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

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Pharmacy and Poisons Board of Hong Kong

CONTENTS

1. Preamble

1.1. According to the Pharmacy and Poisons Regulations (PPR) (Cap. 138A) a subsidiary legislation of the Pharmacy and Poisons Ordinance (PPO) (Cap. 138), pharmaceutical products (PP) must be registered with the Pharmacy and Poisons Board (PPB) before they can be sold, offered for sale or distributed or possessed for the purposes of sale, distribution or other use in Hong Kong.

1.2. The term "pharmaceutical products" is defined in the section 2 of PPO. Application for registration of pharmaceutical products is made to the PPB, a statutory body to determine whether or not that product is a pharmaceutical product and required to be registered. Details of the provisions under PPO and PPR can be browsed at www.elegislation.gov.hk.

1.3. The guidance notes aim to provide general principles and advices to facilitate the trade to decide if products are pharmaceutical products or not. This document is not legally binding and provides only guidance.

1.4. For guidance on classification of advanced therapy products (ATP), please refer to the following website:
https://www.ppbhk.org.hk/eng/files/PPB_Guidance_ATP_Classification_en.pdf

2. Definition of Pharmaceutical Product

2.1. According to section 2 of the PPO, "pharmaceutical product" is defined as:

pharmaceutical product (藥劑製品) —

(a) means a substance or combination of substances that—

(i) is presented as having properties for treating or preventing disease in human beings or animals; or

(ii) may be used in or administered to human beings or animals with a view to—

(A) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or

(B) making a medical diagnosis; and

(b) includes an advanced therapy product.

3. General Principles for Classification

3.1. To determine whether a product is a pharmaceutical product or not, it is on a case by case basis and in the light of:

3.1.1. the definition set out in paragraph 2.1 above;

3.1.2. relevant Court precedents or legal advice from Department of Justice; and

3.1.3. following an assessment of all the available information about the product, which includes full details of product's composition, presentation and purpose. Account will be taken of material being used to promote the product. For details, please refer to paragraph 5 on "Factors Relevant to Deciding Whether a Product is a Pharmaceutical Product".

3.2. Below are the examples of products generally not considered as pharmaceutical products subject to the registration control of PPR:

3.2.1. Proprietary Chinese medicines are exempted from the control of PPO and PPR which are subject to regulatory control under the Chinese Medicine Ordinance (Cap. 549). Under Section 2 of the Chinese Medicine Ordinance (Cap. 549), proprietary Chinese medicines are defined as follows:

"proprietary Chinese medicine" (中成藥) means any proprietary product

a) composed solely of the following as active ingredients-

i) any Chinese herbal medicines; or

ii) any materials of herbal, animal or mineral origin customarily used by the Chinese; or

iii) any medicines and materials referred to in subparagraphs (i) and (ii) respectively;

b) formulated in a finished dose form; and

c) known or claimed to be used for the diagnosis, treatment, prevention or alleviation of any disease or any symptom of a disease in human beings, or for the regulation of the functional states of the human body.

Additional information related to the control of proprietary Chinese medicines may be found at the website of the Chinese Medicine Council of Hong Kong at www.cmchk.org.hk.

3.2.2. A product which the average consumer would regard as something to be eaten, drunk or chewed as part of his/her diet for example, because of its taste, flavor, or nutritional value is unlikely to be classified as pharmaceutical product unless it contains one or more ingredients generally regarded as medicinal substance and indicative of a medical use.

3.2.3. A product which the average consumer would regard as cosmetic, beauty and skin care, sunscreen, toothpastes, deodorants and antiperspirants, hair colourants and hair styling products in nature is unlikely to be classified as pharmaceutical products unless it contains one or more ingredients generally regarded as medicinal substance and indicative of a medical use.

3.2.4. A medical device is generally known 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;

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 primary intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means. Additional information on the control of medical devices may be found at the website of the Department of Health's Medical Device Division at www.mdd.gov.hk.

3.2.5. Whole human blood; or any human blood component, other than plasma prepared by a method involving an industrial process, or under highly manipulation.

4. What is a Pharmaceutical Product?

4.1. As mentioned above, when determining whether a particular product comes within the definition of pharmaceutical product is on a case by case basis, and product information includes full details of product's composition, presentation, purpose and promotional material will be assessed by considering the relevant factors.

5. Factors Relevant to Deciding Whether a Product is a Pharmaceutical Product

5.1. In order to assess a product is regarded as a "pharmaceutical product", it is essential to consider and make known of whether:

5.1.1. the substance or combination of substances is present in the product;

5.1.2. the substance or combination of substances is medicinal or not;

5.1.3. the product is in pharmaceutical dose form (i.e., capsule, tablet, etc.), and the way it is to be used;

5.1.4. the use(s) indicated on the label, packaging/package inserts, promotional materials is/are within the scope of uses under the definition;

5.1.5. any essentially similar pharmaceutical products registered in Hong Kong; and

5.1.6. the product may pose any risk to the public.

