The GCC Regulations for Products Classification

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1. Introduction

Products classification is a crucial step in identifying of the subsequent path within regulatory bodies. The Gulf Cooperation Council (GCC) member-states have come up with a realize that more harmonization, overcoming the regulatory differences, and fostering the joint work of product classification, is needed especially for products that are centrally marketed in the gulf region

Therefore, this guideline has been issued to ensure a unified approach; moreover, it has been adopted from the GCC states guidelines of products classification and regulation.

2. Objectives

This guidance presents the GCC general views as agreed on classification recommendations of specific products or a category of products to assist stakeholders to classify their products, determine the appropriate regulatory scheme, achieve more consistency, and transparency on GCC classification committee activities. However, in areas where a different classification of an individual product exists, among member states, it is important to note that the national regulatory framework must apply, and this guidance shall serve as a tool to support the national classification. Moreover, it is highly important to note that this guidance in not all-inclusive, and it is the responsibility of the applicant to seek a classification advice in case of doubt.

3. General Principles

As a general consideration, product classification decisions will be depending mainly on the statutory definitions as stated in this document taking into account certain criteria such as the mode(s) of action by which the intended purpose is achieved as well as the way the product is presented, and the product's format. For example, a product may be classified as a medical device if it "does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means. If the product acts by such means, it will be classified as a pharmaceutical drug product.

For borderline cases, the GCC classification committee will classify products on a case-by-case basis considering the complexity of the product, product's full characteristics, and the current scientific and regulatory requirements in alignment with the common international practices in order to reach a consensus on the most appropriate regulatory path. However, the

GCC classification committee could take several factors into account in order to determine if the product falls under the pharamaceutical drug definintion or not such as the following:

3.1.Representation made about the product (therapeutic claims , purpose)

- Is the product represented in a manner suggesting it is used for treating, diagnosing, preventing, curing diseases, restoring, correcting or modifying organic functions in human beings
- A claim can be a word, a sentence, a picture, a symbol, a paragraph or an implication on product labels, pack insert, or through advertisements.

3.2.The composition of the product

- Does the product's composition suggest it is an agent used for treating, diagnosing, preventing, curing diseases, restoring, correcting or modifying organic functions in human beings?
- The presence of an ingredient at certain concentration may make the product pharmaceutical or health product.

3.3.Level of action

- Does the product exert solely a superficial effect?
- Does the products act by pharmacological, immunological or metabolic means? The following definitions are intended only to provide guidance as to the meaning of these terms.
  - *Pharmacological* mean is defined 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 blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose-response correlation is indicative of a pharmacological effect.
  - *Immunological* mean is defined as an action in or on the body by stimulation and/or mobilization of cells and/or products involved in a specific immune reaction.
  - *Metabolic* mean is defined as an action, which involves an alteration, including stopping, starting or changing the speed of the normal chemical processes participating in, and available for, normal body function.

3.4.Classification status of other regulatory authorities

- Classification in the country of origin

- Classification in GCC and other Reference countries

3.5.Simialr registered products with the same composition, dosage form & indications.

4. Scope

This guidance document pertains to a product or category of products that is under the responsibility of the GCC regulations.

5. Related Guidelines

This guideline should be read in conjunction with:

- NHRA Pharmaceutical Products Classification Guideline. Kingdom of Bahrain
- Saudi Food & Drug Authority Products Classification Guidance. Kingdom of Saudi Arabia
- Ministerial Decree for Registration and Release of Health Products & Medical Devices. State of Kuwait
- Guidelines for Products Classification. Sultanate of Oman
- UAE Guidelines for the registration of General Sale Pharmaceutical Products and Related Companies. United Arab Emirates

6. Definitions

Alternative Traditional Medicines

Any form of Treatment or therapy outside the realm of conventional modern medicine.

Animal Feed

Any substances, single mixed processed or semi-processed, intended to feed animals, and used as a raw material or as an ingredient in the preparation of manufacturing or processing of feed originating from plant, approved animal source, or aquatic source.

Biological Drug Products

Medicinal products derived from a variety of natural sources or produced by biotechnology methods and other cutting-edge technologies. They include a wide range of products such as vaccines, blood and blood components, allergenics, advanced therapy medicinal products (ATMPs), recombinant proteins and biosimilars.

Combination Product

A product consists of two or more of items subject to more than one different regulation, and it may include:

- **Integrated combination product**
  - A product consists of two or more regulated components that are combined/integrated as a single product.
- **Non-integrated combination product**
  - A product consists of two or more separated items that are contained in the same package. [Co-packaged combination product].
  - Any regulated product packaged separately where the labeling information refers to be used with another specific regulated product where both are required to achieve the intended purpose of use. [Cross-labeled combination product].

Cosmetic Product

Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odors.

Food

Any substance whether processed, semi-processed or unprocessed, which is intended for direct human consumption or to be used in manufacturing, preparing or treating a foodstuff.

Foods for Special Medical Purposes

Category of foods for uses which are specially processed or formulated and presented for the dietary management of patients and may be used only under medical supervision. They are intended for the exclusive or partial feeding of patients with limited or impaired capacity to take, digest, absorb or metabolize ordinary food stuffs or certain nutrients contained therein , or who have other special medically - determined nutrient requirements, whose dietary uses, or by a combination of the two.

Food Supplement

Food supplements: Are food products that are used to supplement the normal diet. Which contains ingredients, alone or in combination, may have a nutritional or physiological effect and often it is concentrated and taken in doses. Food supplements consists of one or more of the following components: vitamins, minerals, fatty acids, amino acids, enzymes, prebiotics and probiotics, collagen, dietary fibers, melatonin, propolis, pollen, herbs or food herbal extracts…etc

Health Product

A Finished labelled product in pharmaceutical dosage forms, that contains low risk ingredients and has indications such as health maintenance, health enhancement and/or modifying physiological functions by exerting pharmacological, immunological or metabolic actions.

Herbal Product

Finished, labeled pharmaceutical dosage form products that contain as active ingredients aerial or underground parts of plants, or other plant material, or combinations of both, that is used to treat or prevent diseases or both.

Homeopathic Drug

Homeopathy is a complementary alternative medical practice based on the use of highly diluted substances, which practitioners claim can cause the body to heal itself. Homeopathic medicines or their stocks/mother tinctures are prepared from natural or synthetic sources that are referenced in pharmacopeial monographs or other recognized documents

Human cells, tissues, or cellular or tissue-bases products (HCT/Ps)

It means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/Ps include, but are not limited to, bone, ligament, skin, dura mater, heart valve, and cornea.

In Vitro Diagnostic (IVD) Medical Device

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.

Medical Device

Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purposes of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury
- Investigation, replacement, modification, or support of the anatomy, or of a physiological process
- Supporting or sustaining life
- Control of conception
- Disinfection of medical devices
- Providing information by means of in vitro examination of specimens derived from the human body;

Which does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which maybe assisted in its intended function by such means.

