File Ref.: FHB/H/53/4

LEGISLATIVE COUNCIL BRIEF

PHARMACY AND POISONS (AMENDMENT) BILL 2019

INTRODUCTION

At the meeting of the Executive Council on 2 July 2019, the Council ADVISED and the Chief Executive ORDERED that the Pharmacy and Poisons (Amendment) Bill 2019 (the Bill), at **Annex A**, should be introduced into the Legislative Council (LegCo).

A

JUSTIFICATIONS

Need for Regulation

2. Advanced Therapy Products (ATPs) are innovative medical products based on genes, cells and tissues. The rapid scientific advancement in the research and development of ATPs offers great medical potential for benefiting patients. At the same time, due to their complicated nature, the risks and long-term side effects of ATPs need to be carefully managed.

3. There is at present no dedicated regulatory framework for ATPs. In view of the high risks associated with the rapid scientific advancement, the Government considers it necessary to introduce a clear and dedicated regulatory framework on the research and therapeutic use of ATPs in order to safeguard public health and facilitate their development. In addition, while other pharmaceutical products are mainly manufactured by pharmaceutical factories, the manufacture of ATPs can be in small batch and personalised. As such, introducing a clear regulatory framework with international standards can facilitate the research and development of scientific institutions. After thorough public consultation in early 2018, the 2018 Policy Address announced that the Government would introduce legislation to regulate ATPs.

Key Features of the Bill

4. The Bill will amend the Pharmacy and Poisons Ordinance (Cap. 138) (the PPO) and the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (the PPR). Key features of the Bill are set out in the ensuing paragraphs.

(a) Definition of ATPs

5. With reference to the definition adopted by the European Union (EU)[1], the definition of ATPs to be added to the PPO would cover any of the following products that is for human use –

(a) a gene therapy product, for example, genetically engineered immune cells for the treatment of certain types of cancer;

(b) a high-risk somatic cell therapy product, for example, cultured stem cells from fat tissue for the treatment of chronic inflammation of the gut; and

(c) a high-risk tissue engineered product, for example, cultured corneal epithelial cells for the treatment of burns of the eyes.

Cells or tissues that have been subject to substantial manipulation[2] and/or intended for non-homologous use[3] are considered as high-risk.

6. We propose that ATPs should form a specific subset of pharmaceutical products under the PPO. As such, requirements for pharmaceutical products under the PPO and other relevant ordinances will apply to ATPs. These include registration prior to marketing, prior approval for clinical trials, licensing of manufacturers and distributors, import/export control, etc.

(b) Licensing Requirements for Manufacturers of ATPs

7. Due to the high-risk and complex nature of ATPs, we propose that all facilities that manufacture ATPs should obtain a licence under the PPO. These include facilities which prepare ATPs upon individual dispensing on a prescription (e.g. a laboratory in hospital), if the process involves substantial manipulation of cells or tissues. In line with the existing requirement for approving clinical trial certificate for pharmaceutical products, facilities which

[1] The existing definition of "pharmaceutical products" under the PPO is modelled on the EU definition. Adopting the EU definition of ATPs could facilitate the integration of new regulatory requirements to the existing regulatory regime under the PPO. The EU definition is also widely accepted internationally.

[2] Manipulations of cells or tissues that alter the biological characteristics, physiological functions or structural properties of the cells or tissues are considered as substantial manipulation. Specifically, substantial manipulation is a manipulation of cells or tissues that is not cutting, grinding, shaping, centrifugation, soaking in antibiotic or antimicrobial solutions, sterilization, irradiation, cell separation, concentration or purification, filtering, lyophilization, freezing, cryopreservation or vitrification.

[3] Non-homologous use means the use of cells or tissues in the recipient is not for the same essential functions as those in the donor.

produce pharmaceutical products, including ATPs, for clinical trial should also be licensed under PPO.

8. Licensed manufacturers of ATPs, similar to those of current pharmaceutical products, are required to comply with the Good Manufacturing Practices (GMP)[4]. Details will be provided in the codes of practice issued by the Department of Health (DH) to facilitate compliance by the trade. Licensed manufacturers of ATPs will also be subject to existing provisions in the PPR which govern manufacturers of pharmaceutical products. Meanwhile, in view of the special nature of ATPs, special requirements on licensed manufacturers of ATPs as listed in paragraphs 9 to 14 below will be included in the Bill to ensure the safety, quality and efficacy of their products.

(c) Labelling Requirements

9. Under the Bill, we propose that ATP manufacturers should be required to label information on unique donation identifiers and product codes on the packaging of ATPs, on top of the information required for all pharmaceutical products. For autologous products (i.e. donor and recipient are the same person), unique patient identifiers and a statement of "for autologous use only" should be labelled to avoid mixing up with other products. The formats of the unique donation identifiers, product codes and patient identifiers are to be specified by the Pharmacy and Poisons Board.

(d) Record Keeping for ATPs

10. Enhanced record keeping requirements are essential to the monitoring of long-term safety and efficacy of ATPs, product tracing and recall. On top of those particulars required for the record of all pharmaceutical products, we propose a requirement for the manufacturers and wholesale dealers supplying the ATPs to the end-users to record the medical practitioner or dentist who is responsible for the use of the product, as well as records related to storage and transport, etc.

11. ATPs are recent development and the scientific advancement in the field evolves rapidly. There is little information on their safety and efficacy, thus a longer record keeping requirement to ensure sufficient monitoring and tracing is required. With reference to international practices, we propose that the records mentioned in paragraph 10 in respect of ATPs should be kept for at least 30 years after the expiry date of the product. The requirements on the

[4] It refers to the GMP of the Pharmaceutical Inspection Co-operation Scheme, which is an international standard for production of pharmaceutical products.

duration of record-keeping in Mainland China and overseas regulatory regimes
B are summarised at **Annex B** for reference. If the manufacturer or wholesale dealer of an ATP ceases to operate, the records should be transferred to the Pharmacy and Poisons Board. Details will be specified in the respective codes of practice.

