

**DEPARTMENT OF HEALTH
PHARMACEUTICAL SERVICE
PHARMACEUTICALS REGISTRATION SECTION**

**Guidance Notes on Classification of Products as “Pharmaceutical Products”
under the Pharmacy and Poisons Ordinance (Cap. 138)**

Preamble

1. Under the Pharmacy and Poisons Ordinance, pharmaceutical products must be registered before they can be imported, or manufactured locally, for supply in Hong Kong.
2. These notes aim at assisting the relevant trade and industry in deciding if a product is classified as “pharmaceutical product” and is therefore subject to registration.

Definition of “pharmaceutical product”

3. “Pharmaceutical product” means any substance, or mixture of substances, for use in human beings or animals, for:
 - a) the diagnosis, treatment, mitigation or prevention of a disease or its symptom;
 - b) the diagnosis, treatment, mitigation of any abnormal physical or physiological state or its symptom; *or*
 - c) altering, modifying, correcting or restoring any organic function.

Exemptions

4. Certain products are exempted from registration under the Pharmacy and Poisons Ordinance. These are:
 - (a) Proprietary Chinese medicines or Chinese herbal medicines as defined in the Chinese Medicine Ordinance. (Note: Proprietary Chinese medicines are still required to be registered under the Chinese Medicine Ordinance, and an import/export licence is still required for their import/export. Please also see **Paragraph 15**); and
 - (b) Medical devices. A **medical device** is defined as any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, 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 purpose(s) of:

- (a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
- (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- (c) investigation, replacement, modification, or support of the anatomy or of a physiological process;
- (d) supporting or sustaining life;
- (e) control of conception (including contraception);
- (f) disinfection of medical devices; *or*
- (g) providing information for medical purposes by means of in vitro examination of specimens derived from the human body;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Examples of medical device are:

- bone cements (including bone cements containing an antibiotic)
- catheters (including heparin-coated catheters)
- contact lens care products
- drug eluting stents
- haemodialysis concentrates
- intra-uterine devices for contraceptive use
- surgical dressings
- surgical sutures

Factors to consider

5. Two factors decide whether or not a product is classified as a “pharmaceutical product”. These are:

- (a) The **usage claims** made in relation to the product; and
- (b) The **composition** of the product.

USAGE CLAIMS

6. The usage claims of a product are the descriptions about what the product is used for. These descriptions usually appear on the product’s label, package insert, pamphlets, etc. If a usage claim is a “medicinal” claim, the product will be

classified as a “pharmaceutical product”. A “medicinal” claim is one that refers to the diagnosis, treatment, mitigation, or prevention, of a specific disease or disease symptom.

Examples of “medicinal” claims

7. The following are examples of “medicinal” claims. Products carrying any such claims are pharmaceutical products requiring registration before sale (the underlined words are the specific disease or disease symptom):

- “this product helps prevent heart disease”
- “this product lowers high cholesterol”
- “this product may lower blood sugar”
- “prevents osteoporosis”
- “relieves premenstrual symptoms”
- “relieves menopausal symptoms”
- “eases period pain/dysmenorrhoea”
- “treatment or management of obesity”
- “headlice treatment”
- “relieves itch from eczema, psoriasis and dermatitis”
- “use of the product eliminates nappy rash”
- “soothes inflammation”
- “symptomatic relief of insect bites and stings”
- prevents/relieves allergies
- prevents acne/pimple
- “this product heals cold sores”
- “cures athlete’s foot”
- “frequent use of the product can alleviate pimples”
- “anti-gingivitis mouthwash”
- “use of the product prevents infections”
- “frequent use fights colds and flus”
- “soothes sore throats”
- “remedy for hay fever”
- “alleviates headaches”
- “clear blocked noses”
- “stop coughs”
- “this product relieves occasional constipation/diarrhoea”
- “prevention of travel sickness”
- “eases heartburn and indigestion”

- “apply liberally to relieve muscle aches and pains”
- “eases difficulty in urination”
- “relieves painful sensitivity of teeth”
- “treats mouth ulcers”
- “fights periodontal diseases”
- “prevents periodontitis”

Examples of claims that are not “medicinal”

8. The following are examples of usage claims which are not “medicinal” and are therefore allowed on products not classified as pharmaceutical products:

