PERIOD: FY 2024/2025

Introduction and Background

The role of the South African Health Products Regulatory Authority (SAHPRA) regarding advertising and marketing of medicines, medical devices and IVDs:

- To ensure that medicines, scheduled substances, medical devices or IVDs for human and veterinary use are marketed according to the requisite regulations.
- The Regulatory Compliance Unit of SAHPRA is responsible for ensuring that advertising and marketing of medicines shall comply with the Medicines Act and its General Regulations. Inappropriate promotion and advertisement of medicines may contribute to the irrational or incorrect use of medicinal products. The impact of accurate and science-based promotional activities is related to the existence of trustworthy and accessible information sources and the level of medical knowledge of the population. Hence, the control of promotion and advertisement of medical products is necessary and should be consistent with the Medicines Act and the General Regulations.
- The control of the advertising and marketing of medicines is supported by the Medicines Act and its Regulations.

Section 18 (2) states that no person shall advertise any medicine or scheduled substance, medical device or IVD for sale unless such advertisement complies with the prescribed requirements.

In terms of **Regulation 42 (4) of the General Regulations**, no advertisement for a medicine may contain a statement which deviates from, is in conflict with or goes beyond the evidence submitted in the application for registration of such medicine concerning its safety, quality or efficacy where such evidence has been accepted by the Authority in respect of such medicine and incorporated into the approved professional information of such medicine. Regulation 42 provides further requirements in terms of what may be advertised and to whom.

Section 19 (1) of the Medicines Act states that: No person shall sell any medicine unless it complies with the prescribed requirements. Therefore, any person who contravenes the provision of this sub-section shall be guilty of an offence.

In terms of section 14 of the Medicines Act, the sale of medicines, medical devices, or IVDs which are subject to registration and are not registered is prohibited. *The definition of "sell" in Medicines Act includes advertising.*

Post-Marketing Surveillance (PMS) refers to the practice of monitoring the quality, safety, and efficacy of medicines after they have been registered and released onto the market. This includes the proactive sampling of advertising and promotional materials in the market to determine if these materials comply with the requirements of the Act and SAHPRA in terms of guidelines - SAHPGL-INSP-RC-07- Guideline for advertisement of Medicines and Health Products.

Objective of Reporting

The objective of this report is to assess whether the random selection of advertising that was conducted monthly from April 2024 to March 2025 complies with the applicable laws, regulations and guidelines; this includes the Medicines Act and Regulations, and the abovementioned guideline.

Advertising sources include journals, reference books, promotional material at the retail level, websites, and social media. In addition to the random inspections, complaints received from the public related to advertising were also investigated.

Evaluation of Results and Annual Reporting

Inspection numbers April 2024 – March 2025	
Total number of advertising inspections	150
Total number of random advertising inspections	55
Total number of complaints or enquiries regarding advertising from the public	95

Challenges faced

Lack of knowledge of pharmaceuticals:

- Some companies (non-pharmaceutical) are not aware of the laws and regulations governing the advertising and promotion of Medicines and IVDs.
- Companies/Individuals are not aware that the products they are selling are pharmaceuticals, which are not registered in this country.
- Companies are not aware of what the definition of a pharmaceutical product is and, therefore are unable to identify these products.
- Companies do not employ qualified personnel who have the knowledge to identify pharmaceutical products.
- Social media platforms do not always remove pharmaceuticals that are being reported via their platforms using their apps. SAHPRA is unable to contact platforms directly to explain the contraventions as well as the challenges the Authority is experiencing.
- There are severe challenges in making contact with some hosts to have websites blocked or removed, as they are masked.
- Some websites that are shut down have the capacity to immediately launch a new site or have backup sites in order to continue their illegal sales. If they are using a traceable host; they move over to an untraceable host, usually in another country.

- **Marketing teams at pharmaceutical companies are not always educated on the laws and regulations of marketing pharmaceutical products:**
    - Websites and social media platforms do not always have a physical address or have a fake physical address.
    - Products advertised on social media are sometimes advertised via fake profiles to help prevent traceability, and products are sent to the purchaser via a courier service.
    - Products being advertised on ecommerce retailer platforms- the company does not always know what is being advertised on their marketplace platform and/or website, where the public can advertise products, and it seems their internal monitoring system is not sufficient.
    - Advertisements on social media and websites not specific in terms of the country of origin; therefore, it is unclear if advertisements fall under SAHPRA's jurisdiction or not.
      Social media platforms do not always remove pharmaceuticals that are being reported via their platforms using their apps. The Authority is unable to contact them directly to explain the contraventions as well as the problems being experienced.
    - Difficulty in making contact with some hosts to have websites blocked or removed, as they are masked.
    - When some websites are shut down, they immediately open up a new one or have backup sites in order to continue their illegal sales.

Interventions by applicants/marketing authorisation holders (MAHs):

- Pharmaceutical companies should train their marketing team on the laws and regulations surrounding the advertising and marketing of pharmaceutical products.
- Companies that provide a market platform for selling products should employ a person with knowledge of pharmaceuticals to prevent illegal advertising of pharmaceutical products.
- Social media platforms should employ personnel with knowledge of pharmaceuticals to identify problems more swiftly and ensure that when complaints are made with regard to advertising, the advertisements are removed immediately.
- Pharmaceutical companies should also take the initiative to contact social media sites and lay complaints about their products being advertised and also involve their legal team to seek advice on how to approach these offenders.
- Appoint a registered pharmacist who can assist with the review and approval of advertising and promotional materials that are published.

Actions taken from SAHPRA:

- Informed applicants of illegal advertisements being posted and requested that they have them removed if it was on their websites, social media accounts, or any other form of advertising.
- Informed applicants when their products are being advertised unlawfully by the public to make them aware and assist in monitoring of these products more carefully and assist in forwarding complaints to social media networks to have them removed as well as inform SAHPRA of these activities.
- Liaise with the Department of Communications and Digital Technologies in South Africa to assist in contacting international hosts.

- Liaise with the Internet Service Providers Association (ISPA) for assistance in the removal of websites whose hosts are registered with the ISPA.
- Inform SAPS or other relevant departments, when necessary, e.g., the Directorate for Priority Crime and Investigation, South African Revenue Services.
- Liaise with social media platforms, when necessary, to have advertisements removed, however, this is not always successful, as we can only report the problems via their app and websites.
- E-commerce retailers have been contacted on numerous occasions by multiple inspectors to inform them of when they were in contravention of the Medicines Act.
- We need to find a way to make direct contact with social media providers/owners/compliance teams

Trends:

- Illegal advertising of registered and unregistered scheduled products to the public (schedule 2 and above).