South African Health Products
Regulatory Authority
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GUIDELINE FOR BORDERLINE PRODUCTS

This guideline is intended to provide guidance to applicants on borderline products and outline the process for product designation requests by applicants. It represents the South African Health Products Regulatory Authority's current thinking on the safety, quality and efficacy of medicines and the safety, quality and performance of medical devices. It is not intended as an exclusive approach. The Authority reserves the right to request any additional information to establish the safety, quality and efficacy of a medicine and the safety, quality and performance of a medical device, in keeping with the knowledge current at the time of application. Alternative approaches may be used, but these should be scientifically and technically justified. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Document History

Final Version	Reason for Amendment	Effective Date [dd Month yyyy]
1	Final Guideline for implementation	05 September 2022

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Contents

Glossary

Abbreviation/ Term	Meaning
Borderline Product	A "b**orderline product**" is a product for which the regulatory pathway for a medicine, medical device, cosmetic, foodstuff, biocidal or general product is not clear until the classification status thereof is decided by the Regulatory Authority and the product is designated to a particular regulatory pathway in South Africa.
Combination Product	**A "combination product**" is a product comprised of two or more components which are regulated as medical products, i.e. medicine and medical device, or biological and medical device, or biological and medicine, or biological and medicine and medical device, and that is physically, chemically or otherwise combined or mixed and produced as a single entity. (Modified from US FDA definition)[1]
Cosmetic	**A 'cosmetic'** means any article, preparation or substance (except a medicine as defined in the Medicines and Related Substances Act, 1965 (Act 101 of 1965)) intended to be rubbed, poured, sprinkled or sprayed on or otherwise applied to the human body, including the epidermis, hair, teeth, mucous membranes of the oral cavity, lips and external genital organs, for purposes of cleansing, perfuming, correcting body odours, conditioning, beautifying, protecting, promoting attractiveness or improving or altering the appearance, and includes any part or ingredient of any such article or substance." (Act No. 54 of 1972: Foodstuffs, Cosmetics and Disinfectants Amendment Act, 1972. Has this Act number changed?)
Health supplement	**"health supplement"** means any substance, extract or mixture of substances as determined by the Authority, sold in dosage forms used or purported for use in restoring, correcting or modifying any physical or mental state by- (a) complementing health;

[1] http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm118332.htm

	(b) supplementing a diet; or (c) a nutritional effect, and excludes injectable preparations, medicines or substances listed as Schedule 1 or higher in the Act;
Immunological	**"Immunological"** is understood as an action in or on the body by stimulation and/or mobilisation of cells and/or products involved in a specific immune reaction;
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)— (a) 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 (b) 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;
Medicine	(a) 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 (b) includes any veterinary medicine.
Metabolic	**"Metabolic"** is understood as an action which involves an alteration of the normal chemical processes participating in, and available for, normal body function. The fact that a product is itself metabolized does not imply that it achieves its principal intended action by metabolic means
Pharmalogical	**"Pharmacological"** is understood as an interaction between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent and, for the purposes of this policy, includes anti-infective activity.

1. INTRODUCTION

According to the World Health Organisation (WHO), “many products are used in the delivery of health care, yet not all fit comfortably within an existing definition for a medical product, more specifically the term “medical device”.

Innovation and advances in technology have brought combination products to market which may be difficult to distinguish as a medicine, medical device, cosmetic, health supplement, or biocidal. These products are called “borderline” products until the classification status thereof is decided by the Regulatory Authority and the product is designated to a particular regulatory pathway.

A lack of clarity in such cases may lead to overlap or conflicting regulatory requirements for a product, or (worse), to no effective regulation being applied. It is in the public interest to ensure the safety, quality and performance of all such “borderline” products through appropriate regulatory controls; either those for medical devices or for other regulated product sectors (e.g. medicines, cosmetics, or health supplements).”

Health products may be broadly categorized according to intent:

(i) those which aim to diagnose, to treat or to prevent disease or the symptoms of disease; and

(ii) general health and wellness products.

Health products which aim to diagnose, to treat and to prevent disease and injury include all medicines (allopathic and complementary) and medical devices (including in vitro diagnostic devices). The regulation of safety and efficacy of medicines is well established for allopathic medicines and recently initiated for complementary medicines. The regulation of safety and performance of medical devices has recently been initiated in South Africa.

