South African Medical Technology Industry Association (*SAMED*)

SUBMISSION TO SAHPRA

Comments to the draft SAHPRA's Broad-Based Black Economic Empowerment Policy

31 August 2023

1. Introduction

SAMED was founded in 1985 and is a not-for-gain voluntary trade association that represents the medical technology industry in South Africa. Its 152 members include manufacturers, distributors, and wholesalers, ranging from micro enterprises to large multinational companies, of medical devices, medical equipment and invitro diagnostics (collectively termed medical technologies or medtech). SAMED is committed to ensuring a sustainable, transformed and ethical medical technology industry in South Africa. SAMED's members are governed by and required to adhere to the Medical Device Code of ethical marketing and business practice.

2. SAHPRA in two roles

SAHPRA relates in two ways with B-BBEE:

(a) SAHPRA as a state entity ("organ of state") being required to comply with the B-BBEE system and to itself obtain a B-BBEE rating; and

(b) SAHPRA as a regulator, which issues licences and permits, being obligated to consider B-BBEE Code compliance when fulfilling its regulatory role.

Elements of the proposed SAHPRA policy appear rather to relate to SAHPRA itself having to comply with B-BBEE using "Statement 004: Scorecards for Specialised Enterprises", issued on 6 May 2015 in GG No. 38766[1], and its own compliance with the Employment Equity Act (EEA).

Reference to SAHPRA's own Employment Equity Plan (second paragraph under heading "3. Scope") and its Procurement Policy can only refer to SAHPRA's own B-BBEE compliance, and not that of licensing / permit applicants. It should be noted that for neither SAHPRA's internal policies, nor for the policy in relation to B-BBEE as a licensing criterion, is Employment Equity a separate requirement. It is included in any entity's B-BBEE rating. There is, however, a separate legal obligation on all entities to comply with the Employment Equity Act, the requirements of which are quite distinct from the B-BBEE Act's requirements. EEA definitions (namely "EAP" and "equitable representation") included in the SAHPRA policy are not related to the implementation of the B-BBEE Act.

Throughout the draft policy, SAHPRA's two distinct roles (as B-BBEE "enforcer" (point (b)) and as itself being required to be B-BBEE compliant (point (a)), seem to be confused.

3. The Empowering Act and the Codes issued thereunder

Section 10 of the Broad-Based Black Economic Empowerment Act, 2003, is referred to in "5. Policy Statement". Having regard to the provisions of section 10 is important when considering how SAHPRA intends to apply B-BBEE when issuing licences. It reads as follows:

10. Status of codes of good practice*—(1) Every organ of state and public entity must apply <u>any relevant code of good practice</u> issued in terms of this Act in—*

(a) determining qualification criteria for the <u>issuing of licences</u>, concessions or <u>other authorisations</u> in respect of economic activity in terms of any law

Two aspects are clear from the section mandating SAHPRA to develop this policy, and, when finalised, to apply B-BBEE in its licensing and authorisation activities:

- SAHPRA has to apply the relevant Codes. There is only one set of Codes applicable to medical device companies, namely the so-called "Generic Codes", issued initially on 10 October 2013, and amended in 2014, 2015 and 2019,[2] and supplemented by, amongst other, the Specialised Scorecard (Statement 004), and the YES (Statement 000). This has various implications:
    - The SAHPRA draft policy statement at 1.4 is incorrect, as there are no "health sector codes" and no "pharmaceutical codes" that would find application;

[1] Also see: https://www.bbbeecommission.co.za/wp-content/uploads/2021/09/Brochure-on-Specialised-Scorecard-06-September-2021-00000003.pdf

[2] GN 1019 of 11 October 2013: Issue of Codes of Good Practice (Government Gazette No. 36928) as amended by Notices No- 226 of 18 March 2014, 396 of May 2015, 407 of 6 May 2015, 444 of 15 May 2015, 303 of 31 May 2019 w.e.f. 30 November 2019, 304 of 31 May 2019 w.e.f. 30 November 2019, of 31 May 2019 w.e.f. 30 November 2019, 306 of 31 May 2019 w.e.f. 30 November 2019.