5.2. Since each product is considered individually, it is not possible to provide a simple list of substances which will be considered as pharmaceutical products. However, as considering whether the substance is medicinal or not, it may be helpful to refer to the substances listed under the heading "A" of the Poisons List whose uses are essentially medicinal. For other examples of substance which are not included in the Poisons List but may generally be regarded as medicinal, please refer to **Appendix 1**.

5.3. Some substances which are commonly found in the health food products lacks of scientific evidence to support their medicinal use, and are normally NOT regarded as medicinal substance. For examples of those substances, please refer to **Appendix 2**.

5.4. As considering whether the use of the product falls within the definition of pharmaceutical products, the context in which the medicinal claims of usage made in the labeling, packaging/package inserts, promotional materials and the overall presentation will be taken into account.

5.5. Some words or phrases which may present the product as having properties for treating or preventing disease are medicinal claims. Although it is not possible to produce an indicative list of all kinds of medicinal claims of usage in this guidance, some examples which may indicate association with medicinal claims are listed in **Appendix 3** for reference.

5.6. Claims to "maintain", "help to maintain", or "support" health or a healthy lifestyle are normally not considered as medicinal in themselves. Examples of those claims are listed in **Appendix 4** for reference.

5.7. Therefore, if a product is found to contain medicinal substance(s) at a reasonable amount with medicinal claims, it would generally be classified as a "pharmaceutical product".

5.8. On the contrary, a product carries claims without any evidence may contravene the Trade Description Ordinance Cap. 362, Laws of Hong Kong.

5.9. For some cases, the general line for deciding whether the product is or is not pharmaceutical had been reached by the PPB. For details of those cases, please refer to **Appendix 5**.

Disclaimer

The guidance notes are only intended to provide general information on the classification of products as "pharmaceutical products" and should not be considered as a substitute for legal or other professional advice. Whenever necessary, please refer to the Pharmacy and Poisons Ordinance and Regulations for details of the requirements. The Pharmacy and Poisons Board of Hong Kong accepts no liability for any loss or damaged caused, arising directly, or indirectly, in connection with reliance on the contents of the guidance notes.

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Appendix 1 - Examples of Substances Not Listed in the Poisons List that may be Medicinal

Examples of substances other than the one listed in the Poisons List may generally be regarded as medicinal are as follows:

- Antibiotic
- Bisacodyl
- Bromhexine
- Famotidine
- Loperamide
- Naphazoline
- Noscapine
- Sennosides
- Coal tar

Appendix 2 - Examples of Substances Normally NOT Regarded as Medicinal

Examples of substances which are normally NOT regarded as medicinal are as follows:

- Animal cartilage
- Amino acids e.g., alanine, arginine, citrulline, cysteine, cystine, glycine, histidine, isoleucine, leucine, lysine, phenylalanine, serine, tyrosine, etc. *(except injection form)*
- Apple cider vinegar
- Bee pollen
- Bioflavonoids, e.g., diosmin, hesperidin, quercetin, rutin, etc.
- Biotin
- Brewer's yeast
- Caffeine
- Camphor (external preparations)
- Casein
- Chitosan
- Chlorophyll
- Choline
- Chondroitin
- Coenzyme Q10 (ubidecarenone)
- Collagen
- Colostrum
- Creatine
- Fibers from fruits and vegetables
- Fish liver oils
- Fish oils
- Gamma aminobutyric acid (GABA)
- Glucosamine *(except injection form)*
- Goat's milk
- Grape seed extract (pycnogenol)

- Herbal substances, e.g., bilberry, blueberry, cranberry, echinacea, garcinia cambogia, ispaghula husk, psyllium husk (plantago ovata), rose hips, saw palmetto, etc. *(except belladonna, cascara, ephedra and yohimbe)*
- Hydroquinone
- Lactic acid producing organisms, e.g., bifidobacterium, lactobacillus *(except genetically modified lactobacillus with a plasmid containing a gene sequence for a protein promoting the healing of skin wounds and an inducible promoter)*
- Lecithin
- Lutein
- lysozyme
- Menthol (external preparations)
- Minerals, e.g., calcium, copper, iodine, iron, magnesium, zinc, etc. *(except injection form)*
- Phystosterols
- Seaweeds, e.g., kelp
- Simethicone/dimethicone for topical use
- Squalene
- Urea
- Vitamins *(except injection form and other preparations under Appendix 5)*
- Wheat germ oil
- Whey protein
- Zeaxanthin

Appendix 3 - Examples of Words or Phrases May Associate with Medicinal Claims

Examples of words or phrases listed below which may indicate association with medicinal claims:

- "this product helps to prevent heart disease"
- "prevents osteoporosis"
- "treatment or management of obesity"
- "headlice treatment"
- "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 can prevent infections"
- "frequent use can fight cold and flu"
- "remedy for hay fever"
- "this product relieves occasional constipation/diarrhoea"
- "prevention of travel sickness"
- "eases heartburn and indigestion"
- "treats mouth ulcers"
- "fights periodontal diseases"
- "prevents periodontitis"

