**No. S 000 —**

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS ACT
(AMENDMENT OF FIRST SCHEDULE)
ORDER 2011

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 2011 and shall come into operation on 2011.

## 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 | "Therapeutic product"—<br>(*a*) means a health product that —<br>(i) contains at least one of the following:<br>(A) a substance derived from naturally occurring materials through a chemical process; | |

| *First column* | *Second column* | *Third column* |
|---|---|---|
| *Category* | *Description* | *Exceptions and limitations* |
| | (B) a substance obtained from chemical change or synthesis, including metabolites from micro-organism and macromolecules produced by chemical synthesis; or | |
| | (C) a substance derived from biological systems, including — | |
| | (CA) whole cells or organisms, such as whole viruses or bacteria used as a vaccine; | |
| | (CB) parts of organisms, such as sub-unit vaccines, blood-derived products or serum-derived products; | |
| | (CC) macro-molecules extracted from or produced by organisms, such as proteins, nucleic acids, proteoglycans, cytokines and growth factors; and | |
| | (CD) biotechnology products, such as recombinant hormones, enzymes and antibodies; and | |

| *First column* | *Second column* | *Third column* |
|---|---|---|
| *Category* | *Description* | *Exceptions and limitations* |
| | (ii) is for use in or on humans for one or more of the following purposes or has one or more of the following effects when used in or on humans:<br>(A) preventing, diagnosing, monitoring, treating, curing or alleviating any disease, disorder, injury, or the symptoms thereof;<br>(B) investigating, modifying or replacing any physiological process;<br>(C) testing the susceptibility of humans to any disease or disorder;<br>(D) contraception;<br>(E) inducing anaesthesia; or<br>(F) destroying or inhibiting micro-organisms that may be harmful to humans; | |
| | (*b*) includes any injectable intended for administration to humans for the treatment of any revision or change in human condition, including any revision or change in the appearance, colour, texture, structure or position of any bodily feature of a person; and | |
| | (*c*) excludes —<br>(i) any medical device;<br>(ii) any product containing human cell or tissue; | |

| *First column* | *Second column* | *Third column* |
|---|---|---|
| *Category* | *Description* | *Exceptions and limitations* |
| | (iii) any product used in the system of therapeutics in which diseases are treated by the use of minute amounts of such substances which are capable of producing in healthy persons symptoms similar to those of the disease being treated; | |
| | (iv) any external medicated embrocation, medicated cream, ointment or inhalant, and which contains essentially the following active ingredients:<br>(A) essential oils;<br>(B) fixed oils derived from plants;<br>(C) methyl salicylate;<br>(D) menthol;<br>(E) camphor; and<br>(F) peppermint; and | |
| | (v) any of the following quasi-medicinal products:<br>(A) anti-dandruff preparations;<br>(B) medicated cosmetics for the treatment of pimples and acne, except preparations containing etretinate or 13-cis-retinoic acid;<br>(C) medicated soap;<br>(D) sweets for relieving cough or throat irritations;<br>(E) medicated plasters;<br>(F) sunscreen or suntan preparations;<br>(G) medicated beverages; | |

| *First column* | *Second column* | *Third column* |
|---|---|---|
| *Category* | *Description* | *Exceptions and limitations* |
| | (H) vitamins or nutritional preparations from natural sources; or | |
| | (I) medicated toothpaste. | ”. |