Access to medicines, apart from those deemed to be of low risk to consumers, in South Africa is controlled through scheduling which enables the application of the sections of the Medicines and Related Substances Act, 1965, which specifies who may possess, sell, prescribe and/or dispense each category of medicines. Scheduling is done on the basis of the risk profiles of the substance(s) included in medicines. Control is also exerted via the prescribed scopes of practice for each healthcare profession.

General health and wellness products may be described as products or devices that meet the following two factors:

- intended for general health and wellness use, and
- present a very low risk to users' safety.

General health and wellness products may include but are not limited to health supplements, exercise equipment, monitoring devices, audio recordings, video games, software programs and other products that are commonly, though not exclusively, available from retail establishments (including online retailers and distributors that offer software to be directly downloaded), when consistent with the two factors above. Recent use of technology has reduced the size and weight of many of these devices to make them mobile and easy to transport. Some of these products may be wearable.

Although not aimed at health and wellness, *per se*, some products that are sold as cosmetics may also be aimed at improving the condition of the skin or hair. Cosmetics are defined in the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972), hereafter referred to as the FCD Act. There are a broad range of products at the cosmetic-medicine-medical device interface. It is recognized that at a minimum, these products are perceived to have cosmetic attributes such as cleansing, improving or altering the complexion, skin, hair or teeth. These products may also have claimed or inherent medical attributes. Examples of these types of products include anti-dandruff shampoos, tooth-whiteners or bleaching products, skin whiteners/ lighteners, antiperspirants and sunburn protectants. Depending on their representation for sale and composition, regulations under the Medicines Act may apply.

The traditional boundaries between medicines, medical devices, general health and wellness products, and cosmetics can sometimes be blurred, and decisions need to be made about where best to regulate them, in the public interest. Figure 1 depicts the overlapping categories of health technologies. A product which falls in more than one domain may be referred to as a "borderline" product.

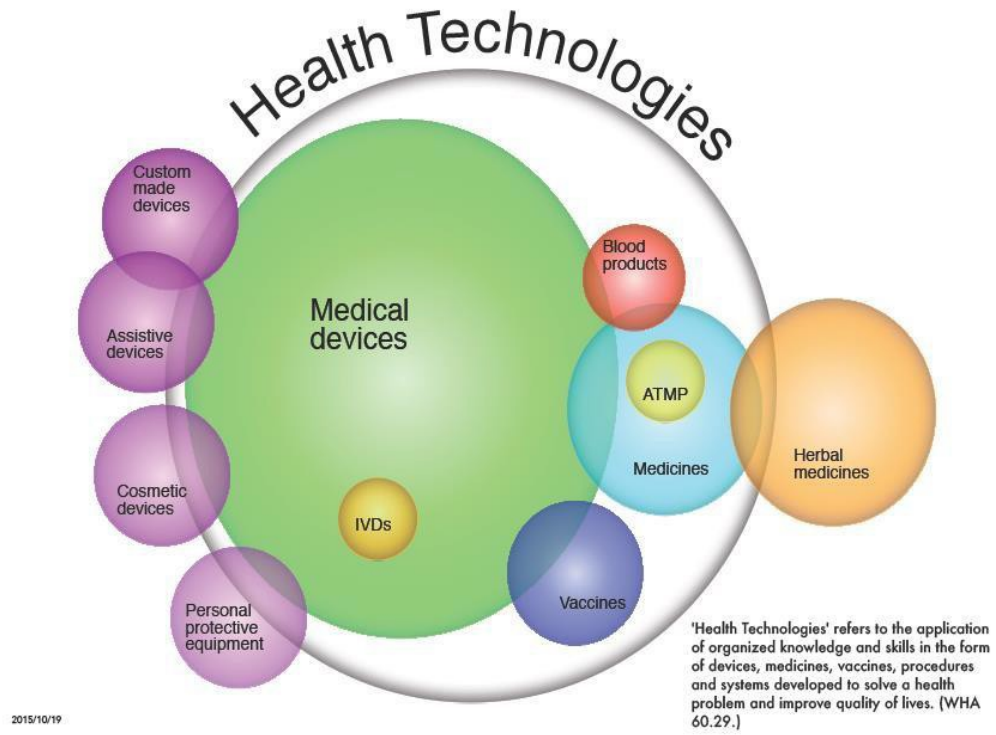

Figure 1 Inter-relation of (medical) products inside and outside healthcare

'Health Technologies" refers to the application of organised knowledge and skills in the form of (medical) devices, medicines, vaccines, procedures and systems developed to solve a health problem and to improve quality of lives. (WHA 60.29.)