Pharmaceutical Drug Product

A- Any substance or combination of substances that are in a finished pharmaceutical dosage form administered to human beings (used externally or internally) and intended for use in the diagnosis, cure mitigation, treatment, or prevention of disease, *OR*,

B- Any substance or articles (other than food) intended to affect the structure or any function of the body to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.

Public Health Pesticides

Any chemical substances, inorganic, organic or natural product or biological product containing elements of microorganisms used in the control of pests (including attractive and repellents substances).

Special Food

Foods for special dietary uses: Foods which are specially processed or formulated to satisfy particular dietary requirements which exist because of a particular physical or physiological condition and/or specific diseases and disorders and which are presented as such. The Composition of these foodstuffs must differ significantly from the composition of ordinary foods of comparable nature.

Tobacco Products

Any products consisting wholly or partially of tobacco leaves as raw material which has been manufactured for the purpose of direct or non-direct smoking or absorption such as Cigarettes, Almeassel tobacco, Meassel Fruit flavored, cigar, as well as E-Liquids and Heated Tobacco Products which are used by Electronic Nicotine Delivery Systems (ENDS)

Veterinary Drug

Any substance or mixture of substances manufactures, sold or represented for use in:

The diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical state, or its symptoms, in animals.

Restoring, correcting or modifying organic function in animals.

7. Pharmaceutical Drug Product

A product will be classified as a pharmaceutical drug product if it falls within either of the two definitions stated above. Definition A of the pharmaceutical drug product relates to the function and/or presentation of the substance, i.e., the substance manufactured in pharmaceutical dosage form and is presented to have a therapeutic effect of treating or preventing diseases. Definition B of the pharmaceutical drug product relates to the function and intended use.

The GCC classification committee will consider the following factors in determining this definition:

- **The intended purpose**

In the context of the drug definitions, depending on the overall presentation of the product, uses or claims including words, symbols, pictures, or any other means, to treat, prevent, alleviate, diagnose or help with a disease and/or a specific symptom will be considered as medical uses. Thus, products with such uses or claims will be subject either to a drug or medical device regulations based on the primary mode of action, (please refer to the medical device section). However, claims, such as maintains, improves, and supports general health are not likely to be considered as medical claims.

- **The primary mode of action**

The GCC classification committee will review all available evidence related to the product and the way it achieves its intended use, this could be contributed to the product's ingredients and/or their concentrations. Products that contain any substance that exerts, or demonstrates a pharmacological, immunological, and/or metabolic function, would be classified as a pharmaceutical drug product. For example, food supplements or cosmetics in concentrations that have a significant effect on the human physiology or the functioning of the body.

- **The dosage form**

The dosage form could affect the product classification in some cases; however, it is not always the solely criterion for classification and it should be reviewed on case-by-case bases. For example, products in oral dosage forms such as powders, liquids, capsules, or tablets..etc., will be regarded under drug jurisdiction if they achieve their primary intended action (treat, prevent, diagnose.. etc.) in or on the human body by pharmacological, immunological or metabolic means.

The following product categories or substances listed below are examples of pharmaceutical drug products:

7.1. One or more vitamins and/or minerals with concentrations above the upper concentration limit of vitamins and minerals (please refer to Appendix. 1). The upper and lower concentrations limits will be calculated according to the product total daily dose.
7.2. Eye preparation that achieves its primary intended purpose by pharmacological, immunological , and/or metabolic means.
7.3. Peritoneal dialysis solutions
7.4. Solution for hemofiltration and hemodiafiltration
7.5. Saline and sterile water that are intended for intravenous injection
7.6. Parenteral nutrition solution
7.7. Therapeutic Radiopharmaceuticals
7.8. Enema solution Products (rectal solution products)
7.9. Anti-lice products containing high risk chemical ingredients such as malathion, permethrin, and pyrethrins

8. Biological Drug Products

A product shall be classified as a biological medicinal product if it meets the above mentioned definition of biological drug product and it include a wide range of products such as the followings:

8.1. Blood Product:

A blood product is any therapeutic substance derived from human blood, including whole blood and other blood components for transfusion, and plasma-derived medicinal products.

Examples: blood components (i.e., red blood cells, platelets and plasma), plasma-derived medicinal products (e.g., albumin, polyvalent and specific immunoglobulins, and blood coagulation factors).

8.2. Hormone:

A hormone is a biological compound used by multicellular organisms to organize, coordinate, and control the functions of their cells and tissues. These chemicals can control everything from metabolism to behavior, and are necessary for organisms to survive and reproduce.

Examples: estrogen, testosterone

8.3. Monoclonal Antibodies:

Monoclonal antibodies are immunoglobulins (Ig) with a defined specificity derived from a monoclonal cell line. Their biological activities are characterized by a specific binding characteristic to a ligand (commonly known as antigen), and may be dependent on immune effector function such as antibody dependent cellular cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC).

Monoclonal antibodies may be generated by recombinant DNA (rDNA) technology, hybridoma technology, B lymphocyte immortalization or other technologies (e.g. display technology, genetically engineered animals).

Monoclonal antibody related products include; single-chain variable fragment (scFv)), fusion proteins, conjugated monoclonal antibodies, bispecific antibodies and radiolabelled antibodies.

8.4. Toxin-Antitoxin Antibody:

Toxin antibody: An antibodies ability to inactivate even the most potent plant and microbial toxins, including botulinum, tetanus, diphtheria, anthrax and ricin toxins.
Antitoxin Antibody: An antibody produced in response to and capable of neutralizing a specific biologic toxin such as those that cause diphtheria, gas gangrene, or tetanus. Antitoxins are used prophylactically and therapeutically.
Examples: Botulinum antitoxin, heptavalent (HBAT)

8.5. Allergenic Products:

Allergen products of biological origin, including the allergen extracts derived from natural source material such as Pollens, molds and mites mainly consist of proteins and glycoproteins. Also allergens produced through recombinant DNA technology

8.6. Vaccine:

A vaccine is an immunogen, the administration of which is intended to stimulate the immune system to result in the prevention, amelioration or therapy of any disease or infection. A vaccine may be a live attenuated preparation of bacteria, viruses or parasites, inactivated (killed) whole organisms, living irradiated cells, crude fractions or purified immunogens, including those derived from recombinant DNA in a host cell, conjugates formed by covalent linkage of components, synthetic antigens, polynucleotides (such as the plasmid DNA vaccines), living vectored cells expressing specific heterologous immunogens, or cells pulsed with immunogen. It may also be a combination of vaccines listed above.

8.7. Biosimilar:

Therapeutic proteins produced by recombinant DNA technology or gene expression method following the footsteps of one licensed reference biotechnological product. They are complex and heterogeneous in their nature; hence they are not considered generics, but as closely similar to the innovator’s drug as possible.

