

Bills Committee on Pharmacy and Poisons (Amendment) Bill 2019

Committee Stage Amendment Proposed by the Government

Purpose

This paper sets out the Committee Stage Amendment (*CSA*) to the Pharmacy and Poisons (Amendment) Bill 2019 (*Bill*) to be proposed by the Government.

Proposed CSA

2. The proposed CSA to clause 13(5) of the Bill and a marked-up version of the clause are at **Annex A** and **Annex B** respectively. The background and rationale of the proposed CSA are set out in the ensuing paragraphs. The proposed CSA is technical in nature.

3. According to the European Union Regulations, the person who markets the advanced therapy medicinal product should transfer relevant data to the regulatory authority in the case of bankruptcy or liquidation. For this Bill, the intention of the Administration is that when the specified person is expected to **terminate operation**, the specified person should transfer the specified documents to the Pharmacy and Poisons Board (*Board*).

4. In the new regulation 39(2)(b) of the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) (*Cap. 138A*), proposed in clause 13(5) of the Bill, a 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 a voluntary arrangement as defined by section 2 of the Bankruptcy Ordinance (Cap. 6) with the specified person's creditors. Taking into account the observations of the Assistant Legal Adviser of the Bills Committee, the proposed CSA will amend regulation 39(2)(b) of Cap. 138A by changing "becomes insolvent" for a specified person that is a company to "is **commenced to be wound up or is dissolved without being wound up**". The wording reflects our policy intention. In preparing the

proposed CSA, reference has been made to para. (2)(g)¹ of Schedule 2 to the Mandatory Provident Fund Schemes (General) Regulation (Cap. 485 sub. leg. A).

5. For the avoidance of doubt, once the specified person has transferred the specified documents to the Board, the documents **will not be returned** to the specified person, even if the event that led to the transfer ceases to exist. The purpose of record keeping can be achieved by the Board's keeping of the specified documents. Meanwhile, as the status of a specified person regarding winding up/dissolution/bankruptcy, etc. may change again, returning the specified documents to the specified person upon the change of status may create unnecessary administrative workload for both the Board and the specified person.

Food and Health Bureau
28 May 2020

¹ Para. (2)(g) of Schedule 2 to the Mandatory Provident Fund Schemes (General) Regulation (Cap. 485 sub. leg. A) is extracted as follows:

“(g) provide for the contract to be terminated if the company constituting the investment manager is commenced to be wound up or is dissolved without being wound up; and”.

Pharmacy and Poisons (Amendment) Bill 2019

Committee Stage

Amendment to be moved by the Secretary for Food and Health

Clause

Amendment Proposed

13(5)

By deleting the proposed regulation 39(2)(b) and substituting—

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

- (i) for a specified person that is a natural person—the specified person becomes bankrupt or enters into a voluntary arrangement as defined by section 2 of the Bankruptcy Ordinance (Cap. 6) with the person’s creditors; or
- (ii) for a specified person that is a company as defined by section 2(1) of the Companies Ordinance (Cap. 622)—the specified person is commenced to be wound up or is dissolved without being wound up,

the specified person must transfer the specified documents to the Board as soon as practicable after the event mentioned in sub-subparagraph (i) or (ii) occurs; and”.

Pharmacy and Poisons (Amendment) Bill 2019
《2019 年藥劑業及毒藥(修訂)條例草案》

Committee Stage Amendment Proposed by the Government
政府建議的委員會審議階段修正案

Mark-up Version
標示版本

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) for a specified person that is a natural person—the specified person becomes bankrupt or enters into a voluntary arrangement as defined by section 2 of the Bankruptcy Ordinance (Cap. 6) with the person’s creditors~~becomes insolvent or bankrupt~~; or

(ii) for a specified person that is a company as defined by section 2(1) of the Companies Ordinance (Cap. 622)—the specified person is commenced to be wound up or is dissolved without being wound up, 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 event mentioned in sub-subparagraph (i) or (ii) occurs~~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.”.

13. 修訂第 39 條(備存紀錄的期間)

- (1) 第 39 條，標題 ——

廢除

“紀錄的期間”

代以

“和移交紀錄”。

- (2) 第 39 條 ——

將該條重編為第 39(1)條。

- (3) 第 39(1)條 ——

廢除

“所有 ——”

代以

“除第(2)款另有規定外，所有 ——”。

- (4) 第 39(1)(e)條 ——

廢除

“所有”。

- (5) 在第 39(1)條之後 ——

加入

“(2) 就先進療法製品而言 ——

- (a) 根據第 28 及 35(1)(a)、(b)、(c)、(ca)及(h)條規定就該製品而備存或保留的所有簿冊、紀錄及文件(*指明文件*)，須由有關持牌批發商或持牌製造商(*指明人士*)保存，保存期為該製品的使用期限後的 30 年；

- (b) 如在(a)段提述的期間屆滿之前，~~指明人士~~——

(i) 就屬自然人的指明人士而言——指明人士破產，或與其債權人作出《破產條例》(第 6 章)第 2 條所界定的自願安排無力償債或破產；或

(ii) 就屬公司(《公司條例》(第 622 章)第 2(1)條所界定者)的指明人士而言——指明人士開始清盤或未經清盤而解散已與其債務人作出《破產條例》(第 6 章)第 2 條所界定的自願安排，

該人士須在第(i)或(ii)節所述的事件發生後在其無力償債或破產或作出該安排後，在切實可行的範圍內，盡快將指明文件移交管理局；及

- (c) 如在(a)段提述的期間屆滿之前，指明人士停止以持牌批發商或持牌製造商身分營運，該人士須在停止營運後的 14 日內，將指明文件移交管理局。”。