South African Health Products
Regulatory Authority
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Communication to Stakeholders

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5.08 DONATION OF MEDICINES, MEDICAL DEVICES AND IVDs

This guideline is provided to outline the principles and process to be followed in the donation of medicines, medical devices and in-vitro diagnostics (IVDs). The guideline is applicable to both persons 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 which 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.

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1. DEFINITIONS

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 an IVD as defined in the Medicines and Related Substances Act, 1965 (Act 101 of 1965) (the Medicines Act).

Medicine means a medicine as defined in the Medicines Act.

Medical device means a medical device as defined in the Medicines Act.

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 provides guidance to health care professionals on the use of medicines which 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.

2. INTRODUCTION

2.1 Purpose

This guideline aims to improve the quality of donations and the management thereof and serve as the basis for policies of the State and other organisations in the giving and receiving of donations of medicines, medical devices and IVDs.

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

[1] World Health Organization. Essential Medicines and Health Products. (http://www.who.int/medicines/services/essmedicines_def/en/ - accessed 05/02/2017)

There are many different scenarios for the donation of medicines, medical devices and IVDs. Donations may take place in acute emergencies or as part of development aid in non-emergency situations. They may involve donations (i.e. direct or through private voluntary organisations), aid by governments or persons authorised to sell medicines, medical devices and/or IVDs.

2.2. Principles for the donation of medicines, medical devices and IVDs

These guidelines are based on the following principles namely:

2.2.1. The donation of a medicine, medical device or IVD should benefit the recipient of the donation and the clients/patients served to the maximum extent possible;

2.2.2. A donation should be given with full respect of the wishes and authority of the recipient;

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

2.2.4. Medicines, medical device and 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;

2.2.5. Donations may include products which are registered in terms of the Medicines Act or those which are not registered;

2.2.6. 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.

2.2.7. Medicines that have been issued to patients and then returned to a pharmacy or other health establishment shall not be accepted as donated medicines. In certain circumstances and in accordance with applicable legislation and guidelines, the re-use of medical devices may be considered.

2.3. Legislative provisions

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, as the case may be.*

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 particular 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. MEDICINES, MEDICAL DEVICE AND IVDs THAT MAY BE DONATED

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

3.2. It is the responsibility of the recipient to specify their needs to prevent unsolicited donations and donations which 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 similar to those of medicines commonly used in South Africa.

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

3.6. Medicines, medical devices or IVDs supplied as donations must comply with all regulatory requirements on safety, quality, efficacy or performance and should not differ from those that are supplied for purposes other than donations.

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

3.8. To avoid delay and additional expense, importation documents must be submitted to the Authority for approval before shipment of a consignment.

3.9. The following supporting documents must be submitted to the Authority:

3.9.1. A list of products to be donated;

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

3.9.3. The expiry dates (if applicable);

3.9.4. In the case of medical devices, a declaration of conformity by the original manufacturer of the medical device that it confirms the safety and performance of the medical device/s to be donated.

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

4. MEDICAL DEVICES AND IVDS THAT MAY NOT BE DONATED

4.1 Medical Equipment

4.1.1 Donations of medical equipment, including laboratory equipment will not be considered if arrangements are not in place to cover the cost of installation, service and supplies required to operate and maintain the medical equipment offered or requested for donation.

4.2 Used Equipment

4.2.1 Donations of used equipment will only be considered where there is assurance that proper support from the manufacturer in the form of repair parts, service and consumables can be provided for an appropriate period of time, with five years being considered the minimum acceptable period where manufacturer support will be available.

4.3 Refurbished Equipment

4.3.1 Donations of refurbished equipment will only be considered where refurbishers of medical devices, who are responsible for restoring equipment to its original working condition for the purpose of resale, are subject to general principles of liability.

4.3.2 Certification against ISO 13485 is required, and equipment must be restored to the manufacturer's original specifications.