Appendix 4 - Examples of Words or Phrases Normally NOT Considered as Medicinal Claims

Examples of words or phrases listed below are normally not considered as medicinal claims in themselves:

- anti-plaque
- teeth whitening/polishing
- prevents teeth decay/prevents teeth cavity
- removes teeth stains
- relieves teeth sensitivity
- fights bad odor
- cleanses acne-prone skin
- energizes skin
- helps to prevent signs of aging
- hypoallergenic
- soothes sensitive skin
- smoothes wrinkles
- skin whitening
- fades dark pigmented areas
- improves skin conditions and relieves dryness
- anti-dandruff (without coal tar, selenium, etc.)
- vitalizes hair
- improves general health

Appendix 5 - Pharmacy and Poisons Board's General Line in Deciding whether the Product is Pharmaceutical or Not

For some cases, the general line for deciding whether the product is or is not pharmaceutical had been reached by the PPB:

Case 1

Topic:	Insect repellant product
Substance:	DEET
Decision:	DEET containing insect repellant do not satisfy the definition of pharmaceutical product under section 2 of PPO, and therefore is not subject to the registration requirement.

Case 2

Topic:	Anti-dandruff product
Substance:	Zinc pyrithione
Decision:	Products containing Zinc pyrithione and presented as anti-dandruff products without medicinal claim, will not be regarded as pharmaceutical products.

Case 3

Topic:	Antiseptic and disinfectant product
Decision:	I. Skin antiseptic products containing chlorhexidine for human or animal use are classified as pharmaceutical products unless otherwise stated, or- a) they are clearly labelled in English and Chinese for washing hands only (or equivalent); or b) chlorhexidine is used as preservative or antimicrobials in cosmetic products.

II. a) Unless otherwise stated, skin antiseptic products for human or animal use without any claims but containing well established active ingredients documented to be effective antiseptics, which include the following-

- Benzalkonium salts;
- Benzethonium salts;
- Cetrimide;
- Hydrogen peroxide; or
- Iodine / Povidone iodine,

are classified as pharmaceutical products regardless of their concentration.

b) General toiletry or cosmetic products containing antiseptic substances as preservatives, or intended for general cleansing or sanitary use, such as hand wash, body wash, cleanser and shampoo are generally not considered as pharmaceutical products.

III. Subject to paragraphs (I) and (II) above, antiseptics and disinfectant products (including Benzalkonium salts, Benzethonium salts, Cetrimide and Chlorhexidine when contained in products other than skin antiseptic products) will not be classified as pharmaceutical products if the concentration of the substance(s) contained in the products is not more than the maximum concentration specified in the following table, provided that they do not carry medicinal claims and are not labelled for use on broken skin.

Substance:

Substance 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%
	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

Case 4

Topic:	DMAA containing products
Substance:	1,3-Dimethylamylamine (DMAA)
Decision:	The Registration Committee of the Pharmacy and Poisons Board decided to regulate 1,3-Dimethylamylamine (DMAA) as pharmaceutical product with effect from 1 April 2013, after considering the pharmacological effects of DMAA, its potential risk of causing adverse effects and the international situations in the control of DMAA.

Case 5

Topic :	Hair care or cosmetic products containing climbazole
Substance:	Climbazole
Decision:	i). Hair care products containing climbazole not exceeding 2% in rinse-off products, or 0.5% in leave-on products are not considered as pharmaceutical products under the PPO, unless they are labelled for medicinal uses; and ii). Cosmetic products containing climbazole as a preservative with a maximum concentration of 0.5% are not considered as pharmaceutical products under the PPO, unless they are labelled for medicinal uses.

Case 6

Topic :	Vitamin products
Substance:	Vitamins
Decision:	In addition to the scenarios mentioned in the previous appendices, vitamin products are not considered as pharmaceutical products unless they belong to the following categories in oral dose form: i). vitamin A with not less than 10,000 I.U. daily dose; ii). vitamin B3 (nicotinic acid) with more than 200 mg daily dose; iii). vitamin D with more than 1,000 I.U. daily dose; and iv). vitamin K except vitamins K1 or K2 with 120 mcg or less daily dose.

Case 7

Topic:	Products containing lovastatin
Substance:	Lovastatin
Decision:	Products containing lovastatin with a daily dose of about 10mg or more would be considered as pharmaceutical product.

Case 8

Topic:	Radiopharmaceuticals that are intended to be used for diagnostic and therapeutic purposes
Substance:	Radiopharmaceuticals
Decision:	Radiopharmaceuticals that are intended to be used for diagnostic and therapeutic purposes are considered as pharmaceutical products. Examples of some registered radiopharmaceuticals include ready-for-use radiopharmaceuticals (such as sodium iodide (iodine-131), and gallium citrate-Ga67) and kits for radiopharmaceutical preparation (such as tetrakis copper tetrafluoroborate, mertiatide, sodium medronate / stannous fluoride, and mebrofenin).