According to the World Health Organization (WHO)[2], "borderline products are generally medical products for which it is unclear which legislation applies. Although they may have some of the attributes of two or more categories of regulated products, they are not necessarily combination products."

The WHO further advises that "to be predictable and transparent, the regulator should develop criteria and mechanisms for determining the appropriate regulatory regime for such products through a guideline. It should

describe considerations and the process whereby an applicant may obtain an advisory opinion from the regulatory

authority. As necessary, that process should allow for consultation with subject matter experts as well as with regulatory authorities from other product sectors like medicines or food. It may also take into account determinations made by regulatory authorities of other jurisdictions. A decision by the regulatory authority on the regulatory status of a product should provide the option of appeal in case the applicant does not agree

[2] https://www.who.int/medicines/areas/quality_safety/quality_assurance/ModelregulatoryFramework_MedDev_QAS16-664Rev2.pdf?ua=1

with the decision". (WHO QAS/16.664, May 2016)

1.1 Purpose

This guideline aims is to provide direction on the classification and regulatory approach for borderline products and to explain how and on what basis SAHPRA decides whether products are heath products or not and to manage these products with clarity and efficiency, as many of these technologies are innovative and potentially of significant value to the health of South Africans, which means they are of significant public interest.

1.2 Scope

The scope of this guideline is to cover all types of borderline products on the medicine, medical device and cosmetic interfaces. This document sets out, in broad terms, the regulatory pathway of specific products and distinguishes those which are regulated as medical devices, those which are regulated as medicines and those which are regulated as cosmetics in South Africa, particularly where the regulation may be on the borderline between the sets of regulations.

The scope of this guideline does not include:

- a combination of products where the components are packaged together; e . g .
  - Medicine or biological product packaged with a delivery device (for example a cough syrup with a measuring spoon)
  - Surgical tray with surgical instruments, drapes, and lidocaine or alcohol swabs OR
- a combination of products where the components are separately provided but labelled for use together:
  - Photosensitizing drug and activating laser/light source
  - Iontophoretic drug delivery patch and controller

Once a product has been classified as a medicine (and not a medical device) at the level of the Act, further classification is required to determine to which category of medicine the product belongs. (The scope of this guideline does not include such determination.)

2. GENERAL CLASSIFICATIONS

2.1 MEDICINE

The action of a medicinal product is typically achieved in or on the human or animal body by pharmacological, immunological or metabolic means.

2.2 MEDICAL DEVICE

A medical device may contain a medicinal substance(s) which acts on the body in a manner ancillary to the device. However, where such substance(s) act in a manner that is the primary intended mode of action, the product is regulated as a medicine rather than a medical device.

Where the primary intended mode of action by which the claimed effect or purpose is not achieved by pharmacological, immunological, or metabolic means, but may be assisted in that effect or purpose by pharmacological, immunological, or metabolic means, the borderline product will be designated as a medical device.

Where the primary intended mode of action is achieved by pharmacological, immunological or metabolic means, and the action occurs *in vitro*, without reintroducing a modified cellular substance to the patient, the product will be designated as a medical device.

Under the medical device definition, a product that is considered to be a “related article” is itself classified as a medical device. Before such a decision is made, however, it must be confirmed that the product does not meet the definition of a medicine under the recommended conditions of use. A product considered to be an “accessory to a medical device” does not possess therapeutic properties of its own related to the purposes of the device: its use is solely to assist in the therapeutic function of the primary medical device. For example, a thermometer to record human body temperature is not in itself a medical device. However, a wearable device which detects, and records body temperature is a medical device if the intended purpose of the device is to detect elevated body temperature associated with a medical condition. Furthermore a “smart thermometer” which detects and records body temperature and attempts to indicate whether the user has a medical condition is also a medical device.

Wearable general health and wellness devices when intended for data gathering — for example, something which measures heart rate or motion — does not constitute a medical device in itself. However, where

the device performs a medical assessment function, or is used as an accessory to a medical device (such as a wearable intended by the manufacturer to be used with a medical device app) and is used specifically to diagnose or monitor a disease, such device is a medical device and must comply with the requirements of the Medicines Act and the medical device regulatory framework.

It should be noted that all devices, wearable or non-wearable, which perform a measuring function, even if not for medical purposes, are required to comply with the Legal Metrology Act (Act 9 of 2014).

2.3 COSMETIC

A Cosmetic is ordinarily administered by rubbing, pouring, sprinkling, spraying or other administration to the external parts of the human body including the epidermis, hair, teeth, mucous membranes of the oral cavity, lips and external genital organs. Therefore, a medical product which is intended to be ingested, inhaled, injected or implanted into the human body to achieve its intended mode of action is not a cosmetic.