8.8. Advanced Therapy Medicinal Products (ATMPs):

Please, refer to GCC ATMPs Classification Guideline

9. Herbal Products

Products containing herbs would be considered as herbal product when it falls within the following criteria as stated in the above-mentioned definition; finished labeled product in

pharmaceutical dosage forms, and the intended usage of the herbal product in treating, preventing or diagnosing diseases.

10.Alternative Traditional Medicines

A product shall be classified under the alternative traditional medicines if it meets the above mentioned definition and it include a diverse range of health practices, approaches, knowledge and beliefs incorporating medicines of plant, animal and/or mineral origin such as the followings:

10.1.Ayurvedic Medicines:

The ancient Indian medical system, also known as Ayurveda, is based on ancient writings that rely on a “natural” and holistic approach to physical and mental health. Ayurvedic medicine is one of the world’s oldest medical systems and remains one of India’s traditional health care systems. Ayurvedic treatment combines products (mainly derived from plants, but may also include animal, metal, and mineral), diet, exercise, and life style. It includes special types of diets, herbs, minerals, and changes based on a system of constitutional categories in lifestyle. Enemas and purgation are used to cleanse the body of excess toxins, based on the below references:

- Ayurvedic Pharmacopeia.
- Indian Medicinal Plants.

10.2.Homeopathic Medicines:

There are two main types of homeopathic medicinal products:

10.2.1. Homeopathic single Remedy

A finished, labeled homeopathic preparation containing a single homeopathic ingredient. The label specifies the pharmacopoeial or common name and potency only. Generally, no indications or dosage regime are specified.

10.2.2. Homeopathic Specialty

A finished, labeled homeopathic preparation containing one or more homeopathic ingredients. The label, container and pack insert may bear a trade (brand) name, indications and dosage regime. They are normally sold over-the-counter in a pharmacy,

direct to the public, for self-treatment conditions (i.e. if inappropriately treated, or left untreated, would generally not lead to serious consequences).

11. Veterinary Drug Product

A product shall be classified as a veterinary drug product if it meets the above mentioned definition and it may include the following categories

11.1. Veterinary Medicinal Product

When a substance, part of a substance or a combination of substances associated with a therapeutic (medicinal) property or pharmacological effect.

11.2. Insecticides:

Veterinary products, which contain substances that kill insects or external parasites, such as pyrethrins, pyrethroids or organophosphate compounds.

11.3. Shampoos:

A shampoo for animals will be considered medicinal if it contains an insecticide or an ingredient, which has a pharmacological effect or is presented as an insecticidal shampoo.

11.4. Teat and Udder Products:

Products applied internally to teats and udders for the prevention of mastitis.

11.5. Herbal Products:

Herbal products require a market authorization if they are medicinal by presentation or function. For example, a product containing pyrethrum, pyrethrins or alkaloids, such as digoxin from Digitalis sp., would be considered medicinal by function.

11.6. Diagnostic Tools (Testing Kits):

Any substance or combination of substances administered to animals with a view to making a medical diagnosis.

12. Health Products

A product would be considered as health product for registration if it meets the following criteria as stated in the above-definition; finished labeled product in pharmaceutical dosage forms, which may contain one or more of the following ingredients (*the list in non-inclusive*),

12.1. Amino acid

12.2. Charcoal

12.3. Tar

12.4. One or more vitamins and/or minerals with concentrations equal or below the upper concentration limit provided that none of these vitamins and/or minerals are below the lower concentration limit. The upper and lower concentrations limits will be calculated according to the product total daily dose. please refer to Appendix. 1

12.5. Medicated throat lozenges or lozenges consists of volatile oils with no unacceptable claim

12.6. Natural enzyme products

12.7. Probiotics and prebiotics that are marketed in pharmaceutical dosage form

12.8. Topical patches, creams, ointments and gels containing counter irritant ingredient as an externally applied substance that causes irritation or mild inflammation of the skin for the temporary relieve of pain in muscles or joints by reducing inflammation in deeper adjacent structure

12.9. Electrolyte products other than those used as fluid replacement for athletes

12.10. Skin Care Products containing urea in a concentration greater than the recommended by the GSO standards for cosmetic products

12.11. Topical products containing organic acids (Alpha-hydroxy acids (AHAs)) in total concentration of organic acids more than the recommended by the GSO standards for cosmetic products

13. Cosmetics

A product will be classified as a cosmetic product if it meets the definition of cosmetics stated above. The GCC classification committee will consider the following criteria in determining this definition:

- **The site of application and dosage form:**

The products should be intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity.

Products that are intended for internal use cannot be considered to be cosmetic products such as:

- Products taken orally (syrup, solution, drink, capsules, tablet…etc)
- Products that are taken through the eyes or nose or ear (drops, sprayer...etc)
- Products intended for injection (Intravenous IV, Intramuscular IM, Subcutanous SC…etc)
- Products that are taken through the anal or vagina (Enema, suppository, solution, tab, capsules… etc)

- **Product main function and claim:**

Cosmetics should be used exclusively or mainly, on the sites of application stated on the definition, to clean, perfume, change the appearance and/or correcting body odors and/or protecting or keeping them in good condition.

Cosmetic products should not presented to have medicinal or therapeutic claims such as treating or preventing disease in human beings, and they should not have a significant physiological effect. The following features of the product should be taken into account:

- Product claims and the context in which the claims are made
- Labeling and packaging/packaging inserts (including graphics)
- Promotional literature, including testimonials and literature issued by third parties on behalf of the supplier
- Advertisements
- Particular target of the marketing information e.g. specific population groups with, or particularly vulnerable to, specific diseases of adverse conditions.

- **Ingredients**

Cosmetic products should not contain any medicinal or therapeutic substances. Also, the cosmetic products shall comply with the GSO safety requirements of cosmetic products

The followings categories could be considered as cosmetics:

13.1. Skin care products such as: facemask, eye contour products, lip care products, hand care products, chemical exfoliation products, skin lightening products

13.2. Skin cleansing products: soap, bath/shower products, make-up remover products, External Intimate hygiene products, other skin cleansing products.

13.3. Body hair removal product

13.4. Chemical depilatories, Physical epilation products, other body hair removal products

13.5. Body hair bleaching product

13.6. Correction of body odor, perspiration, and/or deodorants

13.7. Products with antiperspirant activity, Products without antiperspirant activity.

13.8. Perfumes

13.9. Shaving products

13.10. Make-up products such as foundation, eyeliner, body face paint…etc.

13.11. Sun and self-tanning products

13.12. Hair and scalp care and cleansing products such as shampoo, antidandruff, anti-hair loss, conditioner…etc.

13.13. Hair coloring products Oxidative hair colour products , Non- oxidative hair color products , Hair bleaching and dye remover products , other hair colouring products.

13.14. Hair styling products

13.15. Products for temporary hair styling , Permanent wave products, Hair relaxer / Straightener products, other hair styling products.

13.16. Other hair and scalp products.

13.17. Hair sun protection products , other hair and scalp products

13.18. Nail and cuticle products such as nail varnish, nail make-up, nail glue remover products, nail sculpting products…etc.

