Ministry of Health
Sultanate of Oman

Directorate General of Pharmaceutical Affairs &
Drug Control - Drug Control Department

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Guidelines for Product Classification






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INTRODUCTION

This guideline is made for applicant / Marketing Authorization Holder (MAH) who wishes to register a product with Directorate General of Pharmaceutical Affairs and Drug Control (DGPA&DC) at the Ministry of Health (MOH). Product classification is a pre-registration step at the Directorate. Generally, a product is classified as either pharmaceutical medicine, herbal medicine, health product or medicated medical device as indicated in the below diagram.

Therefore, this guideline is provided to help the applicant to understand the factors on which basis the classification decision has been taken. **Please note that all annexes will be updated on periodic basis.**

The following principles are applied when classifying a product:

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
- Is the product likely to be understood by consumers to have characteristics of a drug
- 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.
- There are three levels of claims according to WHO [(1)]:

  1.1. High level:

  - treats/cures/manages any diseases or disorder
  - prevents any diseases or disorder
  - treats any vitamin/mineral deficiency diseases

1.2. Medium level:

- Health enhancement
- Reduction of risk or diseases or disorder
- Assist in management of a named symptom/ diseases or disorder
- Relief of symptoms of a named diseases or disorder

1.3. Low level:

- Health maintenance, including nutritional supplement
- Vitamin or mineral supplement
- Relief of symptoms

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. Level of action

- Does the product exert solely a superficial effect?
- The following definitions for pharmacological, immunological or metabolic means 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.

4. Classification scheme of other regulatory authorities

- Classification in the country of origin
- Classification in GCC and other Reference countries

5. Other registered products with the same composition, dosage form & indications.

You may seek advices and complete a classification form to determine the product's classification, available at: https://www.moh.gov.om/en_US/product-classification

1. PHARMACEUTICAL MEDICINES

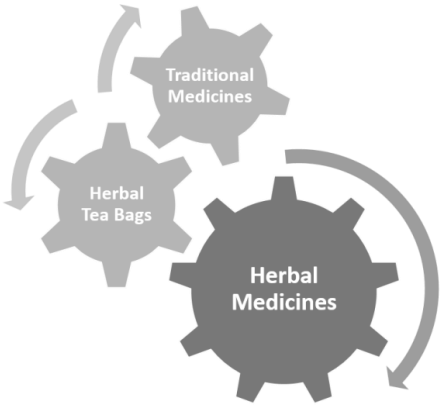
- Pharmaceutical medicines are defined as a substance or a combination of ingredients that are intended to restore, correct, modify physiological functions by exerting pharmacological, immunological or metabolic actions in human beings.

- This includes:
  - New chemical entity (NCE)/ generic products
  - Biotechnology products:
    - Biological products; bacterial and viral vaccines, therapeutic serums, antitoxins, human blood components, antibiotics
    - recombinant DNA
  - Biosimilar products e.g. streptokinase, low molecular weight heparin, erythropoietin, insulin
  - Radiopharmaceuticals
  - Blood, blood components, plasma derived products (e.g. Albumin, immunoglobulins).
  - Any product injected into the body (IV, IM, SC, …) intended for *treatment* only
  - Compounded medications-(Total Parenteral nutrition) solution …
  - Parenteral nutrition solution
  - Peritoneal dialysis solution
  - Blood derivative products
  - Sterile drops/solutions intended for ophthalmic, nasal, ear as long as the mode of action is not physical/mechanical activity.
  - Enema solution products
  - Vaginal suppositories
  - Narcotic and psychotropic medicines

For further details on registration requirements, please refer to circular no. 19/2012, available at: https://www.moh.gov.om/en_us/web/dgpadc/-2

2. HERBAL MEDICINES

- According to WHO, herbal medicines are defined as finished, labeled medicinal products that contain as active ingredients aerial or underground parts of plants, or other plant material, or combinations thereof, whether in the crude state or as plant preparations. Plant material includes juices, gums, fatty oils, essential oils, and any other substances of this nature. Herbal medicines may contain excipients in addition to the active ingredients. In addition, this category will cover the following types of products:



2.1 TRADITIONAL MEDICINES:

- As per WHO, Traditional Medicines are defined as "the sum total of the knowledge, skills, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness".
- Pharmaceutical dosage forms should be suited to the routes of administration which in turn must be consistent with referenced pharmacopeia.
- This includes:
  - Ayurvedic Medicines
  - Homeopathic Medicines
  - Unani Medicines
  - Traditional Chinese Medicines (TCM)