It is generally understood that a cosmetic may exert a negligible organic effect which is local and transient. An example of the latter would be a moisturizer which hydrates by adding water to the epidermis.

2.4 GENERAL HEALTH AND WELLNESS PRODUCTS

"General health and wellness products" or "General health and wellness devices" may be defined as products or devices that

a. are intended for only general health and wellness use, and
b. present a very low risk to users' safety.

General health and wellness products may include but are not limited to health supplements, exercise equipment, monitoring devices, audio recordings, video games, software programs and other products / devices that are commonly, though not exclusively, available from retail establishments (including online retailers and distributors that offer software to be directly downloaded).

2.5 DISINFECTANTS, ANTISEPTICS AND GERMICIDES

Sanitising products may fall into various regulatory groups depending on the:

a. Application surface (human/animal skin or inanimate surface)

b. Environment the sanitiser is used in (place of use)

c. Intended use and function; and

d. Composition

Hand sanitisers for general use, are considered to be general consumer products controlled under the ambit of the FCD Act, if:

a. they do not contain a substance listed in the Schedules to the Medicines Act, and

b. they make general low-level claims against bacteria (for example, kills 99.9 % of bacteria).

Products primarily claiming to kill germs, disinfect or sanitise using an active antimicrobial ingredient, such as the hand sanitisers used in hospital operating rooms, burn units and wards, are designated as medicines.

Antiseptic and anti-bacterial products specifically for use as surgical scrubs in operating theatres and used on human/animal skin in hospital operating rooms, ICUs, burn units, and catheterization laboratories, which make claims to treat / prevent infection are designated as medicines.

Disinfectants and germicides used on inanimate surfaces in low-risk areas within the home, public venues (schools, restaurants), health institutions, health professional consulting rooms and clinics are designated as consumer goods, as per the FCD Act.

Disinfectants, antiseptics and germicides used on inanimate surfaces in areas of high risk (hospital operating rooms, intensive care units (ICUs), burn units, Catheterization Laboratories) are designated as medical devices.

Disinfectants used to clean medical instruments are designated as medical devices.

3. BORDERLINE PRODUCTS

3.1 CRITERIA

In considering how best to regulate a borderline product, the definitions of a medicine, medical device and cosmetic as provided for in the Medicine and Related Substances Act, 1965 (Act 101 of 1965) and the The Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 respectively, will be considered.

In order to decide the regulatory pathway and guide the decision of the authority the following factors will be considered:

a. the method by which the primary mode of action (PMOA) is achieved (in the case of medicines, medical devices);

b. the primary intended purpose of the product;

c. the claim(s) (representations) about what the product does (explicit and implicit);

d. the composition of the product - Although the composition of a product alone does not necessarily determine its designation, the presence of an ingredient, or its concentration, may make the product unsuitable for designation as a cosmetic or as a medicine or medical device;

e. the form of the product;

f. the pharmacological, metabolic or immunological properties of the ingredients (this includes any herbal ingredients) other than the primary mode of therapeutic action;

g. whether there are any similar products on the market;

h. presentation of the product to the public through labelling, packaging, promotional literature, advertisements, websites, social media and customer reviews;

i. level of action of the product - In order to be a cosmetic, the product must exhibit a lack of percutaneous absorption and should not have to be absorbed systemically to achieve the effect;

j. perception of the user - Perception includes the purpose for which the general public uses the product and whether it is likely to be understood by consumers to have characteristics of a cosmetic or medical product;

k. inherent risk-benefit balance based on its constituents and its intended use. In relation to medical devices, the following risk-based classification will be used:

- Class A: Low Risk
- Class B: Low-moderate Risk
- Class C: Moderate-high Risk
- Class D: High Risk

l. classifications in other regulatory jurisdictions - Although SAHPRA may consider the classification decisions of other Regulatory Authorities that SAHPRA aligns with, these will not be binding.

The criteria above may not be given equal weight in support of a decision, as some factors may be more important to consider in one circumstance versus another. Not all criteria need be applied if a decision can be reached after the examination of one or a few criteria. In the event that the standard criteria do not lead to a clear decision, supplementary considerations may be taken into account. The final decision is

dependent on the overall consideration. While all factors are important, ultimately the intended purpose of the product takes precedence in the classification decision.

