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HEALTH PRODUCTS ACT (CHAPTER 122D)

HEALTH PRODUCTS ACT (AMENDMENT OF FIRST SCHEDULE) ORDER 2016

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, makes the following Order:

Citation and commencement

1. This Order is the Health Products Act (Amendment of First Schedule) Order 2016 and comes into operation on 1 November 2016.

Amendment of First Schedule

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

<i>First column</i>	<i>Second column</i>	<i>Third column</i>
<i>Category</i>	<i>Description</i>	<i>Exceptions and limitations</i>
"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,	

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- 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 a 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;
 - (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;
 - (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;

(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»;

(d) which does not contain as an active substance any chemically-defined isolated constituent of any plant, animal or mineral, or any combination thereof; and