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HEALTH PRODUCTS ACT (CHAPTER 122D)

HEALTH PRODUCTS ACT (AMENDMENT OF FIRST SCHEDULE) ORDER 2021

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 2021 and comes into operation on 1 March 2021.

Amendment of First Schedule

2. The First Schedule to the Health Products Act is amended —

- (a) by inserting, immediately after the words “by such means” in paragraph (a) of the definition of “Medical device” in the second column of item 1, the words “, and which is not a cell, tissue or gene therapy product”;
- (b) by inserting, immediately after the words “protein or polypeptide” in paragraph (1)(b)(iv)(D) in the second column of item 3, the words “, or a recombinant vaccine for a preventive purpose”;
- (c) by deleting sub-paragraphs (ii) and (iii) of paragraph (1)(d) in the second column of item 3 and substituting the following sub-paragraph:
 - “(ii) a cell, tissue or gene therapy product;” and
- (d) by inserting, immediately after item 4, the following item:

<i>First column</i>	<i>Second column</i>	<i>Third column</i>
<i>Category</i>	<i>Description</i>	<i>Exceptions and limitations</i>
"5. Cell, tissue or gene therapy product	(1) "Cell, tissue or gene therapy 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, treating, curing or alleviating any disease, disorder, injury, ailment, handicap or abnormal physical or mental state, or any symptom thereof; (ii) for replacing, repairing, regenerating or reconstructing any anatomy, or for modifying or replacing any physiological process; (iii) for regulating, repairing, replacing, adding or deleting a genetic sequence or modifying genetic material;	

- (iv) for supporting or sustaining life;
- (b) has as a constituent any of the following substances or combination of substances:
 - (i) viable or non-viable human cells or tissues;
 - (ii) viable animal cells or tissues;
 - (iii) recombinant nucleic acids, where the effect of the recombinant nucleic acid relates directly to the recombinant nucleic acid sequence that it contains or to the product of the genetic expression of its sequence;
- (c) achieves its primary intended action by pharmacological, immunological, physiological, metabolic or physical means, leading to its use for a therapeutic, preventive, palliative or diagnostic purpose; and
- (d) is not any of the following:
 - (i) a recombinant vaccine for a preventive purpose;

- (ii) an in-vitro diagnostic product;
- (iii) bone marrow, peripheral blood or umbilical or placental cord blood from a human that is minimally manipulated and intended for homologous use;
- (iv) cells and tissues obtained from a patient that are minimally manipulated and re-implanted for homologous use into the same patient during the same surgical procedure;
- (v) organs and tissues that are minimally manipulated and intended for transplant;
- (vi) reproductive cells (sperm, eggs) and embryos intended for assisted reproduction;
- (vii) whole blood and any blood component that is minimally manipulated and intended for treating blood loss or blood disorders.

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

“homologous use” means the use of a cell, tissue or gene therapy product to repair, reconstruct, replace or supplement the cells or tissue of an individual (called the recipient) if the cell, tissue or gene therapy product performs the same basic function or functions in the recipient as the original cells or tissue in the donor in the same anatomical or histological environment;

“minimally manipulated”, in relation to a cell or tissue (but not a gene), means processing the cell or tissue by way of any process so that the biological characteristics or functions of the cell or the structural properties of the tissue (as the case may be) are not altered, such as by —

- (a) cutting or sizing;
- (b) grinding;
- (c) shaping;
- (d) centrifugation;
- (e) soaking in an antibiotic or antimicrobial solution;
- (f) sterilization or irradiation;
- (g) cell separation, concentration or purification;
- (h) filtration;

- (i) lyophilisation;
- (j) freezing;
- (k) cryopreservation; or
- (l) vitrification.”.

Made on 14 February 2021.

CHAN YENG KIT
*Permanent Secretary,
Ministry of Health,
Singapore.*

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