The primary mode of action (PMOA) means “the single mode of action of a borderline product that provides the most important therapeutic action of the product”. The most important therapeutic action is the mode of action expected to make the greatest contribution to the overall intended therapeutic effect(s) of the borderline product. The claimed effect or purpose must be achieved by the most important therapeutic action. In addition to the primary mode of action, the composition and form of the product and the therapeutic effect of the product may be considered to assist in the designation of the product.

A borderline product may be classified as a medicine or a medical device, even when no explicit therapeutic claim is made. A therapeutic claim may also be implicit. Both types of claims are considered when a product is classified. Explicit claims are stated with no ambiguity with regard to their meaning or intent. In contrast, implicit claims made in the representation of a product indirectly suggest a therapeutic benefit. Product representation includes the appearance, labelling, and advertising of a product.

In the absence of either an explicit or implicit claim, a product may be classified (e.g. as a medicine or a medical device) if the intrinsic properties of the product are such that there is no other possible use. For example, acetaminophen has no other use but as a medicine, so the absence of a claim will not change its classification as a medicine.

When considering the claim made for a product, it is important to note whether more than one property can contribute to the overall effect of the product when used for this indication. For example, if a therapeutic substance is shown to modify an organic function as well as a physiological process (body function) or anatomy, then both medicine and medical device definitions can be satisfied. To make the necessary distinction, a comparative risk assessment should be made. Specifically, if it is determined that the greater risk is associated with the modification of an organic function, then the safety, quality and efficacy of the product would be more appropriately assessed under the medicine framework. The reverse will also apply.

Where the product’s composition suggests it is an agent for treating, diagnosing, preventing, monitoring, alleviating disease or injury; or restoring, correcting or modifying organic functions in human beings it is a

medical device or a medicine.

Where the product is represented in a manner suggesting it is used for treating, diagnosing, preventing, monitoring, alleviating disease or injury; or restoring, correcting or modifying somatic, psychic or organic functions in human beings it is a medical device or a medicine.

Products that incorporate or are used to administer a medicine may be regulated as either medical devices or as medicine, depending on the principal intended function of the product and the method by which this action is achieved.

4. REQUEST FOR DESIGNATION (RFD) OF A BORDERLINE PRODUCT

Recommendations as to the designation of borderline products as being subject to medicines, medical devices or cosmetic regulatory action shall be made by the Borderline Products Working Group (WG) appointed by the CRO of SAHPRA.

The WG will consist of technical experts from the relevant multi-disciplines - medicines (including veterinary, complementary, biological), medical devices and cosmetics, to review RFD applications.

The response received by the applicant to the RFD will provide an opinion only as to whether or not the product is deemed a medicine or a medical device as per the Act and cannot classify products that fall under legislation for other types of products. Compliance with other product regulations should be checked with the appropriate authority.

An opinion that the product is not a medicine or a medical device is not an endorsement of the product nor does it provide an approval to sell, supply or advertise the product in South Africa, as it may fall under the remit of other applicable legislation.

The Authority reserves the right to change its view in the event of any information or evidence which has a bearing on the status of the product, including the way in which it is packaged, promoted or presented, or if there is a change in scientific knowledge or the law. The Authority can give no assurance that any particular product, including products under development, will not subsequently be classified as a medicine or medical device.

The decisions of the Authority, as it relates to the classification of the borderline product, will be published

on the Regulatory Authority's website. Publication will help to build a common understanding of the Regulatory Authority's practical implementation of the agreed policy.

The RFD process for borderline products should only be initiated by an applicant when there is a lack of clarity or dispute on the correct regulatory route or classification of the borderline product, after reading this document and consulting with the published guidelines available (Refer to Section 6)

4.1 SUBMITTING AN RFD APPLICATION

An RFD application form (Annexure A) must be submitted to SAHPRA. The completed submission must also include the following documentation and supporting evidence:

a. Table of Contents (paginated with hyperlinks to sections)
b. Cover Letter
c. Package Insert/ Patients Information Leaflet/Brochure/Flier, where relevant
d. Information for Use/ User Manual where relevant
e. Material Safety Data Sheet, where relevant
f. Report of the results on developmental work, including animal/ other testing, where relevant
g. Risk assessment and risk management plan
h. Classification of the product in other jurisdictions recognized by SAHPRA
i. Premarket approval/ Registration/ Marketed as not being subject to premarket approval/ Exemption in SAHPRA aligned regulatory jurisdiction
j. Labelling and Packaging, where relevant
k. Proof of payment

The applicant to ensure that all relevant fields are completed and all supporting documentation is attached. Incomplete applications will be identified as deficient and review will not be progressed until deficiencies are addressed.

