中華人民共和國香港特別行政區政府總部食物及衞生局
Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

Our ref.: FHB/H/23/1 *Tel no:* 3509 8915
Your ref: CB2/BC/4/13 *Fax no:* 2810 7851

香港中區
立法會道1號
立法會綜合大樓
《2014年藥劑業及毒藥（修訂）條例草案》委員會
李國麟主席

李主席：

《2014年藥劑業及毒藥（修訂）條例草案》

有關日前報章上就《2014年藥劑業及毒藥（修訂）條例草案》（"《條例草案》"）建議引入"獲授權人"的制度，表示建議修訂會削弱香港對藥物製造的監管的報導，我們的澄清如下。

2. 《條例草案》建議在《藥劑業和毒藥規例》（第138A章）加入新的第30A至F條，訂明持牌製造商須僱用最少一名"獲授權人"，以確保和證明該製造商生產的每批次藥劑製品均符合《藥品生產質量管理規範》(GMP)的規定、註冊詳情及相關法例的要求。當中，第30C條第2款訂明"獲授權人"的資歷要求為－

(a) 有關的人－
(i) 是註冊藥劑師；或
(ii) 持有在修畢賦權藥劑業及毒藥（裝造商牌照）委員會（"委員會"）認可的課程後頒授的資格；及

(b) 有關的人－

(i) 在香港或香港以外地區，具有最少3年按照有關文件製造藥劑製品的相關經驗（有關文件是《GMP指引》或由香港以外地區的主管當局發出或獲其採納的、與《GMP指引》類似或相等於《指引》的文件）；或

(ii) 符合委員會指明的任何其他準則。

3. 擬議的第 30C 條列明，申請人無論是註冊藥劑師或持有修畢委員會認可課程頒授資格的人士，均必須具有最少三年 GMP 制藥或品質控制的經驗。

4. 從以上的修訂可以看到，註冊藥劑師仍會是"獲授權人"的主要資歷要求。而第 30C 條第 2 款(a)(ii)的要求是與國際上的做法一致。鑒於藥物生產及品質控制的多樣性及複雜性，製藥過程涉及不同科學範疇的考慮，故此"獲授權人"的資歷要求亦需多元化。因此，"獲授權人"應由具備相關知識和經驗的人士出任，而不一定局限由註冊藥劑師出任，擁有有關科學性科目資格和相關資歷的人士同樣可以出任，這是在國際上常見的要求。歐盟也是採用這樣的安排，歐盟的 Directive 2001/82/EC 第 53(2)條(見附件)規定：

> "The qualified person shall be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognized as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology."

5. 衞生署正與顧問公司擬訂相關要求，當中包括認可相關大學資歷以及修畢與製藥相關的課程，預計有關認可架構於今年內提交藥劑業和毒藥管理局（"管理局"）審批及對外

公布詳情。此外，《條例草案》亦建議要求"獲授權人"遵守管理局所定立的《執業守則》；違反註冊條件、《執業守則》或相關法例的"獲授權人"亦需面對取消或暫時吊銷註冊的懲處。

6. 我們希望重申，《條例草案》建議引入"獲授權人"的制度，是按照香港藥物監管制度檢討委員會("檢討委員會")就提升香港在生產藥劑製品方面的 GMP 標準而提出的其中一項建議。檢討委員會的建議已考慮了衞生署在 2009 年 5 月委託來自澳洲專門研究 GMP 的海外專家經參考了全球主要藥物監管當局所採取的新措施而為香港的 GMP 進行顧問研究和提出建議。《條例草案》的建議目的是建立對"獲授權人"的註冊及規管制度，確保他們能有效地履行職責，以便對製藥專業加強要求及規管，以提升本地製造廠的藥物生產及品質控制水平。我們希望以上能澄清報章上的報導。

食物及衞生局局長

(周雪梅女士  代行)

二零一四年五月十九日

— quantity supplied,

— name and address of the recipient,

— batch number.

These records shall be available for inspection by the competent authorities for a period of at least three years.

Article 51

The principles and guidelines of good manufacturing practice for veterinary medicinal products referred to in Article 50(f) shall be adopted in the form of a Directive addressed to the Member States in accordance with the procedure referred to in Article 89(2).

Detailed guidelines shall be published by the Commission and revised as appropriate to take account of scientific and technical progress.

Article 52

1. Member States shall take all appropriate measures to ensure that the holder of the manufacturing authorization has permanently and continuously at his disposal the services of at least one qualified person who fulfils the conditions laid down in Article 53 and is responsible, in particular, for carrying out the duties specified in Article 55.

2. If he personally fulfils the conditions laid down in Article 53, the holder of the authorization may himself assume the responsibility referred to in paragraph 1.

Article 53

1. Member States shall ensure that the qualified person referred to in Article 52 fulfils the minimum conditions of qualification set out in paragraphs 2 and 3.

2. The qualified person shall be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognized as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, medicine, veterinary science, chemistry, pharmaceutical chemistry and technology, biology.

However, the minimum duration of the university course may be three and a half years where the course is followed by a period of theoretical and practical training of at least one year and includes a training period of at least six months in a pharmacy open to the public, corroborated by an examination at university level.

Where two university or recognized equivalent courses coexist in a Member State and where one of these extends over four years and the other over three years, the diploma, certificate or other evidence of formal qualifications awarded on completion of the three-year university course or its recognized equivalent shall be considered to fulfil the condition of duration referred to in the first subparagraph in so far as the diplomas, certificates or other evidence of formal qualifications awarded on completion of both courses are recognized as equivalent by the State in question.

The course shall include theoretical and practical tuition bearing upon at least the following basic subjects:

— experimental physics,

— general and inorganic chemistry,

— organic chemistry,

— analytical chemistry,

— pharmaceutical chemistry, including analysis of medicinal products,

— general and applied biochemistry (medical),

— physiology,

— microbiology,

— pharmacology,

— pharmaceutical technology,

— toxicology,

— pharmacognosy (study of the composition and effects of the active principles of natural substances of plant and animal origin).

Tuition in these subjects should be so balanced as to enable the person concerned to fulfil the obligations specified in Article 55.

In so far as certain diplomas, certificates or other evidence of formal qualifications mentioned in this paragraph do not fulfil the criteria laid down above, the competent authority of the Member State shall ensure that the person concerned provides evidence that he has, in the subjects involved, the knowledge required for the manufacture and control of veterinary medicinal products.

3. The qualified person shall have acquired practical experience over at least two years, in one or more undertakings which are authorized manufacturers, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of veterinary medicinal products.

The duration of practical experience may be reduced by one year where a university course lasts for at least five years and by a year and a half where the course lasts for at least six years.

Article 54

1. A person engaging, in a Member State, in the activities of the person referred to in Article 52 at the date on which