(e) Sample Keeping and Sales Pack Provision

12. The PPR provides that a licensed manufacturer must retain a control sample of each batch of finished products under conditions of storage suitable for that product for a period of not less than one year after the expiry date of the product. However, it is acknowledged internationally that such requirement is not always feasible in the case of ATPs due to scarcity of the materials or limited size of the batches of products. We propose that ATP manufacturers are only required to keep photographs which clearly present the required information of the finished products for a period of not less than one year after the expiry date of the products.

13. Under Regulation 36(4) of the PPR, representative specimen sales packs of the product or representative samples of the substance are required to be provided for registration of a pharmaceutical product. The requirement has become outdated with technological advancement, and imposes an unnecessary hurdle for registration taking into account the scarcity of materials for certain biological products (including ATPs) and related ethical issues with providing such materials for regulatory purposes. Accordingly, we propose to take the opportunity to simplify the requirement, and replace it with the provision of prototypes of the sale packs of the product, which is sufficient for regulatory purposes.

(f) Collection of Cells or Tissues

14. Since the collection of cells or tissues may take place outside the manufacturer's premises, extra requirements in respect of ATPs, such as donor selection and testing, quality control of cells and tissues, record keeping, etc. will be imposed via the licensing conditions of relevant ATP manufacturers.

(g) Penalties

15. We propose that the penalties for offences related to the above requirements under paragraphs 7, 9 to 12 should be set at the same level as other offences under the PPO and PPR, i.e. a maximum fine at level six ($100,000) and imprisonment for two years.

OTHER OPTIONS

16. We have explored the alternative option of introducing a new Ordinance to regulate ATPs instead of amending the PPO and PPR. However, this would deviate from the international practices including the EU regulatory model and cause confusion to the industry, which is undesirable. The proposed approach of regulating ATPs under the existing regulatory framework of the PPO and PPR has received general support during the public consultation.

THE BILL

17. The main provisions of the Bill are set out below –

(a) **Clauses 3 and 4** – amends section 2(1) of the PPO to add new definitions related to ATPs and adds a relevant Schedule;

(b) **Clause 6** – amends regulation 22(1) of the PPR so that specified institutions under PPO, e.g. hospitals, which prepare ATPs upon dispensing would need to obtain a manufacturer's licence if the process involves substantial manipulation of cells or tissues;

(c) **Clauses 7, 9, 10, 11 and 13** – amend the relevant regulations of the PPR regarding record keeping and labelling requirements for ATPs; and

(d) **Clause 12** – amends regulation 36 of the PPR to require prototypes of the sale packs for the purpose of registration of pharmaceutical products.

C The existing provisions being amended are at **Annex C**.

LEGISLATIVE TIMETABLE

18. The tentative legislative timetable will be –

Publication in the Gazette	18 October 2019
First Reading and commencement of Second Reading Debate	30 October 2019
Resumption of Second Reading Debate, Committee Stage and Third	To be notified

Reading

IMPLICATIONS OF THE PROPOSALS

19. The proposals are in conformity with the Basic Law, including the provisions concerning human rights. The proposal will not affect the binding effect of the existing provisions of the PPO and its subsidiary legislation. The proposals have financial, civil service, economic, sustainability and productivity implications as set out in **Annex D**. There are no environmental, family or gender implications arising from taking forward the proposals.

D

PUBLIC CONSULTATION

20. In 2014, the Working Group on Regulation of Premises Processing Health Products for Advanced Therapies (the Working Group)[5] recommended that ATPs should be regulated according to their risks. Subsequently, the Task Force on Regulation of Advanced Therapeutic Products in Hong Kong (the Task Force)[6] was set up in December 2017 to advise the Government in the formulation of the regulatory framework for ATPs and related matters. Following the recommendations of the Working Group and the Task Force, the Government proposed that gene therapy products and high-risk cell and tissue therapy products should be designated as ATPs and regulated as pharmaceutical products under the PPO[7].

21. We conducted a public consultation on the proposed regulatory framework from April to June 2018. During the consultation period, a total of 127 participants attended the three briefing sessions, and 28 written submissions were received. Respondents generally supported the proposal which could provide a clear regulatory framework for development of ATPs. Some requested for more guidelines on the GMP requirements, such as premises design and qualifications of authorised persons, for obtaining a manufacturer's licence. The views received have been summarised in the consultation report published in October 2018 and suitably incorporated in the legislative proposal.

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[5] The Working Group was set up under the Steering Committee on Review of Regulation of Private Healthcare Facilities in 2012. It comprised members from academia in the fields of biotechnology and clinical research, relevant medical specialties and laboratory professions, trade and industry sector and consumer group.

[6] The Task Force comprises eight expert members including the Chairman.

[7] Meanwhile, low-risk cell and tissue products, e.g. blood transfusion, cornea transplant and bone marrow transplant, are not recommended to be designated as ATPs. The Task Force will continue to work on the regulatory arrangement of these low-risk cell and tissue products.

22. We consulted the LegCo Panel on Health Services on the legislative proposal on 15 April 2019. Members generally supported the proposal and urged the Government to introduce the Bill as soon as possible to safeguard public health.

PUBLICITY

23. A press release will be issued. A line-to-take will be prepared and a government spokesperson will be available to answer questions.

ENQUIRY

24. Enquiries on this brief may be directed to Miss Lily Lee, Principal Assistant Secretary (Health) 4, Food and Health Bureau, at 3509 8929.

Food and Health Bureau
16 October 2019

Pharmacy and Poisons (Amendment) Bill 2019

Contents

Annex A

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.

———————

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.

