[FOR PUBLIC CONSULTATION ONLY]

HEALTH PRODUCTS ACT
(CHAPTER 122D)

HEALTH PRODUCTS
(CELL, TISSUE AND GENE THERAPY PRODUCTS)
REGULATIONS 2020

ARRANGEMENT OF REGULATIONS

In exercise of the powers conferred by sections 45, 71 and 72 of the Health Products Act, the Health Sciences Authority, with the approval of the Minister for Health, makes the following Regulations:

PART 1

PRELIMINARY

Citation and commencement

1. These Regulations are the Health Products (Cell, Tissue and Gene Therapy Products) Regulations 2020 and come into operation on 20XX.

Definitions

2.—(1) In these Regulations, unless the context otherwise requires —

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

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

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

"administer", in relation to a substance or an article, means to give or apply it to a human being, whether —

(*a*) orally;

(*b*) by injection or by introduction into the body in any other way; or

(*c*) by external application, whether by direct contact with the body or not;

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

(*a*) the name or a synonym of the active substance 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 substance;

"appropriate quantitative particulars", in relation to a CTGT product, means —

(*a*) the quantity of each active substance of the CTGT product, identified by its appropriate non-proprietary name, in each dosage unit of the CTGT product and expressed in terms of weight, volume, capacity or units of activity; or

(*b*) where there is no dosage unit of the CTGT product, the quantity of each active substance of the CTGT product, identified by its appropriate non-proprietary name, in the container of the CTGT product and expressed in terms of weight, volume, capacity or units of activity or percentage by weight or volume of the total quantity of the CTGT product;

"Authority's website" means the Authority's website at http://www.hsa.gov.sg;

"autologous", in relation to a CTGT product, means a CTGT product that contains cells or tissues that are obtained only from the patient to whom the CTGT product is to be administered;

"Class 1 CTGT product" means a CTGT product that —

(*a*) is the result of only minimal manipulation of human cell or tissue;

(*b*) is intended for homologous use;

(*c*) is not combined or used with —

(i) a health product categorised as a therapeutic product in the First Schedule to the Act; or

(ii) a health product categorised as a medical device in the First Schedule to the Act; and

(*d*) is assigned by the Authority as a Class 1 CTGT product due to a lower health risk to a user of the product;

"Class 2 CTGT product" means a CTGT product that is other than a Class 1 CTGT product;

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

"container", in relation to a CTGT product, means an article or a packaging immediately covering the CTGT product, including any bottle, ampoule, blister pack, sachet, dial dispenser pack, strip pack, syringe, tube, vessel, vial, wrapper or other similar article, but does not include —

(*a*) an article for ingestion; or

(*b*) an outer package or other packaging in which the container is further enclosed;

"dispense", in relation to a CTGT product, means to prepare and supply the CTGT product to a patient, where the preparation and supply is made by —

(*a*) a qualified practitioner or a person acting under the supervision of a qualified practitioner; or

(*b*) a qualified pharmacist or a person acting under the supervision of a qualified pharmacist;

"expiry date", for a CTGT product, means the date after which, or the month and year after the end of which, the CTGT product should not be administered;

"Good Distribution Practice Standard for Medical Devices" means any of the following as shown on the Authority's website:

(*a*) the Singapore Standard for Good Distribution Practice for Medical Devices — Requirements (SS 260);

(*b*) any other good distribution practice standard for medical devices that is approved by the Authority;

"Good Manufacturing Practice Standard" means any of the following as shown on the Authority's website:

(*a*) the Good Manufacturing Practice Standard for CTGT products issued by the Authority;

(*b*) any other good manufacturing practice standard that is approved by the Authority;

"Good Tissue Practice" means the Authority's tissue banking guidelines as shown on the Authority's website;

"healthcare institution licence" means a licence issued under section 5(1) of the Private Hospitals and Medical Clinics Act (Cap. 248);

"healthcare institution licensee" means the holder of a healthcare institution licence for a private hospital or medical clinic;

"homologous use", in relation to the manner in which a CTGT product is used in a recipient, means the repair, reconstruction, replacement, or supplementation of the recipient's cells or tissue with a CTGT product that performs the same basic function or functions in the recipient as in the donor of the cells or tissue in the same anatomical or histological environment;

"international non-proprietary name", for an active substance of 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 substance;

"ISO 13485" means the 2003 or 2016 edition of the publication ISO 13485, Medical Devices — Quality Management Systems — Requirements for Regulatory Purposes, published by the International Organization for Standardization;

"known importer" means a person who has given notice to the Authority under regulation 7 to import a CTGT product until the notice is refused, withdrawn or cancelled;

"known manufacturer" means a person who has given notice to the Authority under regulation 4 to manufacture a CTGT product until the notice is refused, withdrawn or cancelled;

"known wholesaler" means a person who has given notice to the Authority under regulation 11 to supply by wholesale a CTGT product until the notice is refused, withdrawn or cancelled;

"licensed healthcare institution" means a healthcare institution that is licensed under the Private Hospitals and Medical Clinics Act;

"licensed importer" means the holder of an importer's licence;

"licensed manufacturer" means the holder of a manufacturer's licence;

"licensed retail pharmacy" means the premises specified in a pharmacy licence;

"licensed wholesaler" means the holder of a wholesaler's licence;

"licensee", in relation to a CTGT product, means a licensed manufacturer, licensed importer or licensed wholesaler;

"medical clinic" means a medical clinic that is licensed under the Private Hospitals and Medical Clinics Act;

"minimal manipulation", 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;

"non-clinical purpose" means any purpose not involving any application of a CTGT product on, or administration of a CTGT product on, humans;

"private hospital" means a private hospital that is licensed under the Private Hospitals and Medical Clinics Act;

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

"qualified practitioner" means —

(*a*) a registered medical practitioner under the Medical Registration Act (Cap. 174); or

(*b*) a registered dentist under the Dental Registration Act (Cap. 76) whose name appears in the first division of the Register of Dentists maintained and kept under section 13(1)(*a*) of that Act;

"specified premises" means —

(*a*) in the case of a licence — the premises specified in the licence; or

(*b*) in the case of a notice given to the Authority under regulation 4, 7 or 11 — the premises specified in the notice;

"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;

"supply by retail sale" means sale by retail and includes exposure or display as an invitation to treat;

"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;

(*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; and

(*d*) the ability to identify the person who receives the CTGT product at the licensed healthcare institution or the licensed retail pharmacy that administers, dispenses or supplies the CTGT product to a patient;

"trade description" means any description, statement or indication which, directly or indirectly and by any means given, relates to any of the following matters in respect of a CTGT product:

(*a*) the quantity, liquid volume or weight of the CTGT product;

(*b*) the method of manufacture, production, or processing, of the CTGT product;

(*c*) the characteristics, formulation or specifications of the CTGT product;

(*d*) the fitness for purpose (including expiry date), dosage strength, or intended purpose, of the CTGT product;

(*e*) any physical characteristics or presentation of the CTGT product not mentioned in paragraphs (*a*) to (*d*);

(*f*) the testing of the CTGT product by any person and the results of the test;

(*g*) the approval of the CTGT product by any person or its conformity with a product description approved by any person;

(*h*) the place or date of manufacture, production, or processing, of the CTGT product;

(*i*) the name of the person who manufactured, produced or processed the CTGT product.

