SAHPRA
South African
Health Products
Regulatory Authority

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COMMUNICATION TO STAKEHOLDERS

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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

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Table of Contents

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1. INTRODUCTION

1.1 The South African Heath Products Regulatory Authority (SAHPRA) is a statutory body established in terms of Section 2 of the Medicines and Related Substances Act, 101 of 1965, as amended. 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, *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 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.

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1.4 This communication should be read in conjunction with the Medicines and Related Substances Act, Pharmacy Act, 53 of 1974, and the Broad-Based Black Economic Empowerment 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 who 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 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 stipulated in the Economically Active Population data provided by Statistics South Africa.

"Licence" means a licence issued in terms of Section 22C(1)(b) of the Medicines and Related Substances Act, 101 of 1965, to manufacture, import, export, act as a wholesaler of, or

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

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distribute, as the case may be, such medicine, Scheduled substance, medical device or *in vitro* device (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" or "the Authority" means the South African Health Products Regulatory Authority.

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

"**Organ of State**" means-

(a) a national or provincial department as defined in the Public Finance Management Act, 1 of 1999;
(b) a municipality as contemplated in the Constitution;
(c) Parliament;
(d) a provincial legislature; and
(e) a constitutional institution listed in Schedule I of the Public Finance Management Act, 1 of 1999.

"**PFMA"** means the Public Finance Management Act, 1 of 1999.

"**Public Entity**" means a public entity listed in Schedule 2 or 3 of the Public

Finance Management Act, 1 of 1999.

3. PURPOSE

3.1.1 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 licenses in terms of Section 22C(1)(b) of the Medicines Act.

3.1.2 The objectives of this communication are to:

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3.1.2.1 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.

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

4. SCOPE

4.1.1 SAHPRA, as a public entity as defined in the B-BBEE Act, is required to comply with the provision of 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 licenses, concessions, or other authorisations in respect of economic activity in terms of the Medicines Act.

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

4.1.3 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.

4.1.4 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.

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

4.1.6 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.

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

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

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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 the 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 compelled by a court order or if requested, in accordance with the provisions of the Promotion of Access to Information Act, 2000.

Boitumelo Semete-Makokotlela

Dr Boitumelo Semete-Makokotlela
Chief Executive Officer (CEO)
SAHPRA
08 April 2025