# Pharmacy and Poisons (Amendment) Bill 2019

## Contents

# A BILL

# To

Amend the Pharmacy and Poisons Ordinance and the Pharmacy and Poisons Regulations to regulate the manufacture, supply and labelling of, and the keeping of records relating to, advanced therapy products; and to provide for related matters.

Enacted by the Legislative Council.

## Part 1

## Preliminary

**1. Short title and commencement**

(1) This Ordinance may be cited as the Pharmacy and Poisons (Amendment) Ordinance 2019.

(2) This Ordinance comes into operation on a day to be appointed by the Secretary for Food and Health by notice published in the Gazette.

**2. Enactments amended**

The enactments specified in Parts 2 and 3 are amended as set out in those Parts.

# Part 2

# Amendments to Pharmacy and Poisons Ordinance (Cap. 138)

**3. Section 2 amended (interpretation)**

(1) Section 2(1)—

**Repeal the definition of *manufacture***

**Substitute**

"***manufacture*** (製造), in relation to a pharmaceutical product—

(a) means—

(i) the preparation of the product, from purchase or acquisition of materials, through processing and packaging, to its completion as a finished product for clinical trial, sale or distribution; or

(ii) the repackaging of the product as a finished product for clinical trial, sale or distribution; but

(b) does not include the individual dispensing on a prescription or otherwise of the product if the product—

(i) is not an advanced therapy product; or

(ii) is an advanced therapy product the dispensing of which does not involve substantial manipulation of cells or tissues;".

(2) Section 2(1)—

**Repeal the definition of *pharmaceutical product* and *medicine*.**

(3) Section 2(1)—

**Add in alphabetical order**

"***advanced therapy product*** (先進療法製品) means any of the following products that is for human use—

(a) a gene therapy product;

(b) a somatic cell therapy product;

(c) a tissue engineered product;

***gene therapy product*** (基因療法製品)—

(a) means a product—

(i) that contains an active substance containing or consisting of a recombinant nucleic acid that may be used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence; and

(ii) the therapeutic, prophylactic or diagnostic effect of which relates directly to—

(A) the recombinant nucleic acid sequence it contains; or

(B) the product of genetic expression of that sequence; but

(b) does not include a vaccine against an infectious disease;

***manufacturer*** (製造商), in relation to a pharmaceutical product, means a person who manufactures the product;

***medicine*** (藥物) has the same meaning as in the definition of ***pharmaceutical product***;

***pharmaceutical product*** (藥劑製品)—

(a) means a substance or combination of substances that—

(i) is presented as having properties for treating or preventing disease in human beings or animals; or

(ii) may be used in or administered to human beings or animals with a view to—

(A) restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action; or

(B) making a medical diagnosis; and

(b) includes an advanced therapy product;

***somatic cell therapy product*** (體細胞療法製品) means a product that—

(a) contains or consists of any of the following cells or tissues—

(i) cells or tissues that have been subject to substantial manipulation so that their biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered;

(ii) cells or tissues that are not intended to be used for the same essential functions in their recipient as in their donor; and

(b) is presented as having properties for, or may be used in or administered to human beings with a view to—

(i) treating, preventing or diagnosing a disease; or

(ii) restoring, correcting or modifying physiological functions,

through the pharmacological, immunological or metabolic action of those cells or tissues;

***substantial manipulation*** (實質處理), in relation to cells or tissues, does not include the manipulation processes set out in the Schedule;

***tissue engineered product*** (組織工程製品)—

(a) means a product that—

(i) contains or consists of any of the following cells or tissues—

(A) cells or tissues that have been subject to substantial manipulation so that their biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement have been altered;

(B) cells or tissues that are not intended to be used for the same essential functions in their recipient as in their donor; and

(ii) is presented as having properties for, or may be used in or administered to human beings with a view to, regenerating, repairing or replacing a human tissue; but

(b) does not include a product that—

(i) contains or consists of exclusively non-viable human or animal cells or tissues; and

(ii) does not act principally by pharmacological, immunological or metabolic action;".

**4. Section 38 and Schedule added**

After section 37—

**Add**

"**38. Amendment of Schedule**

The Director of Health may, by notice published in the Gazette, amend the Schedule.