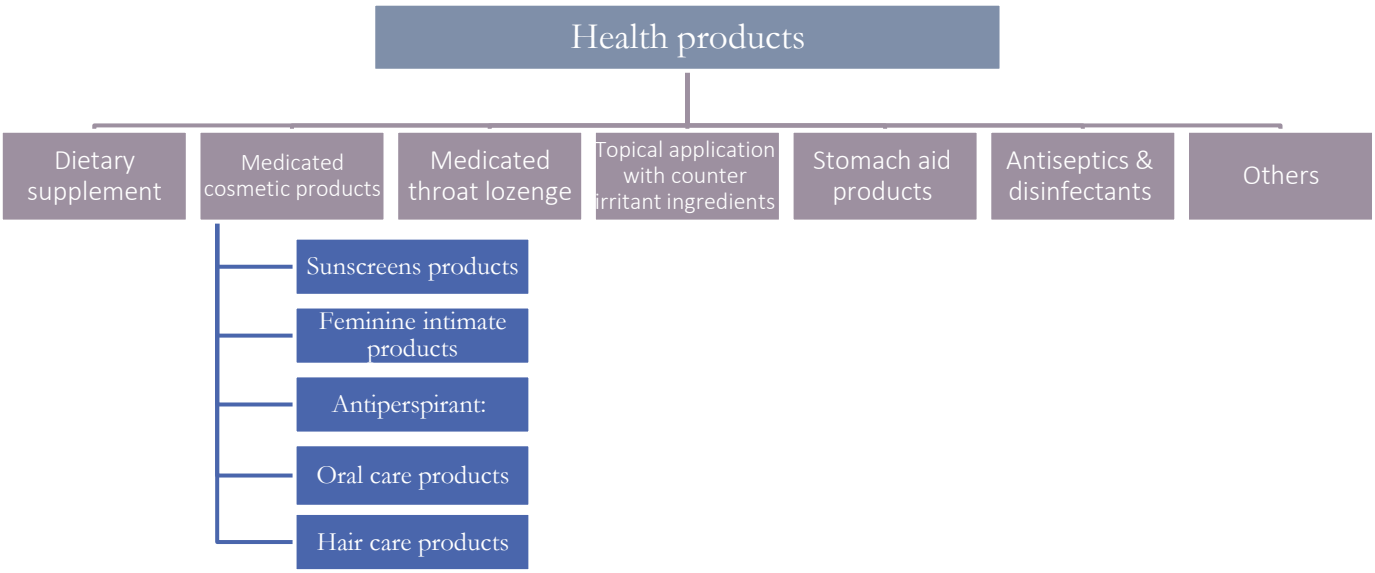
2.2 HERBAL TEA BAGS WITH MEDICAL CLAIMS:

- Herbal tea bags consist exclusively of one or more herbal substances intended for oral aqueous preparation by means of detection, infusion or maceration.[7]
- They contain known herbal ingredients with well-established medicinal use that are mentioned in references pharmacopeia.

For further details on registration requirements, please refer to circular no. 28/2008, available at:
https://www.moh.gov.om/en_us/web/dgpadc/-2

3. HEALTH PRODUCTS

- Heath product are defined as finished labeled products in pharmaceutical dosage forms, which are usually *low risk* ingredients that are intended to restore, correct, modify physiological functions by exerting pharmacological, immunological or metabolic actions. **This includes the following types of products as indicated in the figure below.**



3.1 DIETARY SUPPLEMENT

- Dietary supplements are defined as concentrated sources of nutrients or other substances with a nutritional or physiological effect intended to supplement the diet and contains one or more of the following vitamins/ minerals/ amino acids/ essential oils, natural substances of plant or animal origin, probiotics, prebiotics, enzymes, substances with nutritional or physiological function or contains any combination of any of these.
- The acceptable pharmaceutical dosage forms include, but are not limited to capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop-dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities.

- **For a product to be classified under health products, the product must fulfill the definition of dietary supplements and all requirements mentioned as follows:**
  - a statement to the effect that food supplements should not be used as a substitute for a varied diet
  - a statement to the effect that the product should be stored out of the reach of young children
  - The daily dose of each vitamin and/or mineral must meet at least the minimum dosage value if a general or specific claim is being attributed to them.
  - for vitamin or mineral deficiency, the dosage should be at or above the RDA.

- The daily dose of each vitamin and/or mineral must not exceed the maximum dosage value.

- Products with High Medical Claims OR above the Max. Dosage Values will be classified as Pharmaceutical Medicines.