- SAHPRA cannot, as it states at 2.1.1 assess, or aim to assess "meaningful contribution", nor limit its assessment to "management structures". The B-BBEE Act clearly requires the relevant Code to be applied, i.e. either the Generic Code (in its totality), or a sector-specific Code (of which there are none at present in the health sector).

- SAHPRA is only mandated to exercise this section 10(1) power when *"issuing" licences* in terms of section 22C. A licence is only issued once, and thereafter it is renewed, and no longer "issued" anew. "Renewals" of licences in terms of section 22D is subject only to the payment of a prescribed fee. Furthermore, the suspension or cancellation of licences can only take place as provided for in section 22E and can only take place on the grounds listed in sections 22E(1)(a) – (d).

SAMED is therefore of the view that B-BBEE can be a licensing criterion for *new applications* only in terms of section 22C. The B-BBEE Codes of 2013 must, in their totality, apply as a new licensing criterion under section 22C, and would require amendment to the relevant Guidelines and Forms for such new applicants.

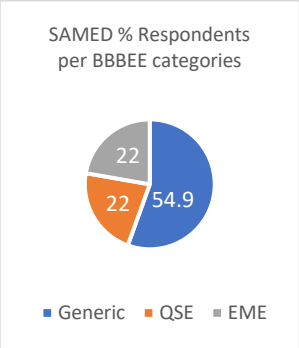
The SAHPRA Draft Policy states at 2.1 that it would apply to "permits" envisaged in section 22C. There are however no permits issued in terms of section 22C, and where other permits might be implied, those apply to specific products (e.g. in section 21). The permits referred to in section 22A are all issued by the Director-General of Health (although it is being done by SAHPRA, presumably on the delegation of powers to it by the Director-General). It is therefore unclear how SAHPRA intends to apply the Policy in relation to "permits".

4. SAMED Commitment to Transformation

At the outset it is important to state that SAMED fully supports the imperative to transform the South African economy. SAMED has now, for many years, had a standing committee on matters of transformation. Where healthcare is concerned, there are a number of constitutional[3] imperatives to consider. These include transformation and the advancement of persons and groups previously disadvantaged by discrimination (section 9(2)), access to healthcare, which includes access to medical devices (section 27(1)(a) and (3)), and obligations in terms of procurement (which hinge on licensing of medical device companies), requiring to be fair, equitable, transparent, competitive and cost-effective (section 217(1)). A medical device company could be totally excluded from the market should it not receive a licence on the basis of B-BBEE, with the unintended consequence of denying patients access to medical technologies supplied by that company.

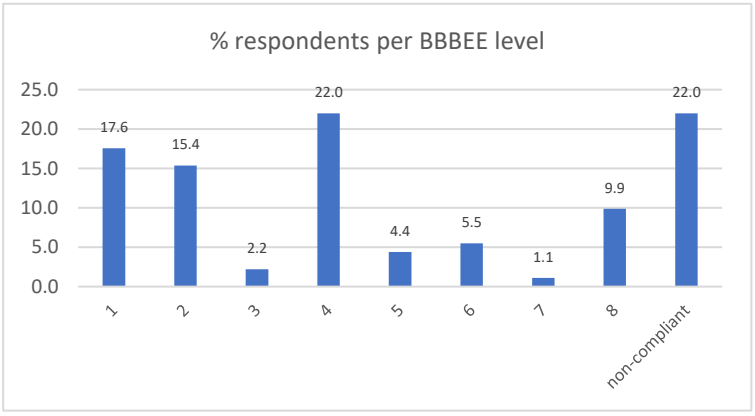
[3] Constitution of the Republic of South Africa, 1996.

5. SAMED Research



As part of preparing this submission, SAMED undertook a survey amongst its members to determine not only current levels of B-BBEE, but also the challenges members may face in implementing B-BBEE. We provide a summary of the results here. Almost 54% of respondents were, in B-BBEE terms "large" entities. However, more than 68% of respondents have less than 50 employees, thereby qualifying as "small" in terms of possibilities in management control, employment equity and skills development.

