SAHPRA
South African Health Products Regulatory Authority

POLICY POSITION OF THE SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY ON ENABLING LOCAL MANUFACTURING

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DOCUMENT REVIEW AND APPROVAL

Revision History

Version	Reason for Amendment	Date of Revision
1	New document	September 2024
2	Inclusion of input from comments received	April 2025

This document has been prepared, reviewed and approved by

Activity	Full Name and Surname (Subject matter experts and/ or owners name)	Designation	Date (dd/mm/yyyy)
Prepared by:	Dr Boitumelo Semete-Makokotlela	Chief Executive Officer	July 2024
Reviewed by:	Mr Bongani Ngcobo	Legal Regulatory Advisor	July 2024
Reviewed by:	Legal Committee	Members	Aug 2024
Reviewed by:	Core Business Senior Managers	Members	July 2024
Reviewed by:	Ms Dudu Ntoko	QMS	September 2024
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Approved by:	SAHPRA Board	Board	June 2025

Distribution List

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

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1. PURPOSE

During the last decade, promoting sustainable access to quality and affordable medicines has been of significant concern to African leaders. More recently the opportunity to promote local, regional and continental production of the medicines needed is considered as part of the overall health systems strengthening package. In accordance with its vision of being responsive and an enabler, SAHPRA has taken the position that, within its mandate of enabling access to medicines based on their safety, quality and therapeutic efficacy as per section 1(3) of the Medicines Act, it will take steps to enable local manufacturing of health products.

2. SCOPE

2.1. Rationale for the Policy Position

2.1.1 During the last decade, promoting sustainable access to quality and affordable medicines has been of significant concern to African leaders. More recently the opportunity to promote local, regional and continental production of the medicines needed is considered as part of the overall health systems strengthening package and is in line with the Pharmaceutical Manufacturing Plan for Africa (PMPA) endorsed in 2007. The challenge of access to the medicines needed on the continent was exacerbated and highlighted during the COVID-19 pandemic with Africans having limited access to COVID-19 vaccines, therapeutics, and diagnostic tools. The COVID-19 pandemic demonstrated that the diverse markets that have delivered low-cost and resilient supplies for routine and other immunisation services were unable to guarantee pandemic vaccine equity in the face of vaccine nationalism. Early doses were secured by countries with access to domestic or regional manufacturing capacity, and/or the resources to make substantial high-risk advance purchases. During the height of the COVID-19 pandemic, Africa had difficulty accessing life-saving vaccines as well as some other health products (medicines and medical devices) needed due to its reliance on supplies from other countries. This situation demonstrated the general and long-standing challenge for Africa of limited access to various health products that could be mitigated to some extent, through investments in self-sufficiency and manufacturing on the continent.

2.1.2 In addition to the PMPA, in response to challenges experienced during the COVID-19 pandemic, the African Union, through the Partnerships for African Vaccine Manufacturing (PAVM) over the course of 2021 and 2022, developed a continental strategy and a Framework for Action (FFA). The goal of the PAVM is to enable the African vaccine

manufacturing industry to develop, produce, and supply over 60 percent of the total vaccine doses required on the continent by 2040. This target is a considerable increase from the current 1 percent manufactured at present, with interim goals of 10 percent by 2025 and 30 percent by 2030. This initiative was further supported when the Global Vaccine Alliance (Gavi) Board indicated its support for the establishment of the African Vaccine Manufacturing Initiative (AVMI), a financing mechanism aimed at creating a sustainable vaccine manufacturing industry on the continent. African vaccine manufacturing is set to expand dramatically as the continent works to safeguard itself against future pandemics and disease outbreaks—and to help prevent delays like the ones African nations faced in receiving COVID-19 vaccines. The aim of this initiative is to support manufacturers in low- and middle-income countries to collectively produce their own vaccines, have the necessary operating procedures and know-how to produce mRNA vaccines at scale and according to applicable good manufacturing practices. While the focus during the pandemic was on vaccines, it is apparent that an African manufacturing strategy needs to encompass a range of health products. An enabling environment is crucial, with regional approaches being key, particularly in countries with no existing manufacturing infrastructure and/or regulatory capacity.

