

**South African Health Products Regulatory Authority
(SAHPRA)**

PAIA MANUAL

South African Health Products Regulatory Authority (SAHPRA)
[PAIA Manual]

Document review and approval

Revision history

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1. SCOPE

- 1.1. This policy shall apply to all Board Members and all SAHPRA staff members.

2. PURPOSE OR BACKGROUND

- 2.1. This information manual ("the Manual") is published in terms of Section 14 of the Promotion of Access to Information Act No. 2 of 2000 ("the Act").
- 2.2. The Act gives effect to the provisions of Section 32 of the Constitution which provides for the right to access to information held by the State and to information held by another person that is required for the exercise and / or protection of any right.
- 2.3. The purpose of the Act is to foster a culture of transparency and accountability in both the public and private sectors by affording any person the right of access to information to enable them to exercise and protect all rights to the full extent required.
- 2.4. The purpose of this Manual is to set out the procedures to be followed and criteria that have to be met for anyone (the requester") to request access to records in the possession or under the control of SAHPRA.
- 2.5. This manual can be accessed on our website at www.sahpra.org.za or by requesting a copy by email from the relevant Information Officer.

3. FUNCTIONS OF SAHPRA

- 3.1. The South African Health Products Regulatory Authority (SAHPRA) is a juristic person and an organ of state within the public administration, established in terms of section 2 of the Medicines and Related Substances Act, 101 of 1965 (the Medicines Act), and mandated in terms of section 2B to:
- 3.2. ensure the efficient, effective and ethical evaluation or assessment and registration of medicines, medical devices and IVDs that meet defined standards of quality, safety, efficacy and performance, where applicable;
- 3.3. ensure that the process of evaluating or assessing and registering medicines, medical devices and IVDs is transparent, fair, objective and concluded timeously;

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- 3.4. ensure the periodic re-evaluation or re-assessment and monitoring of medicines, medical devices and IVDs;
- 3.5. ensure that evidence of existing and new adverse events, interactions, information with regard to post-marketing surveillance and vigilance is being monitored, analysed and acted upon;
- 3.6. ensure that compliance with existing legislation is being promoted and controlled through a process of active inspection and investigation; and ensure that clinical trial protocols are being assessed according to prescribed ethical and professional criteria and defined standards.

4. CONTACT DETAILS OF INFORMATION OFFICERS

- 4.1 In terms of the Act, the Chief Executive, or equivalent officer of a public body is designated as the Information Officer. The details of SAHPRA's Information Officer are as follows:

The Chief Executive

Physical Address:

Building A: Loftus Park

2nd Floor, Kirkness Road

Arcadia

0083

Telephone Number: +2712 501 0300

Email: PAIA@sahpra.org.za

- 4.2 The Chief Executive has, in terms of Section 17 (3) of the Act, delegated the powers and duties conferred and imposed on him/her by the Act to the following officials who shall perform functions of Deputy Information Officers:

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4.2.1 Deputy Information Officers

Name	Information Category
Chief Operations Officer	All SAHPRA categories of information
Chief Financial Officer	All SAHPRA finance and SCM information
Chief Regulatory Officer	All SAHPRA core business information
HR Executive	Employee and research information

- 4.3 The Chief Executive is the internal appellate body for all contested decisions in PAIA matters. Internal appeals must be directed to the Information Officer at PAIA.Appeal@sahpra.org.za.

5. GUIDE ON HOW TO USE THE ACT

A guide to the Act and the rights of requesters is available from SAHRC or from their website: www.sahrc.org.za

Any queries relating thereto must be directed to:

The Research and Documentation Department
South African Human Rights Commission
PAIA Unit
Private Bag 2700
HOUGHTON
2041

Telephone Number: +27 11 484 8300

Telefax Number: +27 11 484 1360

Website: www.sahrc.org.za

E-mail: PAIA@sahrc.org.za

6. HOW TO ACCESS RECORDS HELD BY SAHPRA

The following steps must be considered before submitting a request:

6.1 Step 1: Are you entitled to use the Act to request access?

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6.1.1 Please take note of Section 7 (1) of the Act which states:

"This Act does not apply to a record of a public body or a private body if-

6.1.1.1 that record is requested for the purpose of criminal or civil proceedings;

6.1.1.2 If such record is requested after the commencement of such criminal or civil proceedings as the case may be; and the production of or access to that record for the purpose referred to in paragraph (a) is provided for in any other law.

6.1.2 If Section 7(1) applies, you may not bring a request in terms of this Act. You must use the rules and procedures for discovery of information of the relevant legal forum and proceedings you are involved in.

6.1.3 Please have regard to Section 45 of the Act which entitles SAHPRA to refuse a request for access to a record if: (a) the request is manifestly frivolous or vexatious; or (b) the work involved in processing the request would substantially and unreasonably divert the resources of SAHPRA.

6.2 Step 2: Does the information requested exist in the form of a record?

6.2.1 Please note that the Act only applies to records which are in existence at the time of SAHPRA receiving your request.

6.2.2 The Act does not compel anyone to create a record which is not yet in existence at the time the request is made. For instance, the Act cannot be used to obtain reasons for a decision taken by SAHPRA if such reasons have not been recorded.

6.3 Step 3: Is the record in the possession or under the control of SAHPRA?

6.3.1 SAHPRA is a large organisation and the search for records requested may involve substantial time, resources and expenses.

6.3.2 The Act provides that the record requested must be in the possession or under the control of SAHPRA. However, for the purposes of the Act, a record in the possession or under the control of (a) SAHPRA official or (b) an Independent contractor engaged by SAHPRA is regarded as being a record of that public body or private body, respectively. If you are not sure whether the record is in the possession or under the control of SAHPRA, please indicate that to us in the prescribed

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request form.