When looking at the current B-BBEE levels, performance is spread across all the B-BBEE levels. There is also a non-compliance level of 22%; some 13% do not have a B-BBEE certificate or affidavit, as the case may be, whilst close to 10% do have a certificate, meaning that they did go through a B-BBEE rating process. This also shows the effect of setting B-BBEE as a licensing condition at a specific level. It could lead to significant numbers of medical device suppliers not being licenced by SAHPRA. There is, therefore, significant concern as to how B-BBEE will be applied as part of the section 22C processes.



Respondents were divided in their views on B-BBEE and SAHPRA implementing this policy. Many respondents viewed B-BBEE compliance as not problematic, albeit difficult for some. The benefits of upliftment, increased local ownership, transformation and levelling the playing fields were listed. Other respondents listed concerns relating to whether B-BBEE is SAHPRA's mandate, some respondents felt that the issue of standards in the medical device sector is more pressing. Other concerns were the cost of compliance and that B-BBEE does not really address socio-economic challenges. Smaller companies expressed concern regarding the impact on them, the impact on competitiveness (fewer players and more "middle-men") and whether it will lead to decreases in investment and local manufacturing. Ownership is a concern for both single-owner entrepreneurs, as well as multinational entities that are unable to sell shareholding. 87% of respondents obtain their B-BBEE certificates annually. The implication of this is, should B-BBEE compliance become an annual requirement, licence-holders could face issues with synchronisation between licence retentions, and B-BBEE certificate dates. Others who may not have a B-BBEE certificate in a particular year, would put their SAHPRA licences retention at risk.

6. Specific comments

Below we provide some comments on the various headings in the B-BBEE Policy for the issuing of section 22C licences:

Comments on "Introduction"

Point 1.2 refers to Chapter 2 in the Constitution. As alluded to above, there is more than just section 9 at stake. Property rights could also be adversely affected should SAHPRA implement B-BBEE criteria in, for example, the renewal of licences. A licence relates to the property rights of a company, to commercialise its products. SAMED respondents also referred to concerned regarding the availability of products. If an entity that was previously licenced no longer holds a licence, and medical schemes, for example, reimburse such products, it would not only affect that company, but also the patients and the medical scheme. The same would apply for supply agreements with hospitals and other health facilities.

Point 1.3 refers specifically to "viable" economic empowerment. It is unclear whether SAHPRA intends this to be a criterion and if so, how it would evaluate this.

We commented above in point 1.4 that there are no health sector codes or pharmaceutical codes relating to B-BBEE.

Comments on "2. Purpose"

SAMED understands that SAHPRA must consider the B-BBEE Codes when it licences medical device entities. It is however unclear why "management structures" have been singled out in 2.1.1.2, as there are five B-BBEE pillars, of which management control is only one.

Given the wording in section 10 of the B-BBEE Act, it is unclear why 2.1.2 refers to the "encouragement" of B-BBEE. The role of managers in SAHPRA is also not clear, and appears to be where the conflation of SAHPRA as being B-BBEE compliant itself, with the use of the B-BBEE Codes in licensing of applicants, comes in.

Comments on "3. Scope"

SAHPRA is not empowered to cut employment equity out of the B-BBEE Codes. It is there, and specifically as part of the "management control" pillar in Code Series 200. The sentence relating to the "SAHPRA Procurement Policy" not applicable to DG permits also does not make sense, and again possibly relates to the conflation of SAHPRA as B-BBEE subject ((a) above) versus SAHPRA as regulator ((b)).

This part of the Policy refers to Guidelines to be issued. It is assumed that the details will only be included in such Guidelines, and as such this SAHPRA policy introduces significant elements of uncertainty, on which criteria is envisaged. It becomes really difficult to comment on criteria that are, as yet, unknown.

Although the Policy does not affect registration, the removal of- or non-granting of a licence will mean that the products of that company will, by definition, lose their registration for medicines, and for medical devices, it will not appear on SAHPRA registers, as the device company licence is linked to the product list.

Comments on "4. Definitions"

The reason for the inclusion of these specific definitions is not clear, also as the criteria referred to under point 3, is not yet known. It is also not understood why the definition of SED, without it being mentioned in the Policy, is included.

