立法會
Legislative Council

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Paper for the House Committee

Report of Subcommittee on Pharmacy and Poisons (Amendment) (No. 5) Regulation 2017

Purpose

This paper reports on the deliberations of the Subcommittee on Pharmacy and Poisons (Amendment) (No. 5) Regulation 2017 ("the Subcommittee").

Background

2. Under section 29(1B) of the Pharmacy and Poisons Ordinance (Cap. 138) ("PPO"), the Pharmacy and Poisons Board ("the Board") set up under section 3 of PPO is empowered to make regulations to amend the Poisons List; or any list of articles or substances in the Pharmacy and Poisons Regulations (Cap. 138A) ("PPR"), subject to section 31[1] of PPO and to the approval of the Secretary for Food and Health ("SFH").

3. According to the Administration, arising from an application for registration of a pharmaceutical product, the Board proposes adding Netupitant and its salts ("the relevant substance") to Division A of the First Schedule, Division A of the Third Schedule and Division A of Part I of the Poisons List set out in the Tenth Schedule to PPR. Details of the relevant substance are set out in **Appendix I**. The Board considers the proposal appropriate in view of

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[1] Section 31(1) of the Pharmacy and Poisons Ordinance (Cap. 138) provides for the establishment and composition of a Poisons Committee which is for the purposes of advising the Pharmacy and Poisons Board on the classification and distribution of poisons in Part 1 and Part 2 of the Poisons List and matters relating to the control of the manufacture and distribution of poisons and pharmaceutical products. Under section 31(2) thereof, in determining the distribution of poisons in Part 1 and Part 2 of the Poisons List the Board shall, after considering the advice of the Poisons Committee, have regard to the desirability of restricting to Part 2 substances which are in common use, or are likely to come into common use, and which it is reasonably necessary to include in the said Part 2 if the public are to have adequate facilities for obtaining them.

the potency, toxicity and potential side effects of the relevant substance.

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2017

4. The Pharmacy and Poisons (Amendment) (No. 5) Regulation 2017 ("the Amendment Regulation"), made by the Board under section 29(1B) of PPO with SFH's approval, gives effect to the Board's aforesaid proposal. The Amendment Regulation came into operation on the day of publication in the Gazette, i.e. 13 October 2017.

The Subcommittee

5. At the House Committee meeting on 20 October 2017, Members formed a subcommittee to study the Amendment Regulation tabled at the Legislative Council meeting of 18 October 2017. The membership list of the Subcommittee is in **Appendix II**.

6. Under the chairmanship of Hon CHAN Han-pan, the Subcommittee has held one meeting with the Administration.

Deliberations of the Subcommittee

Registration requirements for pharmaceutical products

7. Some members including Dr Hon KWOK Ka-ki are concerned that spinal muscular atrophy patients are unable to use the drug, viz. Spinraza, for treatment of the disease concerned because it has not yet been registered in Hong Kong. The Administration has advised that application for registration and importation of the drug to Hong Kong has to be initiated by the pharmaceutical company concerned. The Administration has already contacted that company on whether it will make the drug available in Hong Kong. In addition, a mechanism has been put in place to provide, under special circumstances, patients with drugs which have not been registered.

8. Dr Hon KWOK Ka-ki has enquired about who applied for the registration of the relevant substance, the date of receiving the application, the mechanism and time taken for assessing the application and the date of approving the application. In response, the Administration has provided the Subcommittee with the sequence of event for the application containing the new drug ingredient Netupitant which is in **Appendix III**.

9. Regarding Dr KWOK's request for a list of documents to be produced by an applicant for registration of a pharmaceutical product, the Administration has advised that according to Regulation 36 of PPR, products that fall within the definitions of "pharmaceutical product" as stipulated in Section 2 of PPO must fulfill the requirements of PPO on safety, quality and efficacy, and be registered with the Board before they can be sold or distributed in Hong Kong. When applying for the registration of a pharmaceutical product, the applicant should provide sufficient information to the Board to substantiate the pharmaceutical product's fulfilment of the requirements on safety, quality and efficacy. Such information includes the master formula, specifications, certificate of analysis and method of analysis, manufacturer's licence, the Pharmaceutical Inspectorate Co-operation Scheme good manufacturing practice certificate, free sale certificate issued by the drug regulatory authority of the country of origin, sales pack label, relevant scientific data or references, and stability data. If the product under application is a new medicine, the applicant should also submit relevant clinical study data, risk management plan, product insert, and two or more free sale certificates issued by reference countries. All the requirements are listed on the website[2] of the Drug Office of DH.