- 6.3.3 As referred to earlier, Section 45 (b) of the Act entitles SAHPRA to refuse a request for access to a record if the work involved in processing the request would substantially and unreasonably divert the resources of SAHPRA.

6.4 Step 4: Form of Request

- 6.4.1 Access to information listed above shall be requested by:

6.4.2 Completing the Form A ("request form"); and

6.4.3 Payment of the prescribed fee as stated in paragraph 11 of this manual. However, a requester who seeks access to a record containing personal information about that requester is not required to pay the request fee.

6.4.4 The requester must indicate if the request is for a copy of the record or if the requester wants to inspect the records at the offices of SAHPRA.

6.4.5 Access to the aforesaid information will only be granted to the requester in a manner requested, unless such manner would unreasonably interfere with the running and operation of SAHPRA, or damage its records, or infringe its copyright.

6.4.6 If for practical reasons, access cannot be given in the requested manner but in an alternative manner, then the fee for access will be calculated according to the manner that the requester had requested.

6.4.7 If the requester is unable to read or write, or has a disability, then they can make the request for the record orally, in which event the Information Officer will complete the form on behalf of such requester and furnish the requester with such completed form.

6.4.8 The requester must clearly indicate on the request form:

- 6.4.8.1 If they wish to be informed of the success of their request telephonically or in any other manner.

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6.4.8.2 The capacity in which the request is made in the event the information is requested on behalf of somebody else.

6.4.9 The requester may be required to complete a non-disclosure agreement and/or memorandum of agreement to access certain information requested.

7. CONSIDERING THE REQUEST

7.1 Subject to the provisions of the Act, access to information requested from SAHPRA will be given if:

7.1.1 All procedural matters set out in the Act relating to a request are met; and

7.1.2 Access to the requested information is not refused in terms of any ground for refusal set out in the Act.

7.2 The grounds for refusal are outlined in Chapter 4 of Part 2 of the Act, and include mandatory protection of:

7.2.1 Commercial information of the third party.

7.2.2 Certain confidential information.

7.2.3 Safety of individuals, and protection of property.

7.2.4 Records privileged from production of legal proceedings.

7.2.5 Economic interests and financial welfare of the Republic and commercial activities of the public bodies.

7.2.6 Research information of the third party, and protection of the research information of the public body.

7.2.7 Certain information pertaining to operations of the public bodies.

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- 7.3 SAHPRA may also refuse requests that are manifestly frivolous and vexatious or that will lead to substantial and unreasonable diversion of resources.

8. RECORDS AUTOMATICALLY AVAILABLE

- 8.1 In terms of Section 15 of the Act, the following information on the following subjects is available without formal request on SAHPRA's website, posters and brochures:

- 8.1.1 Annual Report.
- 8.1.2 Annual financial statements.
- 8.1.3 General routine information pertaining to SAHPRA.
- 8.1.4 Guidelines.
- 8.1.5 Media Statements.
- 8.1.6 Registers of products, establishments and licences.
- 8.1.7 Fees.
- 8.1.8 Vacancies.
- 8.1.9 Tender information

9. RECORDS THAT MUST BE FORMALLY REQUESTED

- 9.2 Information pertaining to the following subjects must be formally requested in terms of Section 6.4.

- 9.2.1 Legislation and legal matters.
- 9.2.2 Organisation and control.
- 9.2.3 Human Resources.
- 9.2.4 Finance and procurement.
- 9.2.5 Risk management.
- 9.2.6 Services and administration.
- 9.2.7 Communication and public relations.
- 9.2.8 Marketing.
- 9.2.9 SAHPRA operations.
- 9.2.10 Intellectual Property.

- 9.3 The aforesaid information is contained in the following format:

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- 9.3.1 Reports submitted to Board and Committees.
- 9.3.2 Minutes of meetings of Board and Committees.
- 9.3.3 Correspondence (incoming and outgoing).
- 9.3.4 Internal memoranda and e-mails (between applicants and SAHPRA staff).
- 9.3.5 Invoices, statements and requisitions.
- 9.3.6 Reports, statistics (for internal and external reference).

10. REMEDIES FOR NON-COMPLIANCE WITH THE ACT

10.1 If after complying with the procedural requirements mentioned above:

- 10.1.1 The Deputy Information Officer refuses to grant access to information; and such refusal is not based on any ground of refusal mentioned in the Act; the requester may appeal against the decision of such Deputy Information Officer to the Information Officer.
- 10.1.2 The requester may lodge a Court application for further relief if not satisfied with the appeal decision of the Information Officer.

11. FEES

- 11.1 The “request fee” payable by every requester, other than a personal requester referred to in section 22(1) of the Act, is R35.
- 11.2 The “access fees” referred to in section 22(7) of the Act (unless the requester is exempted under section 22(8)) and “fees for reproduction” referred to in section 15(3) of the Act, are as follows:
 - (a) for every photocopy of an A4-size page or part thereof R0.60
 - (b) for every printed copy of an A4-size page or part thereof R0.40
 - (c) held on a computer or in electronic or machine-readable form for a copy in a computer-readable form on - (i) stiffer disc R5 (ii) compact disc R40
 - (d) for transcription of visual images, for an A4-size of part thereof R22 (ii) for a copy of visual images R60
 - (e) for a transcription of an audio record, for an A4-size page or part thereof R12 (ii) for a copy of an audio record R17
- 11.3 The actual postal fee is payable when a copy of a record must be posted to a requester.

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POLICY AUTHORITY

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

Policy Owner:

Policy Manager / Cognisant Person:

Confirmation of Approval

DocuSigned by:
Boitumelo Semete Makokotlala
E2EBB277730A46A...

Dr Boitumelo Semete
Chief Executive Officer

31 May 2021

Date