- The following ingredients/herbs are banned internationally and therefore inclusion of these are not allowed in dietary supplements:
  - Steroids or steroids-like substances
  - Aromatase inhibitors
  - Dimethyl Amyl Amine (DMAA) / Dimethyl Butyl Amine (DMBA)
  - Methylsynephrine/ oxilofrine
  - Picamilon
  - *Acacia rigidula*
  - *Corinanthe* ***yohimbi***
  - *Catha edulis (khat)*
  - *Piper methysticum* (Kava-Kava)
  - *Ephedra sinica*
  - Please refer to for the updated list of other ingredients/herbs that are banned in dietary supplements; available at: https://www.gov.uk/government/publications/list-of-banned-or-restricted-herbal-ingredients-for-medicinal-use and from other updated lists through different health authorities.

- There are three categories of claims that are defined by FDA and can be used for dietary supplements: health claims, nutrient content claims, and structure/function claims.
  1. *Health claims* describe a relationship between a food substance (a food, food component, or dietary supplement ingredient), and reduced risk of a disease or health-related condition. For example, fibers may reduce the risk of coronary heart diseases.
  2. *Nutrient content claims* describe the level of a nutrient in the product, using terms such as free, high, and low, or they compare the level of a nutrient in a food to that of another food, using terms such as more, reduced, and light.
  3. *Structure/function claims* may describe the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body, for example, "calcium builds strong bones." In addition, they may characterize the means by which a nutrient or dietary ingredient acts to maintain such structure or function, for example, "fiber maintains bowel regularity," or "antioxidants maintain cell integrity."

Please refer to; Annex (1) and Annex (2) for the min. max., dosage values and RDA for vitamins and minerals allowed in dietary supplements and Annex (3) for the other permitted active ingredients in dietary supplements.

3.2 MEDICATED COSMETIC PRODUCTS:

- These are defined as topical preparations intended to treat and/or prevent diseases, or otherwise contains active ingredients known to affect the structure or functions of the human body.
    - Any product claiming for the following medical conditions: diaper rash, acne, rashes, hives, rosacea, atopic, dermatitis, psoriasis, pruritus, melisma, post inflammatory hyperpigmentation, insect bites, minor burns, cuts, scrapes, cradle scalps and therapeutic emollient for medical conditions e.g. diabetes, *is classified as Health product.*
    - Any product contains more than the specified concentration of one or more of the ingredients mentioned in Annex (4), *is classified as Health product.*
- Acceptable dosage forms include but are not limited to creams, ointments, balms, gels and lotions. Raines-off products are exempted i.e. classified as cosmetics.

- OTHER PRODUCTS THAT ARE COVERED UNDER MEDICATED COSMETIC PRODUCTS:

1. SUNSCREENS PRODUCTS

- Sunscreen products are used primary for protection from UV radiation.
    - Sunscreen product with medical claims such as reduction of skin cancer or solar keratosis, *is classified as Health product.*
    - Sunscreen product contains more than the specified concentration of one or more of the ingredients mentioned in Annex (5), *is classified as Health product.*

2. FEMININE INTIMATE PRODUCTS

- Feminine intimate products that are classified as health products include:
    - Products with medical claims such as itching, irritation, redness, & vaginal discharge.
    - Products for superficial moisturizing of extreme mucosal dryness [(3)]
    - Products that contain substances with direct physiological effects such as povidone-iodine
    - Products for the regulation of vaginal flora e.g. containing "lactobacillus" [(6)]

3. ANTIPERSPIRANT

- Antiperspirants are personal hygiene products designed to control sweating and body odor.
    - Products intended for Hyperhidrosis or any references to perspiration from hormonal/endocrine changes/malfunction, *is classified as health products.*
    - Products that contains more than the specified concentration of one or more of the ingredients mentioned in Annex (6), *is classified as Health product.*[(5), (8)]

4. ORAL CARE PRODUCTS

- Oral care products are classified as health products if they contain medical claims and/or contains substances exerting pharmacological actions:

- Mouthwashes with medical claims such as mouth ulcers, sore gums, gingivitis, dry mouth (xerostomia) or any references to gums and teeth diseases
- Antiseptic mouthwashes/sprays that contain ingredients such as Povidion-iodine[(1)], Triclosan[(1),(7)], Chlorhexidine[(1),(7)], Cetylpyridinium[(1),(7)], Cetrimide[(1),(7)]
- Phenol as mouth sprays [(2)]
- Toothpastes containing fluorine >1,500ppm (0.15%) [(5), (3), (10)]