(2) For the purposes of these Regulations, a prescription is valid only if the prescription —

(*a*) is in writing and signed by a qualified practitioner; and

(*b*) contains all the following particulars:

(i) the date of the prescription;

(ii) the name and address of the qualified practitioner giving the prescription;

(iii) the name, identity card or other identification document number, and contact details, of the patient to whom the prescription relates;

(iv) the name and total amount of the prescribed CTGT product to be supplied to, and the dose to be taken by, the patient;

(v) where the qualified practitioner giving the prescription intends for the prescription to be repeated, an indication of the number of times, and the time period between which, the prescribed CTGT product may be supplied;

(vi) where the prescription is given by a registered dentist, a declaration by the registered dentist that the prescription is for dental treatment only.

Clinical research CTGT product excluded

3. These Regulations do not apply to or in relation to any CTGT product that is clinical research material as defined in regulation 2(1) of the Health Products (Therapeutic Products as Clinical Research Materials) Regulations 2016 (G.N. No. S 332/2016).

PART 2

CTGT PRODUCT MANUFACTURE — LICENSING AND EXCEPTIONS

Division 1 — Exceptions to need for licence

Exception for manufacturing minimally manipulated CTGT product

4.—(1) For the purposes of section 12(1) of the Act, a manufacturer's licence is not required for the manufacture of a CTGT product that is a result of only minimal manipulation of cell or tissue if the person manufacturing gives notice to the Authority in accordance with paragraph (2) and the notice is not refused, withdrawn or cancelled under these Regulations.

(2) The notice required for paragraph (1) for a CTGT product must —

(*a*) be in the form and manner specified on the Authority's website;

(*b*) be accompanied by the following information in writing:

(i) any information that the Authority requires relating to the particulars of the person giving the notice;

(ii) a description of the CTGT product concerned;

(iii) a statement of the manufacture involved;

(iv) the premises where the manufacture is being or is to be carried out; and

(*c*) be accompanied by the relevant fee specified in the Schedule.

Manufacturing CTGT products for research or non-clinical purposes

5.—(1) For the purposes of section 12(1) of the Act, a manufacturer's licence is not required for the manufacture of a CTGT product that —

(*a*) is solely for —

(i) the purpose of scientific education or research and development; or

(ii) a non-clinical purpose; and

(*b*) is not for any supply to the public.

(2) A manufacturer of a CTGT product for any of the purposes mentioned in paragraph (1)(*a*)(i) or (ii) is not required to maintain records of manufacture in compliance with regulation 33.

Division 2 — Licences

Requirements for manufacturer's licence for CTGT product

6. For the purposes of section 24(2)(*a*)(i) of the Act, the applicant for a manufacturer's licence for the manufacture of a CTGT product that is a result of more than minimal manipulation of cell or tissue must be able —

(*a*) to provide and maintain, or ensure the provision and maintenance of, the staff, premises, equipment and facilities that are necessary for carrying out the manufacture of the CTGT product to be authorised by the licence;

(*b*) to provide and maintain, or ensure the provision and maintenance of, the staff, premises, equipment and facilities for the handling, storage and distribution of the CTGT product that are necessary to prevent the deterioration of the CTGT product while it is in the applicant's ownership, possession or control;

(*c*) to conduct all manufacturing operations in such a way as to ensure that the CTGT product is of the correct identity and conforms with the applicable standards of quality for that CTGT product;

(*d*) to comply with the Good Manufacturing Practice Standard in relation to the manufacture of the CTGT product.

PART 3

CTGT PRODUCT IMPORT — LICENSING AND EXCEPTIONS

Division 1 — Exceptions to need for licence

Exception for importing minimally manipulated CTGT product

7.—(1) For the purposes of section 13(1) of the Act, an importer's licence is not required for the import of a CTGT product that is a result of only minimal manipulation of cell or tissue if the person importing gives notice to the Authority in accordance with paragraph (2) and the notice is not refused, withdrawn or cancelled under these Regulations.

(2) The notice required for paragraph (1) for a CTGT product must —

(*a*) be in the form and manner specified on the Authority's website;

(*b*) be accompanied by the following information in writing:

(i) any information that the Authority requires relating to the particulars of the person giving the notice;

(ii) a description of the CTGT product concerned;

(iii) a statement of the import involved;

(iv) the premises where the import is being or is to be carried out; and

(*c*) be accompanied by the relevant fee specified in the Schedule.

Importing to manufacture CTGT product

8. For the purposes of section 13(1) of the Act, an importer's licence is not required for the import —

(*a*) by a licensed manufacturer of a CTGT product or other health product; or

(*b*) by a known manufacturer of a CTGT product that is a result of only minimal manipulation of cell or tissue,

being a health product or CTGT product (as the case may be) that is required for the purpose of carrying out the manufacture of a CTGT product.

Importing unregistered Class 2 CTGT products for patients' use

9.—(1) For the purposes of section 13(1) of the Act, an importer's licence is not required for the import by a healthcare institution licensee of an unregistered Class 2 CTGT product —

(*a*) on the written instructions of a qualified practitioner practising at a private hospital or medical clinic belonging to the healthcare institution licensee; and

(*b*) for the qualified practitioner mentioned in paragraph (*a*) to administer to a patient of the qualified practitioner.

(2) For the purposes of section 13(1) of the Act, an importer's licence is not required for the import by the holder of a pharmacy licence to import an unregistered Class 2 CTGT product that is for the administration to a patient of a qualified practitioner pursuant to a valid prescription given by the qualified practitioner.

(3) The exception in paragraph (1) or (2) is subject to a condition precedent that the Authority's prior written approval must be obtained for each consignment of a CTGT product that is imported under paragraph (1) or (2), as the case may be.

(4) An application for the Authority's approval under paragraph (3) must be made in the form and manner specified on the Authority's website.

Division 2 — Licences

Requirements for importer's licence for CTGT product

10.—(1) For the purposes of section 24(2)(*a*)(i) of the Act, the applicant for an importer's licence for the import of a CTGT product that is a result of more than minimal manipulation of cell or tissue must be able —

(*a*) to provide and maintain, or ensure the provision and maintenance of, the staff, premises, equipment and facilities for the handling and storage of the CTGT product that are necessary to prevent the deterioration of the CTGT product while it is in the applicant's ownership, possession or control;

(*b*) to ensure that the CTGT product —

(i) is imported on behalf of a healthcare institution licensee for a private hospital or medical clinic pursuant to a valid prescription given by a qualified practitioner practising at the private hospital or medical clinic for the administration to the qualified practitioner's patient;

(ii) is intended to be supplied solely for the purpose of scientific education or research and development, or for a non-clinical purpose;

(iii) is imported solely for the purpose of export;

(iv) is authorised for import by the registrant of the CTGT product; or

(v) is in all respects the same as a registered CTGT product, the registrant of which has not authorised the applicant to import that CTGT product; and

(*c*) to comply with the requirements in the Authority's Guidance Notes on Good Distribution Practice, if the CTGT product is imported in accordance with sub-paragraph (*b*)(i), (iv) or (v).

(2) In addition to the requirements in paragraph (1), an applicant who intends to import a CTGT product under paragraph (1)(*b*)(v) must obtain the Authority's prior approval for each consignment of that CTGT product to be imported.

(3) An application for the Authority's approval under paragraph (2) must be made in the form and manner specified on the Authority's website.

PART 4

CTGT PRODUCT SUPPLY — LICENSING AND EXCEPTIONS

Division 1 — Exceptions to need for licence

Exception for supplying minimally manipulated CTGT product by wholesale

11.—(1) For the purposes of section 14(1) of the Act, a wholesaler's licence is not required for the supply by wholesale of a CTGT product that is a result of only minimal manipulation of cell or tissue if the person supplying by wholesale gives notice to the Authority in accordance with paragraph (2) and the notice is not refused, withdrawn or cancelled under these Regulations.