3. DEFINITIONS

3.1. The following terms are used in this document:

Abbreviations/ Terms	Meaning
AMA	African Medicines Agency
COVID-19	Coronavirus Disease of 2019
AMRH	Medicines Regulatory Harmonisation initiative
FFA	Framework for Action
Gavi	Global Vaccine Alliance
IVDs	In Vitro Diagnostics
AVMI	African Vaccines Manufacturing Initiative
mRNA	messenger ribonucleic acid
PMPA	Pharmaceutical Manufacturing Plan for Africa

PAVM	Partnerships for African Vaccine Manufacturing
Zazibona	The Medicine Regulatory Harmonisation Programme of the Southern African Development Community

4. ROLES & RESPONSIBILITIES

4.1. The following are key roles and responsibilities in this document:

Title	Description of Roles and Responsibilities
SAHPRA Board	Approves the Policy and monitors implementation
CEO	Oversee the implementation and enforces the Policy
SAHPRA staff	Implements the policy
Industry	Engages with SAHPRA as per the Policy.
Other stakeholders	Engages with SAHPRA as per the Policy.

5. RELATED INFORMATION AND DOCUMENTS

5.1. The following references are used:

Title	Document Number	Applicable Clause / Section
Medicines and Related Substances Act	Act No. 101 of 1965	Section 2A
General Regulations in terms of the Medicines and Related Substance Act, 1965 (Act No. 101 of 1965).	N/A	

6. CONTENT

6.1. Policy position

6.1.1 In terms of section 2A of the Medicines and Related Substances Act 101 of 1965 (the Medicines Act) the objects of the South African Health Products Regulatory Authority (SAHPRA) are "*to provide for the monitoring, evaluation, regulation, investigation, inspection, registration and control of medicines, Scheduled substances, clinical trials and medical devices, IVDs and related matters in the public interest*". The vision of the SAHPRA is to be "*an agile and responsive African health products regulator that is globally recognised as an enabler of access to safe, effective and quality health products in South Africa*." In accordance with its vision of being responsive and an enabler, SAHPRA has taken the position that, within its mandate of enabling access to medicines based on their safety, quality and therapeutic efficacy as per section 1(3) of the Medicines Act, it will take steps to enable the local manufacturing of health products. This approach is aligned with SAHPRA's policy relating to the priority review of health products (Request for Priority Review of New Medicines and only Type II Variation Applications).

6.1.2 This policy position is aimed at facilitating the long-term security of supply of health products in South Africa by supporting local manufacturers through shorter evaluation times and reduced fees for the assessment.

6.1.3 SAHPRA will ensure that any prioritisation of applications will be transparent, fair, objective, timeous, efficient, effective and without favour or prejudice, while focusing primarily on safety, quality, and therapeutic efficacy. This policy position will be incorporated into SAHPRA's Priority Review guideline, which as per SAHPRA practice will incorporate the industry's input.

6.1.4 A range of other national stakeholders, such as the Department of Trade, Industry and Competition, National Department of Health, Industrial Development Cooperation, Department of Agriculture and the Department of Science and Innovation, play an important role in supporting local manufacture. SAHPRA's position is limited to what is within its mandate as per the Medicines Act and does not supplant interventions enabled by other legislation.

6.2 Definition of manufacture

6.2.1 The General Regulations published in terms the Medicines Act defines manufacture as follows:

"manufacture" means all operations including purchasing of material, processing, production, packaging, releasing, storage and shipment of medicines and related substances in accordance with quality assurance and related controls".

6.2.2 Defining whether the product is locally manufactured can be based on several factors which are based on the product under consideration and activities conducted.

a. For "local" the term can have a "jurisdiction" or territorial context (e.g. taking place within a country, regardless of who owns the business) or an "ownership" context (e.g. owned by nationals in full, or in part as a majority).
b. For "production", a wide range of manufacturing activities may be undertaken, ranging from producing the active pharmaceutical ingredient(s) and formulating the product to only packaging the finished pharmaceutical product. The range of activities which can be considered as "production" are shown in Figure 1 below.
c. It must be noted that this policy only applies to the locus of manufacture i.e. products manufactured in South Africa. Whether or not the product is exported has no impact on whether or not an activity is considered to be local manufacturing.