Annex B

Requirements on the Duration of Record-Keeping in relation to Advanced Therapy Products (ATPs) in Mainland China and Overseas Regulatory Regimes

Regulatory Regime	Record-Keeping Requirement of Manufacturing/ Distribution Information
European Union	Market Authorization Holder, Manufacturer and Sponsor of clinical trial: 30 years
Mainland China	Medical Institution: 30 years (for cell and tissue products that are used in the same medical institution)
The United States of America	Manufacturer: 10 years (federal requirement for cell and tissue products)
Japan	Manufacturer and Distributor: 30 years for regenerative medicine

2. Interpretation

(1) In this Ordinance, unless the context otherwise requires—

authorized seller of poisons (獲授權毒藥銷售商) means a registered pharmacist, body corporate or unincorporated body of persons that is authorized to carry on a business of retail sale of poisons under section 11; *(Replaced 58 of 1986 s. 2. Amended 2 of 2015 s. 4)*

Board (管理局) means the Pharmacy and Poisons Board established under section 3;

certificate of good standing (良好聲譽證明書) means a certificate issued under section 9A; *(Added 68 of 1995 s. 24)*

code of conduct (《行為守則》) means a code of conduct issued under section 4B as revised from time to time under that section; *(Added 2 of 2015 s. 4)*

code of practice (《執業守則》) means a code of practice issued under section 4B as revised from time to time under that section; *(Added 2 of 2015 s. 4)*

court (法庭) includes a magistrate; *(Added 2 of 2015 s. 4)*

dispense (配發、配藥) means supplying a medicine or poison on and in accordance with a prescription given by a registered medical practitioner, a registered dentist or a registered veterinary surgeon; and also means the compounding or mixing of substances, including poisons, and the supplying of the same and ***dispensing*** (配發、配藥) shall be construed accordingly; *(Added 58 of 1986 s. 2. Amended 96 of 1997 s. 39)*

institution (機構) means—

(a) any hospital or maternity home within the meaning of the Hospitals, Nursing Homes and Maternity Homes Registration Ordinance (Cap. 165);

(b) any clinic within the meaning of the Medical Clinics Ordinance (Cap. 343); *(Amended 84 of 1992 s. 7)*

(c) any such hospital, maternity home or clinic maintained by the Government; *(Amended 84 of 1992 s. 7; 2 of 2012 s. 3)*

(ca) any military hospital or any maternity home or clinic of the Hong Kong Garrison; or *(Added 2 of 2012 s. 3)*

(d) any hospital, maternity home or clinic managed or controlled by the Hospital Authority established under the Hospital Authority Ordinance (Cap. 113); *(Added 84 of 1992 s. 7)*

label (標籤) means any statement forming part of or affixed to a container in which pharmaceutical products are sold, which statement may, subject to any regulations made under this Ordinance, be printed in English or Chinese; *(Amended 68 of 1995 s. 2)*

licensed manufacturer (持牌製造商) means a holder of a licence to manufacture pharmaceutical products issued under any regulations made under section 29; *(Added 2 of 2015 s. 4)*

licensed wholesale dealer (持牌批發商) means a holder of a wholesale dealer licence; *(Added 2 of 2015 s. 4)*

listed seller of poisons (列載毒藥銷售商) means a person whose name is entered on the list kept under section 25 of persons entitled to conduct the retail sale of poisons included in Part 2 of the Poisons List; *(Amended E.R. 4 of 2015)*

manufacture (製造) means— *(Amended 2 of 2015 s. 4)*

(a) the preparation of pharmaceutical products, from purchase or acquisition of materials, through processing and packaging, to their completion as finished products for sale or distribution; or

(b) the repackaging of pharmaceutical products as finished products for sale or distribution,

but does not include the individual dispensing on a prescription or otherwise of any pharmaceutical product, and ***manufacturer*** (製造商) has a corresponding meaning; *(Amended 2 of 2015 s. 4)*

pharmaceutical product (藥劑製品) and ***medicine*** (藥物) mean any substance or combination of substances— *(Amended 2 of 2015 s. 4)*

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

(b) that may be used in, or administered to, human beings or animals, either with a view to—

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

(ii) making a medical diagnosis; *(Replaced 50 of 1977 s. 2. Amended 2 of 2015 s. 4)*

poison (毒藥) means a substance which is specified in the Poisons List;

Poisons List (毒藥表) means the Poisons List prescribed by regulations made under section 29; *(Amended 2 of 2015 s. 4)*

practising certificate (執業證明書) means a certificate issued under section 10A; *(Added 50 of 1977 s. 2)*

registered (註冊) means—

(a) in relation to a pharmacist, a person whose name has been entered on the register of pharmacists under section 5;

(b) in relation to premises, such premises as are entered on the register of premises under section 13;

(c) in relation to a medical practitioner, a person duly registered or deemed to be registered under the Medical Registration Ordinance (Cap. 161);

(d) in relation to a dentist, a person duly registered or deemed to be registered under the Dentists Registration Ordinance (Cap. 156);

(e) in relation to a veterinary surgeon, a person duly registered under the Veterinary Surgeons Registration Ordinance (Cap. 529); *(Added 96 of 1997 s. 39)*

sale by way of wholesale dealing (以批發經營方式銷售) means the sale of goods to a person who is authorized by this Ordinance to resell such goods;

Secretary (秘書) means the secretary to the Board;

sell (售、銷售) includes—

(a) offer or expose for sale;

(b) supply without payment; and

(c) offer or expose for supply without payment,

and ***sold*** (售、銷售) and ***seller*** (銷售商) shall be construed accordingly; *(Replaced 58 of 1986 s. 2)*

specified form (指明格式), in relation to a purpose under this Ordinance, means the form specified for that purpose by the Board under section 29A; *(Added 2 of 2015 s. 4)*

Tribunal (審裁處) has the meaning assigned to it by section 30; *(Added 50 of 1980 s. 2. Amended 2 of 2015 s. 4)*

wholesale dealer licence (批發商牌照) means a wholesale dealer licence issued under any regulations made under section 29. *(Added 2 of 2015 s. 4)*

(Amended 38 of 1977 s. 24; 96 of 1997 s. 39)

(1A) In the definition of ***manufacture*** in subsection (1)—

packaging (包裝) means any operation, including filling and labelling, that a bulk product (being a product that has completed all processing stages up to, but not including, final packaging) has to undergo to become a finished product. *(Added 2 of 2015 s. 4)*

(2) It shall be a sufficient compliance with any requirement in this Ordinance that premises be under the personal control of a registered pharmacist if for not less than two-thirds of the hours of each day the premises are open for business a registered pharmacist is present at the premises and exercises control and supervision over the persons employed therein.