The prescribed application fee and proof of payment must accompany the application. For the current fee payable, refer to the latest fee schedule as published in the Government Gazette and published on the SAHPRA website.

Payments should be made as per 17.05 "Guideline on the payment of fees to SAHPRA", accessible here: https://www.sahpra.org.za/wp-content/uploads/2021/01/SAHPRA-Payment-Guideline-Nov-2020.pdf

The completed application should be submitted electronically to: borderlineproducts@sahpra.org.za using the identified code.

4.2 TIMELINES FOR PROCESSING OF RFD APPLICATIONS

Applications will be processed within 30 working days of receipt thereof.

A query letter will be sent to the applicant in the event that an application does not meet the evaluation criteria. The deficiencies identified within the application will be documented in the query letter.

The applicant is required to respond to the deficiencies noted in the query letter within ten working days.

NOTE: Only two cycles will be permitted, i.e. the applicant will have two opportunities to address deficiencies identified in the application by submitting a response to SAHPRA within the defined timelines. If the response/s (limited to a maximum of two cycles) from the applicant does not adequately address the deficiencies identified in the application, the application will not be recommended and the application fee will be forfeited.

5. REFERENCES

The following related documents are referenced:

5.1 ACTS AND REGULATIONS

Medicines and medical devices are regulated by the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and the General Regulations, Complementary Regulations and Medical device Regulations respectively.

Cosmetics are regulated by Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972)

5.2 GUIDELINES

8.05 Classification of Medical Devices and IVDs, and

WHO Reference

6. VALIDITY

This guideline is valid for a period of 5 years from the effective date of revision. It will be reviewed on this timeframe or as and when required.

7. ANNEXURES

7.1 ANNEXURE A: MEDICINE AND MEDICAL DEVICE CLASSIFICATIONS

The table below notes the current classification of classes of medicines and medical devices. The list is not intended to be an exhaustive list but to be used as an aid to the classification of products.

"MD" indicates the product is regarded as a medical device and 'M' indicates the product is regarded as a medicine

PRODUCT	APPLICABLE REGULATION	COMMENT
1. Contact lens care products		
a. Disinfecting	MD	
b. Cleaning solutions	MD	
c. Rinsing solutions	MD	
d. Hydrating solutions	MD	
e. Wetting agents	MD	
f. Comfort drops	MD	Considered to be accessories to medical devices when specifically intended for use as a result of wearing contact lenses. Considered to be medicinal products if therapeutic claims are made and contain an active ingredient.
2. Other ophthalmics		
a. Artificial tears (unmedicated)	MD	Considered to be medical devices if therapeutic claims are made. Medicated drops are considered to be medicines
b Artificial tears (medicated)	M	
c. Other eye drops (medicated)	M	
d. Other eye drops (unmedicated)	MD	If claims are made to treat or alleviate damage to the eye– see the manual of decisions [6].
e. Fluorescein ocular strips for diagnosis.	M	Note: these may be accepted as medical devices **only** when specifically intended for the fitting of contact lenses. For diagnostic purposes the

PRODUCT	APPLICABLE REGULATION	COMMENT
		medicines regulations will apply.
f. Injectable fluorescein	M	
g. Rose Bengal	M	
h. Solution for preserving corneal material prior to transplant	MD	Will generally be regarded as Class D medical devices
i. Ocular endotamponades	MD	
j. Viscoelastic/viscosurgical products	MD	
3. Surgical dressings		
a. Non-medicated	MD	
b. Medicated	MD/M	
4. Non-medicated dermatological creams	MD	Including those containing zinc oxide (without pharmacological action)
5. Sutures and ligatures		
a. Absorbable	MD	
b. Non-absorbable	MD	
c. Biological sealants	M/MD	
6. Resorbable bone plates/polylactic/polyglycolic acid	MD	
7. Hard tissue scaffolds		
a. Hydroxyapatite with/out collagen	MD	
b. Calcium phosphate with/out collagen	MD	
c. Bioglas	MD	
d. Coral	MD	
e. Cartilage repair systems	M/MD	
8. Soft tissue fillers		
a. Collagen (non-human)	MD	