5. HAIR CARE PRODUCTS

- Topical hair care products are classified as health products if:
  - They are intended to control/prevent/ reduce/eliminate the occurrence of dandruff or the associated symptoms i.e. itching, irritations, redness, flacking, scaling if they contains ingredients with direct physiological effects.
  - They are claiming to treat or prevent alopecia.
  - They are intended for treatment or prevention of head lice infestation irrespective of their composition. Please note that products act by physical or mechanical means are considered as medicated medical devices.
- Permitted active ingredients include:
  - salicylic acid >3%[(5), (7), (10)], selenium sulfide (>1%)[(5), (10)], sulfur (>2%)[(1), (7), (5)], coal tar (>10%)[(1), (5)], ethyl lauroyl arginate HCl (>0.8%)[(10)],
  - pyrithione zinc (>1%)[(2), (5)], permethrin, pyrethrins, pyrethroids, malathion Lotion USP 0.5%.

Please refer to; Annex (4), Annex (5) & Annex (6) for the active ingredients allowed in cosmetic medicated products, sunscreens and antiperspirants respectively with their restricted concentrations.

3.4 MEDICATED THROAT LOZENGE

- These are defined as medicated tablet intended to be dissolved slowly in the mouth for the temporary relief of sore throat, lubricate and soothe irritated tissues of the throat.
  - Please refer to Annex (7) for the permitted active ingredients.

3.5 TOPICAL APPLICATION WITH COUNTER IRRITANT INGREDIENTS

- Topical products known as external applied substances that causes irritation or mild inflammation of the skin for reliving pain in muscles, joints, and viscera distal to the site of application.
  - Please refer to Annex (8) for the permitted active ingredients.
  - Dosage forms include but are not limited to: creams, ointments, gels (patches are considered as medicated medical devices)

3.6 STOMACH AIDS PRODUCTS

- These products are used as laxative, antacids or for gas discomfort products, e.g.:
  - Sodium bicarbonate [1], [2], [8], Citric acid anhydrous[1], [8], Sodium citrate anhydrous[1], [8]
  - Charcoal [2], [7], [8]
  - Aluminum, Magnesium or calcium salts [2]
  - Calcium carbonate [2]

3.7 ANTISEPTIC & DISINFECTANTS:

- These products are defined as preparations for external use intended for local application on human body to eradicate microbial contamination, and its repeated use does not cause a change or damage to the body tissue.
  - Some of the antiseptic cleansing products are intended as personal hand hygiene while others are used to help prevent infection in minor wounds, cuts and scratches.
  - Please refer to Annex (9) for the permitted active ingredients

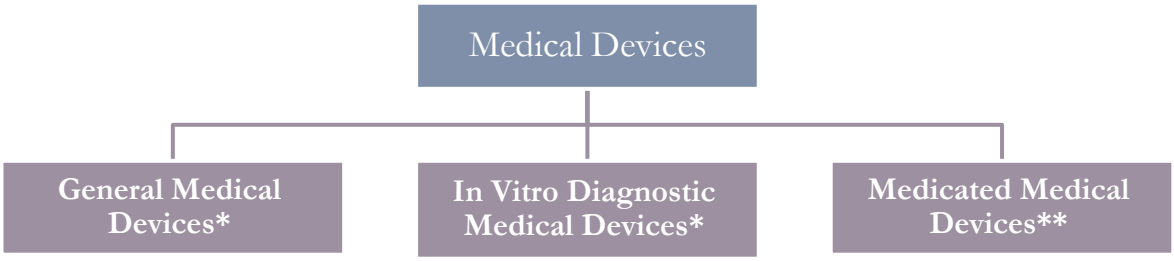
3.8 OTHERS

- Insect repellents that are in direct contact with human skin [7] e.g. permethrin 0.5%.
- Products intended for the treatment of addiction[6] e.g. Nicotine
- Oral Rehydration Salts [1], [2], [8]
- Lidocaine approved as active ingredients in delay creams, throat lozenges [1].
- Other pharmacopeial preparations e.g. Tincture Benzoin Compound, Potassium Permanganate, Gention Violet, and Mercurochrome.

For further details on registration requirements, please refer to circular no. 46/2008 available at: https://www.moh.gov.om/en_us/web/dgpadc/-2

4. MEDICAL DEVICES

- According to WHO, medical devices are defined as any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose 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
- They do not achieve their primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assessed in its intended function by such means.
- Medical devices can be classified into three sub-categories based on their risks and the regulatory controls required to provide assurance of safety and effectiveness as indicated in the diagram below.