13.19. Oral hygiene products

13.20. Toothcare products, Toothpaste, Tooth cleansing powder / salt, other tooth care products, Toothpaste products contain ingredients in a concentration as Recommended by the GSO standards for cosmetic products:

NOTE 1:

Cosmetic products must comply with the Gulf technical regulations and standards:

- GSO 1943: Safety Requirements of Cosmetics and Personal Care Products
- GSO 2528: Cosmetic Products- Technical Regulation of Cosmetic and Personal Care Products Claim

14. Medical Device

The product must meet the medical device definition. The GCC classification committee will consider the following criteria in determining the medical device definition:

- **The intended purpose**

The product would be considered under medical device regulation if it is intended by the manufacture for one or more of the following purposes:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease or compensation for, an injury
- Investigation, replacement, modification, or support of the anatomy, or of a physiological process
- Supporting or sustaining life
- Control of conception
- Disinfection of medical devices
- Providing information by means of in vitro examination of specimens derived from the human body

- **The primary mode of action**

As per the medical device definition, the product must not achieve its intended purpose in or on the human body by pharmacological, immunological, or metabolic means. If a product acts primarily by pharmacological, metabolic or immunological actions, then, the product is considered a pharmaceutical drug product (please refer to pharmaceutical drug product section of this document).

However, products that may contain substances exert a pharmacologic, immunologic or metabolic action may not be excluded from medical device regulation if the product is assisted by such means and do not act on or in human body in a manner that is more than ancillary.

- **The product form**

The medical device definition states that Medical device “means any instrument, apparatus, implement machine, implant device, in vitro reagent or calibrator, software, material or other similar or related article . . .”. The GCC classification committee interpretation is that “similar

or related article" under this definition should mean any article in any form. However, "similar or related articles" may be classified as devices as long as they intended for the purposes and meet the conditions stipulated in the medical device definition.

The following list includes the main categories of medical devices with illustrative examples, however the list it is not inclusive:

14.1. In-Vitro Diagnostic Medical Devices (IVDs)

- Reagents used for clinical diagnostic
- The calibrators and control materials used to verify the performance of the analyzers
- Kits that contain IVDs such as Blood glucose meters and strips
- Pregnancy test and ovulation test kit

14.2.Topical products

- Silicon based products for scar management (sheets, gels, sprays...etc.)
- Non-medicated dressing used as a physical barrier, for compression or for absorption of exudates such as hydrogel dressings and Alginate dressing
- Devices principally intended to manage the micro-environment of a wound such as honey wound dressing gel
- Wound dressing with antimicrobial substance such as silver to protect the dressing and reduce odor
- Anti-lice Products which act by non-pharmacological, non-immunological, non-metabolic means
- Heat/cold pads for pain relief
- Wound irrigation solution (water/ saline based)

14.3. General hygiene products

- Sanitary pads claiming pain relief by physical means
- Nipple shields to protect or relieve sore, damaged or cracked nipples or to be which is used to cover and protect the nipple of a nursing mother
- Surgical Razors and clippers for specific medical purpose

14.4. Dental Devices

- Dental filling materials, fissures, sealants, crowns and bridges
- Dental impression materials and (mixer/syringe /trays).

- Dental alloys, root canal preparations, etc.
- Orthodontic materials, removable dental prosthesis
- Dental units
- Pulp tester

14.5. Ophthalmic products

- Eye drops intended for the alleviation dryness or discomfort caused by environmental factors
- Spectacle lenses used to protect the eyes from light
- Contact lenses for therapeutic use
- Products used for disinfecting, cleaning, rinsing or, hydrating contact lenses
- Sunglasses and spectacle frames
- Ophthalmic irrigation solutions principally intended for irrigation as balanced salt solution
- Ophthalmic viscoelastic devices

14.6. Nasal and ear preparations

- Nasal normal saline products such as spray, drops
- Ear wax removal products that acts by physical or mechanical meaning

14.7. Lubricants, moisturizing and gels

- Artificial saliva
- Non-medicated sexual lubricants during sexual intercourse
- Body orifice gel intended to facilitate entry of a device into a body orifice in the body
- Coupling gel applied between an analytical device and the patient, allowing signals to pass through the skin during an examination

14.8.Devices for blood and organ products

- Hemodialysis solution
- Organ preservation, transport, nutrition solution
- Blood bags (including those containing or coated with an anticoagulant)
- Devices intended for temporary storage and transport of organs for transplantation (i.e., containers, bags and similar products)
- Devices intended for long term storage of biological substances and tissues such as corneas, sperm, human embryos, etc. (i.e., containers, bags and similar products)

- Fridges specifically intended for storing blood, tissues etc

14.9. Contraception devices

- Intrauterine contraceptive device
- Latex condoms without local anesthetic & spermicide
- Contraceptive diaphragms
- Female condoms

14.10. Devices/products for Personal protection

- Surgical and examination gloves
- Medical facemasks
- Surgical apparel which includes surgical caps, hoods, masks, gowns, drapes, operating room shoes and shoe covers, and isolation masks and gowns
- Surgical non-medicated sponges

14.11. In Vitro Fertilization (IVF) and Assisted Reproduction Technologies (ART) products

- Devices manufactured utilizing animal tissues or derivatives rendered non- viable
- Devices incorporating, as an integral part, a human blood derivative or a medicinal product is liable to act on the human body with action ancillary to that of the devices
- Media intended for use in the IVF process to support the growth storage of the embryo

14.12. Radiation Emitting Device/products

- Imaging Products (X-ray, CT, MRI, US, and Nuclear imaging products)
- Diagnostic Radioactive materials
- Digital imaging/x-ray film cassette

14.13. Assistive/supportive products

- Wheelchairs
- Patient's beds
- Hearing aids
- Walking crutches
- Patient hoists

14.14. Sterilization and disinfection

Any article intended to be used for disinfection of medical devices is considered to be a medical device because it is explicitly stated in the definition of medical device and, therefore,

is a standalone medical device. However, a disinfectant that is specifically intended for the disinfection of a specific medical device is considered an accessory to this device.

- Ethylene oxide sterilizer
- Detergents for sterilization of medical devices
- Disinfectants for dental water line and the fluid pathways of haemodialysis machine
- Denture disinfecting products
- Medical Washers
- A pre-sterilization device to clean instruments before being sterilized is considered a medical device. For example, Ultrasonic cleaning unit.

