



**BROAD-BASED BLACK ECONOMIC EMPOWERMENT
POLICY FOR ISSUANCE OF LICENCES AS PER SECTION 22C
OF THE MEDICINES ACT**

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DOCUMENT REVIEW AND APPROVAL

Revision History

Version	Reason for Amendment	Date of Revision
1	New document.	April 2023

This document has been prepared, reviewed, and approved by

Activity	Full Name and Surname (Subject matter experts and/ or owners name)	Designation	Date
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Reviewed by:	Legal Committee	members	April 2023
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Reviewed by:	Senior Managers		April 2023
Reviewed by:	QMS		April 2023
TORS			April 2023
Approved by:	SAHPRA Board		

Distribution List

UNIT/ ENTITY	DESIGNATION
Officer of the CEO	Chief Executive Officer
SAHPRA Board	Chairperson
Industry	
SAHPRA	EXCO, Senior Managers and Managers

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1 INTRODUCTION

- 1.1 SAHPRA is a statutory body established in terms of section 2 of the Medicines and Related Substances Act (Act 101 of 1965), as amended hereafter referred to as the “Medicines Act”, to provide for the monitoring, evaluation, regulation, investigation, inspection, registration, and control of health products, scheduled substances, clinical trials and related matters in the public interest. SAHPRA must, in order to achieve its objects *inter alia*-
- a) ensure the efficient, effective and ethical evaluation or assessment of health products that meet defined standards of quality, safety, efficacy and performance, where applicable;
 - b) ensure that the process of evaluating or assessing and registering health products is standardized, transparent, fair, objective and concluded timeously, and
 - c) ensure the periodic re-evaluation or re-assessment and monitoring of health products.
- 1.2 SAHPRA is committed to upholding the principles enshrined in Chapter 2 of the Constitution of the Republic of South Africa, 1996, which promotes the rights of all people of South Africa and affirms the democratic values of human dignity, equality and freedom.
- 1.3 Therefore, SAHPRA is required to implement integrated socio-economic strategies to ensure viable economic empowerment of all black people including Woman, Youth, People living with disabilities.
- 1.4 Strategies must include supporting the health sector codes, the pharmaceutical sector codes and generic sector codes.

2 PURPOSE

2.1 The objectives of this policy are to:

Integrate all the elements of B-BBEE into the relevant Authority's activities in relation to its function of issuing licenses to manufacture, wholesale, distribute or import and export health products as well as the permits as envisaged in section 22c of Medicines Act.

- 2.1.1 This policy is in support Authority's comprehensive B-BBEE strategy to achieve the objectives set out in the B-BBEE Act, such as.
 - 2.1.1.1 Contribution to the economic transformation in order to enable meaningful participation of black people in the economy;
 - 2.1.1.2 Enabling the achievement of a substantial change in the composition of the licensee's management structures.
- 2.1.2 Encourage license applicants to comply with the B-BBEE Act in order to achieve broad-based and meaningful participation in the economy which will lead to sustainable development and general prosperity;
- 2.1.3 Assign clear executive responsibilities;
- 2.1.4 Ensure monitoring and evaluation of implementation of the policy within the Authority
- 2.1.5 To act in compliance with the frameworks mentioned in paragraph 3 below

3 SCOPE

This policy aims to promote the achievement of the objectives outlined in the B-BBEE Act by considering the code of good practice when determining qualification criteria for the issuing of licences and in so doing, ensures consistency with the applicable legislative frameworks and the vision of the Authority.

This policy does not cover matters of employment equity and preferential procurement as these are covered in the Employment Equity plan of SAHPRA and the SAHPRA procurement policy nor does it cover the permits as issued by the Director-General as envisaged in the Medicines Act.

It must be noted that a detailed guideline will be developed to support the implementation of this policy. This guideline will determine how SAHPRA, in compliance with the generic codes, will determine the criteria when issuing licenses as per section 22c of Medicines Act.

This policy does not affect the current SHAPRA registration process for health products. Which focused on the safety, quality, efficacy as well as performance of the health products.

4. DEFINITIONS

Unless the context indicates otherwise, the following words and phrases used in this document have the following meanings:

"Broad-Based Black Economic Empowerment" as defined in the BBEE Act means the economic empowerment of all black people including Empowerment women, workers (persons contributing to the economy), youth, people living with disabilities and people

living in rural areas through diverse but integrated socio-economic strategies that include, but are not limited to:

- (a) Increasing the number of black people that manage own and control enterprises and productive assets
- (b) facilitating ownership and management of enterprises and productive assets by communities, workers, cooperatives and other collective enterprises
- (c) human resource and skills development
- (d) achieving equitable representation in all occupational categories and levels of the workforce
- (e) preferential procurement from enterprises that are owned or managed by black people; and
- (f) investment in enterprises that are owned or managed by black people.

“**EAP**” means Economically active population;

“**Equitable Representation**” means Demographic representation reflecting the national levels as stipulated in the Economically Active Population census data provided by Statistic South Africa;

“**Licence**” means a licence and permits issued in terms of the Medicines Act to manufacture, import, export, act as a wholesaler of or distribute, as the case may be, such medicine, Scheduled substance, medical device or IVD upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the Authority may determine.

