South African Health Products
Regulatory Authority
Building A
Loftus Park
Arcadia
Pretoria

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GUIDELINE FOR DONATION OF MEDICINES, MEDICAL DEVICES, AND IVDs

This guideline provides an outline of the principles and process to be followed in the donation of medicines, medical devices, and in vitro diagnostics (IVDs). The guideline applies to both people and entities wishing to make donations and the recipients of such donations. The South African Health Products Regulatory Authority (the Authority) may at any time in terms of Section 19(2) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), (the Medicines Act), request any additional information relating to the donation of a medicine, medical device, or IVD. In addition, the Authority may make amendments to this guideline in keeping with the knowledge that is current at the time. The Authority is committed to ensuring that all medicines, medical devices, and IVDs that are donated are of the required quality, safety, efficacy, or performance.

Document History

Final Version	Reason for Amendment	Effective Date [dd Month yyyy]
1	First publication released for implementation and comment	29 April 2003
2	Updated to include new contact details and reference to ZA-CTD	September 2010
3	Updated to include medical devices and IVDs	April 2020
4	Updated to include donation to the Private Sector	30 October 2025

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

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Glossary

Abbreviation/ Term	Meaning
Essential In-Vitro Diagnostics List	WHO model list of essential in vitro diagnostics. The EDL is a health policy document, based on scientific evidence, consisting of a list of categories of IVD tests and recommendations for using those tests in relation to the assay format, test purpose, specimen type, and health care setting.
Essential medicine	Means a medicine that satisfies the priority health care needs of the population and is selected with due regard to disease prevalence and public health relevance, evidence of clinical efficacy and safety, and comparative costs and cost-effectiveness.1 The EML status of a medicine is independent of its pack size but is dependent on its dosage form and indication
Health establishment	means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services
In vitro diagnostic (IVD)	means a medical device, whether used alone or in combination, intended by the manufacturer for the *in vitro* examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes;
Medicine	means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in (i) the diagnosis, treatment, mitigation, modification, or prevention of disease, abnormal physical or mental state, or the symptoms thereof in humans; or (ii) restoring, correcting, or modifying any somatic or psychic or organic function in humans;, and includes any veterinary medicine;
Medical Device	**"medical device"** means any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material, or other similar or related article, including Group III and IV Hazardous Substances contemplated in the Hazardous Substances Act, 1973 (Act No. 15 of 1973)— intended by the manufacturer to be used, alone or in combination, for humans or animals, for one or more of the following: (i)diagnosis, prevention, monitoring, treatment, or alleviation of disease; (ii)diagnosis, monitoring, treatment, alleviation of, or compensation for an injury; (iii)investigation, replacement, modification, or support of the anatomy or of a physiological process; (iv)supporting or sustaining life; (v)control of conception; (vi)disinfection of medical devices; or

	(vii)providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and which does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human or animal body, but which may be assisted in its intended function by such means;
Medical Product	means medicines, medical devices, including IVDs
National Essential Medicines List Committee (NEMLC)	means the non-statutory, advisory committee appointed by the Minister of Health, responsible for the development and management of the national EML and standard treatment guideline (STGs). The STGs and EML guide clinical practice at all public sector health establishments and inform procurement of medicines in the public sector.
Standard Treatment Guidelines (STGs)	means the implementation mechanism of the EML, which guides health care professionals on the use of medicines that appear on the EML and consists of a collection of chapters containing disorder groups, background information on the disorder, treatment regimens, as well as other relevant information.

1. INTRODUCTION

1.1 Purpose

This guideline guides the appropriate, ethical, and effective donation of medicines and medical devices, including IVDs in South Africa, ensuring alignment with national legislation, public health needs, and safety standards in the donation of medicines, medical devices including IVDs, while promoting accountability and equity in resource-limited settings.

Over the years, there has been an enormous increase in scientific knowledge about the mode of action, effects, and side effects of medicines, medical devices, including IVDs. It is important for all stakeholders to understand that these products have both benefits and risks, that they must be used carefully and appropriately, and that some can do more harm than good.

There are many different scenarios for the donation of medicines, medical devices, including IVDs. Donations may take place in cases of unexpected disease outbreaks or as part of development aid in anticipated disease outbreaks, in case of shortages of Critical Medicines, Medical devices, including IVDs, and Post post-clinical trials access. They may involve donations (i.e. direct or through private voluntary organisations), aid from governments or persons authorised to sell medicines, medical devices and/or IVDs.

While most donation guidelines focus on the public health sector, there is an increasing need to support the private healthcare sector, including registered clinics, private hospitals, non-profit health providers, and emergency relief organisations. These guidelines ensure donations of medicines, Medical Devices, including IVDs to the public and private sector are safe, lawful, transparent, and patient-centered.

