No. S 000

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS ACT (AMENDMENT OF FIRST SCHEDULE) ORDER 2015

In exercise of the powers conferred by section 4(2) of the Health Products Act, the Minister for Health, after consultation with the Health Sciences Authority, hereby makes the following Order:

Citation and commencement

1. This Order may be cited as the Health Products Act (Amendment of First Schedule) Order 2015 and shall come into operation on 2015.

Amendment of First Schedule

2. The First Schedule to the Health Products Act is amended by inserting, immediately after item 2, the following item:

First column	*Second column*	*Third column*
Category	*Description*	*Exceptions and limitations*
"3. Therapeutic product	(1) "Therapeutic product" means any substance that — (*a*) is intended for use by and in humans for a therapeutic, preventive, palliative or diagnostic purpose, including any of the following purposes: (i) for preventing, diagnosing, monitoring, treating, curing or alleviating any disease, disorder, ailment, injury, handicap or abnormal physical or mental state, or any symptom thereof;	

(ii) for investigating, modifying, or replacing any physiological process;

(iii) for influencing, controlling or preventing conception;

(iv) for inducing anaesthesia;

(*b*) has as its constituent any of the following active ingredients:

(i) any chemical or botanical element, naturally-occurring chemical or botanical material or chemical product obtained by chemical change or synthesis;

(ii) any metabolite from a micro-organism;

(iii) any macromolecule extracted from an organism; or

(iv) any substance derived from a biological system, including any of the following:

(A) a whole cell or micro-organism, such as a whole virus or bacterium used as a vaccine;

(B) a part of a micro-organism, such as a sub-unit vaccine;

(C) a plasma-derived product; or

(D) a biotechnology-derived substance, such as a protein or polypeptide;

(*c*) exerts an inherent effect either pharmacologically, chemically or by other physiological means, leading to its use for a therapeutic,

preventive, palliative or diagnostic purpose; and

(*d*) is not any of the following:

(i) a medical device;

(ii) any product containing human or animal cell or tissue;

(iii) any substance administered to humans with a view to regulating, repairing, replacing, adding or deleting a genetic sequence;

(iv) whole blood or any blood component;

(v) any Chinese proprietary medicine;

(vi) any homoeopathic medicine;

(vii) any medicated oil or balm;

(viii) any quasi-medicinal product;

(ix) any traditional medicine.

(2) For the purposes of paragraph (1) —

"Chinese proprietary medicine" means any medicinal product used in the system of therapeutics according to the traditional Chinese method, that is to say, any medicinal product —

(*a*) which has been manufactured into a finished product;

(*b*) which contains one or more active substances derived wholly from any plant, animal or mineral, or any combination thereof; and

(*c*) which is, or all of the active substances of which are, described in the current edition of "A Dictionary of

Chinese Pharmacy" «中药大辞典» or "The Chinese Herbal Medicine Materia Medica" «本草纲目»,

but does not include —

(i) any medicinal product to be administered by injection into a human body; or

(ii) any medicinal product which contains as an active substance any chemically-defined isolated constituent of any plant, animal or mineral, or any combination thereof;

"current edition", in relation to any publication which describes a Chinese proprietary medicine, means an edition which is current at the time the Chinese proprietary medicine in question is sold or supplied, and includes any amendment, addition or deletion made to that edition of the publication up to that time;

"homoeopathic medicine" means any substance used in the system of therapeutics in which a disease is treated by the use of minute amounts of one or more substances which, in their undiluted forms, are capable of producing in healthy humans symptoms similar to those of the disease being treated;

"medicated oil or balm" means any external medicated embrocation, medicated cream, ointment or inhalant, and which contains one or more of the following active ingredients:

(*a*) any essential oil;

(*b*) any fixed oil derived from plants;

(*c*) methyl salicylate;

(*d*) menthol;

(*e*) camphor; or

(*f*) peppermint;

"medicinal product" has the same meaning as in the Medicines Act (Cap. 176);

"quasi-medicinal product" means —

(*a*) any anti-dandruff preparation;

(*b*) any medicated cosmetic product for the treatment of pimples or acne, except any preparation containing etretinate or 13-cis-retinoic acid;

(*c*) any medicated soap;

(*d*) any sweet for relieving coughs or throat irritations;

(*e*) any medicated plaster;

(*f*) any sunscreen or suntan preparation;

(*g*) any medicated beverage;

(*h*) any vitamin or nutritional preparation from any natural source; or

(*i*) any medicated toothpaste;

"traditional medicine" means any medicinal product consisting of one or more substances derived from any plant, animal or mineral, or any combination thereof, but does not include the following:

(*a*) any medicinal product to be administered by injection into

a human body;

(*b*) any vaccine to be administered to a human;

(*c*) any product derived from human blood;

(*d*) any item specified in the Poisons List in the Schedule to the Poisons Act (Cap. 234);

(*e*) any Chinese proprietary medicine.

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