PRODUCT	APPLICABLE REGULATION	COMMENT
b. Silicone elastomer dispersions, e.g. Bio/uroplastique	MD	
9. Bone cements		
a. Polymethylmethacrylate with/out antibiotic	MD	
10. Joint replacements coated with:		Coatings of human origin are not regarded as medical devices
a. Hydroxyapatite/calcium phosphate	MD	
b. Bone growth factor (beta BGF)	MD	Used alone controlled as a medicine
c. Genetically engineered BGF	MD	Used alone controlled as a medicine
11. Inhalation products		
a. Prefilled metered dose inhalers	M	
b. Chamber spacers for use with metered dose inhalers	MD	(b), (c), (d) & (e) may be sold with medication and their performance/drug delivery will be assessed by a drug regulatory authority as part of the medicines Marketing Authorisation application.
c. Spinhalers -} refillable	MD	
d. Diskhalers -} refillable	MD	
e. Other empty or re-fillable inhalers	MD	
12. Powered nebulisers		
a. Device	MD	May be sold with medication and their performance/drug delivery will be assessed by a drug regulatory authority as part of the medicines Marketing Authorisation application.
b. Medication	M	
13. Insulin injection		
a. Disposable pen injectors integral with insulin cartridge	M	
b. Re-usable insulin pens	MD	
c. Sterile single-use syringes (empty)	MD	
d. Insulin	M	
14. Blood bags		
a. Sterile empty	MD	
b. Sterile with anticoagulant	MD	
c. Platelet additive solutions	MD	
15. Dialysis products		

PRODUCT	APPLICABLE REGULATION	COMMENT
a. Equipment	MD	
b. Peritoneal solution including CAPDs	MD	
c. Haemodialysis solution	MD	
d. Haemofiltration solution	M	
e. Solutions for on-line haemodiafiltration	M	
16. Anaesthetic and other medical gases and oxygen cylinders		
b. Bulk supply gas including cylinder	M	
c. Oxygen concentrators	MD	
d. Ozone generators	MD	
17. Monoclonal antibodies		
a. In vitro diagnostics	*MD	
b. Immunotoxins	M	
18. Human tissues		
a. Dura grafts	M	
19. Dental products		
a. Pit and fissure sealants	MD	
b. Root canal sealers: medicated/non-medicated	MD	
c. Root canal dressings (e.g. polyantibiotic pastes, antiseptics)	M	
d. Pulp capping material	MD/M	If used for drug delivery, then product covered as a medicine.
e. Dry socket preparation	MD/M	If used for drug delivery, then product covered as a medicine.
f. In vivo diagnostics, e.g. disclosing tablets	MD	
g. Haemostatic agents and astringents	M/MD	Depends on product mode of action, see guidance.
h. Aluminium sulphate / salts astringents	MD	
i. Retraction cords: medicated /non-	MD	

PRODUCT	APPLICABLE REGULATION	COMMENT
medicated		
j. Fluoride preparations: e.g. tablets, gels, varnishes	M/MD	Depends on primary mode of action and the claims being made for the product.
k. Hard tissue scaffolds	MD	
l. Desensitising agents: physical/pharmacological	MD/M	Depends on mode of action
m. Periodontal dressings: medicated/non medicated	MD	
n. Periodontal antibacterials: e.g. gels, ointments, fibres	M	
o. Varnishes: protective/drugs delivery	MD/M	Depends on primary mode of action and the claims being made for the product.
p. Toothache preparations	M	
q. Artificial saliva	MD	
r. Mouth ulcer preparations: medicated/non-medicated	M/MD	
s. Antibacterial mouthwashes/ gels	M	Depends on primary purpose, some may be cosmetics if no medical claims made
20. Contraception products		
a. IUDs without pharmacological action	MD	
b. Diaphragms	MD	
c. Condoms with/out spermicide	MD	
d. IUDs with hormone action	M	
e. Spermicidal preparations e.g. creams pessaries, sponge film	M	Where primary purpose is a drug delivery system
21. Impregnated devices a. Antithrombotic coatings gelatin/heparin/protein b. Bacteriological coatings chlorhexidine/benzalkonium chloride/silver/salts/ antibiotics	MD MD	Unless primary purpose is to treat infection
22. Disinfectants		These products overlap with the FCD Act. Only products intended for a 'medical' purpose will be covered by the medicines or medical device regulations.
a. Topical disinfectants for use on human skin	M	
b. Alcohol only wipes / swabs for use on human skin for medical purposes	MD	

