SAHPRA
South African Health Products Regulatory Authority

COMMUNICATION REGARDING THE DEVELOPMENT OF A POLICY RELATING TO THE ISSUING OF LICENCES IN TERMS OF SECTION 22C(1)(b) OF THE MEDICINES AND RELATED SUBSTANCES ACT 101 OF 1965 IN ACCORDANCE WITH BROAD-BASED BLACK ECONOMIC EMPOWERMENT PRINCIPLES

DOCUMENT REVIEW AND APPROVAL

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This document has been prepared, reviewed, and approved by

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Distribution List

UNIT/ ENTITY	DESIGNATION
Officer of the CEO	Chief Executive Officer
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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 Act. The objects of the Authority are to provide for the monitoring, evaluation, regulation, investigation, inspection, registration, and control of health products (medicines and medical devices), scheduled substances, clinical trials and related matters in the public interest. SAHPRA must, in order to achieve its objects i*nter 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 standardised, 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 SAHPRA supports integrated socio-economic strategies to facilitate viable economic empowerment in accordance with broad-based black economic empowerment (B-BBEE) principles.

1.4 This communication should be read in conjunction with the Medicines Act, the Pharmacy Act (Act 53 of 1974) and the Broad-Based Black Economic Empowerment Act (Act 53 of 2003) (the B-BBEE Act).

2. DEFINITIONS

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

"**Broad-Based Black Economic Empowerment**"[1] means the viable economic empowerment of all black people, in particular women, workers, youth, people with disabilities and people living in rural areas, through diverse but integrated socioeconomic 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

[1] Broad-Based Black Economic Empowerment Act 53 of 2003

communities, workers, cooperatives, and other collective enterprises;

(c) human resource and skills development;

(d) achieving equitable representation in all occupational categories and levels in 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;

Black people mean Africans, Chinese, Coloureds and Indians, collectively

"**Equitable representation**" means demographic representation reflecting the national levels as stipulated in the Economically Active Population census data provided by Statistics South Africa;

"Licence" means a licence issued in terms of the section 22C(1)(b) of the Medicines and Related Substances Act 101 of 1965 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.

"SAHPRA" means the South African Health Products Regulatory Authority

"**The Medicines Act"** means the Medicines and Related Substances Act 101 of 1965

3. PURPOSE

3.1 This communication is developed in accordance with the B-BBEE Act, specifically section 10(1)(a), as it relates to the Authority's function of issuing licences in terms of section 22C(1)(b) of the Medicines Act.

3.2 The objectives of this communication are to:

3.3 encourage persons applying for a licence in terms of section 22C(1)(b) of the Medicines Act to comply with the B-BBEE Act in order to achieve broad-based and meaningful participation in the economy;

3.4 .support the Authority's comprehensive B-BBEE strategy to achieve the objectives set out in the B-BBEE Act.

4. SCOPE

4.1 SAHPRA is required to comply with the B-BBEE Act by applying any relevant code of good practice issued in terms of that 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.

4.1.1 This communication aims to support the objectives outlined in the B-BBEE Act.

4.1.2 This Communication applies to persons applying for a licence in terms of section 22C(1)(b) of the Medicines Act whose business falls within the scope.

4.1.3 Where an applicant for a licence has complied with the B-BBEE Code of a specific sector, SAHPRA will consider such sector code when processing the application for a licence in terms of section 22C(1)(b of the Medicines Act .

4.1.4 A detailed guideline describing the approach to be followed when issuing licenses as per section 22C(1)(b) of the Medicines Act will be published.

4.1.5 This communication does not cover matters of employment equity and preferential procurement which are provided for in the Employment Equity plan of SAHPRA and the SAHPRA procurement policy.

4.1.6 This communication does not affect the registration process for medicines and medical devices which focus on the safety, quality, efficacy of medicines, and the safety, quality and performance of medical devices.

4.1.7 This communication does not apply to the issuing of permits by the Director- General of the National Department of Health.

5. PROCESS TO BE FOLLOWED

5.1 SAHPRA intends to follow a two phased process.

5.1.1 In phase 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.

5.1.2 SAHPRA will utilise the information gathered from applicants to understand the industry landscape and inform the development of criteria to be applied in a future policy document.

5.1.3 Based on the learnings of the first phase, SAHPRA will develop criteria to be applied in the licensing process in terms of section 22C(1)(b) of the Medicines Act. Consultation with all relevant stakeholders will take place during phase 2 of this process.

6. CONFIDENTIALITY

Information provided by an applicant for a licence will not be disclosed to a third party and will be treated confidentially. Information will only be disclosed where required and if requested, in accordance with the provisions of the Promotion of Access to Information Act, 2000.

7. POLICY APPROVAL

The Executive Committee will be responsible for the maintenance and review of the policy. developed in phase 2.