2024/> [Accessed 10 Oct 2025].