- In Vitro diagnostic medical devices mean 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, including blood and tissue donations, solely to provide information on:
    - a physiological or pathological state
    - a congenital abnormality
    - predisposition to a medical condition or a disease
    - safety and compatibility with potential recipients
    - treatment responses or reactions
    - monitor therapeutic measures
- This includes: kits, reagents, calibrators, control materials, specimen receptacles, software, and related instruments, apparatus, systems or other articles.

- Medicated medical devices are known as combination products which are defined as two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products or biological and drug products;
- They are typically products containing ingredients that they exert their actions by physical means (including mechanical action, physical barrier, replacement of or support to organs or body functions). They rely on chemical-physical processes such as local pH changes, sequestering actions of molecules.

- <u>Currently the following products require full assessment prior marketing authorization approval as medicated medical devices:</u>

1. Ophthalmic Products
    a. Contact Lens Care Products (disinfecting, cleaning solutions, rinsing solution, hydrating solutions, wetting agents, comfort drops)[6], [8]
    b. Artificial tears[6], [8]
    c. Normal saline eye drops/sprays[6], [8]
    d. Solution for preserving corneal material prior to transplant[6], [8]

2. Topical Applications
    a. Corn, wart and calluses removal preparation (pads, plasters, …)
    b. Head Lice Product which contains *only* ingredients with physical actions (Silicon oil-based preparations; dimethicone Isopropyl, myristate/cycolmethicone) [6]
    c. Substances for chemical peeling with medical claims[3]
    d. Topical Products used to treat nail fungus containing silicon based ingredients
    e. Silicon based products for scar management (sheets, gels, sprays..)

3. Medicated dressings/pads
    a. Surgical bandages containing Zinc Oxide without pharmacological action[6]
    b. Nibble shields to protect or relief sore, damaged or cracked nipples or to be which is used to cover and protect the nipple of a nursing mother[7]
    c. Sanitary pads claiming pain relief by physical means[7]
    d. Heat/cold pads for pain relief[7]
    e. Hydrogel dressings/alginate dressings e.g. to reduce fever[7]
    f. Wound dressing containing honey to manage the microorganism of a wound or silver to protect the dressing and prevent odor.
    g. Medicated dressings/pads

4. Others
    a. Nasal normal saline drops / sprays[1], [7]
    b. Artificial saliva[6], [8]
    c. Local injections for cosmetic purposes / soft tissue fillers (Dermal fillers) e.g. Collagen, Hyaluronic acid, Botulinum toxin [6], [8]

d. Agents/solutions for the transport, nutrition & storage of organs intended for transplants[6], [8]
e. Personal / Sterile lubricating gels [7], [8]
f. Absorbable homeostatic agents [7]
g. Hemodialysis solution[6], [8]
h. Vaginal tablets containing Lactobacillus
i. Rectal suppositories containing Hydrophilic polymers
j. Products containing Ectoine as eye, nasal or throat applications
k. Ear was removal products e.g. glycerin, olive oil

*Registration requirements are under process for general medical devices & in-vitro diagnostic medical devices.

**For further details on registration requirements for medicated medical devices, please refer to circular no. 20/2012, available at: https://www.moh.gov.om/en_us/web/dgpadc/-2.

BORDERLINE PRODUCTS:

Most of the products are easily classified into pharmaceutical medicines, herbal medicines, health products or medicated medical device and consequently identifying under which regulation should these products follow to get the marketing authorization. However, there are still some products, which are said in the borderline area where the characteristics of the products are not clearly identified. In the case of these borderline products, the decision must be taken on a case-by case basis.

DIETARY SUPPLEMENTS:

- Dietary supplements as defined earlier are classified as health products if the product is formulated in pharmaceutical dosage form i.e. capsules, pastilles, tablets, pills, sachets of powder, ampoules of liquids, drop-dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities. These products are intended to supplement the diet for the general population.