14.15. Devices without an intended medical purpose

- Contact lenses or other items intended to be introduced into or onto the eye.
  For Example: Non-prescription colored contact lenses
- Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
  For Example: Solid body contour modifying implant (e.g. Clavicle or collarbone piercing.
- Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing .
  For Example: Dermal fillers
- Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.
  For Example: Body sculpting equipment
- High intensity electromagnetic radiation (e.g., infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
  For Example: Intense pulsed light (IPL) machines for body hair removal

- Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

  For Example: Transcranial (no surgically invasive) stimulation

15. Food

A product would be considered as food if it falls within the above-mentioned definition of food product. The GCC classification committee will consider the following criteria in determining the food definition:

- **The intended purpose**

The food definition relates mainly to the intended use and product presentation. Food products should consumed or presented mainly for their nutritional value, hydration, taste, flavor, as part of diet as well as in manufacturing, preparing, or treating food.
Products intended or presented by any means to treat or prevent a disease in human body cannot be food products.

- **Ingredients**

Food products must not contain an active medicinal substance or any sunstance that exerts or demonstrates a pharmacological, immunological, and/or metabolic function.

- **The dosage form**

Food products generally intended for ingestion in food-like forms. Therefor; they should not be manufactured in pharmaceutical dosage forms such as capsules, tablets, pills..etc, as well as should not intended or presented to be used with any of the following adminstration routs:

- Injections (IV, IM, SC…etc)
- Anal or vaginal routs (enema, supposotiry, solution, tab, capsules… etc)
- Through the eyes, nose or ear (drops, sprayer, inhalers..etc)
- Topicals (creams, gels, ointments. patches..etc)
- Oral vapings

Food products may include any of the following categories:

15.1. Meat and meat products.

15.2. Fish and Shell-Fish Products.

15.3. Milk and dairy products.

15.4. Processed fruits and vegetables products.

15.5. Cereals, Pulses and Nuts and Their Products.

15.6. Vegetable fats, Oils and Their Products.

15.7. Water and Beverages, which do not contain ingredients with medicinal effect.

15.8. Electrolyte products (Oral Rehydration Solution), which do not contain ingredients with medicinal effect and unacceptable claim.

15.9. Honey and foods that contain bee products such as royal jelly, bee pollen and propolis

15.10. Energy drinks.

15.11. Food additives that are intended for food industrial uses.

15.12. Food sweeteners.

15.13. Infant and baby foods, such as Cereal-based food, Rusks, High protein food and others.

15.14. Foods for special medical purposes, such as Nutritionally complete formula, Nutritionally incomplete formula, Formulas for metabolic "genetic" disorders in patients over 12 months, and Oral Rehydration Solutions

15.15. Proteins, Carbohydrates and Amino acids products that are used as food supplement

15.16. Vitamins and minerals supplements with concentrations equal or below the upper concentration limit. The upper and lower concentrations limits will be calculated according to the product total daily dose. please refer to Appendix. 1

15.17. Lozenges, which do not contain unacceptable claim or any ingredient with medicinal effect, and the concentration individual ingredients must not exceed the maximum value permitted as follows:

- Menthol must not exceed the maximum value permitted of 5 mg as single serving size, and to a maximum daily serving of 50 mg
- Eucalyptus oil of 0.5 mg as single serving size.

15.18. Collagen products that may contain vitamins and minerals, and must not exceed the maximum daily serving of 10 g

15.19. Food products that contain Moringa leaves

15.20. Novel foods, which do not contain ingredients with medicinal effect.

15.21. Prebiotic and Probiotic for industrial use.

15.22. Food products, which contain fish oil

15.23. Fibers products

15.24. Sports food such as sports drinks, products in powder forms that are intended for sports people and persons who exercise to achieve specific nutritional or functional support

15.25. Weight management products which do not contain unacceptable claim

NOTE 2:

Food products must comply with the Gulf technical regulations and standards such as but not limited to: (*Please refer to GSO website for more standards and technical regulations for other food products*)

- GSO 654: General Requirements for prepackaged foods for special dietary use
- GSO 136: General Requirements For Handling Of Foods For Special Medical Purposes
- GSO 2333: Requirements For Nutrition And Health Claim In The Food
- GSO 2397: Foods For Special Dietary Uses – General Requirements For Athlete Food
- GSO 2539: Vitamins And Minerals Permitted For Use In Foodstuff
- GSO 2106: Infants Formula And Formula For Special Medical Purposes Intended For Infants
- GSO 2522: Sports Drinks (Electrolyte Drinks)

16. Tobacco

It includes the following product types:

16.1. Cigarettes

16.2. Cigars and Tuscan cigars

16.3. Sijaritus

16.4. Almeassel tobacco

16.5. Hand-rolling tobacco and A mixture of tobacco pipe

16.6. E-Liquids and Heated Tobacco Products which are used by Electronic Nicotin Delivery Systems (ENDS)

16.7. Non-nicotine e-liquids which are used by electronic smoking device, and does not contain any medical ingredients or medical claims

16.8. Non-smoked tobacco such as (Timpak, shamma, swika etc.) is prohibited.

NOTE 3:

Tobacco products must comply with the Gulf technical regulations and standards such as but not limited to: (*Please refer to GSO website for more standards and technical regulations for other tobacco products*)

- GSO 597: Cigarettes
- GSO 2047: Tuscan cigars and cigarettes
- GSO 2051: Tobacco and its products- Sijaritus
- GSO 1415: Almeassel tobacco
- GSO 1749: Fruit flavored Almeassel tobacco
- GSO 2050: A mixture for tobacco pipe

17. Animal Feed and Public Health Pesticides

Animal Feed includes the following types:

17.1.Feed materials

Is a product of vegetable or animal origin, the main purpose of which is to meet the nutritional needs of animals and which is used for oral feeding, in their natural state, fresh or preserved. Such as:

- Cereal grains and their derivatives,
- Forages and roughage
- Oil seeds, oil fruits and their derivatives,
- Other seeds and fruits and their derivatives
- Legume seeds and their derivatives,
- Tubers, roots
- Milk and milk-based products,
- Fish, other marine animals and their products,
- Minerals,
- Land animal products and their derivatives

17.2.Feed additives

Are substances, micro-organisms or preparations that are intentionally added to feed for technological purposes, to improve its taste, to increase its nutritional value, or to improve the animal's performance, whether these ingredients contain nutritional value or not.

Zootechnical feed additives	Nutritional feed additives	Sensory feed additives	Technological feed additives
Digestibility enhancer	Vitamins	Colorant	Acidity regulators
Gut flora	Minerals	Flavors	Silage additive
Substance for environment	Amino acids		Antioxidant
Enzyme	Urea		Gelling agent

17.3.Premixture:

Are Mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, and is intended for incorporation in compound feedingstuffs, feed materials or water and not meant for direct feeding to animals.

17.4.Compound feed:

A mixture of at least two feed materials, whether or not containing feed additives.

18. Borderline Products

Please refer to GHC borderline guidance.

19. Combination Products

Combination products are products that consist of two or more items subject to different jurisdictions, and they may fall into the following categories:

19.1.Integrated combination product

A product consists of two or more regulated components that are combined/integrated as a single product.

