

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS ACT
(AMENDMENT OF FIRST SCHEDULE) ORDER 2020

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 2020 and comes into operation on 20XX.

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 item 1, the words “, and which is not a cell, tissue or gene therapy product”;
- (b) by deleting the words “protein or polypeptide” in paragraph (1)(b)(iv)(D) of item 3 and substituting the words “protein or polypeptide, or a recombinant vaccine for a preventive purpose”;
- (c) by deleting sub-paragraphs (ii) and (iii) of item 3(1)(d) 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>Exceptions and limitations</i>
<i>Category</i>	<i>Description</i>	
“5. Cell, tissue or gene therapy product	<p>(1) “Cell, tissue or gene therapy product” means any substance that —</p> <p>(a) is intended for use by and in humans for a therapeutic, preventive, palliative or diagnostic purpose, including any of the following purposes:</p> <ul style="list-style-type: none"> (i) for preventing, diagnosing, treating or curing any disease, disorder or injury, 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; <p>(b) has as a constituent any of the following substances or combination of substances:</p> <ul style="list-style-type: none"> (i) viable or non-viable human cells or tissues; 	

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- (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

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- 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”, in relation to the manner in which a cell, tissue or gene therapy product is used in a recipient, means the repair, reconstruction, replacement, or supplementation of a recipient’s cells or tissues with a cell, tissue or gene therapy product that performs the same basic function or functions in the recipient as in the donor of the cells or tissues in the same anatomical or histological environment;
 - “minimally manipulated”, in relation to the processing of a cell or tissue, means processing by way of —
 - (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,

such that the biological characteristics or functions of the cell or the structural properties of the tissue (as the case may be) are not altered.

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