- However there are other dietary products that are designed and formulated for specific groups of people and usually comes in powder form, are classified as dietary supplements (under the responsibilities of Department of Nutrition)
- Examples of these include:
  - Milk formula regardless the flavor, types, preparations
  - Other dietary supplements with medical claims i.e. products intended as special supplements during pregnancy, special formulas for diabetic patients or gluten free dietary products for celiac diseases
  - Sport products in powder forms
  - Energy drinks where they should comply with GSO no. (GSO FDS/1926:2012CE) and Caffeinated Energy Drinks.
  - Fruit beverages
  - Artificial sweeteners

COSMETICS AND HEALTH PRODUCTS

- Cosmetic products are known as any substance or preparations intended to be placed in contact with the various external parts of 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 and/or correcting body odors and/or protecting them or keeping them in good condition.
- This may include bath & shower preparations, shaving products, etc.…
- Cosmetic products:
  - Must be free of prohibited substances according to other updated international regulations
  - Must be compatible with restricted substances according to the enclosed annexes

- Must not come in pharmaceutical dosage forms
- Must not include medical claims

- The main differences between health products and cosmetics are based on two factors:
  a) *Claims made about the product*
     - Common example is antiperspirants, which usually fit the definition of cosmetic products, as the main purpose is to correct body odors. However If they are intended for hyperhidrosis, in this case they are classified as health products.

  b) *The composition of the product*, although the composition of a product alone does not necessarily determine its classification. For example, sunscreens where the concentration of the product is the major factor to determine its classification.

PHARMACEUTICAL MEDICINES AND MEDICATED MEDICAL DEVICES.

- In order to decide whether a product is classified as a pharmaceutical medicine or a medical device, the following points should be considered:
  - The principal purpose of the product taking into account the way the presentation of the product
  - The method by which the active ingredient achieves its action.

- The action of a pharmaceutical medicine is usually achieved by pharmacological, immunological or metabolic means. In the case of a medical device, the principal intended action is typically achieved by physical means (including mechanical action, physical barrier, replacement of, or support to, organs or body functions).
- Eye drops are very common example where a product fall in this gray area. They are considered as pharmaceutical medicines when they act in pharmacological actions while they are medical devices if they are used for cleaning; rinsing or hydrating contact lenses i.e. act in physical means.

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.

ANNEX (3): OTHER INGREDIENTS PERMITTED IN DIETARY SUPPLEMENTS

1.	**Vitamins**	The product should not go beyond the max. dosage values as per annex (1)
2.	**Minerals**	The product should not go beyond the max. dosage values as per annex (2)
3.	**Amino Acids**	- Alanine, Asparagine, Aspartic Acid - Cysteine, Cysteine HCl, - Glutamine, Glycine - Histidine, Histidine HCl, Hdroxylysine, Hydroxyproline - Isoleucine, - Lysine, Lysine HCl, - Ornithine, Ornithine Aspartate, Ornithine Monohydrocholride, - 1-Phenylalanine, Proline - Serine - Taurine, Threonine, dl- Threonine, Tyrosine - Valine
4.	**Microorganisms whole/extracted:** **(pre- and probiotics)**	- Inulin[3] - Brewers Yeast[2], [3] - Lactobacillus johnsonii/ Lactobacillus rhamnosus[3] / Lactobacillus gasseri - Saccharomyces boulardii/Saccharomyces cerevisiae[2] - Bifidobacterium bifidum / Bifidobacterium longum
5.	**Marine Algae**	- Spiriulina[2], [3]
6.	**Substances produced from bees in a pharmaceutical dosage form**	- Royal Jelly [2], [5], [8] - Bee Pollen [5], [8] - Propolis [2], [5], [8]
7.	**Essential Fatty Acids**	- Fish oil - Omega 3, EPA/DHA[2], [3] - Gamma- linoleic acid[3] - Linoleic acid - Alpha- linoleic acid - Cod liver oil[2]
8.	**Botanical Extracts**	- Aloe Extract[3] - Borage oil[3] - Clove oil - Cranberry seed oil - Evening primrose oil - Flax seed oil [3] - Garlic Extract[3] - Ginger Extract[3] - Ginseng extract[3] - Green Tea Extract[2], [3] - Peppermint oil - Sunflower oil[2] - Wheat germ oil[2]

9.	**Dietary Fibers**	- Ispaghulla/psyliium husk [2), (4)] - Cellulose and derivatives of cellulose [(4), (8)] - Pectin (4)
10.	**Natural Enzyme [(8), (5), (7)]**	- Amylase - Bromelin[(2)] - Catalase - Diatase - Ficin - Lactase [(3)] - Panceratin - Papain [(3)] - Pepsin - Superoxide dismutase
11.	**Miscellaneous Products**	- Carnitine[(3)] - Chitosan[(2), (3)] - Chlorophyll Complex[(8)] - Co enzyme Q10[(2), (3)] - Glucosamine[(2), (3)] - Hayloronic acid[(4)] - Inositol[(3)] - Lecithin (choline salts) [(2), (5), (8)] - Lutein[(3), (5)] - Lycopene[(2), (3), (5)] - Shark cartilage/shark liver oil[(2)] - Soy protein/soy isoflavone[(3)] - Taurine[(3), (5)] - Collagen

