South African Health Products
Regulatory Authority
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COMMUNIQUE

COMMUNICATION TO INDUSTRY ON THE AMENDED POST MARKETING REPORTING OF ADR FOR HUMAN MEDICINES IN SOUTH AFRICA

To: All applicants

From: Vigilance Unit

Date: 11 May 2021

The South African Health Products Regulatory Authority (SAHPRA), have reviewed the Post Marketing Reporting of ADR guideline following concerns raised by the industry on the version 7 of the guideline published September 2020. In addition to the review, SAHPRA conducted a webinar with holders of certificate of registration to further discuss the concerns and proposed responses to the queries.

SAHPRA is pleased to announce that the review is complete and version 8 of the guideline is published for implementation on the SAHRA website. Version 8 of the guideline is applicable from January 2020 going forward, owing to the reporting requirements concerns raised by the industry, specifically on PSUR/PBRER and medication errors.

For further enquiries /information contact:

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About SAHPRA

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products and clinical trials in South Africa. Health products include complementary medicines, medical devices and in vitro diagnostics (IVDs). SAHPRA also has the responsibility of overseeing the radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973).

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of South Africans:

- Safety
- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.