South African Health Products Regulatory Authority (SAHPRA)

Med Safety App Privacy Statement

Document review and approval

Revision history

Version	Author	Date	Revision
1	Mr. T. Ramosangoana (IT Manager)	22 January 2021	1st version
2			
3			

This document has been reviewed by

	Reviewer	Date reviewed
1	SAHPRA Management Committee	
2	SAHPRA Executive Committee	
3		
4		
5		

This document has been approved by

	Subject matter experts and / or owners Name	Date approved
1	EXCO	
2	CEO	
3		
4		

Policy	**:**	**Med Safety Privacy Statement**
Section	**:**	**IT01**

Contents

1. PURPOSE

1.1. To document how South African Health Products Regulatory Authority's manages applicant's data and protects such data on Med Safety App. SAHPRA is committed to protecting your data privacy and security. This privacy shall apply on SAHPRA and its participation in Med Safety App.

1.2. This data protection policy shall ensure SAHPRA:

- Complies with data protection law and follow good practice
- Protects the rights of applicants, and their products
- Protects itself from the risks of a data breach.
- This Privacy Policy sets out the manner in which personal information is collected, stored, and used by SAHPRA in terms of the process of Adverse Drug Reaction (ADR) Reporting through the Med Safety App.

2. DEFINITIONS

2.1. What is Data?

Data means facts and statistics collected by South African Health Products Regulatory Authority for reference or analysis and this data can be as written documents/records or electronic format.

2.2. Why do we need data?

The Regulator requires data in order to ensure the protection and promotion of public health and patient safety by ensuring that medicines are used safely and meet appropriate standards of safety, quality, efficacious.

2.3. What is ADR?

An adverse drug reaction (ADR) means a noxious and unintended response to a medicine, including lack of efficacy, and which occurs at doses normally used in man and which can also result from overdose, misuse or abuse of a medicine. The reaction may be a known side effect of the medicine or vaccine or it may be new and previously unrecognized. ADR can be caused by any therapeutic agent, including prescribed and over the counter (OTC) medicines, vaccines, and complementary medicines, and all of these should be reported.

ADR Reporting data is used by SAHPRA to identify and monitor early signs of medicine-related safety concerns that may require further investigation. It is important for people to report problems experienced with medicines or medical devices as these are used to identify issues which might not have been previously known about. Through this process, the Regulator aims to minimize the risk of harm to patients.

2.4. Who is SAHPRA or the Regulator?

South African Health Products Regulatory Authority is a 3A entity of the Department of Health established in terms of the Medicines and Related Substances Act ("the Medicines Act") with the objects of providing monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, scheduled substantives, clinical trials and medical devices, IDV's and related matters in the public interest

3. HOW DOES SAHPRA PROTECTS PERSONAL AND CONFIDENTIAL DATA?

3.1. General safeguarding. All confidential information from SAHPRA will be restricted from the view of the public. As a Regulator only those who have access to such information should be allowed to view the information.

3.2. Safeguarding of electronic information. Access to computer systems containing confidential information should be restricted to only those entrusted to keep the information confidential. Employees' logins and passwords should not be shared with others.

3.3. Restricted distribution. Distribution of confidential information should be restricted to those who have a legitimate business need to know it whenever feasible.

4. PERSONAL INFORMATION

SAHPRA holds and receives personal information relating to the reporter and patient.

4.1. Reporter (Patient or Health Care Profession)

4.2. This can include, but not limited to:

4.2.1 Name and Surname;
4.2.2 Contact details, email address, telephone number; and
4.2.3 Any other information relating to the applicant.

4.3. Patient

4.3.1 Name and Surname;
4.3.2. Physical Address;
4.3.3. Contact details, email address, telephone.
4.2.4. Date of Birth and/or ID Number

5. DATA USE

Personal and Applicant's data is of no value to the Regulator unless it can be use. However, it is when personal and applicant's data is accessed and used that it can be at the greatest risk of loss, corruption or theft.

6. THIRD PARTY ACCESS

6.1. The Med Safety App is developed in conjunction with other external partners/service providers who may to access to the data contained in this app.

6.2. In terms of the SLAs/MOUs (NDAs) the third parties may not use the data for any purpose other than intended for.

6.3. that in some instances, additional follow-up of a particular case may be necessary and therefore the reporter may be contacted by SAHPRA on a particular ADR report to request further information

7. COMPLIANCE

7.1. The law requires that the Regulator to take reasonable steps to ensure data is kept accurate and up to date.

7.2. The more important it is that the personal or applicant's data is accurate, the greater the effort by the Regulator to should put into ensuring its accuracy.

8. APPLICANT'S RIGHT TO ACCESS DATA

8.1. All individual who are the subject of personal data in possession of the Regulator are entitled to:
8.1.1. Ask how to gain access to it should the arises;
8.1.2. Be advised of the accuracy or inaccuracy of the data received by the Regulator.

9. RETENTION AND DISPOSAL

We only keep your personal information for as long as necessary to fulfill the purpose we collect it for, including reporting or legal requirements.

10. DISCLOSING DATA FOR OTHER REASONS

10.1. In certain circumstances, Data personal or applicant's data can be disclosed to law enforcement agencies without the consent of the owner of the data.
10.2 Data may be disclosed in terms of the Promotion of Information Access Act, Act No 2 of 2000.

11. POLICY UPDATES

SAHPRA has the right to update and improve this privacy policy in accordance with new data protection laws. We will inform you of any changes to this privacy policy if we believe the changes would impact on your rights or introduce a new purpose in processing your information.

12. CONTACTING US

If you have any questions about this Privacy Policy, the practices of this system or your dealings with this system please contact us at enquireis@sahpra.org.za or Telephone Number 012 501 0300.

POLICY AUTHORITY

EXCO is responsible for the maintenance and review of this policy. This policy will be reviewed every 3 years or when the need arises.

Policy Owner:
Policy Manager / Cognisant Person:

RECOMMENDED:

DocuSigned by:
Boitumelo Semete-Makokotlela
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15 April 2021

Dr. Boitumelo Semete **Date**

Chief Executive Officer