1.2 Scope

~~The guidelines apply to all local and international donors – not exclusive of manufacturers, distributors, NGOs, and international health agencies, private healthcare institutions, non-profit organizations, and private pharmacies operating legally within South Africa, who wish to donate medicines or medical devices including IVDs to the South African public or private healthcare providers.~~

The guideline applies to Medicines, medical devices, including IVDs donated by both local and international donors including but not exclusive manufacturers, distributors, NGOs, and international health agencies, private healthcare institutions, non-profit organizations, and private pharmacies operating legally within South Africa, to the South African public or private healthcare providers.

The scope of this guideline does not cover Veterinary medicines.

1.3 Principles for the donation of medicines, medical devices and IVDs

The guideline is based on the following principles:

1.3.1 Medicines, medical devices, including IVDs, donated must be of acceptable quality, safety, efficacy, or performance. For example, if the quality, safety, efficacy or performance of an item is unacceptable in the country from which it originates, it is also unacceptable as a donation;

1.3.2 Donations must take place in line with current government policies and administrative arrangements;

1.3.3 The donation of a medicine, medical device including IVDs, should benefit the recipient of the donation and the clients/patients served to the maximum extent possible;
1.3.4 A donation should be given with full respect for the wishes and authority of the recipient;
1.3.5 Donations may include medical products that are registered in terms of the Medicines Act or those that are not registered;
1.3.6 There should be effective communication between the donor and the recipient - donations should be based on an expressed need and should not be sent unannounced.
1.3.7 Medicines that have been issued to patients and then returned to a pharmacy or other health establishment shall not be accepted as donated medicines.
1.3.8 Reprocessed Medical Devices, including IVDs intended by the original manufacturer for single use shall not be accepted as donated medical devices, including IVDs.
1.3.9 Medical devices intended by the original manufacturer to be reusable may be considered for donation, following review by the Authority.

1.3.10 Donated medicines, Medical Devices, including IVDs, must not be sold for profit under any circumstances
1.3.11 Donations should not be used for marketing or promotional purposes.
1.3.12 Donations to private entities must not create unfair advantage, disrupt markets, or compromise public health objectives.

2. LEGAL PROVISION

Section 1 of the Medicines Act defines "sell" as follows:
"sell" *means sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise; and "sale" and "sold" have corresponding meanings;*
Section 1(3) of the Medicines Act states:

In determining whether or not the registration or availability of a medicine is in the public interest, regard shall be had only to the safety, quality and therapeutic efficacy thereof in relation to its effect on the health of a person or any animal.

Section 21 of the Medicines Act states:

(1) The Authority may, in writing, authorize any person to sell during a specified period to any specified person or institution a specified quantity of any medicine, medical device, or IVD which is not registered.

(2) Any medicine, medical device, or IVD sold in pursuance of any authority granted under subsection (1) may be used for such purposes and in such manner and during such period as the Authority may in writing determine.

(3) The Authority may at any time, by notice in writing, withdraw any authority granted in terms of subsection (1) if effect is not given to any determination made in terms of subsection (2).

Regulation 29 of the General Regulations made in terms of the Medicines Act (Government Notice 859, 25 August 2017) states:

Authorisation of sale of an unregistered medicine for certain purposes

(*1) Subject to the provision of information, requirements and conditions as determined by the Authority, a person desiring to sell an unregistered medicine subject to registration in terms of section 14 of the Act, for purposes other than a clinical trial, shall apply to the Authority, on an application form obtainable from the office of the Chief Executive Officer, for authorisation in terms of Section 21 of the Act to sell such a medicine.*

2) An application referred to in sub-regulation (1) must be accompanied by the prescribed fee and must contain at least the following information-

(a) duly completed application form;

(b) product brochure containing relevant chemical, pharmaceutical, pre-clinical pharmacological and toxicological data, and where applicable, human or animal pharmacological and clinical data with the medicine concerned;

(c) witnessed informed consent document, where applicable;

(d) details of registration or pending registration of the medicine with any other regulatory authority, if available;

(e) evidence of compliance of the manufacturer of the medicine with Good Manufacturing Practice standards as determined by the Authority;

(f) reasons why a South African registered medicine cannot be used; and

(g) any other information as may be required by the Authority.

(3) The person under whose supervision the unregistered medicine or substance is prescribed shall submit to the Authority-

(a) any adverse event report;

(b) progress reports after every six months from the date following commencement of the use of the unregistered medicine; and

(c) progress report 30 days after the completion or termination of the use of the medicine.

(4) The Authority may-

(a) impose any additional conditions;

(b) request additional information;

(c) inspects the site where the unregistered medicine is manufactured, stored or administered; or

(d) withdraw the authorisation to treat the patient or animal,

if the Authority is of the opinion that the safety of any patient or animal is compromised, that the scientific reasons for administering the unregistered medicine have changed or for any other reason as determined by the Authority.

(5) A medicine referred to in sub-regulation (1) shall be properly labelled and the package shall sufficiently identify the information as per the provisions of regulation 12(5)(c).