(3) Where in this Ordinance any document is required to be signed by any person, that person shall write his name or make his mark on the document but the affixing of a chop shall not be an adequate signature.

2. Interpretation

(1) In these regulations, unless the context otherwise requires—

antimonial poisons (含銻毒藥) means organic and inorganic compounds of antimony;

arsenical poisons (含砷毒藥) means organic and inorganic compounds of arsenic;

authorized person (獲授權人) means a person whose name is entered in the register of authorized persons; *(2 of 2015 s. 32)*

British Pharmaceutical Codex (英國藥學藥典), ***British Pharmacopoeia*** (英國藥典), ***British National Formulary*** (英國國家處方集) and ***British Veterinary Codex*** (英國獸醫藥方集) include the supplements thereto;

food (食物) includes a beverage;

GMP Guide (《指引》) means the Good Manufacturing Practice Guide issued under regulation 28A as revised from time to time under that regulation; *(2 of 2015 s. 32)*

medicine for the internal treatment of human and animal ailments (用於治療人類及動物病患的內服藥物) includes any medicine to be administered by injection, but does not include any mouth-wash, eye-drops, eye-lotion, ear-drops, nasal drops, douche or similar article;

register of authorized persons (獲授權人名冊) means the register of authorized persons kept under regulation 30B; *(2 of 2015 s. 32)*

specified form (指明格式), in relation to a purpose under these regulations, means the form specified for that purpose under regulation 38B; *(2 of 2015 s. 32)*

Tribunal (審裁處) means the Pharmacy and Poisons Appeal Tribunal established by section 30 of the Ordinance; *(L.N. 369 of 1980)*

veterinary institution (獸醫機構) means a veterinary hospital, veterinary clinic or other premises where sick animals are treated.

(2) In these regulations any reference to an alkaloid shall include a reference to any salt of that alkaloid, and, in a case where the esters of an alkaloid are included in the Poisons List by virtue of the words "its esters", to any esters of that alkaloid.

(3) Any reference in the Schedules to these regulations to the percentage of a poison contained in any substance or preparation shall, unless otherwise expressly provided, be construed in the following manner, that is to say, a reference to a substance or preparation containing 1 per cent of any poison means—

(a) in the case of a solid, that 1 gramme of the poison is contained in every 100 grammes of the substance or preparation;

(b) in the case of a liquid, that 1 millilitre of the poison, or, if the poison itself is a solid, 1 gramme of the poison, is contained in every 100 millilitres of the substance or preparation,

and so in proportion for any greater or less percentage.

(4) Substances listed in Divisions A in the Schedules to these regulations are those whose uses are essentially medicinal, whilst substances listed in Divisions B are not normally used medicinally. *(L.N. 41 of 2007)*

(5) Where in these regulations reference is made to a numbered section the reference shall be a reference to that section of the Ordinance.

(6) Where functions are conferred on a committee by any provision of these regulations, references in such provision to ***the Committee*** shall be construed as references to the executive committee established under section 4A of the Ordinance for the purpose of performing such functions. *(L.N. 369 of 1980)*

22. Supply of medicines to out-patients from certain institutions, etc.

(1) Nothing in the Ordinance or in these regulations, except regulation 16 and this Part, shall apply with respect to— *(L.N. 262 of 1995)*

(a) any medicine dispensed in an institution where the dispensing is under the supervision of a registered pharmacist or other person as may be approved by the Director of Health; or *(L.N. 76 of 1989)*

(b) any medicine for the treatment of animals supplied from a veterinary institution which is under the superintendence of a registered veterinary surgeon, *(L.N. 614 of 1997)*

if the requirements of this regulation are satisfied in relation thereto.

(2) The medicine shall not be supplied except by, or on and in accordance with a prescription of, a duly registered medical practitioner for the purposes of medical treatment, or a registered dentist for the purposes of dental treatment, or a registered veterinary surgeon for the purposes of animal treatment. *(L.N. 614 of 1997)*

(3) In a case where a substance included in the Schedule 1 is supplied, a record shall be kept on the premises in such a way that there can readily be traced at any time during a period of 2 years after the date on which the substance was supplied the following particulars—

(a) the name and quantity of the poison supplied;

(b) the date on which the poison was supplied;

(c) the name and address of the person to whom the poison was supplied; and

(d) the name of the person who supplied the poison or who gave the prescription upon which it was supplied.

(4) The container of the medicine shall be labelled—

(a) with a designation sufficient to identify the institution or veterinary institution from which it was supplied; and *(L.N. 137 of 1978; 2 of 2015 s. 39)*

(b) *(Repealed 2 of 2015 s. 39)*

(c) in the case of a poison supplied from a veterinary institution, with the words "For animal treatment only 祇限醫治禽畜用".

(5) The medicine shall be clearly labelled with instructions for use in either English or Chinese. *(2 of 2015 s. 39)*

(6) In the case of a medicine to which regulation 16 applies the requirements of that regulation shall be satisfied in addition to the requirements of this regulation.