ANNEX (4): MEDICATED COSMETIC PRODUCTS:

S.	Ingredient Name	Concentration	References
1.	Allantoin	> 2%	(5)
2.	Aluminum hydroxide gel	> 5%	(5)
3.	Benzoyl peroxide	> 5%	(2), (5)
4.	Calamine	> 25%	(2), (5)
5.	Cod liver oil	> 14%	(2), (5)
6.	Glycerin/glycerol	> 45%	(5)
7.	Kaolin	> 20%	(5)
8.	Alpha hydroxyl acids i.e. lactic acid malic acid, glycolic acid, …	> 10%	(5), (7)
9.	Lanolin (Wool fat)	> 15.5%	(5)
10.	Salicylic acid	> 2%, > 3% in rains off products	(5), (7)
11.	Sulfur	> 2%	(5), (7)
12.	Urea	> 10% Other products intended to be diluted in bath water may contain levels exceeding 10% of urea	(2), (5), (7)
13.	Zinc carbonate/ Zinc acetate	> 2%	(5)
14.	Zinc oxide	> 25%	(2), (5), (7)
15.	Dimethicone	> 30%	(5)

ANNEX (5): SUNSCREEN PRODUCTS

S.	Medicinal Ingredient	CAS No.	Concentration	References
1.	4-Aminobenzoic acid/ PEG-25 PABA	150-13-0 116242-27-4	> 10%	(2), **(3),** (4), (5), **(8)**
2.	Amiloxate/ Isoamyl P-methoxycinnamate	71617-10-2	> 10%	(3), (8)
3.	Avobenzone	70356-09-1	> 5%	**(3)**, (4), (5), **(8)**
4.	Bemotrizinol	187393-00-6	> 10%	(3), (8)
5.	Benzylidene Camphore Sulfonic Acid	56039-58-8	> 6%	(3), (8)
6.	Bisimidazylate	180898-37-7	> 10%	(3), (8)
7.	Bisoctrizole	103597-45-1	> 10%	(3), (8)
8.	Camphor Benzalkonium Methosulphate	52793-97-2	> 6%	(3), (8)
9.	Cinoxate/ Ethoxyethyl methoxycinnamate	104-28-9	> 3%	(2), **(4)**, **(5)**, (8)
10.	Diethanolamine methoxycinnamate	56265-46-4 / 73560-31-3	> 10%	(2), (4), (5), (8)
11.	Diethyllamino Hydroxybenzoyl Hexyl Benzoate	302776-68-7	> 10%	(3), (8)
12.	Dioxybenzone	131-53-3	> 3%	(2), (4), (5), (8)
13.	Drometrizole trisiloxane	155633-54-8	> 15%	(3), (5), (8)
14.	Ecamsule/ Mexoryl SX	92761-26-7	> 10%	(3), (5), (8)
15.	Ensulizole/ Phenylbenzimidazole sulfonic acid	27503-81-7	> 8%	**(3)**, (4), (5), (8)
16.	Enzacamene	36861-47-9 38102-62-4	> 4%	(3), (5), (8)
17.	Homosalate	118-56-9	> 10%	(2), **(3)**, (4), (5), (8)
18.	Iscotrizinol	154702-15-5	> 10%	(3)
19.	Meradimate/ Menthyl anthrnilate	134-09-8	> 5%	(4), (5), (8)
20.	Octinoxate/ ethylhexyl methoxycinnamate	5466-77-3	> 10%	**(3)**, (4), (5), **(8)**
21.	Octisalate	118-60-5	> 5%	(3), (4), (5), (8)
22.	Octocrylene	6197-30-4	> 10%	(2), (3), (4), (5), (8)
23.	Octyl triazone/ Ethylhexyl Triazone	88122-99-0	> 5%	(3), (8)
24.	Oxybenzone	131-57-7	> 6%	(2), **(3), (4), (5),** (8)

