



The Impact of Pharmacovigilance on Public Safety: A SAHPRA Mandate

Thought Leadership Article



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Introduction

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine-related problems, which play a crucial role in ensuring public safety. The South African Health Products Regulatory Authority (SAHPRA) is at the forefront of pharmacovigilance efforts in South Africa, working tirelessly to safeguard public health.

SAHPRA's Mandate and Role in Pharmacovigilance

SAHPRA's mandate is to regulate all health products, including medicines, medical devices, and in vitro diagnostics, to ensure their safety, efficacy, and quality. Pharmacovigilance is a critical component of

this mandate, as it involves monitoring the safety of these health products throughout

their lifecycle. SAHPRA's pharmacovigilance activities include collecting and analysing adverse event reports received from patients/public, healthcare professionals, and pharmaceutical companies, conducting risk assessments, and implementing risk minimisation measures.

Case Study 1: The role of pharmacovigilance in the COVID-19 Vaccine Rollout

The COVID-19 pandemic has underscored the importance of pharmacovigilance in ensuring the safety of vaccines. SAHPRA has been actively involved in monitoring the safety of COVID-19 vaccines through its

pharmacovigilance system. This includes collecting and analysing adverse event reports, conducting risk assessments, and communicating safety information to the public and healthcare professionals.

One notable example is the monitoring of rare adverse events, such as blood clotting disorders, associated with certain COVID-19 vaccines. Post-vaccination surveillance linked the J&J (Janssen) COVID-19 vaccine to rare cases of Thrombosis with Thrombocytopenia Syndrome (TTS), a serious disorder characterised by blood clotting.

SAHPRA's pharmacovigilance efforts enabled the timely identification of these rare events, leading to updated guidance on vaccine use and risk mitigation strategies. SAHPRA collaborated with the National Immunisation Safety Expert Committee (NISEC) and issued updated product information and informed consent guidelines. Despite the low incidence, SAHPRA ensured transparency and continued benefit–risk assessments of these vaccines.

Additionally, through pharmacovigilance communication strategies, all the misinformation peddled by antivaxxers was continuously clarified to the public. These proactive approaches have helped to maintain public confidence in the safety of COVID-19 vaccines and ensure the success of the vaccination campaign.

Case Study 2: The Valproate Conundrum

Valproate (used to treat epilepsy and bipolar disorder) is associated with the risk of malformations or birth defects in a

developing embryo or fetus during pregnancy. SAHPRA issued a Dear Healthcare Professional Letter (DHCPL) in March 2022 to alert healthcare professionals. Pharmacovigilance data and international alerts (especially from the European Medicines Agency) prompted SAHPRA's action. This resulted in strengthened risk communication and increased awareness among prescribers and patients, with the intention to reduce in utero exposure.

Case Study 3: Pholtex Deregistration

Pholcodine-containing medicines were deregistered from the South African market due to the increased risk of sudden, severe, and life-threatening allergic reactions occurring during surgery. There is a link between the use of pholcodine-containing medicines and the risk of a sudden, severe, and life-threatening allergic (anaphylactic) reaction when neuromuscular blocking agents (NMBAs) are administered during general anaesthesia. NMBAs are used as muscle relaxants during surgery. The use of pholcodine-containing medicines, up to 12 months before surgery, increases the risk of anaphylactic reaction in patients who receive NMBAs.

Pharmacovigilance System Requirements

SAHPRA requires applicants and Holders of Certificates of Registration to comply with specific pharmacovigilance system requirements. These requirements are designed to ensure that any adverse effects or other drug-related problems are promptly identified and addressed. Key components of the pharmacovigilance system include:

- A qualified person responsible for pharmacovigilance
- A pharmacovigilance system master file
- Adverse event reporting and management system
- Risk management activities

Role of Stakeholder Collaboration in Pharmacovigilance

Effective pharmacovigilance requires collaboration among various stakeholders, including healthcare professionals, patients, pharmaceutical companies, and regulatory authorities. SAHPRA works closely with these stakeholders to ensure the timely reporting and management of adverse events. This collaborative approach enhances the overall effectiveness of pharmacovigilance efforts and contributes to public safety.

For instance, SAHPRA collaborates with healthcare professionals to promote the reporting of adverse events and provide training on pharmacovigilance practices. Additionally, SAHPRA engages with pharmaceutical companies to ensure that they fulfill their pharmacovigilance obligations, including the submission of periodic safety update reports and risk management plans.

Technological Innovations in Pharmacovigilance

Technological advancements have significantly enhanced pharmacovigilance practices. SAHPRA leverages various technologies to improve the collection, analysis, and dissemination of safety data. For example, SAHPRA has implemented an electronic adverse event reporting system,

which facilitates the timely and efficient reporting of adverse events by healthcare professionals and patients.

Furthermore, SAHPRA utilises data analytics and artificial intelligence (AI) to identify safety signals and trends in adverse event data. These technologies enable SAHPRA to conduct more comprehensive and accurate risk assessments, ultimately enhancing public safety.

Challenges and Opportunities in Pharmacovigilance

Despite significant progress in pharmacovigilance, several challenges remain. One of the key challenges is the underreporting of adverse events, which can hinder the timely identification of safety issues. SAHPRA is actively working to address this challenge by raising awareness about the importance of adverse event reporting and providing training to healthcare professionals.

Another challenge is the need for harmonisation of pharmacovigilance practices across different countries and regions. SAHPRA collaborates with international regulatory authorities and participates in global pharmacovigilance initiatives to promote the harmonisation of safety standards and practices.

Looking ahead, there are several opportunities to further enhance pharmacovigilance practices. The integration of real-world data, such as electronic health records and patient registries, into pharmacovigilance systems can provide valuable insights into the safety and effectiveness of health products. Additionally, the use of advanced data

analytics and AI can further improve the detection and management of safety signals.

Conclusion

Pharmacovigilance is a critical component of SAHPRA's mandate to ensure the safety, efficacy, and quality of health products. Through its robust pharmacovigilance system, SAHPRA has made significant contributions to public safety, as demonstrated by the case studies above. The collaborative efforts of various stakeholders, coupled with technological innovations, have further enhanced the effectiveness of pharmacovigilance practices.

As SAHPRA continues to navigate the evolving landscape of health product safety, it remains committed to safeguarding public health through proactive and comprehensive pharmacovigilance efforts. By addressing challenges and leveraging opportunities, SAHPRA aims to further strengthen its pharmacovigilance system and ensure the continued safety of health products for all South Africans.

SAHPRA: Safety First!