



MEDIA STATEMENT

SAHPRA dismisses unfounded misinformation campaign deliberately misrepresenting its draft B-BBEE Policy by some sectors of society and media organisations

Embargo: Immediate Release

Pretoria, 22 July 2024 – The South African Health Products Regulatory Authority (SAHPRA) is disappointed with the unfounded fallacies and misrepresentation in circulation and churned out by some media organisations without verification, in what presents as a misinformation campaign devoid of any intent to rely on facts. SAHPRA’s draft B-BBEE Policy is proposed in order to comply with requirements of the Broad-Based Black Economic Empowerment Act, 53 of 2003, in particular Section 10(1)(a), which demands of all state entities to enact policy that can encourage inclusive economic participation. The draft policy, which may be accessed on the SAHPRA website at <https://www.sahpra.org.za/documents-for-comments/>, is a result of a robust consultation process with all material stakeholders.

The misinformation campaign is premised on deliberate falsehoods that do not exist within SAHPRA’s proposed policy and racially charged misrepresentations which the draft policy had clearly expressed itself on and the SAHPRA executive had addressed with stakeholders and interested parties who have attended stakeholder engagement meetings as part of the draft policy’s consultation process, the most recent of which was held in June 2024, attended by more than 300 delegates representing the lengths and breaths of the health products industry in South Africa. A recording of this session is available at <https://www.sahpra.org.za/event/sahpras-hybrid-stakeholder-engagement-meeting/>. To set the record straight, we address all the falsehoods currently in circulation below:

Falsehood 1: SAHPRA's draft B-BBEE policy sets "racial requirements" for the registration of medicines

Truth: The draft policy has not set any quotas for the ownership of pharmaceutical businesses based on race or gender. This is not within SAHPRA's mandate and does not exist in any legislative frameworks that govern SAHPRA's work and/or those that SAHPRA is responsible for implementing. As such this lie is dismissed with the contempt it deserves, as it lacks any basis in facts and does not exist anywhere within SAHPRA documents.

Falsehood 2: SAHPRA will use the B-BBEE to assess medicine registration applications and thus affect access to medicines

Truth: This is a deliberate misrepresentation of SAHPRA's draft B-BBEE Policy. The draft policy clearly and prominently indicates that this would not be the case, and that SAHPRA's health products registration processes would continue to solely rely on the safety, quality, efficacy, and performance of the health products. Any insinuations to the contrary are mischievous and do not exist in the policy currently or in SAHPRA's future plans.

Falsehood 3: The draft B-BBEE policy is aligned with the National Health Insurance and seeks to exclude certain persons from state procurement

Truth: This wild conspiracy lacks any basis in reality and is indicative of an overactive but malicious imagination. There is no connection anywhere in the proposed policy to the NHI, in fact the policy clearly states that it is not concerned with any preferential policy frameworks. These are not in SAHPRA's scope of responsibility.

The draft policy seeks to ensure that the pharmaceutical industry moves towards developing sector codes and/or criteria similar to what has been successfully implemented in various other sectors of the economy including agriculture, mining, finance, tourism, and defence, among others. This is in compliance with the requirements of the B-BBEE Act and has no bearing whatsoever on any assumed conspiracies.

Falsehood 4: The policy will deny participation in the pharmaceutical industry by SMEs as they may not be able to acquire B-BBEE certificates

Truth: SAHPRA is on record reiterating the following facts:

1. B-BBEE compliance affidavits by small businesses will be acceptable in the place of B-BBEE certificates; and
2. The B-BBEE level of a business is of no effect in the medicines registration process, and this will stay the case even once the policy is implemented.

The policy seeks to increase participation by previously marginalised persons and has no intent whatsoever to decrease participation by or exclude any persons based on race or gender. SAHPRA is on record indicating this, and this is also clearly stipulated in the policy.

SAHPRA remains committed to executing its legislative mandate and all Health Product registration processes in line with its core purpose, to assess and register medicines, medical devices and in-vitro diagnostics (IVDs) in line with the requisite standards to protect the health and well-being of South Africans, being to ensure the safety, efficacy, and quality of health products.

Thus, SAHPRA invites all stakeholders and interested persons to peruse the draft policy available on the SAHPRA website at this link <https://www.sahpra.org.za/documents-for-comments/> and submit substantiated comments by 09 September 2024.

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About SAHPRA:

SAHPRA is tasked with regulating (monitoring, evaluating, investigating, inspecting and registering) all health products. This includes clinical trials, complementary medicines, medical devices and *in-vitro* diagnostics (IVDs). Furthermore, SAHPRA has the added responsibility of overseeing radiation control in South Africa. SAHPRA's mandate is outlined in the Medicines and Related Substances Act, 101 of 1965, as amended, as well as the Hazardous Substances Act, 15 of 1973.

SAHPRA has three pillars to ensure that medicines, medical devices and IVDs meet the requisite standards to protect the health and well-being of all who reside in South Africa:

- Safety
- Efficacy
- Quality

It is these three pillars that define the ethos of SAHPRA.

Notes to Editors:

Should you request an interview, please send your request to media@sahpra.org.za and copy Madimetja.Mashishi@sahpra.org.za.

SAHPRA will publish this media release on its website. Navigate to the News section on the website.

A podcast will be recorded and posted on the home page. Scroll down the home page to “**SAHPRA TV and Podcasts**”. Podcasts appear on the right-hand side. Updates on vaccine registration can be accessed here:

Vaccines - News and updates (sahpra.org.za) - <https://www.sahpra.org.za/news-and-updates/vaccines-news-and-updates/>