For examples:

- Prefilled drug delivery systems (syringes, insulin injector pen, metered dose inhaler)
- Device coated or impregnated with a drug or biologic (transdermal patch, drug eluting stent)

19.2.Non-integrated combination product:

19.2.1. A product consists of two or more separated items that are contained in the same package. [Co-packaged combination product].

For examples:

- First aid kits containing devices (bandages, gauze), and drugs (antibiotic ointments, pain relievers)
- Drug or vaccine vial packaged with a delivery device

19.2.2. Any regulated product packaged separately where the labeling information refers to be used with another specific regulated product where both are required to achieve the intended purpose of use. [Cross-labeled combination product].

For examples:

- Light-emitting device and a light-activated drug
- Drug/biological product utilizes a device where it is required that the two should be cross-labeled.

In order to classify the combination and designate the leading regulatory agency for premarket review, the following points will be considered:

- The intended purpose of the product taking into account the way the product is presented
- The primary mode of action by which the intended purpose is achieved.

Products that achieve their primary intended purpose by pharmacological, immunological or metabolic action in/on the body; shall be regulated as pharmaceutical drug product.

While products that do not achieve their principal intended action in or on the body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means, shall be regulated as medical device.

Examples of combination products with the leading agency:

Product	Classification
Pre-filled drug delivery systems intended to administer pharmacologically active substance	Integrated Combination product regulated as Pharmaceutical Drug Product
Blood bag containing anticoagulant, where the anticoagulant intended to collect and preserve blood and its components (not for direct intravenous infusion)	Integrated Combination product regulated as Medical Device
Intravascular catheter securement device containing antimicrobial/antiseptic agent where the antimicrobial agent intended to reduce catheter colonization, suppress regrowth of microorganism's, and reduce catheter-related bloodstream infections in patients with central venous or arterial catheters	Integrated Combination product regulated as Medical Device
A Helicobacter pylori breath test kit containing labelled urea	Non-Integrated Combination product (cross-labelled) where urea is regulated as Pharmaceutical Drug Product, and the sample container is regulated as a Medical IVD

Appendix. 1

Vitamins and Mineral Concentrations

ANNEX (1): LEVELES OF VITAMINES [5]

Life Stage Group		Biotin (µg /day)			Vitamin B_9/ Folate/ Folic acid (µg /day)[a]			Vitamin B_3/ Niacin (mg/day)[b]			Vitamin B_1/ Thiamine (mg/day)			Vitamin B_6 (mg /day)		
		Min	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max
Infants	0-12 months	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Children	1-3 years	1.0	8	500	15	150	300	0.6	6	10	0.04	0.5	100	0.05	0.5	30
	4-8 years	1.0	12	500	15	200	400	0.6	8	15	0.04	0.6	100	0.05	0.6	40
Adolescents	9-13 years	1.0	20	500	15	300	600	0.6	12	20	0.04	0.9	100	0.05	1.0	60
	14-18 years	1.8	25	500	30	400	800	1.0	16 (M) 14 (F)	30	0.07	1.2 (M) 1.0 (F)	100	0.10	1.3 (M) 1.2 (F)	80
Adults	≥ 19 years	1.8	30	500	30	400	1,000	1.0	16 (M) 14 (F)	500	0.07	1.2 (M) 1.1 (F)	100	0.10	1.6	100
Pregnancy	19-50 years	-	30	-	-	600	-	-	18	-	-	1.4	-	-	1.9	-
Breastfeeding	19-50 years	-	35	-	-	500	-	-	17	-	-	1.4	-	-	2.0	-

Life Stage Group		Vitamin B_5/ Pantothenic acid (mg /day)			Vitamin B_2/ Ribo flavin (mg /day)			Vitamin B_{12}/ Cobamamide (µg /day)			Vitamin C/Ascorbic Acid (mg/day)			Vitamin D (µg /day)[c]		
		Max	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max
Infants	0-12 months	-	-	-	-	-	-	-	-	-	-	-	-	0.5	10	25
Children	1-3 years	0.2	2	500	0.04	0.5	100	0.09	0.9	1,000	2.2	15	400	0.8	15	25
	4-8 years	0.2	3	500	0.04	0.6	100	0.09	1.2	1,000	2.2	25	650	0.8	15	25
Adolescents	9-13 years	0.2	4	500	0.04	0.9	100	0.09	1.8	1,000	2.2	45	1,200	0.8	15	25
	14-18 years	0.4	5	500	0.08	1.3 (M) 1.0 (F)	100	0.14	2.4	1,000	6.0	75 (M) 65 (F)	1,800	1.0	15	25
Adults	≥ 19 years	0.4	5	500	0.08	1.3 (M) 1.1 (F)	100	0.14	2.4	1,000	6.0	90 (M) 75 (F)	2,000	1.0	17	25
Pregnancy	19-50 years	-	6	-	-	1.4	-	-	2.6	-	-	85	-	-	15	-
Breastfeeding	19-50 years	-	7	-	-	1.6	-	-	2.8	-	-	120	-	-	15	-

CONT'D/

Life Stage Group		Vitamin K (µg /day) [d]			Vitamin A: as retional (µg /day) [e]			Vitamin E: as D-alpha-tocopherol (mg /day) [f]		
		Min	RDA	Max	Min	RDA	Max	Min	RDA	Max
Infants	0-12 months	-	-	-	30	400	600	-	-	-
Children	1-3 years	3	30	30	30	300	600	0.6	6	200
	4-8 years	3	55	55	30	400	900	0.6	7	300
Adolescents	9-13 years	3	60	60	30	600	1,700	0.6	11	600
	14-18 years	6	75	75	65	900 (M) 700 (F)	2,800	1.0	15	800
Adults	≥ 19 years	6	120 (M) 90 (F)	120	65	900 (M) 700 (F)	3,000	1.0	15	1,000
Pregnancy	19-50 years	-	90	-	-	770	-	-	15	-
Breastfeeding	19-50 years	-	90	-	-	1,300	-	-	19	-

(a) If a product is intended to be used as a parenteral supplement, it must have at least 400µg of folate per day

(b) For products providing > 35mg of niacin, a specific use or purpose must be made.
For products providing ≥ 10mg, a warning must be added as "may cause flushing of the skin".

(c) 1IU of vitamin D = 0.025µg of cholecalcierol (D_3)/ergocholecalcierol (D_2)

(d) For product containing vitamin K at all doses, a warning must be added as "If you are taking blood thinners, consult a health care practitioner prior to use".

(e) **1µg of vitamin A as rational = 6µg vitamin A beta-carotene.**
1IU of vitamin A = 0.3µg of vitamin A as rational, 1IU of vitamin A = 0.6µg of vitamin A beta-carotene.