4.3.3 User manuals and all accessories required to use the equipment must be provided.

4.4 Imaging and radiology

4.4.1 The donation of radiological equipment will only be considered where there is assurance of compliance with the Hazardous Substances Act, 1973 (Act 15 of 1973) and matters such as specialized training, professional installation and the need for specialized maintenance support in the field.

4.5 In vitro diagnostics

4.5.1 The donation of IVDs will only be considered where there is assurance of test validation within the South African laboratory and clinical setting.

5. REGISTRATION STATUS OF MEDICINES, MEDICAL DEVICES OR IVDs TO BE DONATED

5.1. The Medicines Act prohibits the sale (which includes the supply and use) of any medicine, medical device or IVD which is subject to registration which is not registered.

5.2. Donated medicines should be registered for use in South Africa in terms of the Medicines Act.

5.3. The Authority may, however, in terms of Section 21 of the Medicines Act authorise the sale of an unregistered medicine, medical device or IVD subject to such conditions as the Authority may determine.

5.4. In the case of the proposed donation of a medicine, medical device or IVD, which is required in terms of Section 14 of the Act to be registered, but is not registered in terms of the Medicines Act, an application for authorisation for the sale of an unregistered medicine, medical device or IVD must be submitted to the Authority. Products to be donated may not be supplied to the proposed recipient until such authorisation has been provided.

5.5. In the case of medicines, medical devices and IVDs which have not been called up for registration, donated products may only be sourced from a medical device or IVD establishment, manufacturer, wholesaler or distributor who is the holder of a licence issued in terms of Section 22C(1)(b) of the Medicines Act. In the case of medical devices and IVDs, the products to be donated must also have been specified in terms of Regulation 5(1)(d) of the Regulations relating to medical devices and IVDs in the original application for a licence or the application for an amendment to an existing licence, and comply with any other provisions as required by the Authority.

5.6. The Authority may in terms of Section 22B of the Act, if it deems it expedient and in the public interest, disclose information in respect of the prescribing, dispensing, administration and use of a medicine, scheduled substance, medical device or IVD. This information may be published by the Director-General of the NDOH or released to the public in a manner which he or she thinks fit.

6. QUALITY ASSURANCE

6.1. As far as possible, the presentation, strength, formulation and pack size of donated products should be similar to that of products available in South Africa.

6.2. All donated medicines, medical devices and IVDs must originate from a reliable source and comply with acceptable standards and requirements in terms of quality, safety and efficacy, in both the country of manufacture and South Africa.

6.3. Donated medicines, medical devices and IVDs **which are required to be registered in terms of the Act,** but are not registered, must be accompanied by the relevant documentation that includes:

6.3.1. Authorisation provided by the Authority in terms of section 21 of the Medicines Act;

6.3.2. For the donation of a medicine:

6.3.2.1. The relevant certificate of analysis, certificate of origin and related confirmation of good manufacturing practice; and

6.3.2.2.A World Health Organisation (WHO) GMP Certificate (where applicable).

6.4. For the donation of a medical device or IVD:

6.4.1.1. Certificate of Free Sale confirming evidence that the medical device and/or IVD is legally sold or distributed in the open market, freely without restriction, and approved by the regulatory authorities in at least one of the six jurisdictions recognised by the Authority (Australia, Brazil, Canada, Europe, Japan, United States of America);

6.4.1.2. Evidence of ISO13485:2016 certification of the original manufacturer for each medical device and/or IVD;

6.4.1.3. Copy of Instructions for Use for each medical device;

6.4.1.4. Copy of labelling and packaging of each medical device. (NOTE: Any change in product name or branding will invalidate the originating approval of a medical device); and

6.4.1.5.For a Class C and Class D medical device and/or IVD - evidence of pre-market approval or registration for the medical device and/or IVD from at least one of the six jurisdictions recognised by the Authority, pre-qualification by the WHO or compliance with any other requirements as determined by the Authority from time to time.