(2) The notice required for paragraph (1) for a CTGT product must —

(*a*) be in the form and manner specified on the Authority's website;

(*b*) be accompanied by the following information in writing:

(i) any information that the Authority requires relating to the particulars of the person giving the notice;

(ii) a description of the CTGT product concerned;

(iii) a statement of the supply by wholesale involved;

(iv) the premises where the supply by wholesale is being or is to be carried out; and

(*c*) be accompanied by the relevant fee specified in the Schedule.

Wholesale supply of CTGT product for research or non-clinical purposes

12. For purposes of section 14(1) of the Act, a wholesaler's licence is not required for the supply by wholesale of a CTGT product that —

(*a*) is solely for —

(i) the purpose of scientific education or research and development; or

(ii) a non-clinical purpose; and

(*b*) is not for any supply to the public.

Class 2 CTGT product transferred between healthcare institutions

13. For the purposes of section 14(1) of the Act, a wholesaler's licence is not required for the transfer by a healthcare institution licensee of a licensed healthcare institution to a healthcare institution licensee of another licensed healthcare institution of an unregistered Class 2 CTGT product that —

(*a*) is imported in accordance with the exception in regulation 9(1) for a qualified practitioner to administer to a patient of the qualified practitioner; or

(*b*) is manufactured for the administration to a patient of any qualified practitioner,

if the CTGT product is intended for administration to the same patient in that other licensed healthcare institution.

Wholesale supply of CTGT product imported solely for export

14.—(1) For the purposes of section 14(1) of the Act, a wholesaler's licence is not required for the supply by wholesale —

(*a*) of a CTGT product imported —

(i) under the authority of an importer's licence; and

(ii) solely for the purpose of export; and

(*b*) in accordance with the terms and conditions of the importer's licence.

(2) For the purposes of section 14(1) of the Act, a wholesaler's licence is not required for the supply by wholesale of a known importer of a CTGT product that is imported by the known importer solely for the purpose of export.

Wholesale supply of self-manufactured CTGT product

15. For the purposes of section 14(1) of the Act, a wholesaler's licence is not required for the supply by wholesale of a CTGT product by —

(*a*) a known manufacturer of that CTGT product; or

(*b*) a licensed manufacturer of that CTGT product,

if that manufacturer provides and maintains, or ensures the provision and maintenance of, the staff, premises, equipment and facilities for the distribution of the CTGT product that are necessary to prevent the deterioration of the CTGT product while it is in the manufacturer's ownership, possession or control.

Division 2 — Supply of CTGT product without registration

Prescribed exceptions

16.—(1) For the purposes of section 15(1) of the Act, the prescribed exceptions to the prohibition against the supply of an unregistered health product, are the following:

(*a*) the supply of a CTGT product by a qualified practitioner to the qualified practitioner's patient;

(*b*) the supply of a CTGT product by a licensed or known importer to a private hospital or medical clinic in accordance with the requirement in regulation 10(1)(*b*)(i);

(*c*) the supply by a healthcare institution licensee for a private hospital or medical clinic of a CTGT product that is imported under regulation 9(1) to a patient of a qualified practitioner practising at the private hospital or medical clinic;

(*d*) the supply by a healthcare institution licensee for a private hospital or medical clinic of a CTGT product that is imported in accordance with the requirement in regulation 10(1)(*b*)(i) or under regulation 9(1) to another private hospital or a medical clinic;

(*e*) the supply of a CTGT product that is manufactured at a private hospital or a medical clinic to —

(i) a patient of a qualified practitioner practising at the private hospital or medical clinic;

(ii) a patient of a qualified practitioner practising at another private hospital or medical clinic; or

(iii) another private hospital or medical clinic;

(*f*) the supply of a CTGT product for —

(i) the purpose of scientific education or research and development; or

(ii) a non-clinical purpose,

provided there is no supply of the CTGT product to the public;

(*g*) the supply by wholesale of a CTGT product that is —

(i) manufactured solely for export; or

(ii) imported solely for re-export;

(*h*) the supply in accordance with regulation 17 of a Class 1 CTGT product that is —

(i) manufactured by a licensed manufacturer or a known manufacturer who has given a notice to manufacture under regulation 4 that has not been refused, cancelled or withdrawn;

(ii) imported by a licensed importer or a known importer who has given a notice to import under regulation 7 that has not been refused, cancelled or withdrawn; or

(iii) supplied by a licensed wholesaler or a known wholesaler who has given notice to the Authority under regulation 11 to supply the CTGT product by wholesale and the notice has not been refused, cancelled or withdrawn.

(2) For the purposes of paragraph (1)(*h*), a CTGT product is treated as a Class 1 CTGT product if it would have been so assigned had the CTGT product been registered.

Supply of Class 1 CTGT product

17.—(1) For the purposes of section 17(1) of the Act and without affecting regulation 39, a person who supplies a Class 1 CTGT product in accordance with regulation 16 (except for paragraph (1)(f) and (*g*)) must, before every supply of the CTGT product —

(*a*) notify the Authority in the form and manner specified on the Authority's website of the supply of the CTGT product, and receive the Authority's written acceptance of the notification;

(*b*) provide the information to the Authority about the CTGT product that the Authority requires in the form and manner specified on the Authority's website;

(*c*) ensure, in relation to a CTGT product that is imported or obtained from a facility or establishment outside Singapore, that the facility or establishment is approved or licensed by the regulatory agency of the foreign jurisdiction, or accredited by an international accreditation body as specified by the Authority, to supply the CTGT product in that jurisdiction; and

(*d*) ensure that the CTGT product is free from infectious agents.

(2) For the purposes of paragraph (1), a CTGT product is treated as a Class 1 CTGT product if it would have been so assigned had the CTGT product been registered.

Duty to obtain consent and provide information for supply of unregistered Class 2 CTGT product in certain circumstances

18.—(1) A person may supply an unregistered Class 2 CTGT product under regulation 22 or 23 if the person obtains consent from the patient for the supply of that CTGT product.

(2) The consent mentioned in paragraph (1) must be obtained after the patient has been informed of all the following:

(*a*) that the CTGT product to be supplied to the patient has not been registered with or approved by the Authority;

(*b*) that the safety, efficacy and quality of the CTGT product to be supplied to the patient has not been evaluated by the Authority.

Supply of CTGT product manufactured under contractual agreement with licensed or known manufacturer

19.—(1) Without affecting any other provision in these Regulations, the prohibition in section 15(1) of the Act against the supply of a health product, unless the health product is registered, does not apply to a CTGT product that is manufactured in accordance with paragraph (2) and is supplied in either of the following cases:

(*a*) by a licensed manufacturer or known manufacturer to a private hospital or medical clinic for the use of a patient at that private hospital or medical clinic;

(*b*) by the holder of a healthcare institution licence for a private hospital or medical clinic to a patient at that private hospital or medical clinic.

(2) For the purposes of paragraph (1), if the CTGT product is a result of more than minimal manipulation of cell or tissue, the CTGT product must be manufactured —

(*a*) under an agreement between the licensed manufacturer and the holder of the healthcare institution licence for the private hospital or medical clinic;

(*b*) in accordance with its formulation and specifications, and the written instructions of a qualified practitioner practising at the private hospital or medical clinic for the use solely by or in connection with the patient at that hospital or clinic;

(*c*) in specified premises or any other premises that the Authority approves; and

(*d*) in accordance with the terms and conditions specified in the manufacturer's licence held by the licensed manufacturer.

(3) Paragraph (2)(*b*) does not apply to prohibit the supply of an unregistered CTGT product to any patient at the private hospital or medical clinic, if the requirements in paragraph (2)(*a*), (*c*) and (*d*) are

satisfied and the manufacture consists only of changing the outer package or other packaging in which the container is further enclosed for the purpose of dispensing the CTGT product.