- anti-plaque
- teeth whitening/polishing
- prevents tooth decay/ prevents teeth cavity
- removes teeth stains
- relieves teeth sensitivity
- fights bad odor
- cleanses acne-prone skin
- energizes skin
- helps prevent signs of ageing
- hypoallergenic
- soothes sensitive skin
- smooths wrinkles
- skin whitening
- fades dark pigmented areas
- improves skin conditions and relieves dryness
- anti-dandruff (provided that the product does not contain climbazole, coal tar, pine tar, selenium, , etc)
- vitalizes hair
- improves general health

COMPOSITION

9. This is usually shown on the product’s label, or in the product ingredients list provided by the manufacturer. If the composition includes a drug substance, the product will be classified as a pharmaceutical product.

10. A “drug substance” is one which is used for the diagnosis, treatment, mitigation, or prevention, of a specific disease or disease symptom. Many

substances are, by nature, “drug substances”. Examples are antibiotics and pain relievers.

Examples of ‘drug substances’

11. The following are some substances which, if contained in a product and that product is in a pharmaceutical dosage form (e.g. tablet, capsule), the product will be classified as a pharmaceutical product:

- Androstenediol
- Androstenedione
- 1,4 Butanediol (BD)
- Climbazole
- Digestive enzymes, e.g. pancreatin, lipase, amylase, cellulase, bromelain, papain, etc.
- Fish liver oils (because these are traditional sources of vitamins A and D)
- Gamma butyrolactone (GBL)
- Gamma hydroxybutyric acid (GHB)
- Glucosamine
- Hydroxyapatite
- Laetrile (Vitamin B17, amygdalin)
- N-N-Dimethylglycine (DMG, Pangamic acid)
- Retinoic acid (Tretinoin)
- Selenium for anti-dandruff use
- Sennosides
- Tars (coal tar or pine tar)
- Vitamins

Examples of substances which are NOT “drug substances”

12. The following are examples of substances which are **not** “drug substances”. Products containing them are not classified as pharmaceutical products (*except if they are in a pharmaceutical dosage form (e.g. tablet, capsule) and carry “medicinal” claims*):

- Alpha lipoic acid
- Animal cartilage
- Amino acids (except if in injection form, which are pharmaceutical products), e.g. alanine, arginine, citrulline, cysteine, cystine, glycine, histidine, isoleucine, leucine, lysine, phenylalanine, serine, tyrosine, etc.

- Apple cider vinegar
- Bee pollen
- Bioflavonoids (e.g. diosmin, hesperidin, quercetin, rutin)
- Biotin
- Brewer's yeast
- Caffeine
- Casein
- Chitosan
- Chlorophyll
- Choline
- Chondroitin
- Coenzyme Q10 (Ubidecarenone)
- Collagen
- Colostrum
- Creatine
- DHEA (Dehydroepiandrosterone)
- Fibers from fruits and vegetables
- Fish oils (Note: not fish *liver* oils)
- Gamma aminobutyric acid (GABA)
- Goat's milk
- Grape seed extract (Pycnogenol)
- Herbal substances not commonly used as medicinal ingredients, e.g. bilberry, blueberry, cranberry, echinacea, garcinia cambogia, ispaghula husk, psyllium husk (*plantago ovata*), rose hips, saw palmetto
(Examples of herbal substances which **are** considered as “pharmaceutical products” when contained in pharmaceutical dosage forms are: cascara, belladonna, ephedra and yohimbe).
- Hyaluronic acid and salts for topical use
- Hydroquinone
- Lactic acid producing organisms (e.g. lactobacillus, bifidobacterium)
- Lecithin
- Lutein
- Melatonin
- Minerals (except if in injection form, which are pharmaceutical products), e.g. calcium, copper, iodine, iron, magnesium and zinc
- Nucleic acids, e.g. DNA (deoxyribonucleic acid), RNA (ribonucleic acid)
- Omega-3 triglycerides, e.g. DHA (docosahexanoic acid), EPA (eicosapentaenoic acid)

- Phytosterols
- Seaweeds, e.g. kelp
- Simethicone/dimethicone (skin products only)
- Squalene
- Urea
- Wheat germ oil
- Whey protein
- Zeaxanthin
- Zinc Pyrithione