S.	Medicinal Ingredient	CAS No.	Concentration	References
25.	Padimate O/ Octyl dimethyl PABA	21245-02-3	> 8%	(2), (3), (4), (5), (8)
26.	Polyacrylamidomethyl Benzylidene Camphore	113783-61-2	> 6%	(3), (8)
27.	Polysilicone-15	207574-74-1	> 10%	(3), (8)
28.	Sulisobenzone	4065-45-6	> 5%	(2), (4), **(3)**, (5), (8)
29.	Titanium dioxide	13463-67-7	> 25%	(2), (3), (4), (5), (8)
30.	Triethanolamine salicylate/ Trolamine salicylate	2174-16-5	> 12%	(2), (4), (5), (8)
31.	Tris-biphenyl Triazin	31274-51-8	> 10%	(3), (8)
32.	Zinc oxide	1314-13-2	> 25%	(2), (3), (4), (5), (8)

ANNEX (6): ANTIPERSPIRANTS

S.	Ingredient Name	Concentration	References
1.	Zinc phenolsulfonate	>6%,	(10)
2.	Iodopropynyl butylcarbamate	> 0.0075 %	(10)
3.	Ethyl Lauroyl Arginate HCl	> 0.8 %	(10)
4.	Triclosan	> 0.3 %	(10)
5.	Aluminum chloride	> 15%	(5)
6.	Aluminum chlorohydrate	> 25%	(5)
7.	Aluminum chlorohydrex	> 25%	(5)
8.	Aluminum dichlorohydrate	> 25%	(5)
9.	Aluminum dichlorohydrex	> 25%	(5)
10.	Aluminum sesquichlorohydrate	> 25%	(5)
11.	Aluminum sesquichlorohydrex	> 25%	(5)
12.	Aluminum zirconium compounds	> 20%	(5), (10)

ANNEX (7): MEDICATED THROAT LOZENGES

Ingredients	References
Analgesic/Anesthetic	
Menthol	(1), (5), (7)
Phenol	(2), (5)
Resorcinol/ Hexylresorcinol	(5), (7)
Benzocaine	(1), (5)
Dyclonine hydrochloride	(5)
Benzyl alcohol	(5), (7)
Salicyl alcohol	(5)
Demulcent	
Slippery elm bark powder	(5)
Gelatin	(5)
Pectin	(5)
Antiseptic	
Cetylpyridinium chloride	(1), (5), (7)
Domiphen bromide	(5)
Dequalinium chloride	(5)
Eucalyptus oil	(1), (2), (5), (7)

- Some other volatile oils that can be used in throat lozenges and medicated space sprays as active ingredient, these include:
  - Anise oil [1, 2]
  - Chamomile oil [2]
  - Cinnamon bark oil [2]
  - Clove bud oil [1, 2]
  - Fennel oil [2]
  - Ginger oil [2]
  - Lavender oil [1]
  - Lemon oil [1]
  - Nutmeg oil [2]
  - Peppermint oil [1]
  - Thyme oil [1]

ANNEX (8): TOPICAL APPLICATION WITH COUNTER IRRITANT INGREDIENTS

S.	Ingredient Name	References
1.	Allyl Isothiocyanate	(5)
2.	Ammonium Hydroxide (Ammonia Water)	(5)
3.	Camphor	(1), (2), (5)
4.	Capsaicin	(1), (2), (5)
5.	Clove Essential Oil	(1), (2), (5)
6.	Eucalyptus Essential Oil	(1), (2), (5)
7.	Eucalyptol/ Cineole	(1), (2), (5)
8.	Menthol	(1), (2), (5)
9.	Methyl Nicotinate	(5)
10.	Methyl Salicylate	(1), (2), (5)
11.	Thymol	(1), (2), (5)
12.	Turpentine Essential Oil	(5)

ANNEX (9): ANTISEPTIC & DISINFECTANTS:

S.	Ingredient name(s)	References
1.	Benzalkonium chloride	(1), (2), (5), (7)
2.	Benzathonium chloride	(5), (7)
3.	Benzocaine	(1), (2)
4.	Cetalkonium chloride	(1), (2)
5.	Cetrimide	(1), (2)
6.	Cetylpyridinium chloride	(1), (2)
7.	Chlorhexidine gluconate	(1), (5), (7)
8.	Chloroxylenol	(5), (7)
9.	Disodium undecyenamidi MEA sulfosuccinate	(2)
10.	Hydrogen peroxide	(1), (2), (5), (7)
11.	Isopropyl alcohol	(2)
12.	Methylated spirit/ Surgical spirit	(1), (2)
13.	Methylbenzthonium chloride	(7)
14.	Para-chloro-meta-xylenol	(2)
15.	Povidion-iodine	(1), (2), (5), (7)
16.	Triclocarbon	(7)
17.	Tricolsan	(1), (2), (5), (7)

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