Division 3 — Licences

Requirements for wholesaler's licence for CTGT product

20. For the purposes of section 24(2)(*a*)(i) of the Act, the applicant for a wholesaler's licence for the supply by wholesale of a CTGT product that is a result of more than minimal manipulation of cell or tissue must be able —

(*a*) to provide and maintain, or ensure the provision and maintenance of, the staff, premises, equipment and facilities for the handling and storage of the CTGT product that are necessary to prevent the deterioration of the CTGT product while it is in the applicant's ownership, possession or control; and

(*b*) to comply with the requirements in the Authority's Guidance Notes on Good Distribution Practice.

PART 5

SUPPLY REQUIREMENTS

Wholesale supply of Class 2 CTGT products

21.—(1) For the purposes of section 17(1) of the Act, the supply by wholesale of a Class 2 CTGT product by a person to another (called the recipient) must be in accordance with the following requirements —

(*a*) there is a written order, signed by the recipient —

(i) stating the recipient's name and address, trade, business or profession, and the name and total quantity of the Class 2 CTGT required for supply to the recipient; and

(ii) that is not cancelled before the supply is carried out;

(*b*) before each supply is carried out, the person must be satisfied that the recipient carries on the trade, business or profession stated in the order and that the trade, business or profession is one in which the Class 2 CTGT product is used; and

(*c*) after each supply is carried out, the person must insert in the appropriate entry in the record of supply prescribed by regulation 34(2)(*b*), a reference number by which the order can be identified.

(2) Paragraph (1) does not apply to the supply by wholesale of a Class 2 CTGT product under regulation 14 or 19.

Supply by retail sale of CTGT products

22. For the purposes of section 17(1) of the Act, a person must not supply by retail sale any CTGT product unless —

(*a*) the supply is made at or from a licensed retail pharmacy in accordance with regulation 3(1) and (2) of the Health Products (Licensing of Retail Pharmacies) Regulations 2016 (G.N. No. S 330/2016);

(*b*) the supply is made at or from a licensed healthcare institution to a patient of that healthcare institution, and in accordance with the written instructions of a qualified practitioner practising in that healthcare institution; or

(*c*) the person is a qualified practitioner or a person acting in accordance with the oral or written instructions of a qualified practitioner, and the supply is made to a patient under the care of the qualified practitioner.

Supply by administration of CTGT products

23. For the purposes of section 17(1) of the Act, a person must not administer any CTGT product to a patient unless the person is a qualified practitioner or a person acting in accordance with the oral or written instructions of a qualified practitioner.

Records of supply of prescribed CTGT products

24.—(1) A supplier must, in respect of the supply by retail sale of any CTGT product prescribed by a qualified practitioner, keep at the premises where or from which the CTGT product is supplied a record, complying with paragraphs (2) and (3), of every such supply.

(2) The record required under paragraph (1) must contain all the following particulars:

(*a*) the date of supply;

(*b*) the name, identity card or other identification document number, and contact details, of the person to whom the CTGT product is supplied;

(*c*) the name of the CTGT product, being either the proprietary name or the appropriate non-proprietary name, and the total amount supplied;

(*d*) if the CTGT product is supplied by a qualified pharmacist or a person acting under the supervision of a qualified pharmacist, or at or from a licensed retail pharmacy, the name and address of the qualified practitioner who signed the prescription.

(3) The record in paragraph (1) must be made on the day on which the CTGT product is supplied or, if that is not reasonably practicable, within 24 hours after that day, and must be kept for a period of at least 30 years after the expiry date of the CTGT product or any other shorter period that the Authority allows in a particular case.

(4) A supplier must make available for inspection by the Authority at all reasonable times any record made under paragraph (1).

Supply by dispensing CTGT products

25.—(1) For the purposes of section 17(1) of the Act, a relevant person may dispense a CTGT product only if the outer package or container of the CTGT product is labelled with all the following information in English:

(*a*) the name of the person to whom the CTGT product is to be administered;

(*b*) the name, address and any identification number or logo of the licensed healthcare institution or licensed retail pharmacy where the CTGT product is supplied or dispensed;

(*c*) the date that the CTGT product is dispensed;

(*d*) the directions for the use of the CTGT product;

(*e*) the name of the CTGT product, being either the proprietary name or the appropriate non-proprietary name;

(*f*) the qualitative and quantitative description of any active substance in the CTGT product;

(*g*) the conditions under which the CTGT product is to be stored;

(*h*) the appropriate control number, such as a serial number, batch number or lot number;

(*i*) the expiry date of the CTGT product in day (if applicable), month and year format and in a manner that avoids any confusion as to which is the day (if applicable), which is the month and which is the year;

(*j*) in relation to an autologous CTGT product, the unique patient identifier and the words "for autologous use only" or similar wordings;

(*k*) the list of excipients, including preservative systems, for the CTGT product;

(*l*) any warning that is necessary for the CTGT product;

(*m*) any precaution relating to the disposal of any unused CTGT product or any waste derived from the CTGT product (where appropriate) and any available collection system for the unused CTGT product or waste.

(2) A CTGT product may be dispensed only in accordance with the following requirements:

(*a*) where the qualified practitioner giving the prescription does not specify that the prescription is to be repeated, the relevant person dispensing the CTGT product must —

(i) when dispensing, mark the prescription in a manner so as to permanently attach the person's name and address and the dispensing date to the prescription; and

(ii) retain the prescription for a period of at least 2 years after dispensing the CTGT product;

(*b*) where the qualified practitioner giving the prescription specifies that the prescription may be repeated, the relevant person dispensing the CTGT product —

(i) must not dispense more than the total number of times specified on the prescription;

(ii) when dispensing, must mark the prescription in such a manner as to permanently attach the person's name and address and the dispensing date to the prescription; and

(iii) must retain the prescription for a period of at least 2 years after dispensing the CTGT product for the last time.

(3) In this regulation, "relevant person" means a qualified practitioner or a person acting under the supervision of a qualified practitioner.

PART 6

PRESENTATION OF CTGT PRODUCTS

Trade descriptions

26.—(1) For the purposes of section 18(1) of the Act, the presentation of a CTGT product must comply with all the following requirements:

(*a*) a trade description which is false or misleading must not be applied to the CTGT product;

(*b*) a trade description which explicitly or implicitly suggests that the supply or use of the CTGT product is promoted or endorsed by the Authority, the Ministry of Health or the

Health Promotion Board must not be applied to the CTGT product.

(2) For the purposes of paragraph (1)(*a*), a trade description is false or misleading if —

(*a*) it contains any false statement or information concerning the CTGT product; or

(*b*) it is likely to create an erroneous impression regarding the formulation, specifications, quality, safety, efficacy or uses of the CTGT product.

(3) For the purposes of paragraph (1), a person applies a trade description to a CTGT product if the person —

(*a*) affixes or annexes the trade description to, or in any manner marks it on or incorporates it in —

(i) the CTGT product; or

(ii) any thing in or on the CTGT product or with which the CTGT product is supplied;

(*b*) places the CTGT product in, on or with any thing which the trade description has been affixed or annexed to, marked on or incorporated in; or

(*c*) makes any oral or written statement of the trade description, or uses the trade description in any other manner, which is likely to be understood as referring to the CTGT product.

(4) A person supplying a CTGT product is taken to have applied a trade description to the CTGT product if —

(*a*) the CTGT product is supplied pursuant to a request in which the trade description is used; and

(*b*) it is reasonable in the circumstances to infer that any CTGT product so supplied will correspond to that trade description.

Information to be provided with CTGT products

27.—(1) In addition to regulation 26, a CTGT product must, for the purposes of section 18(1) of the Act, be accompanied by all the following information (where applicable) when it is supplied:

(*a*) the name of the CTGT product, being the proprietary name and the appropriate non-proprietary name;

(*b*) the qualitative and quantitative description of any active substance in the CTGT product;

(*c*) an appropriate control number, such as a serial number, batch number or lot number;

(*d*) the expiry date of the CTGT product in day (if applicable), month and year format and in a manner that avoids any confusion as to which is the day (if applicable), which is the month and which is the year;

(*e*) where the CTGT product is registered, the registration number assigned to the registered CTGT product by the Authority;

(*f*) the conditions under which the CTGT product must be stored;

(*g*) in relation to an autologous CTGT product, the unique patient identifier and the words "for autologous use only" or similar wordings;

(*h*) the list of excipients, including preservative systems, for the CTGT product;

(*i*) any warning that is necessary for the CTGT product;

(*j*) any precaution relating to the disposal of any unused CTGT product or any waste derived from the CTGT product (where appropriate) and any available collection system for the unused CTGT product or waste;

(*k*) the name and address of the registrant or the manufacturer, as the case may be.

(2) All information accompanying the CTGT product mentioned in paragraph (1) —

(*a*) must be provided in English; and

(*b*) must be legible and indelible.

Re-labelling of unregistered Class 2 CTGT products without manufacturer's licence or notice

28. Without affecting regulation 27, a person who imports, or supplies by wholesale, any unregistered Class 2 CTGT product, at the request of a qualified practitioner for the use of the qualified practitioner's patient, may attach a different label to that CTGT product without holding a manufacturer's licence.

Corrective measures in relation to contravening trade descriptions or failure to provide prescribed information

29.—(1) Where any manufacturer, importer, supplier or registrant of a CTGT product has applied a trade description in contravention of regulation 26, the Authority may order that manufacturer, importer, supplier or registrant (as the case may be) to do all or any of the following:

(*a*) to stop disseminating, publishing or using the trade description with immediate effect;

(*b*) to stop applying the trade description to the CTGT product, or to stop supplying the CTGT product applied with the trade description, with immediate effect;

(*c*) to take any measures that may be reasonable and necessary in the circumstances to discontinue or remove any trade description that may already have been applied, disseminated, published or used;

(*d*) to apply, disseminate or publish a corrective trade description in the manner and containing the information that the Authority requires.

(2) Where any manufacturer, importer, supplier or registrant of a CTGT product fails to provide any information required by regulation 27 to accompany the supply of the CTGT product, the Authority may order that manufacturer, importer, supplier or registrant (as the case may be) to take the corrective measures that the Authority requires, including —

(*a*) to stop supplying the CTGT product with immediate effect; or

(*b*) to take any measures that may be reasonable and necessary in the circumstances to ensure that the CTGT product is only supplied with the required information.

(3) A person to whom an order under paragraph (1) or (2) is directed must comply with the order at the person's own cost and within the time specified in the order or, if no time is specified in the order, within a reasonable time after the date of the order.

(4) A person who fails to comply with paragraph (3) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

(5) Without affecting paragraph (4), the Authority may take any steps that the Authority thinks reasonable and necessary to implement the requirements of an order directed to any person under paragraph (1) or (2), and recover any costs and expenses reasonably incurred by the Authority in so doing from the person.

PART 7

REGISTRATION OF CTGT PRODUCTS

Requirements for registration

30. For the purposes of section 30(2)(*a*)(iii) of the Act, the Authority may, after carrying out an evaluation under section 33 of the Act, register a Class 2 CTGT product, if the Authority is satisfied —

(*a*) that the overall intended benefits to a patient to whom the CTGT product is administered outweigh the overall risks associated with the administration of the CTGT product; and

(*b*) based on the formulation, manufacturing process controls, specifications and shelf life of the CTGT product, and the stability of the CTGT product under the recommended storage conditions, that the CTGT product is suitable for its intended purpose and that any risk associated with its administration is minimised.

Disclosure of information on applications for registration

31. For the purposes of section 66(2)(*d*) of the Act, the Authority may disclose, for the information of the public and in the manner determined by the Authority, any particulars of applications for the registration of CTGT products which it receives that it determines, provided that the particulars to be disclosed under this regulation exclude —

(*a*) any trade secret; and

(*b*) any information that has commercial value that would be, or would be likely to be, diminished by the disclosure.

PART 8

DUTIES AND OBLIGATIONS OF MANUFACTURERS, IMPORTERS, ETC., OF CTGT PRODUCTS

Division 1 — General duties

Routine inspections, etc

32.—(1) An enforcement officer may conduct routine inspections of —

(*a*) any premises that are used for the manufacture, supply or storage of CTGT products; and

(*b*) any conveyance that is being used for the transport of CTGT products.

(2) An enforcement officer conducting a routine inspection under paragraph (1) may —

(*a*) require any person having possession or control of any CTGT product that is found during the inspection to provide, without charge, a sample of that CTGT product for the Authority's examination; and

(*b*) take or cause to be taken any photograph of —

(i) the premises or conveyance mentioned in paragraph (1); or

(ii) any property or material found on the premises or in the conveyance.

Duty to maintain records of manufacture

33.—(1) A manufacturer of a CTGT product must maintain records of —

(*a*) any information relating to the CTGT product and its manufacture that the Authority specifies on the Authority's website or, if the manufacturer is the holder of a manufacturer's licence, in the manufacturer's licence; and

(*b*) the manufacture of each batch of the CTGT product and of the tests carried out on each batch, in the manner specified on the Authority's website or in the relevant licence issued by the Authority, if applicable.

(2) The manufacturer must maintain for any CTGT product the records mentioned in paragraph (1) —

(*a*) where the records do not relate to traceability, for the longer of the following periods:

(i) one year after the expiry date of the CTGT product;

(ii) 5 years after the date of manufacture of the CTGT product; and

(*b*) where the records relate to traceability, 30 years after the expiry date of the CTGT product or any other shorter period that the Authority allows in a particular case.

(3) A manufacturer of a CTGT product who fails to comply with paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) A person who, in compliance or purported compliance with paragraph (1), provides the Authority or an enforcement officer with any record which the person knows is false or misleading shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duty to maintain records of receipt and supply

34.—(1) Paragraphs (2) and (3) apply to a person (*P*) who is —

(*a*) a manufacturer, importer, wholesaler or registrant of a CTGT product; or

(*b*) the supplier of a CTGT product in accordance with regulation 9 or 16(1)(*a*), (*b*) or (*e*).

(2) *P* must —

(*a*) if *P* is not the manufacturer of the CTGT product, maintain a record of every receipt by *P* of the CTGT product;

(*b*) maintain a record of every supply by *P* of the CTGT product; and

(*c*) produce for inspection by the Authority or an enforcement officer the record of every receipt or supply as and when required by the Authority or enforcement officer.

(3) *P* must ensure that every record mentioned in paragraph (2) —

(*a*) contains, in relation to each receipt by *P* of the CTGT product, all the following information:

(i) the proprietary name or appropriate non-proprietary name of the CTGT product, if the CTGT product is supplied by a manufacturer, importer or wholesaler, as the case may be;

(ii) the date on which the CTGT product is received;

(iii) the name and address of the person from whom the CTGT product is received;

(iv) the quantity of the CTGT product received;

(v) the identification number (including the control number, lot number, batch number or serial number) of the CTGT product received;

(*b*) contains, in relation to each supply by *P* of the CTGT product, all the following information:

(i) the proprietary name or appropriate non-proprietary name of the CTGT product;

(ii) the date on which the CTGT product is supplied;

(iii) the name and address of the person to whom the CTGT product is supplied;

(iv) the quantity of the CTGT product supplied;

(v) the identification number (including the control number, lot number, batch number or serial number) of the CTGT product supplied; and

(*c*) is retained for at least 30 years after the expiry date of the CTGT product or any other shorter period that the Authority allows in a particular case.

(4) A person who fails to comply with paragraph (2) or (3) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(5) A person who, in compliance or purported compliance with paragraph (2) or (3), provides the Authority or an enforcement officer with any record which the person knows is false or misleading shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duty to maintain system of traceability

35.—(1) Every manufacturer, importer, supplier or registrant of a CTGT product must establish and maintain a system of traceability that complies with paragraph (2).

(2) The system mentioned in paragraph (1) must at the minimum enable the traceability of the CTGT product and its starting and raw materials, including all substances that may come into contact with the cells or tissue it contains during any of the following processes:

(*a*) sourcing;

(*b*) procurement;

(*c*) processing;

(*d*) testing;

(*e*) packaging;

(*f*) storage;

(*g*) transport;

(*h*) delivery to the licensed healthcare institution or the licensed retail pharmacy where the CTGT product is used, administered, supplied or disposed, as the case may be.

(3) Every supplier must ensure that a system of traceability is in place and maintained at or from a licensed healthcare institution or a licensed retail pharmacy in order that that the CTGT product administered or supplied may be linked to the patient who received it, and vice versa.

(4) Every manufacturer, importer, supplier or registrant mentioned in paragraphs (1) and (3) must keep all data obtained from the system of traceability for at least 30 years after the expiry date of the CTGT product or any other shorter period that the Authority allows in a particular case.

(5) A person who fails to comply with paragraph (1), (2), (3) or (4) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(6) A person who, in compliance or purported compliance with paragraph (1), (2), (3) or (4), provides the Authority or an enforcement officer with any record which the person knows is false or misleading shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duty to maintain records of defects and adverse effects

36.—(1) Every manufacturer, importer or registrant of a CTGT product must —

(*a*) maintain a record of every event or other occurrence that reveals any defect in the CTGT product or that concerns any

adverse effect arising from the administration of the CTGT product; and

(*b*) produce that record for inspection by the Authority or an enforcement officer as and when required by the Authority or enforcement officer.

(2) A person mentioned in paragraph (1) must ensure that every record mentioned in that paragraph —

(*a*) contains all the following information:

(i) the proprietary name or appropriate non-proprietary name of the CTGT product which is defective or of which an adverse effect has arisen from its administration;

(ii) the date on which the person first became aware of the event or occurrence;

(iii) the identification number or mark (including the control number, lot number, batch number or serial number) of the CTGT product;

(iv) the nature of the defect or adverse effect;

(v) any other information that the Authority specifies in writing; and

(*b*) is retained for at least 2 years after the expiry date of the CTGT product.

(3) A person who fails to comply with paragraph (1) or (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) A person who, in compliance or purported compliance with paragraph (1) or (2), provides the Authority or an enforcement officer with any record which the person knows is false or misleading shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duty to report defects and adverse effects

37.—(1) For the purposes of section 42(1)(*a*) of the Act, every manufacturer, importer, supplier or registrant of a CTGT product must, upon becoming aware of any defect in the CTGT product, report the defect to the Authority —

(*a*) if the defect represents a serious threat to persons or public health, within 48 hours; or

(*b*) in all other cases, within 15 days,

after the manufacturer, importer, supplier or registrant (as the case may be) first receives notice of the defect.

(2) For the purposes of section 42(1)(*b*) of the Act, every manufacturer, importer, supplier or registrant of a CTGT product must, upon becoming aware of any serious adverse reaction arising from the administration of the CTGT product, report the serious adverse reaction to the Authority immediately, but in any case no later than 15 days after the manufacturer, importer, supplier or registrant first becomes aware of the serious adverse reaction.

(3) In this regulation, "serious adverse reaction" means an adverse effect that is unintended and occurs in association with the administration of a CTGT product in humans, and that —

(*a*) may result in a person's death;

(*b*) may threaten a person's life;

(*c*) results in a person being hospitalised or prolongs a person's existing stay in hospital;

(*d*) results in a person's persistent or significant disability or incapacity;

(*e*) results in a congenital anomaly or birth defect; or

(*f*) is judged to be medically important even though the effect might not be immediately life-threatening or result in death or hospitalisation, but may jeopardise the person's health or may require intervention to prevent the person's death or one of the other outcomes mentioned in sub-paragraphs (*c*), (*d*) and (*e*).

Duty to notify Authority concerning recall

38.—(1) For the purposes of section 44(1) of the Act, every manufacturer, importer, supplier or registrant of a CTGT product who recalls or intends to recall a CTGT product must immediately, but in any case no later than 24 hours before the start of the recall or intended recall, notify the Authority of, and the reasons for, the recall or the intended recall.

(2) The notice in paragraph (1) must be made in the form and manner that the Authority requires.

(3) Where the Authority has been notified of the recall or the intended recall of a CTGT product under paragraph (1), the Authority may by notice require the manufacturer, importer, supplier or registrant of the CTGT product to do either or both of the following:

(*a*) investigate the matter occasioning the recall of the CTGT product and provide a report of the findings of the investigation to the Authority;

(*b*) take any other measures that the Authority thinks necessary.

(4) A person to whom a notice in paragraph (3) is given must comply with the notice at the person's own cost and within the time specified in the notice or, if no time is specified in the notice, within a reasonable time after the date of the notice.

(5) A person who fails to comply with paragraph (4) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Duty of supplier of unregistered Class 1 CTGT product to provide information

39. Where a CTGT product would have been assigned to Class 1 had it been registered and the CTGT product is supplied without being registered in accordance with regulation 19, the Authority may, under section 41(1) of the Act, by notice, require the supplier of the CTGT product to provide to the Authority, within the time specified in the notice, the name and address of the manufacturer, importer or

wholesaler (as the case may be), from whom the supplier obtained the CTGT product.

Division 2 — Duties specific to licensed and known manufacturers, importers and wholesalers

Duty of licensed or known manufacturer

40.—(1) Without affecting any other provision in this Part, a licensed manufacturer or a known manufacturer of a CTGT product —

(*a*) must ensure, and maintain objective evidence to establish, that the manufacture of the CTGT product complies with the following standards:

(i) in the case of a known manufacturer — Good Tissue Practice;

(ii) in the case of a licensed manufacturer — Good Manufacturing Practice Standard;

(*b*) must provide and maintain, or ensure the provision and maintenance of, the staff, premises, equipment and facilities that are necessary for carrying out, in accordance with the manufacturer's licence or the notice given under regulation 4, those stages of the manufacture of the CTGT product that are undertaken by the manufacturer;

(*c*) must not carry out any stages of manufacture of the CTGT product in any premises that are not specified premises;

(*d*) must provide and maintain, or ensure the provision and maintenance of, the staff, premises, equipment and facilities for the handling and storage of the CTGT product that are necessary to prevent the deterioration of the CTGT product while it is in the manufacturer's ownership, possession or control;

(*e*) must only use the specified premises, or any other premises that the Authority approves, for handling or storing the CTGT product;

(*f*) must carry out, or arrange for a testing laboratory to carry out, tests on the strength, quality and purity of the CTGT product to ensure that the standards of the CTGT product comply with any applicable standard set by the Authority for the CTGT product;

(*g*) must conduct all manufacturing operations in such a way as to ensure that the CTGT product is of the correct identity and conforms with the applicable standards of strength, quality and purity; and

(*h*) must ensure that any tests for determining conformity with the applicable standards and specifications applying to the CTGT product are, unless otherwise provided in the licence or the notice given under regulation 4, applied to samples taken after all manufacturing processes have been completed, or at any earlier stage in the manufacture that the Authority approves.

(2) In this regulation, "testing laboratory" means —

(*a*) in the case of a known manufacturer — a testing laboratory determined by the known manufacturer; or

(*b*) in the case of a licensed manufacturer — the testing laboratory specified in the licence.

Duty of licensed or known importer

41. Without affecting any other provision in this Part, a licensed importer or a known importer of a CTGT product —

(*a*) must ensure, and maintain objective evidence to establish, that the handling and storage of the CTGT product complies with the following standards:

(i) in the case of a known importer — the Authority's Guidance Notes on Good Distribution Practice, Good Distribution Practice Standard for Medical Devices or ISO 13485;

(ii) in the case of a licensed importer — the Authority's Guidance Notes on Good Distribution Practice as specified on the Authority's website;

if the CTGT product —

(iii) is imported on behalf of a healthcare institution licensee for a private hospital or medical clinic pursuant to a valid prescription given by a qualified practitioner practising at the private hospital or medical clinic for the use of the qualified practitioner's patient;

(iv) is authorised for import by the registrant of the CTGT product; or

(v) is in all respects the same as a registered CTGT product, the registrant of which has not authorised the applicant to import that registered CTGT product;

(*b*) must provide and maintain, or ensure the provision and maintenance of, the staff, premises, equipment and facilities for the handling and storage of the CTGT product that are necessary to prevent the deterioration of the CTGT product while it is in the importer's ownership, possession or control; and

(*c*) must not use, for any purpose mentioned in paragraph (*b*), any premises other than the specified premises, or any other premises that the Authority approves.

Duty of licensed or known wholesaler

42. Without affecting any other provision in this Part, a licensed wholesaler or a known wholesaler of a CTGT product —

(*a*) must ensure, and maintain objective evidence to establish, that the handling, storage and distribution of the CTGT product complies with the following standards:

(i) in the case of a known wholesaler — the Authority's Guidance Notes on Good Distribution Practice, Good

Distribution Practice Standard for Medical Devices or ISO 13485;

(ii) in the case of a licensed wholesaler — the Authority's Guidance Notes on Good Distribution Practice;

(*b*) may only supply the CTGT product by wholesale to a person who may lawfully supply that CTGT product in accordance with the Act;

(*c*) must provide and maintain, or ensure the provision and maintenance of, the staff, premises, equipment and facilities for the handling, storage and distribution of the CTGT product that are necessary to prevent the deterioration of the CTGT product while it is in the wholesaler's ownership, possession or control; and

(*d*) must not use, for any purpose mentioned in paragraph (*c*), any premises other than the specified premises, or any other premises that the Authority approves.

Duty of known manufacturer, importer or wholesaler to provide information

43. Where a CTGT product that is the result of only minimal manipulation of cell or tissue, the Authority may, under section 41(1) of the Act, by notice, require the known manufacturer, known importer or known wholesaler (as the case may be) relating to that CTGT product to provide to the Authority, within the time specified in the notice, any information relating to that CTGT product that the Authority requires.

Responsible person

44.—(1) A holder of a licence must appoint one or more persons as a responsible person to be named as such in the licence.

(2) The holder of a licence must ensure that —

(*a*) the responsible person has adequate knowledge of the activities to be carried out and of the procedures to be performed under the licence;

(*b*) the responsible person has relevant working experience relating to those activities and procedures;

(*c*) in the case of a manufacturer's licence, the responsible person named in the licence has practical experience in production supervision or in testing and checking to ensure the quality of CTGT products or any other health products that are related to the CTGT products;

(*d*) in the case of an importer's licence or wholesaler's licence for the import or supply of any CTGT product, the responsible person named in the licence has practical experience in the handling, storage and distribution of CTGT products to ensure their quality or any other practical experience that the Authority approves; and

(*e*) at any time, there is at least one responsible person who is contactable by the Authority by way of a mobile telephone number or an email address.

(3) The holder of a licence must ensure that the responsible person discharges the duties imposed on the responsible person by the terms of the licence.

(4) The holder of a licence must ensure that no person other than the person named as the responsible person in the licence may act as the responsible person.

Offence for contravention of duties

45. A person who fails to comply with regulation 40, 41, 42 or 44 shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Changes affecting licences

46.—(1) A licensee must notify the Authority of —

(*a*) any change or proposed change to any particulars provided by the licensee to the Authority in relation to the application for the licensee's licence; and

(*b*) any change or proposed change that significantly affects the activities of the licensee that are authorised by that licence.

(2) A notice under paragraph (1) must —

(*a*) be made in the form and manner that the Authority requires;

(*b*) be submitted within the time that the Authority specifies in the conditions of the licence;

(*c*) be accompanied by the particulars, information, documents and samples that the Authority requires;

(*d*) be accompanied by the relevant fee specified in the Schedule; and

(*e*) if required by the Authority, be accompanied by a statutory declaration by the licensee verifying any information contained in or relating to the notice.

(3) A licensee must not, without the Authority's approval, make any change that significantly affects the activities of the licensee that are authorised by the licensee's licence.

(4) An application for the Authority's approval under paragraph (3) must be made in the form and manner specified on the Authority's website.

(5) For the purposes of paragraphs (1) and (3), a change that significantly affects the activities of a licensee that are authorised by the licensee's licence includes a change of one or more of the following:

(*a*) the premises where the licensee operates;

(*b*) the facilities and equipment used by the licensee;

(*c*) the operations and processes carried out by the licensee;

(*d*) the responsible person mentioned in regulation 44.

(6) A licensee who fails to comply with paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(7) A licensee who —

(*a*) in compliance or purported compliance with paragraph (1), provides the Authority with any notice under paragraph (1) which the licensee knows is false or misleading; or

(*b*) fails to comply with paragraph (3),

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Changes affecting notices

47.—(1) A known manufacturer, known importer or known wholesaler of a CTGT product must —

(*a*) inform the Authority in writing of any change in any information earlier provided in the notice given by the known manufacturer, known importer or known wholesaler under regulation 4, 7 or 11 (as the case may be), within 14 days after that change occurred; and

(*b*) give notice to the Authority in the form and manner that the Authority determines that the person has ceased to manufacture, import or supply (as the case may be) the CTGT product.

(2) A person who fails to comply with paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

False notice

48. A person who, in relation to any notice given under regulation 4, 7 or 11 (as the case may be) or 47 —

(*a*) makes any statement or furnishes any document which the person knows to be false in a material particular; or

(*b*) by the intentional suppression of any material fact, furnishes information which is misleading in a material particular,

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Division 3 — Duties specific to registrants

Changes concerning registered CTGT products

49.—(1) A registrant of a registered CTGT product must, unless the change is of a type specified on the Authority's website to be one for which the Authority's approval is not required, obtain the Authority's prior approval before effecting —

(*a*) any change to any particulars provided in relation to the registration of the CTGT product; or

(*b*) any change that may affect the quality, safety or efficacy of the CTGT product.

(2) An application for the Authority's approval under paragraph (1) must —

(*a*) be made in the form and manner that the Authority requires;

(*b*) be submitted within the time that the Authority specifies in the conditions of the registration of the CTGT product;

(*c*) be accompanied by the particulars, information, documents and samples that the Authority requires;

(*d*) be accompanied by the relevant fee specified in the Schedule; and

(*e*) if required by the Authority, be accompanied by a statutory declaration by the registrant verifying any information contained in or relating to the application.

(3) Where the Authority's approval is required under paragraph (1), the registrant of the CTGT product must ensure that no supply is made of the CTGT product that is subject to the proposed change until after the Authority has given its approval for the change.

(4) A registrant of a CTGT product who fails to comply with paragraph (1) shall be guilty of an offence and shall be liable on

conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(5) A registrant of a CTGT product who —

(*a*) in compliance or purported compliance with paragraph (1), provides the Authority with any information under paragraph (1) which the registrant knows is false or misleading; or

(*b*) fails to comply with paragraph (3),

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Information on validity of data submitted to or considered by Authority

50.—(1) A registrant of a CTGT product must, within 15 days after receiving any information that adversely affects the validity of any data provided by the registrant to the Authority relating to the quality, safety or efficacy of any CTGT product to which the registrant's registration relates, inform the Authority of that information.

(2) A registrant of a CTGT product who fails to comply with paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(3) A registrant of a CTGT product who, in compliance or purported compliance with paragraph (1), provides the Authority with any information which the registrant knows is false or misleading, shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $20,000 or to imprisonment for a term not exceeding 12 months or to both.

Submission of benefit-risk evaluation reports

51.—(1) The Authority may require any registrant of a CTGT product to submit, within the period specified by the Authority, a benefit-risk evaluation report relating to the CTGT product.

(2) Where the Authority has not specified any period within which a benefit-risk evaluation report is required to be submitted, a registrant of a CTGT product who is required by the Authority to submit that report must submit the report —

(*a*) for an initial period of 2 years, at intervals of 6 months commencing from either the date of registration of the CTGT product, or its international birth date, whichever is earlier; and

(*b*) for the next 3 years, annually.

(3) A person who fails to provide a benefit-risk evaluation report —

(*a*) as required by the Authority under paragraph (1); or

(*b*) within the period stipulated under paragraph (2),

shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

(4) In paragraph (2)(*a*), "international birth date", for a CTGT product, means the date of the first marketing approval granted to any person for the sale of the CTGT product in any country in the world.

Duty to carry out risk management plan

52.—(1) The Authority may, for the purposes of minimising risks relating to unsafe and inefficacious use of CTGT products, direct a registrant of a CTGT product to implement a risk management plan which includes, but is not limited to, the following:

(*a*) producing and distributing educational material;

(*b*) producing and distributing safety information;

(*c*) performing clinical studies of the CTGT product;

(*d*) implementing active surveillance programmes of the CTGT product;

(*e*) implementing programmes to restrict the supply of the CTGT product.

(2) A registrant of a CTGT product who fails to comply with a direction of the Authority under paragraph (1) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

PART 9

MISCELLANEOUS

Certification of CTGT products intended for export

53.—(1) The Authority may, on the application of a person who intends to export a CTGT product, issue to the person a certificate certifying —

(*a*) in a case where the CTGT product is registered under the Act, that it is so registered; or

(*b*) in a case where the CTGT product is not so registered, that it complies with the standards or requirements specified in the certificate.

(2) An application for a certificate under paragraph (1) must —

(*a*) be made in the form and manner specified on the Authority's website; and

(*b*) be accompanied by the relevant fee specified in the Schedule.

Certificate of manufacturing standard of CTGT products

54.—(1) The Authority may, on the application of a person who manufactures —

(*a*) a CTGT product; or

(*b*) an active substance or starting material used in the manufacture of a CTGT product,

(called the manufacturer) and on being satisfied, after completion of an assessment of conformity, that the manufacturer conforms to an applicable Good Manufacturing Practice Standard, issue a GMP Certificate to the manufacturer subject to any terms and conditions that the Authority thinks fit.

(2) Every GMP Certificate issued is valid for the period specified in the certificate, being not longer than 3 years starting on the date of commencement of the assessment mentioned in paragraph (1).

(3) An application for a GMP Certificate must —

(*a*) be made in the form and manner specified on the Authority's website; and

(*b*) be accompanied by the relevant fee specified in the Schedule.

(4) In this regulation and the Schedule, "GMP Certificate" means a certificate issued by the Authority to certify compliance with an applicable Good Manufacturing Practice Standard.

Certificate of distribution standard of CTGT products

55.—(1) The Authority may, on the application of a person who distributes a CTGT product and on being satisfied, after completion of an assessment of conformity, that the person conforms to an applicable Good Distribution Practice Standard, issue a GDP Certificate to the person subject to any terms and conditions as the Authority thinks fit.

(2) Every GDP Certificate issued is valid for a period specified in the certificate, being not longer than 3 years starting on the date of commencement of the assessment mentioned in paragraph (1).

(3) An application for a GDP Certificate must —

(*a*) be made in the form and manner specified on the Authority's website; and

(*b*) be accompanied by the relevant fee specified in the Schedule.

(4) In this regulation and the Schedule —

"GDP Certificate" means a certificate issued by the Authority to certify compliance with an applicable Good Distribution Practice Standard;

"Good Distribution Practice Standard" means the Authority's Guidance Notes on Good Distribution Practice and any other good distribution practice standard approved by the Authority.

Other certificates or documents

56. The Authority may, on the application of any person and upon payment of the relevant fee specified in the Schedule, issue any other certificate or document to the applicant that the Authority thinks fit.

Product quality surveillances

57.—(1) The Authority may at any time conduct a product quality surveillance for the purposes of ensuring that a CTGT product is not a non-compliant health product within the meaning of section 48(*a*) of the Act.

(2) The Authority may require a manufacturer, importer, wholesaler, supplier or registrant of a CTGT product to provide, without charge, any number of samples of the CTGT product for evaluation by the Authority in the product quality surveillance.

(3) A person who fails to comply with a requirement of the Authority under paragraph (2) shall be guilty of an offence and shall be liable on conviction to a fine not exceeding $10,000 or to imprisonment for a term not exceeding 6 months or to both.

Non-compliant CTGT products

58. For the purposes of section 48(*a*)(iii) of the Act, a CTGT product is considered as being non-compliant if it fails to comply with the product quality characteristics, specifications and labelling approved by the Authority —

(*a*) at the time of the registration of the CTGT product; or

(*b*) under regulation 49.

Confidential information

59. For the purposes of section 66(2)(*d*) of the Act, the Authority may disclose any confidential information relating to the quality, safety or efficacy of a CTGT product, if —

(*a*) that disclosure is, in the opinion of the Authority, necessary to protect the health or safety of members of the public; or

(*b*) that disclosure is to a Government department or statutory body in order to enable the Government department or statutory body to perform its public functions.

Fees

60.—(1) The fees specified in the Schedule are payable in respect of the matters set out in that Schedule.

(2) An application fee mentioned in the Schedule must be paid when the application is submitted to the Authority.

(3) An evaluation fee for the registration of a CTGT product specified in the Schedule is payable upon the Authority's acceptance of the CTGT product for evaluation after the Authority has conducted an initial screening.

(4) For the purposes of section 31(*a*) of the Act, the prescribed retention fee is set out in the Schedule and is payable on or before each anniversary of the date of registration of the CTGT product.

(5) For the purposes of section 37(2) of the Act, the Authority may cancel the registration of a CTGT product if the retention fee is not paid within 60 days after the anniversary of the date of the registration of the CTGT product.

(6) The Authority may, in any particular case or class of cases, waive or refund the whole or any part of any fee payable or paid under these Regulations.

THE SCHEDULE

FEES

[TO BE CONFIRMED]