SAHPRA
South African Health Products Regulatory Authority

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

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DOCUMENT REVIEW AND APPROVAL

Revision History

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2		

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)
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Reviewed by:	Legal Committee	Members	Aug 2024
Reviewed by:	Senior Managers	Members	July 2024
Reviewed by:	QMS		September 2024
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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 needed to address critical public health needs.

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, addressing critical public health needs. An enabling environment is crucial, with regional approaches being key, particularly in countries with no existing manufacturing infrastructure and/or regulatory capacity. All categories of people, process and governance to which the Policy applies]

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
CEO / Chairperson of the Board	Sets the Policy, implements and enforces the Policy.
SAHPRA staff	Implements the policy
Industry	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
General Regulations in terms of the Medicines and Related Substance Act, 1965 (Act No. 101 of 1965).	N/A	
Medicines and Related Substances Act as amended	Act No. 101 of 1965	Section 2A

6. CONTENT

6.1. Policy position

6.1.1 In terms of section 2A of the Medicines and Related Substances Act, 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 local manufacturing of health products needed to address critical public health needs. 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, 11 December 2023) which address a public health need. This policy position is aimed at facilitating long term security of supply.

6.1.2 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 industry's input. At this stage, the policy position excludes medical devices and IVDs as the process to be applied in the registration of these products is still under development. 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 Land Reform and Rural Development 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.

6.1.3 In addition, SAHPRA in an active member of Zazibona (the Medicine Regulatory Harmonisation Programme of the Southern African Development Community) and of the

African Medicines Regulatory Harmonisation (AMRH) initiative. SAHPRA will also collaborate with the African Medicines Agency (AMA) and other national regulatory authorities to support regional and continental manufacturing.

6.2 Definition of manufacture

6.2.1 The General Regulations published in terms the Medicines Act define 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.

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.

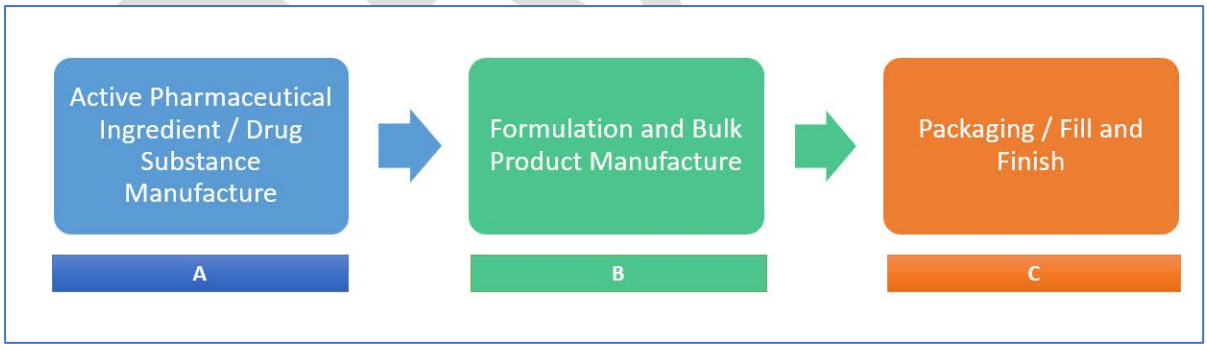

Figure 1: Manufacturing activities for pharmaceutical products.

6.2.3 Although the term local manufacturing in the medical and pharmaceutical sector is widely used, institutions such as the DTIC have defined "local manufacture" as value addition during the manufacturing process. Some form of local business activity [product assembly or manufacturing] must take place to confirm value add. The use of local resources (materials

and labour) contributes to value add. The African Union recognizes the local site of manufacturing where the product is made locally and not so much the production process or value addition as local manufacturing.

6.2.4 Based on these considerations, SAHPRA will define local manufacture as follows.

a. Step A + Step B + Step C; or
b. Step B + Step C

Step C alone *will not be considered* local manufacturing, with the exception of fill and finish operations for particular biological medicines, such as vaccines.

6.2.5 SAHPRA's Priority Review Policy will be amended to indicate that if a medicine 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, it is intended to stipulate in this policy that a company may not move its manufacturing business outside of South Africa upon having received priority review for one or more of its products from SAHPRA.

6.3 Summary of key principles

6.3.1 Prioritisation of applications for registration of a product based on local manufacturing must consider an element of public health need (i.e. whether there are sufficient registered products available on the South African or African market).

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

6.3.3 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.

6.3.4 For particular biological medicines, such as vaccines, fill and finish activities may be considered local or regional manufacture.

6.3.5 As part of SAHPRA's participation in Zazibona and AMRH, as well as collaboration with the AMA and other national regulatory authorities, regional and continental manufacturing will be supported.

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: _____ _____
[Name and Surname] Date

CONFIRMATION OF APPROVAL

Approved by:

_____ _____
[Name and Surname] Date
SAHPRA Board Chairperson

8. ADDENDA