6.2.3 The description of manufacturing activities is outlined below:

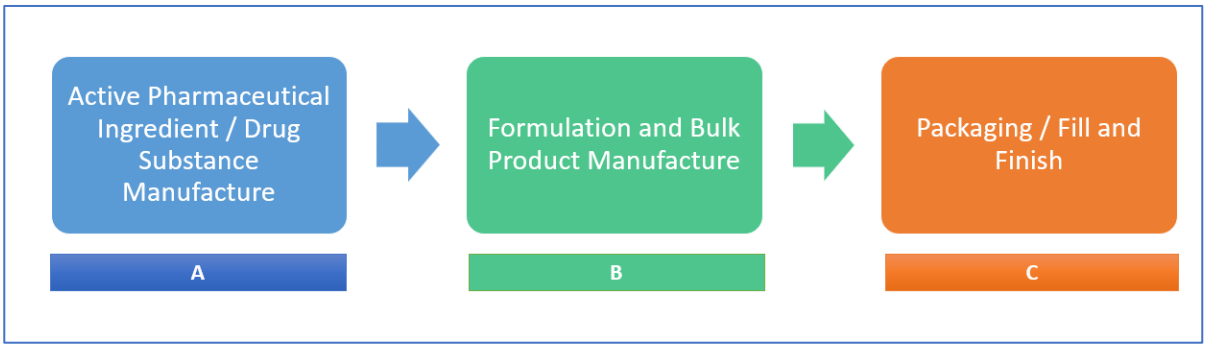

Figure 1: Manufacturing activities for pharmaceutical products.

- **Formulation and bulk product manufacturing** refers to the process of combining active pharmaceutical ingredient (API) and excipients to create bulk product.

- **Fill and Finish** typically involves formulation, sterilization, filling (introducing the drug product into its primary container), sealing, inspection, labelling and packaging.
- **Packaging** means taking the bulk product and performing primary packaging, secondary packaging and labelling of finished product.

Based on these considerations, SAHPRA will define local manufacture as activities along all or any of these three steps indicated in Figure 1

6.2.4 SAHPRA's Priority Review guideline will be amended to indicate that if a health product meets the abovementioned criteria, it may be prioritised for review. However, once a priority review has been granted, due to the qualification of meeting the local manufacturing criteria, a company **may not move** its manufacturing activities outside of South Africa upon having received priority review for one or more of its products from SAHPRA. SAHPRA Regulatory Compliance unit will conduct regular inspections of the locally manufacturing companies to ensure compliance with this Policy.

6.2.5 Wherein there is a motivation for moving manufacturing activities outside of South Africa, the Holder of the Certificate of registration must submit a variation application which will be considered on a case-case basis.

6.2.6 For those applications that are deemed to meet the criteria of locally manufactured health product as indicated in section 6.2.2 and are approved for priority review then the standard fee for product registration will apply and not the priority review fee. The Priority Review guideline will operationalise the criteria further

6.3 Summary of key principles

6.3.1 Prioritisation of applications based on local manufacturing must consider sites that already manufacture the product in South Africa (demonstrated demand for the product).

6.3.2 Active pharmaceutical ingredient or drug substances may be imported but must be formulated into bulk product by a SAHPRA-licenced manufacturer prior to packaging for the product to be considered locally manufactured.

6.3.3 Type II Variation applications for inclusion of local sites for the manufacture of products will be prioritised. For those variations that are deemed to meet the criteria and are prioritised for review, the standard variations fee will apply and not the priority review fee.

6.4 References

6.4.1 Pharmaceutical Manufacturing Plan for Africa (PMPA), 2012

6.4.2 2nd Interagency consultation for local production of essential medicines and health products 18 June 2018, Geneva

7. POLICY AUTHORISATION

7.1. The Policy Owner/ Manager is responsible for the maintenance and review of this Policy. This Policy will be reviewed every 3 years or when the need arises.

Policy Owner:

Policy Manager / Cognisant Person: Boitumelo Semete-Makokotlela SIGNIFLOW _____ _____

[Dr Boitumelo Semete-Makokotlela] 23 June 2025

CONFIRMATION OF APPROVAL

Approved by:

_____ _____

[Prof Helen Rees] 23 June 2025

SAHPRA Board Chairperson

8. ADDENDA