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Food and Health Bureau, Government Secretariat
The Government of the Hong Kong Special Administrative Region
The People's Republic of China

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19 May 2014

Prof Hon Joseph LEE Kok-long
Chairman
Bills Committee on Pharmacy and Poisons (Amendment) Bill 2014
Legislative Council Complex
1 Legislative Council Road
Hong Kong

Dear Prof Hon Lee,

Pharmacy and Poisons (Amendment) Bill 2014

In response to an earlier newspaper report alleging that the proposed registration system of authorized person (AP) as introduced by the Pharmacy and Poisons (Amendment) Bill 2014 (the Bill) would undermine the regulation of pharmaceutical products manufactured in Hong Kong, our clarification is as follows.

2. The Bill proposes to add new regulations 30A to 30F to the Pharmacy and Poisons Regulations (Cap. 138A) (the Regulations). Under those proposed regulations, a licensed manufacturer is required to employ at least one AP to ensure and certify that each and every batch of pharmaceutical products manufactured by the manufacturer is in compliance with the Good Manufacturing Practice (GMP) Guide, registered particulars and requirements of relevant legislations. In particular, regulation 30C(2) stipulates the qualification requirements for APs as follows :

(a) the person -

(i) is a registered pharmacist; or

(ii) holds a qualification awarded on completion of a course recognised by the Pharmacy and Poisons (Manufacturing Licensing) Committee (the Committee); and

(b) the person -

(i) has at least 3 years' relevant experience in Hong Kong or a place outside Hong Kong in manufacturing pharmaceutical products in accordance with the GMP Guide or a document similar or equivalent to that Guide issued or adopted by a competent authority of a place outside Hong Kong; or

(ii) meets any other criteria that the Committee may specify.

3. The proposed regulation 30C provides that all applicants, both registered pharmacists and persons holding a qualification awarded on completion of a course recognised by the Committee, must have at least 3 years' experience in GMP pharmaceutical product manufacturing or quality control.

4. As shown by the above amendments, being a registered pharmacist remains to be the major qualification requirement for APs. The requirement stipulated in regulation 30C(2)(a)(ii) is in line with international practice. Given the diversified and complicated nature of pharmaceutical products manufacturing and quality control, various scientific considerations are involved in the course of pharmaceutical product manufacturing, the qualification requirements for APs also need to be diversified. In this regard, the positions of APs should be filled by persons who possesses relevant expertise and experience, and should not be restricted to registered pharmacists. Any person who possesses the required qualifications in scientific disciplines or equivalent qualifications could also act as an AP. This is a common international practice which is also adopted by the European Union (EU). Article 53 (2) of the EU's Directive 2001/82/EC (see Annex) provides that:

> "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. The Department of Health (DH) and the consultant are now drawing up the relevant requirements for APs, including, inter alia, holding recognised university qualifications and completion of courses related to pharmaceutical product manufacturing. It is expected that the recognition system will be submitted to the Pharmacy and Poisons Board (the Board) for consideration and make available to the public within this year. In addition, the Bill proposes to require APs to comply with the codes of practice issued by the Board; and provides for deregistration or suspension of the registration of AP if the conditions of registration, the codes of practice or relevant legislations are contravened.

6. We would like to reiterate that the proposed AP system as introduced by the Bill is made in accordance with one of the recommendations put forth by the Review Committee on Regulation of Pharmaceutical Products in Hong Kong (the Review Committee) in respect of upgrading Hong Kong's GMP standards in manufacturing pharmaceutical products. The Review Committee's recommendations have taken into account the study and recommendations on Hong Kong's GMP made by a consultancy study, which was commissioned by the DH and conducted by overseas GMP experts from Australia in May 2009, in the light of the latest practices adopted by major drug regulatory authorities in the world. The objective of this proposal put forth by the Bill is to establish a registration and regulatory system for APs to ensure that they are capable of discharging their duties for strengthening the requirements and regulation of pharmaceutical industry and raising the standards of pharmaceutical product manufacturing and quality control of local manufacturers. We hope the above can help clarify the issue raised in the newspaper report.

Yours sincerely,

(Miss Fiona CHAU)
for Secretary for Food and Health

— 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