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## Schedule

[ss. 2 & 38]

## Manipulation Processes that are Not Substantial Manipulations

1. Cutting
2. Grinding
3. Shaping
4. Centrifugation

5. Soaking in antibiotic or antimicrobial solutions

6. Sterilization

7. Irradiation

8. Cell separation, concentration or purification

9. Filtering

10. Lyophilization

11. Freezing

12. Cryopreservation

13. Vitrification".

# Part 3

## Amendments to Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A)

**5. Regulation 2 amended (interpretation)**

(1) Regulation 2(1)—

**Add in alphabetical order**

"***expiry date*** (使用期限)—see paragraph (1A);".

(2) After regulation 2(1)—

**Add**

"(1A) For the purposes of these regulations, the expiry date of a pharmaceutical product is the date determined by the manufacturer of the product—

(a) on the basis of the product's specifications; and

(b) on the assumption that the product is stored under conditions suitable to it,

as the date after which the product should not be used.".

**6. Regulation 22 amended (supply of medicines to out-patients from certain institutions, etc.)**

Regulation 22(1)—

**Repeal**

"and this Part, shall apply"

**Substitute**

", this Part and Part 7, applies".

**7. Regulation 28 amended (records to be kept by licensed wholesale dealers or licensed manufacturers)**

After regulation 28(2)(c)—

**Add**

"(ca) for an advanced therapy product supplied for use by a registered medical practitioner or registered dentist—the name and address of the practitioner or dentist;".

**8. Regulation 29 amended (licensing of manufacturers)**

Regulation 29(1A)(a)(i)—

**Repeal**

"or (f)"

**Substitute**

", (f) or (g)".

**9. Regulation 31 amended (labelling by licensed manufacturers)**

(1) Regulation 31(1)—

**Repeal subparagraph (d)**

**Substitute**

"(d) for a pharmaceutical product registered under regulation 36—the number of the registration certificate issued under regulation 36(5);".

(2) Regulation 31(1)(e)—

**Repeal**

"and".

(3) Regulation 31(1)(f)—

**Repeal the full stop**

**Substitute a semicolon.**

(4) After regulation 31(1)(f)—

**Add**

"(g) for an advanced therapy product—

(i) the product code, and the unique donation identifier, assigned in accordance with the codes of practice issued by the Board; and

(ii) if the product is for autologous use only—

(A) the unique recipient identifier assigned in accordance with the codes of practice issued by the Board; and

(B) the English words "For autologous use only" or the Chinese characters "只供自體使用".".

(5) Regulation 31(2)(c)(ii)—

**Repeal the semicolon**

**Substitute a full stop.**

(6) Regulation 31(2)—

**Repeal subparagraph (d).**

**10. Regulation 33 amended (duties of licensed manufacturers regarding identity, purity, safety, etc.)**

(1) Regulation 33(4), after "(4B)"—

**Add**

"or (4D)".

(2) After regulation 33(4B)—

**Add**

"(4C) Paragraph (4D) applies to a licensed manufacturer of an advanced therapy product containing or consisting of cells or tissues.

(4D) The manufacturer is only required to keep photographs that clearly present the particulars mentioned in regulation 31(1) of each batch of finished products for a period of not less than 1 year after the expiry date of the products.".

(3) Regulation 33(6)—

**Repeal**

"and (4B)(c)"

**Substitute**

", (4B)(c) and (4D)".

(4) Regulation 33(6)—

**Repeal**

"or (4B)(c)"

**Substitute**

", (4B)(c) or (4D)".

(5) Regulation 33(7)—

**Repeal the definition of *expiry date*.**

**11. Regulation 35 amended (records to be kept by licensed manufacturers)**

(1) After regulation 35(1)(c)—

**Add**

"(ca) for an advanced therapy product sold or supplied for use by a registered medical practitioner or registered dentist—the name and address of the practitioner or dentist;".

(2) Regulation 35(1)(f)—

**Repeal**

"thereon by him; and"

**Substitute**

"on the complaints by the manufacturer;".

(3) Regulation 35(1)(g)—

**Repeal**

"retained."

**Substitute**

"retained; and".

(4) After regulation 35(1)(g)—

**Add**

"(h) for an advanced therapy product containing or consisting of cells or tissues—

(i) the name and address of the person from whom the cells or tissues used for the preparation of the product were obtained; and

(ii) the unique donation identifier assigned in accordance with the codes of practice issued by the Board.".

(5) Regulation 35(2)—

**Repeal**

"or (g)"

**Substitute**

", (g) or (h)".

(6) Regulation 35(3), after "(1)(c)"—

**Add**

"or (ca)".