Comments on "6. Policy Position"

It is not clear how SAHPRA would "verify" a B-BBEE level – B-BBEE verification can only be undertaken by entities that SANAS has accredited to do so.

6.2 Refers to two phases, firstly to understand the B-BBEE landscape, and then to consider B-BBEE as a licencing criterion:

6.2.1.4 refers to SAHPRA gathering information to "understand the industry structure and health products supply" to "inform the development of criteria". It is not clear what SAHPRA has in mind here, and what it hopes to glean from the submitted B-BBEE certificates. SAHPRA should also bear in mind that, for a significant portion of the industry, it is lawful to obtain one's BEE status by means of an affidavit.

Section 6.2.2 appears to imply that SAHPRA would require a specific B-BBEE level. It is not clear whether that would be in line with section 10 of the B-BBEE Act. In setting a specific level, some medical device licence holders may find it difficult or impossible to reach a specific score that leads to a level of more than 6 or perhaps a 5. The reason for this lies in the nature and also structure of medical device enterprises – many are small in terms of staffing (affecting management control and skills development scores), most import significant portions of their products (affecting the procurement score in "supplier development"), and many are unable to sell ownership in the local entity. This is as non-performance in ownership, and/or not achieving subminimum in skills development and supplier development (the "priority pillars"), is accompanied by a level drop in B-BBEE score from the achieved score. This means that even if a company achieves a score leading to a level 7 of B-BEE compliance, not scoring sub-minimums in any of the priority pillars will mean that their score is reduced to level 8, or from 8 to non-compliance.

Based on a presentation that was provided to ITG on this draft policy, it seems that SAHPRA is grappling with the extent to which B-BBEE would be part of the "qualification criteria" for the issuing of licences. SAMED appreciates the honesty and willingness of SAHPRA to engage with this important matter. The options were presented as, for example, giving a faster licencing approval time to better B-BBEE scoring medical device licensing applicants. SAMED believes that B-BBEE could be "a" criterion, alongside others, for the issuing of new licenses, however other factors, such as the impact of access to medical devices and competition in public sector business (both of which are also constitutional imperatives) must also be considered. SAMED also believes that to be fair,

the specific contextual factors relating to the specific level achieved by an applicant must be considered. Lastly, any criterion that would violate the Promotion of Administrative Justice Act, e.g. by simply giving preference based on a B-BBEE level, would be problematic as criteria for administrative justice include fairness, and that rational and relevant factors must be considered when regulatory decisions are made. The weighing up of relevant factors must be done in a careful, nuanced manner, to be constitutional.

Comment on "7. Legislative Framework"

The Pharmacy Act does not apply in the instance of medical devices. The extent to which SAHPRA may have to change the Medicines Act in order to set a particular level of B-BBEE compliance is not clear. This has been the case in mining legislation, for example.

Comment on 8 - 14

The exact way in which the listed documents and persons would play a role in the consideration of B-BBEE in medical device company licensing is not clear and should be spelt out. Again, it appears as if SAHPRA's own B-BBEE compliance (point (a) above) and that of it as a regulator considering the B-BBEE Codes for applications, are conflated. 10.2.4 specifically appears to refer to SAHPRA's own BEE status.

These sections in the policy appear to be grounded in general business and HR policies of companies, and not tailored for the specific purposes of licensing whilst considering the B-BBEE Codes.

7. Conclusion

SAMED wishes to engage SAHPRA in person on this policy and potential criterion as it believes it will have significant impact for its members. SAMED also urges consideration of the difficult economic circumstances in which companies find themselves currently.

In summary, SAMED understands and supports the importance of ensuring transformation in the South African economy, and that SAHPRA is, by legislation, obligated to consider B-BBEE in issuing licences. However, the manner in which B-BBEE becomes a consideration (one of the criteria) when doing so, is important. This cannot be done as a blunt instrument, e.g. "level x or you do not get your licence", or "level y and you get preference", or "if you do not maintain or enhance your B-BBEE level you lose your licence".

This policy should ensure meaningful social and economic transformation, whilst preserving principles of administrative justice and increased access to healthcare.