6.5. Donated medicines, medical devices and IVDs which are **not required to be registered in terms of the Medicines Act** must be accompanied by the relevant documentation that includes:

6.5.1. A completed application form for donation of a medicine, medical device of IVD which is not required to be registered;

6.5.2. Details of registration or pending registration with any other regulatory authority;

6.5.3. For the donation of a medicine:

6.5.3.1. The relevant certificate of analysis, certificate of origin and related confirmation of good manufacturing practice; and

6.5.3.2.a WHO GMP Certificate (where applicable).

6.5.4. For the donation of a medical device or IVD:

6.5.4.1. Certificate of Free Sale confirming evidence that the medical device and/or IVD is legally sold or distributed in the open market, freely without restriction, and approved by the regulatory authorities in at least one of the six jurisdictions recognised by Authority;

6.5.4.2. Evidence of ISO13485:2016 certification of the original manufacturer for each medical device and/or IVD;

6.5.4.3. Copy of Instructions for Use for each medical device;

6.5.4.3 Copy of labelling and packaging of each medical device. (NOTE: Any change in product name or branding will invalidate the originating approval of a medical device); and

6.5.4.5. For a Class C and Class D medical device and/or IVD - evidence of pre-market approval or registration of the medical device and/or IVD from at least one of the six jurisdictions recognised by Authority, pre-qualification by the WHO, or compliance with any other requirements as determined by the Authority from time to time.

6.6. The approval granted by the Authority will only be valid for a specific consignment as per approval granted.

6.7. All donated medicines, medical devices or IVDs should have a shelf life of at least 12 months remaining upon delivery unless the Authority has approved a shorter shelf life for a product.

7. TRANSPORT AND LOGISTICS

7.1. All donated medicines, medical devices and IVD should be packed and transported in accordance with good distribution practice.

7.2. Donated medicines, medical devices and IVDs must be delivered, free of charge, to delivery points within South Africa according to the delivery schedule submitted by the recipient.

8. PRESENTATION, PACKING AND LABELLING

8.1. All donated medicines, medical devices and IVDs must be labelled in at least English.

8.1.1. For medicines, the label should contain at least the international non-proprietary name (INN), batch number, expiry date, name and address of the manufacturer, quantity and storage conditions. Where applicable the dosage form, strength, and the route of administration should be indicated.

8.1.2. For medical devices and IVDs the label must be compliant with the regulations for the labelling of medical devices and IVDs in terms of the Medicines Act.

8.2. Donated medicines, medical devices and IVDs must be packed in containers that comply with international shipping regulations and accompanied by a detailed packing list. To facilitate the administration, storage and distribution of donations in emergency situations donated products should not be mixed with other supplies in the same carton.

9. INFORMATION AND MANAGEMENT

9.1. The government of South Africa through the Affordable Medicines Directorate of the NDoH should be informed of all medicine donations that are considered, prepared or actually under way.

9.2. Prior approval for the donation of unregistered medicines, medical devices and IVDs should be obtained from the Authority to avoid unnecessary delays at the port of entry. The information should extend to delivery dates, possible delays, port of entry, method of transport, and information as required in ports. The Authority will provide information to the NDoH of applications for donations received.

9.3. The declared value of a donated medicine, medical device or IVD should be based on the current public sector price, or the single exit price (ex logistics) or, if such information is not available, on the wholesale world-market price of its generic equivalent. Import tax, clearing and handling charges will be based on the declared value of the product/s donated.

9.4. All costs of international and local transport, warehousing, port clearance, quality testing and appropriate storage and handling should be paid by the donor, unless specifically agreed otherwise with the recipient of the donation in advance. Similarly, the cost of the disposal of a medicine, medical device and IVD donation adjudged to be unsuitable should be borne by the donor.

10. CONTACT DETAILS

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Department of Health: Dr Sandile Buthelezi - dg@health.gov.za

11. REFERENCES

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