(E.R. 3 of 2015)

28. Records to be kept by licensed wholesale dealers or licensed manufacturers

(2 of 2015 s. 48)

(1) A licensed wholesale dealer or licensed manufacturer must record the following particulars for each transaction by which any poison included in Part 1 of the Poisons List or any pharmaceutical product is acquired by him whether by way of import, purchase, gift or otherwise— *(L.N. 137 of 1978; 2 of 2015 s. 48)*

(a) the date of the transaction;

(b) the name of the supplier;

(c) the name of the poison or pharmaceutical product;

(ca) the batch number, pack size and unit of quantity of the poison or pharmaceutical product; *(2 of 2015 s. 48)*

(d) the total quantity of the poison or pharmaceutical product;

(e) the nature of the transaction; and

(f) a reference to the invoice or other documents supporting the transaction.

(2) A licensed wholesale dealer or licensed manufacturer must record the following particulars for each transaction by which any poison included in Part 1 of the Poisons List or any pharmaceutical product is disposed of, whether the disposition is by way of export, sale, gift or otherwise— *(L.N. 137 of 1978; 2 of 2015 s. 48)*

(a) the date of the transaction;

(b) the nature of the transaction;

(c) the name of the person to whom the poison or pharmaceutical product is supplied;

(d) the total quantity of the poison or pharmaceutical product;

(e) a reference to the invoice or other documents supporting the transaction;

(f) the name of the poison or pharmaceutical product;

(fa) the batch number, pack size and unit of quantity of the poison or pharmaceutical product; *(2 of 2015 s. 48)*

(g) the balance of the poison or pharmaceutical product remaining in his possession after the transaction.

(3) For each poison in Part 1 of the Poisons List or pharmaceutical product there shall be a separate entry in the records and all transactions involving that poison or pharmaceutical product shall be entered in a part of the records reserved for that poison or pharmaceutical product.

(4) Unless the Committee approves another system of recording, all records of transactions must be in the specified form.

(5) Every transaction to which these regulations relate shall be recorded within 72 hours after the time it took place.

(6) Records of sales or supplies maintained under this regulation shall be supported by documents signed by the purchaser.

(7) In the case of an import or export transaction, the licensed wholesale dealer or licensed manufacturer must retain all shipping and other documents supporting the transaction. *(L.N. 137 of 1978)*

(8) A licensed wholesale dealer must set up and maintain a system of control that will enable the rapid and, so far as practicable, complete recall of any lot or batch of a pharmaceutical substance or product from sale to the public in the event of the pharmaceutical substance or product being found to be dangerous or injurious to health. *(L.N. 137 of 1978)*

(2 of 2015 s. 48; E.R. 3 of 2015)

29. Licensing of manufacturers

(1) A person must not manufacture any pharmaceutical product on any premises unless he is the holder of a licence to manufacture pharmaceutical products on those premises.

(1A) For the purposes of paragraph (1), a person is not regarded as manufacturing a pharmaceutical product only by affixing to the container of the product a label—

(a) that does not state any of the following particulars—

(i) particulars mentioned in regulation 31(1)(a), (b), (e) or (f);

(ii) particulars regarding the dosage, route or frequency of administration of the product;

(iii) the name of the product; and

(b) that does not obscure, change or obliterate any of the following particulars labelled on the container—

(i) particulars mentioned in subparagraph (a);

(ii) particulars mentioned in regulation 31(1)(c). *(2 of 2015 s. 50)*

(2) *(Repealed 2 of 2015 s. 50)*

(3) The Committee may, subject to any conditions it thinks fit to impose, issue a licence to manufacture pharmaceutical products in the specified form on payment of the fee prescribed in the Schedule 9.

(4) In any of the circumstances specified in paragraph (4A), the Committee may—

(a) revoke a licence to manufacture pharmaceutical products or suspend it for a period it thinks fit;

(b) issue a warning letter to the licensed manufacturer; or

(c) vary a condition of the licence imposed under paragraph (3). *(2 of 2015 s. 50)*

(4A) The circumstances are—

(a) that, in the Committee's opinion, the licensed manufacturer has contravened—

(i) a condition of the licence or any of these regulations; or

(ii) a code of practice applicable to the licensed manufacturer or the GMP Guide; or

(b) that the licensed manufacturer has been convicted of—

(i) an offence under the Ordinance or any of the regulations made under section 29, the Dangerous Drugs Ordinance (Cap. 134), the Antibiotics Ordinance (Cap. 137) or the Undesirable Medical Advertisements Ordinance (Cap. 231); or

(ii) an offence under section 6C or 6D of the Import and Export Ordinance (Cap. 60), section 52, 54 or 61 of the Public Health and Municipal Services Ordinance (Cap. 132) or section 7, 7A or 9 of the Trade Descriptions Ordinance (Cap. 362). *(2 of 2015 s. 50)*

(4B) The Committee may, subject to any conditions it thinks fit to impose, suspend for a period not exceeding 3 years (***suspension period***) the operation of a decision made under paragraph (4)(a) so that the decision takes effect only if a condition so imposed is contravened during the suspension period, and in the case of such a contravention, the decision takes effect on the date specified by the Committee having regard to all the circumstances of the case. *(2 of 2015 s. 50)*

(5) For the purpose of certifying that a manufacturer is licensed under this regulation, the Committee, subject to any conditions it may impose and to the payment of the fee prescribed in the Schedule 9, may issue to the manufacturer—

(a) a certificate for manufacture; or

(b) an interim-certificate for manufacture,

in the specified forms.