PRODUCT	APPLICABLE REGULATION	COMMENT
c. Wipes/swabs with medicinal substance (chlorhexidine, cetrimide, iodine etc)	M	
d. Disinfectants specifically intended for disinfecting medical devices	MD	
e. Disinfectants for use on inanimate surfaces for medical purposes	MD	Intended for use in high-risk environments/ clinical and healthcare settings will be regarded as MD
23. Plasma volume expanders	M	
24. In vivo diagnostic agents		
a. X-ray contrast media including MRI	MD	
b. Barium meal	MD	
c. other in vivo imaging agents	MD	
d. labelled urea for *H. pylori* test	MD	
e. gases for lung function tests	MD	
25. Transdermal patches		
a. Disposable with medicinal product	M	
b. Iontophoresis device (non-disposable/reusable)	MD	
26. Irrigation solutions (including those used in the eye)	MD/M	For mechanical rinsing purposes including those with antimicrobial agents where this is ancillary to the physical rinsing is regarded as a medical device. Where the product contains a pharmacologically active substance / antimicrobial intended for disinfection then the product is likely to be considered a medicine. **Note:** Eye washes for emergency purposes are usually considered to be medical devices.
27. 'Activated' medicinal products		
a. Medicinal product	M	
b. Activating device e.g. laser	MD	
28. Administration products		These products are covered by medical device regulations even though they may be supplied in the same pack as the medicine unless they form the closure of the container (e.g. bottle cap/dropper assembly)
a. Medicine spoons	MD	
b. Droppers	MD	
c. Oral syringes	MD	

PRODUCT	APPLICABLE REGULATION	COMMENT
d. Eye baths	MD	
29. IVF media	MD	Will generally be regarded as Class C medical devices
30. Agents for transport, nutrition and storage of organs intended for transplantation	M	Will generally be regarded as Class C medical devices
31. Artificial skin systems	M	Products that do **not** contain material of human origin, will be covered by the medical device regulation but products that do contain material of human origin are **not** covered.
32. Viscoelastic gels for joint lubrication	M/MD	Depends on mode of action
33. Parenteral fluids (diluents)		
a. Water for injection	M	
b. Saline	M	
34. Head lice products	M/MD	Such products will either be medical devices or medicines, depending upon their mode of action.
35. Corn plasters		Note that products containing salicylic acid will be considered as Class C medical devices under rule 13 due to the analgesic properties of salicylic acid. Products containing other acids (e.g. trichloracetic, nitric) for the treatment of corns are considered as class B medical devices.
a. Containing salicylic acid	MD	
b. Containing other acids	MD	
36. Pre-filled, single use, syringes specifically intended for mechanical flushing of ports and catheters (saline / heparin etc)	MD	These are accepted as medical devices provided that they are specifically intended for the mechanical flushing of medical devices such as ports and catheters, even when the flush may result in the fluid entering the body. Such products must be clearly contraindicated for direct systemic administration. Classification will depend upon the ingredients contained in the flushing solution. Pre-filled syringes intended for systemic administration are always regulated as medicinal products.
37. Other products		
a. Weight loss tablets	M/MD	Depends on mode of action and claims made.

PRODUCT	APPLICABLE REGULATION	COMMENT
		Products that act pharmacologically or metabolically and claim to suppress appetite, burn fat, speed up metabolism or treat obesity are likely to be regarded as medicines. Fat absorption and bulking agents are likely to be regulated as medical devices if making a medical claim (e.g. treatment rather than just a slimming product). Products not regulated as devices or medicinal products are likely to be regulated as food, provided no medicinal claims are made.
b. Activated charcoal / carbon solutions for treatment of acute poisoning	MD	
c. Products for the regulation of vaginal flora containing lactobacillus	M	
d. Leeches and maggots	MD	
e. Products for the treatment of addiction to nicotine	M	
38. Specific veterinary products		
therapeutic lasers	MD	
electro – acupuncture	MD	
Lameness locator	MD	
Ear tags	MD	
Neck collars that contain ectoparasiticides	MD/M	
Premixes that contain feed additives	MD/M	
Identification Micro chips	MD	
Burdizzo castration forceps	MD	
Intra-rumen magnets	MD	
Endotracheal tubes	MD	
Oesophageal tubes	MD	
Fetotomes	MD	
Restraining equipment	MD	
Dog muzzles	MD	
Spray races	MD/M	
Cages	MD	
Intrammamary devices	MD/M	
Mechanical teat seals	MD	

PRODUCT	APPLICABLE REGULATION	COMMENT
Dosing guns	MD	
Game capture darts	MD/M	
Hoof and footcare sealants	MD/M	
Nasal sealants	MD/M	
Teat dips	MD/M	
Eye protectants: during anaesthesia	MD/M	
Obstetrical/rectal lubricants	MD/M	
Insemination devices	MD	
Semen extenders	MD	
Vaginal sponges	MD/M	