(f) **1mg of vitamin E as D-alpha-tocopherol = 0.5mg of vitamin E as DL-alpha-tocopherol.**
1IU of vitamin E = 0.67mg of D-alpha-tocopherol. 1IU of vitamin E= 0.45mg of DL-alpha-tocopherol.
For products, providing vitamin E ≥ 180 mg D-alpha-tocopherol, a warning must be added as "If you have cancer, consult a health care practitioner prior to use".
For products, providing vitamin E ≥ 268 mg D-alpha-tocopherol, a warning must be added as "If you have cardiovascular disease or diabetes, consult a health care practitioner prior to use".
For products, providing vitamin E ≥ 360 mg D-alpha-tocopherol, a warning must be added as "If you are taking blood thinners, consult a health care practitioner prior to use"

ANNEX (2): LEVELES OF MINERALS [5]

Life Stage Group		Calcium (mg /day)			Chromium (µg /day)			Cobalt (µg /day)			Copper (µg /day)			Iodine (µg /day)		
		Min	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max
Infants	0-12 months	-	200	-	-	-	-	-	-	-	-	-	-	-	-	-
Children	1-3 years	65	700	1,500	-	-	-	0.004	0.04	44	35	340	700	6	90	133
	4-8 years	65	1,000	1,500	-	-	-	0.004	0.05	44	35	440	2,500	6	90	200
Adolescents	9-13 years	65	1,300	1,500	-	-	-	0.004	0.08	44	35	700	4,000	6	120	400
	14-18 years	65	1,300	1,500	-	-	-	0.006	0.10	44	65	890	6,500	14	150	800
Adults	≥ 19 years	65	1,100	1,500	2.2	30 (M) 20 (F)	500	0.006	0.10	44	65	900	8,000	14	150	800
Pregnancy	19-50 years	-	1,000	-	-	30	-	-	0.11	-	-	1,000	-	-	220	-
Breastfeeding	19-50 years	-	1,000	-	-	45	-	-	0.12	-	-	1,300	-	-	290	-

Life Stage Group		Iron(mg/day)[a]			Magnesium-(mg /day)[b]			Manganese (mg /day)[c]			Molybdenum (µg/day)			Phosphorus (mg /day)		
		Min	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max	Min	RDA	Max
Infants	0-12 months	0.6	11 (>6M)	40	-	-	-	-	-	-	-	-	-	-	-	-
Children	1-3 years	0.6	7	40	12	80	65	-	-	-	-	-	-	62	460	2,000
	4-8 years	0.6	10	40	12	130	110	-	-	-	-	-	-	62	500	2,000
Adolescents	9-13 years	0.6	8	40	12	240	350	-	-	-	-	-	-	62	1,250	2,000
	14-18 years	1.4	11 (M) 15 (F)	45	20	410 (M) 360 (F)	350	-	-	-	-	-	-	62	1,250	2,000
Adults	≥ 19 years	1.4	8 (M) 13 (F)	45	20	420 (M) 320 (F)	500	0.13	2.3 (M) 1.8 (F)	9	2.5	45	2,000	62	700	2,000
Pregnancy	19-50 years	-	27	-	-	355	-	-	2.0	-	-	50	-	-	700	-
Breastfeeding	19-50 years	-	9	-	-	315	-	-	2.6	-	-	50	-	-	700	-

CONT'D/

Life Stage Group		Selenium (µg /day) [d]			Silicon (mg/day)			Zinc[5](mg /day) [e]		
		Min	RDA	Max	Min	RDA	Max	Min	RDA	Max
Infants	0-12 months	-	-	-	-	-	-	0.2	2	2
Children	1-3 years	-	-	-	-	-	-	0.4	3	7
	4-8 years	-	-	-	-	-	-	0.4	5	12
Adolescents	9-13 years	-	-	-	-	-	-	0.4	8	23
	14-18 years	-	-	-	-	-	-	0.7	11 (M) 9 (F)	34
Adults	≥ 19 years	3.5	55	200	>0	-	84	0.7	11 (M) 8 (F)	50
Pregnancy	19-50 years	-	60	-	-	-	-	-	11	-
Breastfeeding	19-50 years	-	70	-	-	-	-	-	12	-

(a) For products providing > 35mg of iron, a specific use or purpose must be made and a warning must be made as "may cause constipation, diarrhoea and/or vomiting"

(b) For products providing > 350mg of magnesium, a specific use or purpose must be made and a warning must be made as "may cause diarrhea".

(c) For products providing >5mg of manganese, a waning must be added as "If you have a liver disorder, consult a health care practitioner prior to use".

(d) For products providing >200µg of selenium, a waning must be added as "If you have a history of non-melanoma skin cancer, consult a health care practitioner prior to use".

(e) A warning must be added as "Zinc supplements, can cause a copper deficiency". For products providing > 40mg of zinc, a specific use or purpose must be made.

Definitions:

Recommended Dietary Allowance (RDA): The average daily dietary nutrient intake level sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in a particular life stage and gender group.

Maximum dosage value: The highest medicinal ingredient quantity, which a product can supply in a daily dose to support its safe use.

Minimum dosage value: The lowest medicinal ingredient quantity, which a product can supply in a daily dose to support recommended claims.

		الامارات	البحرين	السعودية	عمان	قطر	الكويت
Pharmaceutical/Medicinal drug products	الجهة التنظيمية:	وزارة الصحه ووقاية المجتمع	الهيئة الوطنية لتنظم المهن والخدمات الصحية	SFDA	وزارة الصحة	وزارة الصحة العامة	وزارة الصحة
	الإدارة:	إدارة الدواء	تنظيم المستحضرات الصيدلانية	إدارة المنتجات -الإدارة التنفيذية للشؤون التنظيمية - قطاع الدواء	المديرية العامة للصيدلة والرقابة الدوائية	إدارة الصيدلة والرقابة الدوائية	الرقابة الدوائية و الغذائية إدارة تسجيل و مراقبة الادوية الطبية و النباتية
	القسم:	قسم تسجيل الأدوية والمنتجات الصحية والطبية	تنظيم المستحضرات الصيدلانية	قسم دعم تسجيل الأدوية البشرية	دائرة الرقابة الدوائية	قسم التسجيل والتسعير الدوائي	قسم تسجيل الادوية البشرية
Biological Drug Products	الجهة التنظيمية:	وزارة الصحه ووقاية المجتمع	الهيئة الوطنية لتنظم المهن والخدمات الصحية	SFDA	وزارة الصحة	وزارة الصحة العامة	وزارة الصحة
	الإدارة:	إدارة الدواء	تنظيم المستحضرات الصيدلانية	إدارة المنتجات - الإدارة التنفيذية للشؤون التنظيمية - قطاع الدواء	المديرية العامة للصيدلة والرقابة الدوائية	إدارة الصيدلة والرقابة الدوائية	الرقابة الدوائية و الغذائية إدارة تسجيل و مراقبة الادوية الطبية و النباتية
	القسم:	قسم تسجيل الأدوية والمنتجات الصحية والطبية	تنظيم المستحضرات الصيدلانية	قسم دعم تسجيل الأدوية البشرية	دائرة الرقابة الدوائية	قسم التسجيل والتسعير الدوائي	قسم تسجيل الادوية البشرية