Examples of products which are “pharmaceutical products”

13. The following are examples of “pharmaceutical products”:

- Anti-acne skin products
- Products for the treatment or management of drug abuse
- Nicotine replacement therapies for smoking cessation

Examples of products which are NOT “pharmaceutical products”

14. The following are examples of products that are **not** classified as “pharmaceutical products”, *provided that they do not carry “medicinal” claims*:

- Aqueous cream
- Antiseptic or disinfectant products containing any of the ingredients specified in the **Appendix** at not more than the stated concentration, and where applicable in the specified circumstances, *provided that they are not labelled for use on the broken skin or wounds*
- Chemicals for laboratory use
- Contraceptive devices, e.g. intrauterine devices, vaginal sponge, foams and creams; condoms with or without spermicides (e.g. nonoxynol 9), except condoms containing local anaesthetics, e.g. benzocaine, lignocaine
- Contact lens care products
- Cosmetics and toiletries (including those containing vitamins, alpha hydroxy acids (AHAs) or glycolic acid)
- Deodorants and antiperspirants
- Diagnostic agents used outside the human body (e.g. blood glucose testers, urine glucose testers)
- Emulsifying ointment
- Toothpastes, including those containing fluorides and/or potassium nitrate

(except those containing medications like tranexamic acid)

- Disinfectants which are **not** to be used on the human or animal body (i.e. those for cleaning floors, utensils, instruments, etc.)
- Insect repellents (e.g. those containing DEET (Diethyltoluamide) or citronella oil)
- Nutritional supplements in powder or liquid form used as meal replacements
- Products presented and sold as food, e.g. chocolates, breakfast bars, biscuits, drinks
- Sunscreen products
- Hair colourants
- Hair styling products

Proprietary Chinese medicines

15. Products which only contain ingredient(s) that are customarily used by the Chinese or are found in Chinese herbal publications such as 中華本草 may be classified as proprietary Chinese medicines and are subject to regulation under the Chinese Medicine Ordinance. Enquiries relating to such products should be addressed to the Chinese Medicines Section of the Department of Health, 2/F, Public Health Laboratory Centre, 382 Nam Cheong Street, Shek Kip Mei, Kowloon (Telephone number : 2319 5119).

16. Common examples of ingredients which may be found in Chinese herbal publications are :

- Alfalfa
- Aloe vera
- Calamine
- Chlorella
- Citronella oil
- Eucalyptus Oil
- Evening primrose oil
- Flaxseed/linseed
- Garlic
- Ginger
- Ginkgo biloba
- Green tea
- Harp Seal (oil) (*Phoca groenlandica*)
- Milk thistle

- Peppermint Oil
- Propolis
- Psyllium seed (Plantago psyllium)
- Red yeast rice
- Royal jelly
- Senna (leaves and pod)
- Sheep placenta
- Soybean/Soy isoflavones
- Spirulina
- St. John's wort
- Valerian
- Yam

Disclaimer

17. These notes are for guidance only. They should not be taken as a complete or definitive statement of the law.

Antiseptic and disinfectant products not classified as pharmaceutical products
(Please refer to paragraph 14 for details)

Ingredient contained in the product	Maximum concentration
Benzalkonium salts	6% when used diluted or in rinse-off preparations 1% when used undiluted or in leave-on applications
Benzethonium salts	0.1%
Cetrimide	3%
Cetylpyridinium salts	2.5% when used in diluted or in rinse-off preparations 0.3% when used undiluted or in leave-on applications
Chlorhexidine salts	20% when used diluted or in rinse-off preparations 2% when used undiluted or in leave-on applications
Chloroxylenol	4.8% when used diluted or in rinse-off preparations 0.5% when used undiluted or in leave-on applications
Dichloroxylenol	2%

Ingredient contained in the product	Maximum concentration
Ethyl alcohol	All concentrations
Isopropyl alcohol	All concentrations
Phenoxyisopropanol	2% in rinse-off applications or used diluted 1% in leave-on applications or used undiluted
Salicylic acid	2%
Thymol	1%
Triclocarban	1%
Triclosan	2% when used diluted 1% when used undiluted