**12. Regulation 36 amended (registration of pharmaceutical products and substances)**

Regulation 36—

**Repeal paragraph (4)**

**Substitute**

"(4) Prototypes of the sales packs, and proposed wordings of the labels, of the product or substance must be made available for inspection by the Committee.".

**13. Regulation 39 amended (period of keeping of records)**

(1) Regulation 39, heading—

**Repeal**

"**Period of keeping**"

**Substitute**

"**Keeping and transfer**".

(2) Regulation 39—

**Renumber the regulation as regulation 39(1).**

(3) Regulation 39(1)—

**Repeal**

"All—"

**Substitute**

"Subject to paragraph (2), all—".

(4) Regulation 39(1)(e)—

**Repeal**

"all".

(5) After regulation 39(1)—

**Add**

"(2) For an advanced therapy product—

(a) all books, records and documents required to be kept or retained in respect of the product under regulations 28 and 35(1)(a), (b), (c), (ca) and (h) (***specified documents***) must be preserved by the relevant licensed wholesale dealer or licensed manufacturer (***specified person***) for a period of 30 years after the expiry date of the product;

(b) if, before the period referred to in subparagraph (a) expires, the specified person—

(i) becomes insolvent or bankrupt; or

(ii) has entered into a voluntary arrangement as defined by section 2 of the Bankruptcy Ordinance (Cap. 6) with the specified person's creditors,

the specified person must transfer the specified documents to the Board as soon as practicable after the specified person becomes insolvent or bankrupt or has entered into the arrangement; and

(c) if, before the period referred to in subparagraph (a) expires, the specified person ceases to operate as a licensed wholesale dealer or licensed manufacturer, the specified person must transfer the specified documents to the Board within 14 days after the cessation.".

**14. Regulation 40 amended (penalties)**

Regulation 40, after "(4B)"—

**Add**

", (4D)".

## Explanatory Memorandum

The main purpose of this Bill is to regulate advanced therapy products (***ATPs***) under the legislative framework of the Pharmacy and Poisons Ordinance (Cap. 138) (***Ordinance***) and the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (***Regulations***).

2. The Bill contains 3 Parts.

### Part 1—Preliminary

3. Clause 1 sets out the short title and provides for commencement.

### Part 2—Amendments to Ordinance

4. Clause 3 amends section 2(1) of the Ordinance to repeal and substitute certain definitions used in the Ordinance. In particular—

(a) the expression "manufacture", under the new definition—

(i) includes the preparation of pharmaceutical products, or the repackaging of pharmaceutical products as finished products, for clinical trial; but

(ii) does not include the individual dispensing of pharmaceutical products under certain circumstances (clause 3(1)); and

(b) the expression "pharmaceutical product", under the new definition, includes ATPs (clause 3(3)).

5. Clause 3(3) also adds certain definitions used in the Ordinance, including—

(a) ***advanced therapy product***;

(b) ***gene therapy product***;

(c) ***somatic cell therapy product***; and

(d) ***tissue engineered product***.

6. Clause 4 adds a Schedule to the Ordinance to set out a list of manipulation processes that are not substantial manipulations, and adds section 38 to the Ordinance to empower the Director of Health to amend the Schedule.

**Part 3—Amendments to Regulations**

7. Clause 5 amends regulation 2 of the Regulations to add the definition of ***expiry date***.

8. Clause 6 amends regulation 22(1) of the Regulations so that the exception provided for in that regulation does not apply to the manufacture of pharmaceutical products.

9. Clause 7 amends regulation 28(2) of the Regulations to provide for the records that must be kept by licensed wholesale dealers or licensed manufacturers for each transaction by which ATPs are supplied for use by registered medical practitioners or registered dentists.

10. Clause 9 amends regulation 31 of the Regulations to provide for the labelling requirements in relation to ATPs and registered pharmaceutical products.

11. Clause 10 amends regulation 33 of the Regulations to require the licensed manufacturers of ATPs containing or consisting of cells or tissues to keep photographs of the particulars of the products.

12. Clause 11 amends regulation 35 of the Regulations to provide for the records that must be kept by licensed manufacturers of ATPs.

13. Clause 12 amends regulation 36 of the Regulations to remove the requirement in relation to the submission of actual sale packs of pharmaceutical products or substances.

14. Clause 13 amends regulation 39 of the Regulations to provide for—

(a) the period for which records must be kept by licensed wholesale dealers or licensed manufacturers in relation to ATPs; and

(b) the transfer of records if the record keeper is no longer in business.