Section 18B of the Medicines Act which deals with the sampling of medicines, medical devices or IVDs (amended by Medicines and Related Substances Amendment Acts, No. 72 of 2008 and No. 14 of 2015 which came into effect on 1 June 2017) provides that:

(*1) No person shall sample any medicine, medical device or IVD*

(2) Use of medicine, medical devices or IVDs for exhibition or appraisal purposes shall be as prescribed.

(3) For the purposes of this section 'sample' means the free supply of medicine, medical devices or IVDs by a device or IVD establishment, manufacturer or wholesaler or its agent to a pharmacist, medical practitioner, dentist, veterinarian, practitioner, nurse or other person registered under the Health Professions Act, 1974 (Act No. 56 of 1974), or any professional or person authorized to use the device.

NOTE: The Minister of Health, has in terms of section 36(1) of the Medicines Act, excluded medicines, medical devices and IVDs donated to the State, or provided to the State as a sample as part of the submission of a bid for a tender published by the State, from the provisions of section 18B of the Act: Provided that such donations are made or samples provided in accordance with guidelines as determined by the Authority and the relevant procedures required by the State (Date of notice – 22 May 2020).

3. REQUIREMENTS FOR DONATED MEDICINES, MEDICAL DEVICES, INCLUDING IVDs

3.1 All donations should be based on the health needs of the recipient within the Republic of South Africa.

3.2 It is the responsibility of the recipient to specify their needs so as to prevent unsolicited donations and donations that arrive unannounced and unwanted.

3.3 Medicines donated to the State must appear on the Standard Treatment Guidelines/Essential Medicines List of the National Department of Health (NDoH) and must be compatible with overall government policy. Exceptions may be made on recommendation of the National Essential Medicines List Committee (NEMLC).

3.4 The presentation, strength, and formulation of donated medicines should, as far as possible, be like those of medicines commonly used in South Africa.

3.5 Donations of medical devices, including IVDs, must be in line with Government policy.

3.6 Donated Medical Devices, including IVD's must come with clear **operation** manuals and maintenance instructions in at least English and all the necessary accessories and consumables

3.7 Medicines, medical devices, including IVDs supplied as donations, must comply with all regulatory requirements on safety, quality, efficacy and or performance and should not differ from those that are authorized for sale

3.8 The importation of medicines, medical devices, including IVDs, which are not registered in terms of the Medicines Act, must be reviewed and authorised by the Authority.

3.9 To avoid delay and additional expense, importation documents must be submitted to the Authority for approval before shipment of a consignment. Refer to SAHPGL-INSP-RC-02- Guideline for the Importation and Exportation of Medicines

3.10 A minimum of 12 months' shelf life must remain at the time of delivery unless otherwise approved by SAHPRA and the recipient.

3.11 Narcotics and psychotropics (Controlled Substances) require an additional permit for import obtained from SAHPRA

3.12 The following supporting documents must be submitted to the Authority via email on regulatorycompliance@sahpra.org.za:

3.12.1 A list of products to be donated;

3.12.2 Quantity of the products to be donated

3.12.3. The name and address of the original manufacturer(s) of the product/s;

3.12.4. The expiry dates (if applicable);

3.12.5. The name and address of the recipient

3.12.6 A request letter on the company letterhead

3.13 In the case of medical devices, including IVDs, a declaration of conformity by the original manufacturer of the medical device that the medical device conforms to the safety and performance principles of medical device.

3.14 Donations of medicines, medical devices, including IVDs that do not comply with the requirements, will be rejected and sent back to the donor at the donor's expense.

3.15 Specific Provisions for donations to the private Sector

3.15.1 When donating to private entities (non-profit or for-profit), the donor and recipient must provide assurance that donated items will be used free of charge

3.15.2 Donations must not be used for commercial promotion

3.15.3 A signed agreement between the donor and the recipient, outlining intended use, distribution, and reporting obligations must be submitted to the Authority.

3.15.4 The donor must obtain authorization from the National Department of Health, to ensure that the donation is in line with the public health needs and ethical considerations.

3.16 Post-Trial Access (Named-patient access) after 4 years of completion of a Clinical Trial

3.17 The Authority reserves the right to inspect any donated products for compliance purposes.

4. REFERENCES

WHO Guidelines for Medicine Donations (4th edition)

South African Essential Medicines List (EML)

SAHPRA Guidelines on Medical Devices and Section 21 Applications

SAHPRA Guidelines on the Importation and Exportation of Medicines and Medical Devices including IVDs

National Health Act (Act 61 of 2003)

Medicines and Related Substances Act (Act 101 of 1965)

Medical device Regulations

5. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision and replaces the **5.08 DONATION OF MEDICINES, MEDICAL DEVICES AND IVDs**. It will be reviewed on this every five(5) years or as and when required.