(6) For the purpose of exporting pharmaceutical products manufactured by a licensed manufacturer, the Committee may, subject to any conditions it may impose and to the payment of the fee prescribed in the Schedule 9, issue to the manufacturer — *(2 of 2015 s. 50)*

(a) a free sale certificate of pharmaceutical product; or

(b) a certificate of pharmaceutical product,

in the specified forms. *(L.N. 449 of 1991)*

(7) Any applicant or licensed manufacturer aggrieved by a decision of the Committee under this regulation may, in the prescribed manner, appeal to the Tribunal against that decision. *(L.N. 369 of 1980)*

(L.N. 369 of 1980; 2 of 2015 s. 50; E.R. 3 of 2015)

31. Labelling by licensed manufacturers

(2 of 2015 s. 53)

(1) Subject to paragraph (4), a licensed manufacturer shall label or cause to be labelled the container of each pharmaceutical product, with the following particulars— *(2 of 2015 s. 53)*

(a) the appropriate designation of—

(i) the substance or substances from which the pharmaceutical product was manufactured;

(ii) each of the active constituents of the product; or

(iii) each of the ingredients from which the product was compounded;

(b) in the case where the appropriate designation of each of the active constituents or ingredients of a product is given, the appropriate quantitative particulars of those constituents or ingredients;

(c) the name and address of the manufacturer; *(2 of 2015 s. 53)*

(d) the number of the certificate of drug/product registration or the provisional certificate of drug/product registration of the pharmaceutical product issued by the Board; *(L.N. 137 of 1978; 2 of 2015 s. 53)*

(e) the batch number of the pharmaceutical product; and *(2 of 2015 s. 53)*

(f) the expiry date of the pharmaceutical product. *(2 of 2015 s. 53)*

(2) For the purposes of paragraph (1)—

(a) the expression ***appropriate designation*** (適當稱號), in relation to a substance, constituent or ingredient, means —

(i) in the case of a poison included in the Poisons List, the name with which the container of the poison is for the time being required to be labelled in accordance with regulation 13;

(ii) in the case where a substance, constituent or ingredient is not a poison and is described in any of the monographs contained in the edition of the British pharmacopoeia, the British Pharmaceutical Codex or the British Veterinary Codex which was last published before the date on which the article was sold or supplied, the description set out at the head of that monograph; and

(iii) in any other case the accepted scientific name or the name descriptive of the true nature and origin of the substance, constituent or ingredient;

(b) the expression ***appropriate quantitative particulars*** (適當數量詳情), in relation to the active constituent or ingredient of a pharmaceutical product, means—

(i) the percentage or quantity of that constituent or ingredient contained in the pharmaceutical product sold or supplied; or

(ii) in the case of a pharmaceutical product which is in pill, capsule, tablet or similar article, either the percentage or quantity of the substance or substances comprising or forming part of the pills, capsules, tablets or similar articles, or the quantity of each constituent or ingredient in each pill, capsule, tablet or article; *(2 of 2015 s. 53)*

(c) ***batch number*** (批次編號), in relation to a pharmaceutical product, means a unique combination of numbers, letters or other symbols from which—

(i) the batch or lot to which the product belongs can be identified; and

(ii) the production and distribution history of the product can be determined; *(2 of 2015 s. 53)*

(d) ***expiry date*** (使用期限), in relation to a pharmaceutical product, means the date determined, on the basis of the product's specifications registered under regulation 36(3)(a)(ii), by the manufacturer as the date after which the product should not be used, assuming that the product is stored under conditions suitable to the product. *(2 of 2015 s. 53)*

(3) For the purposes of paragraph (1) the container to be labelled shall, where the pharmaceutical product is packed by the manufacturer in more than one container, be the container which is likely to be sold or distributed to the ultimate user of the product.

(4) In the case of a pharmaceutical product intended for export it shall be a sufficient compliance with this regulation if the container of the product is labelled with the following particulars—

(a) the name and address of the manufacturer; and

(b) such other details as the importing country may require. *(L.N. 137 of 1978)*

33. Duties of licensed manufacturers regarding identity, purity, safety, etc.

(2 of 2015 s. 55)

(1) Subject to paragraph (1A), a licensed manufacturer must test each lot or batch of raw or bulk material intended to be used in the manufacture of pharmaceutical products to ensure identity and purity.

(1A) Raw or bulk material the identity and purity of which the manufacturer thereof has certified by a certificate of analysis does not require a test by a licensed manufacturer under paragraph (1).

(2) A licensed manufacturer must ensure that the registrable particulars of each batch of pharmaceutical products in a finished form correspond exactly with the registered particulars of the products. *(2 of 2015 s. 55)*

(3) Every parenteral product shall be manufactured in accordance with the method of preparation of injections laid down by the British Pharmacopoeia or other Pharmacopoeia with which the particular product is intended to comply.

(4) Unless paragraph (4B) applies, a licensed manufacturer must retain a control sample of each batch of finished products under conditions of storage suitable to that product for a period of not less than 1 year after the expiry date of the product.

(4A) Paragraph (4B) applies to a licensed manufacturer in respect of a batch of pharmaceutical products if all of the following conditions are satisfied—

(a) the products are enclosed in a primary container in which the products are to be sold or supplied;

(b) the process of manufacture that the manufacturer carries out, in respect of the products, only involves one or more of the following—

(i) adding a package insert;

(ii) replacing a package insert;

(iii) (if the products are intended for export) affixing a label to any labelled container of the products, and the label does not obscure, change or obliterate any of the following particulars appearing on that labelled container—

(A) particulars required to be labelled under regulation 31(4);

(B) the name of the products;

(C) the batch number of the products;

(D) the expiry date of the products;

(iv) (if the products are not intended for export) affixing a label to any labelled container of the products, and the label does not obscure, change or obliterate any of the following particulars appearing on that labelled container—

(A) the registered particulars of the products;

(B) the batch number of the products;

(C) the expiry date of the products;

(c) throughout the process of manufacture, the primary container remains closed. *(2 of 2015 s. 55)*

(4B) The manufacturer is only required to retain a sample of the following of the batch of finished products for a period of not less than 1 year after the expiry date of the products—

(a) if paragraph (4A)(b)(i) applies, the package insert added;

(b) if paragraph (4A)(b)(ii) applies, the replacing package insert;