Herbal Products	الجهة التنظيمية:	وزارة الصحه ووقاية المجتمع	الهيئة الوطنية لتنظم المهن والخدمات الصحية	SFDA	وزارة الصحة	وزارة الصحة العامة	وزارة الصحة
	الإدارة:	إدارة الدواء	تنظيم المستحضرات الصيدلانية	إدارة المنتجات - الإدارة التنفيذية للشؤون التنظيمية - قطاع الدواء	المديرية العامة للصيدلة والرقابة الدوائية	إدارة الصيدلة والرقابة الدوائية	الرقابة الدوائية و الغذائية إدارة تسجيل و مراقبة الادوية الطبية و النباتية
	القسم:	قسم تسجيل الأدوية والمنتجات الصحية والطبية	تنظيم المستحضرات الصيدلانية	قسم دعم تسجيل المستحضرات العشبية والبيطرية	دائرة الرقابة الدوائية	قسم التسجيل والتسعير الدوائي	شعبة تسجيل الادوية العشبية
Alternative traditional medicines	الجهة التنظيمية:	وزارة الصحه ووقاية المجتمع	الهيئة الوطنية لتنظم المهن والخدمات الصحية	not marketed in Saudi Arabia currently	وزارة الصحة	وزارة الصحة العامة	وزارة الصحة
	الإدارة:	إدارة الدواء	تنظيم المستحضرات الصيدلانية		المديرية العامة للصيدلة والرقابة الدوائية	إدارة الصيدلة والرقابة الدوائية	الرقابة الدوائية و الغذائية إدارة تسجيل و مراقبة الادوية الطبية و النباتية
	القسم:	قسم تسجيل الأدوية والمنتجات الصحية والطبية	تنظيم المستحضرات الصيدلانية		دائرة الرقابة الدوائية	قسم التسجيل والتسعير الدوائي	شعبة تسجيل الادوية العشبية او المستحضرات الصحية

Veterinary Drug products	الجهة التنظيمية:	وزارة التغيير المناخي والبيئة	الهيئة الوطنية لتنظم المهن والخدمات الصحية	SFDA	وزارة الثروة الزراعية والسمكية وموارد المياه.	وزارة البلدية والبيئة	وزارة الصحة
	الإدارة:	إدارة التنمية والصحة الغذائية	تنظيم المستحضرات الصيدلانية	إدارة المنتجات - الإدارة التنفيذية للشؤون التنظيمية - قطاع الدواء		ادارة الثروة الحيوانية	الرقابة الدوائية و الغذائية إدارة تسجيل و مراقبة الادوية الطبية و النباتية
	القسم:		تنظيم المستحضرات الصيدلانية	قسم دعم تسجيل المستحضرات العشبية و البيطرية			شعبة تسجيل الادوية البيطرية
Health Products	الجهة التنظيمية:	وزارة الصحه ووقاية المجتمع	الهيئة الوطنية لتنظم المهن والخدمات الصحية وزارة الصحة	SFDA	وزارة الصحة	وزارة الصحة العامة	وزارة الصحة
	الإدارة:	إدارة الدواء	تنظيم المستحضرات الصيدلانية وزارة الصحة: إدارة الصحة العامة	إدارة المنتجات - الإدارة التنفيذية للشؤون التنظيمية - قطاع الدواء	المديرية العامة للصيدلة والرقابة الدوائية	إدارة الصيدلة والرقابة الدوائية	الرقابة الدوائية و الغذائية إدارة تسجيل و مراقبة الادوية الطبية و النباتية

	القسم:	قسم تسجيل الأدوية والمنتجات الصحية والطبية	تنظيم المستحضرات الصيدلانية قسم التغذية	قسم دعم تسجيل المستحضرات العشبية و البيطرية	دائرة الرقابة الدوائية	قسم التسجيل والتسعير الدوائي	شعبة تسجيل المستحضرات الصحية
Cosmetics	الجهة التنظيمية:	وزارة الصناعه والتكنولوجيا (هيئه الإمارات للمواصفات والمقاييس	وزارة الصحة	SFDA	وزارة التجارة والصناعة وترويج الاستثمار		وزارة الصحة
	الإدارة:		أدارة الصحة العامه	إدارة تسجيل المنتجات - الإدارة التنفيذية للتسجيل و التراخيص - قطاع العمليات	المديرية العامة للمواصفات والمقاييس		الرقابة الدوائية و الغذائية إدارة تسجيل و مراقبة الادوية الطبية و النباتية
	القسم:		قسم صحة البيئة	قسم تسجيل الأدوية و منتجات التجميل	دائرة المواصفات والمقاييس		قسم تسجيل المستحضرات التجميلية
Medical Devices	الجهة التنظيمية:	وزارة الصحه ووقاية المجتمع	الهيئة الوطنية لتنظيم المهن والخدمات الصحية	SFDA	وزارة الصحة		وزارة الصحة
	الإدارة:	إدارة الدواء	الرقابة على الاجهزة الطبية	إدارة تسجيل المنتجات- الإدارة التنفيذية للتسجيل و التراخيص - قطاع العمليات	المديرية العامة للصيدلة والرقابة الدوائية		الرقابة الدوائية و الغذائية

							إدارة تسجيل و مراقبة الادوية الطبية و النباتية
	القسم:	قسم تسجيل الأدوية والمنتجات الصحية والطبية	الرقابة على الاجهزة الطبية	قسم تسجيل الأجهزة والمنتجات الطبية	دائرة الرقابة على الأجهزة والمستلزمات الطبية		شعبة تسجيل الأجهزة الطبية
Food	الجهة التنظيمية:	وزارة التغيير المناخي والبيئة	وزارة الصحة	SFDA	وزارة الصحة	وزارة الصحة العامة	وزارة الصحة
	الإدارة:	إدارة السلامة الغذائية	الصحة العامه	إدارة تسجيل المنتجات-- الإدارة التنفيذية للتسجيل و التراخيص - قطاع العمليات	المديرية العامة للشؤون الصحية	إدارة سلامة الغذاء	الرقابة الدوائية و الغذائية إدارة تسجيل و مراقبة الادوية الطبية و النباتية
	القسم:		التغذية	قسم تسجيل الغذاء والأعلاف	دائرة التغذية	قسم صحة المنافذ ومراقبة الأغذية	قسم تسجيل الأغذية
Tobacco	الجهة التنظيمية:	وزارة الصناعه والتكنولوجيا (هيئه الإمارات للمواصفات والمقاييس)	وزارة الصحة	SFDA	وزارة التجارة والصناعة وترويج الاستثمار		الهيئة العامة للبيئة
	الإدارة:		الصحة العامه	إدارة منتجات التبغ - - قطاع الغذاء	المديرية العامة للمواصفات والمقاييس		

	القسم:		قسم مكافحة الأمراض - مكافحة التدخين	قسم الشؤون التنظيمية لمنتجات التبغ	دائرة المطابقة		