“**SED**” means Socio-Economic Development

5. **POLICY STATEMENT**

This Policy has been established to ensure SAHPRA strives to achieve compliance with the B-BBEE Act, specifically section 10(1)(a) in its function of issuing licenses to manufacture, wholesale, distribute or import and export health products as per section 22C(1)(b) of the Medicines Act.

6. **POLICY POSITION**

6.1 SAHPRA must comply with B-BBEE Act by applying any relevant code of good practice issued in terms of the B-BBEE Act in determining qualification criteria for the issuing of licences, concessions, or other authorisations in respect of economic activity in terms of the Medicines Act.

6.2 SAHPRA will implement this policy in two (2) phases

6.2.1 **Phase 1(1 year process)**

6.2.1.1 SAHPRA will require an applicant to submit its B-BBEE level certificate when applying for a licence. This requirement will be effective on a date to be communicated to industry.

6.2.1.2 SAHPRA verify the B-BBEE level status

6.2.1.3 Should an applicant fail to submit its B-BBEE level certificate, or the certificate not be verifiable, SAHPRA will not issue a licence to such applicant

6.2.1.4 SAHPRA will utilize the information gathered to understand the industry structure and

health products supply to inform the development of criteria to be applied
6.2.1.5 SAHPRA will then develop, consult with industry, including relevant stakeholders and finalise criteria to be applied when licence applications are reviewed and eventually issued

6.2.2 **Phase 2 (Post year 1)**

6.2.2.1 SAHPRA will utilize the applicant B-BBEE level as per the approved criteria to review and issue licences

7. **LEGISLATIVE FRAMEWORK**

7.1 This policy should be read in conjunction with the following:

7.1.1 Medicines and Related Substances Act 101 of 1965;

7.1.2 Pharmacy Act 53 of 1974;

7.1.3 Broad-Based Black Economic Empowerment Act 53 of 2003; as amended

8. **AUTHORITY POLICY FRAMEWORK**

8.1 This policy should be read in conjunction with the following Authority's documents, policies, programme, and frameworks aimed at addressing the various elements of transformation

8.1.1 SAHPRA Annual Performance Plan.

8.1.2 SAHPRA Strategic plan

9. **RESPONSIBILITIES**

9.1 The Board give its full support to the SAHPRA B-BBEE Policy.

9.2 All management levels are responsible for the correct application of this Policy.

9.3 The promotion of this Policy is a key function of all management levels within the Authority.

10. **THE ROLE OF MANAGEMENT EXECUTIVE COMMITTEE MEMBERS:**

10.1 The Executive Committee ("EXCO") consist of:

10.1.1 Chief Executive Officer;

10.1.2 Chief Financial Officer;

10.1.3 Chief Regulatory Officer;

10.1.4 Chief Operations Officer, and

10.1.5 Human Resources Executive

10.2 All Exco members are responsible for:

10.2.1 Continually promoting SAHPRA's commitment to the democratic values of human dignity, equality, inclusivity, mutual respect, and empowerment of internal and external stakeholders.

10.2.2 Ensuring that the objectives of this B-BBEE policy for issuance of licences as per section 22c of the medicines Act and B-BBEE Act are integrated into SAHPRA's Strategy and SAHPRA's Annual Performance Plan.

10.2.3 Ensuring the implementation of this B-BBEE Policy in accordance with the generic codes for all licensing application in terms of the Medicines Act.

10.2.4 Providing quarterly reports to the SAHPRA board on progress made in terms of the B-BBEE objectives.

11. THE ROLE OF SENIOR MANAGERS AND MANAGERS:

11.1 All Managers are responsible for:

11.1.1 Continually promoting SAHPRA's commitment to the democratic values of human dignity, equality, inclusivity, mutual respect, and empowerment of internal and external stakeholder.

11.1.2 Initiating and implementing changes relating to B-BBEE in terms of the objectives set out in the SAHPRA B-BBEE policy and B-BBEE Act on licensing application

11.1.3 Ensuring the implementation of the B-BBEE Policy for issuance of licences as per section 22c of the medicines Act.

11.1.4 Providing quarterly reports through respective senior managers to EXCO on progress made in terms of the B-BBEE objectives and motivate deviations, if any.

11.1.5 Making recommendations for changes that would facilitate the achievement of the B-BBEE objectives on licensing application.

12. IMPLEMENTATION

12.1 It is the responsibility of all EXCO members and their respective Senior Managers as well as Managers to achieve the objectives of this Policy in the various areas which the Policy intends to address.

12.2 Giving effect to this Policy is grounded in the implementation of SAHPRA's Strategic objectives and Annual Performance Plan.

13. PUBLICATION

13.1 Information provided by the applicant licence application will be treated confidentially and only disclosed where required and if requested, in accordance with the provisions of the Promotion of Access to Information Act, 2000.

13.2 The Policy will be published on the SAHPRA website.

14. NON-COMPLIANCE

14.1 Should SAHPRA staff members fail to comply with this policy, SAHPRA will therefore invoke its disciplinary policy and procedures

15. POLICY APPROVAL

The Executive Committee is responsible for the maintenance and review of this Policy.

Effective Date:

Review Date:

30 April 2024

Policy Owner: Chief Executive Officer

Policy Manager / Cognizant Person: CEO

Confirmation of Approval:

**Prof H Rees
Chairperson**

Date

Draft