(c) if paragraph (4A)(b)(iii) or (iv) applies, the label affixed. *(2 of 2015 s. 55)*

(5) A licensed manufacturer must set up and maintain a system of control that will enable the rapid and, so far as practicable, complete recall of any lot or batch of a pharmaceutical substance or product from sale to the public in the event of the pharmaceutical substance or product being found to be dangerous or injurious to health. *(L.N. 137 of 1978)*

(6) Despite paragraphs (4) and (4B)(c), a licensed manufacturer is not required to comply with paragraph (4) or (4B)(c) (as applicable) in respect of a batch of pharmaceutical products if the manufacturer is not regarded as manufacturing the products for the purposes of regulation 29(1). *(2 of 2015 s. 55)*

(7) In this regulation—

batch number (批次編號) has the meaning given by regulation 31(2)(c);

expiry date (使用期限) has the meaning given by regulation 31(2)(d);

labelled container (帶標籤容器), for a pharmaceutical product, means a container of the product on which the following particulars appear—

(a) the name of the product;

(b) the batch number of the product;

(c) the expiry date of the product;

package insert (包裝附頁) has the meaning given by regulation 36(3A);

primary container (最內層容器), for a pharmaceutical product, means the container that is in direct contact with the product;

registered particulars (註冊詳情) has the meaning given by regulation 35A;

registrable particulars (須註冊詳情) has the meaning given by regulation 35A. *(2 of 2015 s. 55)*

(2 of 2015 s. 55)

35. Records to be kept by licensed manufacturers

(2 of 2015 s. 57)

(1) A licensed manufacturer must maintain adequate records in respect of each pharmaceutical product prepared by him, showing— *(2 of 2015 s. 57)*

(a) the quantities of all substances used in the manufacture of the product;

(b) the quantity of the product manufactured;

(c) the name and the address of the person to whom the pharmaceutical product was sold or supplied;

(d) the nature and results of tests made on each lot or batch of raw or bulk materials used in the product;

(e) the nature and results of tests made on each batch of finished product;

(f) any complaints received relating to the product and the action taken thereon by him; and

(g) the nature and result of any tests made on the samples retained. *(L.N. 228 of 1975)*

(2) A record showing the matters mentioned in paragraph (1)(a), (b), (d), (e) or (g) must be completed when the manufacturing process or test concerned is being carried out. *(2 of 2015 s. 57)*

(3) A record showing the matters mentioned in paragraph (1)(c) must be completed within 72 hours after the transaction concerned takes place. *(2 of 2015 s. 57)*

(4) For the purposes of paragraph (1)(f)—

(a) a record showing a complaint must be completed within 72 hours after the complaint is received by the licensed manufacturer; and

(b) a record showing an action taken in respect of a complaint must be completed within 72 hours after the action is taken. *(2 of 2015 s. 57)*

36. Registration of pharmaceutical products and substances

(1) Subject to paragraphs (1A), (1B) and (1C), no person shall sell, offer for sale or distribute or possess for the purposes of sale, distribution or other use any pharmaceutical product or substance unless the product or substance is registered with the Board— *(L.N. 85 of 1987; L.N. 366 of 1995)*

(a) by the licensed manufacturer, or a licensed wholesale dealer who has entered into a contract with the licensed manufacturer under which the licensed manufacturer is required to manufacture the pharmaceutical product or substance, if the pharmaceutical product or substance is manufactured in Hong Kong;

(b) by a person referred to in section 28A(1) or (3) who imports the pharmaceutical product or substance into Hong Kong, if the pharmaceutical product or substance is manufactured outside Hong Kong; or

(c) by the local branch, subsidiary, representative, agent or distributor of a manufacturer outside Hong Kong. *(L.N. 137 of 1978; 23 of 1998 s. 2; 2 of 2015 s. 58)*

(1A) Nothing in paragraph (1) shall apply in the case of possession or use where the pharmaceutical product or substance—

(a) has been imported into Hong Kong—

(i) to be exported outside Hong Kong; or *(2 of 2015 s. 58)*

(ii) by a licensed manufacturer for the purpose of manufacture or the compounding of pharmaceutical preparations; *(2 of 2015 s. 58)*

(iii) *(Repealed 2 of 2015 s. 58)*

(ab) is possessed or is to be used for the purpose of treatment by a registered medical practitioner or a registered dentist of a particular patient or for the purpose of treatment by a registered veterinary surgeon of a particular animal; *(2 of 2015 s. 58)*

(b) has been manufactured in Hong Kong to be exported outside Hong Kong; *(L.N. 85 of 1987; 2 of 2015 s. 58)*

(c) is to be administered for the purposes of a clinical trial that is to be conducted in accordance with a clinical trial certificate issued under regulation 36B(3); or *(2 of 2015 s. 58)*

(d) is to be administered for the purposes of a medicinal test that is to be conducted in accordance with a medicinal test certificate issued under regulation 36B(3). *(2 of 2015 s. 58)*

(1B) For the avoidance of any doubt, a pharmaceutical product or substance is registered with the Board, for the purposes of paragraph (1), if and only if its registrable particulars are those which correspond exactly with the registered particulars of a registered product or substance. *(L.N. 366 of 1995)*

(1C) It shall be a defence to a charge against any person for contravening paragraph (1) if the person proves that he did not know and could not with reasonable diligence have discovered that the product or substance was not registered with the Board. *(L.N. 366 of 1995)*

(2) Application for the initial registration of a pharmaceutical product or substance shall be made in the specified form and shall be accompanied by the fee prescribed in the Schedule 9. *(2 of 2015 s. 58)*

(2A) In considering an application for registration of a pharmaceutical product which contains as active ingredients any Chinese herbal medicines or proprietary Chinese medicines as defined in section 2 of the Chinese Medicine Ordinance (Cap. 549) or other materials of herbal, animal or mineral origin customarily used by the Chinese for medicinal purpose, the Board shall seek advice from the Chinese Medicines Board established under the Chinese Medicine Ordinance (Cap. 549). *(47 of 1999 s. 175)*

