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HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS (THERAPEUTIC PRODUCTS AS CLINICAL RESEARCH MATERIALS) (AMENDMENT) REGULATIONS 2021

In exercise of the powers conferred by sections 71(1) and 72(1) of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

Citation and commencement

1. These Regulations are the Health Products (Therapeutic Products as Clinical Research Materials) (Amendment) Regulations 2021 and come into operation on 1 March 2021.

Amendment of regulation 1

2. Regulation 1 of the Health Products (Therapeutic Products as Clinical Research Materials) Regulations 2016 (G.N. No. S 332/2016) (called in these Regulations the principal Regulations) is amended by deleting the words "Therapeutic Products as".

Amendment of regulation 2

3. Regulation 2(1) of the principal Regulations is amended —

(*a*) by inserting, immediately before the definition of "administer", the following definition:

" "active substance", in relation to a CTGT product, means a substance that —

(*a*) is usable in the manufacture of a CTGT product as an active constituent; and

(*b*) achieves its intended action by pharmacological, immunological, physiological, metabolic or physical means;";

(*b*) by deleting the definition of "appropriate non-proprietary name" and substituting the following definition:

" "appropriate non-proprietary name", in relation to an active ingredient of a therapeutic product or an active substance in a CTGT product, means —

(*a*) the name or a synonym of the active ingredient or the active substance (as the case may be) described in the relevant monograph appearing in the latest edition of any specified publication; or

(*b*) in any other case, its international non-proprietary name or the accepted scientific name or other name descriptive of the true nature of the active ingredient or the active substance, as the case may be;";

(*c*) by deleting the definition of "clinical research material" and substituting the following definition:

" "clinical research material" means any of the following that is manufactured, imported or supplied for the purpose of being used in any clinical research by way of administration to a subject in accordance with the protocol for the research:

(*a*) a therapeutic product;

(*b*) a CTGT product that is treated as a Class 1 CTGT product under the CTGTP Regulations and for which no notice has been submitted under

regulation 4, 7 or 10 (as the case may be) of the CTGTP Regulations;

(*c*) a CTGT product that is treated as a Class 2 CTGT product under the CTGTP Regulations;

(*d*) a placebo;";

(*d*) by inserting, immediately after the definition of "codeine cough preparation", the following definitions:

" "CTGT product" means a health product categorised as a cell, tissue or gene therapy product in the First Schedule to the Act;

"CTGTP Regulations" means the Health Products (Cell, Tissue and Gene Therapy Products) Regulations 2021 (G.N. No. S 104/2021);";

(*e*) by inserting, immediately after the definition of "institutional review board", the following definition:

" "international non-proprietary name", for an active ingredient of a therapeutic product or an active substance in a CTGT product, means a name which has been selected by the World Health Organization as a recommended international non-proprietary name for the active ingredient or the active substance, as the case may be;"

(*f*) by inserting, immediately after the definition of "in-store pharmaceutical officer", the following definition:

" "licensed healthcare institution" means a healthcare institution that is licensed under the Private Hospitals and Medical Clinics Act (Cap. 248);";

(*g*) by inserting, immediately after the words "therapeutic product" in the definition of "prescription-only medicine", the words "or a CTGT product";

(*h*) by deleting the definition of "proprietary name" and substituting the following definition:

" "proprietary name" means a word or words used in connection with the supply of a therapeutic product or CTGT product for the purpose of indicating that it is the product of a particular person who manufactures, selects the name of, certifies or deals with that product, or offers it for supply;";

(*i*) by inserting, immediately after the definition of "regulated clinical trial", the following definition:

" "specified publication" means any of the following:

(*a*) the British Pharmacopoeia;

(*b*) the European Pharmacopoeia;

(*c*) the United States Pharmacopoeia and the National Formulary;

(*d*) any other publication that is specified on the Authority's website;"; and

(*j*) by deleting the full-stop at the end of the definition of "therapeutic product" and substituting a semi-colon, and by inserting immediately thereafter the following definition:

" "traceability", in relation to a CTGT product, means —

(*a*) the ability to locate and identify the CTGT product and its starting and raw materials at any point in time during its manufacture, import, supply or administration, including the sourcing, procurement, processing, testing, packaging, storage, transport, delivery and disposal of the CTGT product;

(*b*) the ability to identify the donor and tissue bank, blood bank or manufacturing facility that receives, processes or stores any cells or tissue that the CTGT product contains;

(*c*) the ability to locate and identify all data relating to any raw material or other substance that comes into contact with any cells or tissue that the CTGT product contains; and

(*d*) the ability to identify the person who receives the CTGT product at a licensed healthcare institution or a licensed retail pharmacy at which the CTGT product is administered, dispensed or supplied to a subject.".

Amendment of regulation 5

4. Regulation 5(1) of the principal Regulations is amended by inserting, immediately after the words "clinical research material that", the words "is a therapeutic product and that".

Amendment of regulation 6

5. Regulation 6(1) of the principal Regulations is amended by deleting the words "clinical research material which" and substituting the words "clinical research material that is a therapeutic product and that".

Amendment of regulation 10

6. Regulation 10(1) of the principal Regulations is amended by inserting, immediately after the words "clinical research material that is a", the words "therapeutic product and".

New regulation 14A

7. The principal Regulations are amended by inserting, immediately after regulation 14, the following regulation: