

Health Products (Cell, Tissue and Gene Therapy Products) Regulations 2021

Table of Contents

Enacting Formula

Part 1 PRELIMINARY

1 Citation and commencement

2 Definitions

3 Clinical research CTGT products excluded

Part 2 CTGT PRODUCT MANUFACTURE — LICENSING AND EXCEPTIONS

Division 1 — Exceptions to need for licence

4 Manufacturing minimally manipulated CTGT products

5 Manufacturing other CTGT products for research or non-clinical purposes

Division 2 — Licences

6 Requirements for manufacturer's licence for CTGT products

Part 3 CTGT PRODUCT IMPORT — LICENSING AND EXCEPTIONS

Division 1 — Exceptions to need for licence

7 Importing minimally manipulated CTGT products

8 Importing to manufacture CTGT products

Division 2 — Licences

9 Requirements for importer's licence for CTGT products

Part 4 CTGT PRODUCT SUPPLY — LICENSING AND EXCEPTIONS

Division 1 — Exceptions to need for licence

10 Supplying minimally manipulated CTGT products by wholesale

11 Wholesale supply of other CTGT products for research or non-clinical purposes

12 Class 2 CTGT products transferred between healthcare institutions

13 Wholesale supply of CTGT products imported solely for export

14 Wholesale supply of self-manufactured CTGT products

Division 2 — Supply of CTGT products without registration

15 Prescribed exceptions

16 Supply of Class 1 CTGT products

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

18 Supply of CTGT products manufactured under agreement with licensed or known manufacturer

Division 3 — Licences

19 Requirements for wholesaler's licence for CTGT products

Part 5 SUPPLY REQUIREMENTS

20 Wholesale supply of Class 2 CTGT products

21 Supply by retail sale of CTGT products

22 Supply by administration of CTGT products

23 Records of supply of prescribed CTGT products

Part 6 PRESENTATION OF CTGT PRODUCTS

24 Trade descriptions

25 Information to be provided with CTGT products

26 Supply by dispensing CTGT products

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

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

Part 7 REGISTRATION OF CTGT PRODUCTS

29 Requirements for registration

30 Disclosure of information on applications for registration

Part 8 DUTIES AND OBLIGATIONS OF MANUFACTURERS, IMPORTERS, ETC., OF CTGT PRODUCTS

Division 1 — General duties

31 Routine inspections, etc.

32 Duty to maintain records of manufacture

33 Duty to maintain records of receipt and supply

34 Duty to maintain system of traceability

35 Duty to maintain records of defects and adverse effects

36 Duty to report defects and adverse effects

37 Duty to notify Authority concerning recall

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

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

39 Duty of licensed or known manufacturer

40 Duty of licensed or known importer

41 Duty of licensed or known wholesaler

42 Duty of known manufacturer, importer or wholesaler to provide information

43 Responsible person

44 Offence for contravention of duties

45 Changes affecting licences

46 Changes affecting notices

47 False notice

Division 3 — Duties specific to registrants

48 Changes concerning registered CTGT products

49 Information on validity of data submitted to or considered by Authority

50 Submission of benefit-risk evaluation reports

51 Duty to carry out risk management plan

Part 9 CERTIFICATION

52 Certification of CTGT products intended for export

53 Certificate of manufacturing standard of CTGT products

54 Certificate of distribution standard of CTGT products

55 Other certificates or documents

Part 10 GENERAL PROVISIONS

56 Product quality surveillances

57 Non-compliant CTGT products

58 Confidential information

59 Fees

60 Saving and transitional provisions

THE SCHEDULE Fees

No. S 104

**HEALTH PRODUCTS ACT
(CHAPTER 122D)**

**HEALTH PRODUCTS
(CELL, TISSUE AND GENE THERAPY PRODUCTS)
REGULATIONS 2021**

In exercise of the powers conferred by sections 45, 71(1) and 72(1) of the Health