(3) The particulars to be registered shall—

(a) in the case of a product or substance, be—

(i) its name;

(ii) its specifications;

(iii) its label;

(iv) its package insert, if any;

(v) the name and address of the manufacturer; and

(vi) the name and address of the applicant;

(b) in the case of a product, further be—

(i) its dose form;

(ii) the quantity or quantities of the dose form contained in its unit package or unit packages;

(iii) the name and quantity of all its active ingredients;

(iv) the name and quantity of all its excipients; and

(v) its proposed indication, dosage and route of administration. *(L.N. 366 of 1995)*

(3A) For the purposes of paragraph (3)—

active ingredient (有效成分) means an ingredient of the product which is not an excipient;

excipient (賦形劑) means an ingredient of the product which does not contribute to its pharmacological action or which so contributes only by regulating the release of an active ingredient;

label (標籤) means any statement forming part of or affixed to the container or package of the product or substance;

package insert (包裝附頁) means any leaflet, notification or other document supplied with the container or package of the product or substance, but does not include a label. *(L.N. 366 of 1995)*

(4) Representative specimen sales packs of the product or representative samples of the substance shall be made available for inspection by the Committee. In the case of products not yet marketed the Committee may accept prototypes of the packs and proposed wordings of the labels on the understanding that these will be replaced by actual sale packs not later than 6 months after registration of the product or substance.

(5) The Committee may, subject to any conditions it thinks fit to impose, register a pharmaceutical product or substance by issuing to the applicant a registration certificate in the specified form and the certificate is valid for a period of 5 years from the date of registration on payment of the fee prescribed in the Schedule 9. *(2 of 2015 s. 58)*

(6) The Committee shall advise the applicant whether the pharmaceutical product or substance appears in the Poisons List and if so, under which classification.

(7) A registration certificate issued under paragraph (5) shall be renewable on— *(2 of 2015 s. 58)*

(a) payment of the fee prescribed in the Schedule 9; and

(b) providing the Committee with the up-to-date information specified by the Committee regarding the pharmaceutical product or substance. *(2 of 2015 s. 58)*

(7A) A renewal under paragraph (7) is subject to any conditions the Committee thinks fit to impose. *(2 of 2015 s. 58)*

(7B) The Committee may vary a condition imposed under paragraph (5) or (7A) if it thinks fit to do so. *(2 of 2015 s. 58)*

(8) The Committee may deregister a pharmaceutical product or substance, suspend the registration of a pharmaceutical product or substance for a period specified by the Committee, or issue a warning letter to the holder of a registration certificate, if it is of the opinion that a condition of the registration is contravened or if it considers it to be in the public interest to do so. *(2 of 2015 s. 58)*

(8A) Where the Committee refuses to register or deregisters a pharmaceutical product or substance it shall forward to the applicant or permit holder, as the case may be, a notice of refusal or of deregistration and shall state in such notice its reasons for refusal to register or for deregistration. *(L.N. 137 of 1978)*

(9) Any applicant or holder of a registration certificate aggrieved by a decision of the Committee under this regulation may, in the prescribed manner, appeal to the Tribunal against that decision. *(L.N. 369 of 1980; 2 of 2015 s. 58)*

(10) *(Repealed L.N. 369 of 1980)*

(11) *(Repealed L.N. 366 of 1995)*

(L.N. 137 of 1978; L.N. 369 of 1980; E.R. 3 of 2015)

39. Period of keeping of records

All—

(a) poisons books;

(b) books kept under section 28(3);

(c) certificates given under section 22(1)(a) kept by authorized sellers of poisons;

(d) books or other form of records and documents required to be kept or retained by licensed wholesale dealers or licensed manufacturers under regulation 28; and *(2 of 2015 s. 63)*

(e) all records and documents required to be kept or retained by licensed manufacturers under regulation 35, *(2 of 2015 s. 63)*

shall be preserved by the authorized seller of poisons, licensed wholesale dealer or licensed manufacturer, as the case may be, in the premises in which the transaction recorded took place— *(2 of 2015 s. 63)*

(i) for a period of 2 years from the date of the last entry therein; or

(ii) in relation to a certificate or document, for a period of 2 years from the date of the transaction.

40. Penalties

Any person who contravenes any of the provisions of regulation 9(1) or (4), 10, 10A, 11, 12, 15, 16(1) or (2), 18, 19, 20, 21(1) or (2), 22(2), (3), (4) or (5), 23(1), (2) or (3), 24, 25, 27, 28, 29(1), 30(1), 31(1), 32, 33(1), (2), (3), (4), (4B) or (5), 34, 35, 36(1), 36A(6)(b), 38(1), 38A or 39 commits an offence and is liable on conviction to the penalties specified in section 34 of the Ordinance.

(L.N. 262 of 1995; L.N. 366 of 1995; 2 of 2015 s. 64)

Annex D

Financial, Civil Service, Economic, Sustainability and Productivity Implications

Financial and civil service implications

The Food and Health Bureau, the DH and other relevant bureaux/departments will endeavor to absorb additional workload, if any, from within their existing resources. Any additional resources, if required, will be sought with justifications in accordance with the established mechanism. The fines collected in connection with the offences relating to the regulation of ATPs will be credited to the General Revenue Account in accordance with the established practice.

Economic, sustainability and productivity implications

2. The proposal would provide a dedicated regulatory framework for ATPs for safeguarding the public health. It would strengthen public confidence towards ATPs and would be conducive to the development of the biomedical sector. The benefits brought by the proposal to the community as a whole should outweigh the administrative and operational costs of ATP manufacturers and wholesale dealers, though the exact magnitude is difficult to quantify precisely.