Possession of controlled pharmaceutical products for personal use

10. Some members including Hon James TO are concerned whether a person commits an offence if he/she is in possession of those pharmaceutical products, which are subject to the same control as those consisting of the relevant substance, ("controlled pharmaceutical products") for his/her personal use with a prescription by a non-locally registered medical practitioner. In this connection, they have enquired about the relevant policy and legislation.

11. According to the Administration, importation and exportation of pharmaceutical products are controlled under the Import and Export Ordinance (Cap. 60) ("IEO") which is enforced by the Customs and Excise Department. Under sections 6C and 6D of IEO, importation and exportation of pharmaceutical products must be covered by licences issued by DH under delegated authority of the Director-General of the Trade and Industry Department. Contravention of such provisions are criminal offences and are subject to a maximum penalty of a fine of $500,000 and imprisonment of two years upon conviction. Nevertheless, under section 6(1)(c)(i) of the Import and Export (General) Regulations (Cap. 60A), pharmaceutical products imported or exported in the accompanied personal baggage of a person entering

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[2] The address of the website is http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/guid.pdf?v=72jz3h.

or leaving Hong Kong for his or her personal use and in reasonable quantity may be exempted from the licensing requirement. He or she should bring along a letter from the prescribing doctor certifying the name, quantity and dosage of the pharmaceutical products concerned so as to make it available for inspection as and when required.

Internet sale of pharmaceutical products

12. Some members including Hon James TO have enquired about regulation of Internet sale of controlled pharmaceutical products and details of the relevant legislation. Noting that the Amendment Regulation came into operation on 13 October 2017, Mr TO is concerned whether a person commits an offence for purchasing pharmaceutical products consisting of the relevant substance from the Internet with a prescription from a locally registered medical practitioner.

13. According to the Administration, PPO imposes different levels of restriction on the sale and supply of registered pharmaceutical products. Pharmaceutical products consisting of the relevant substance are classified under PPO as Part 1 poisons[3], Schedule 1 poisons[4] and Schedule 3 poisons[5] and the corresponding retailers or wholesalers should also obtain relevant licences. Under section 21 of PPO, pharmaceutical products containing Part 1 poisons (which include Schedule 1 poisons) are "Pharmacy-only medicines". The sale of such medicines does not require doctor's prescription but they have to be sold in licensed pharmacies under the direction and supervision of a registered pharmacist. According to sections 23 and 28 of PPO, no person shall have in his or her possession any Part 1 poisons unless the possession is in accordance with the provisions of PPO. Nevertheless, PPO does not prohibit any person from possession of Part 1 poisons where medicines containing such poisons are supplied in accordance with PPO by a registered medical practitioner for the purposes of medical treatment, by a registered dentist for the purposes of dental treatment or by a registered veterinary surgeon for the purposes of animal treatment; or where medicines containing such poisons are dispensed or supplied in accordance with the relevant provisions under PPO by a licensed pharmacy on its registered premises.

14. The Administration has further advised that any person who is involved in illegal sale (including Internet sale) or possession of unregistered pharmaceutical products or Part 1 poisons contravenes PPO and is subject to a maximum penalty of a fine of $100,000 and imprisonment of two years upon

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[3] They are poisons listed in Part 1 of the Poison List set out in the Tenth Schedule to PPR.

[4] They are poisons listed in the First Schedule to PPR.

[5] They are poisons listed in the Third Schedule to PPR.

conviction of each offence. DH has advised members of the public, via its website, video clips and pamphlets, not to purchase or use products with doubtful ingredients or sources. As unregistered pharmaceutical products have not been assessed by the Board, their safety, quality and efficacy could not be ascertained. The Hong Kong registration number for a registered pharmaceutical product should be labelled on the sales pack in the form of "HK-XXXXX". Members of the public can search for information on registered pharmaceutical products in Hong Kong by using the "Search Drug Database" function on the website[6] of the Drug Office by entering the product's English name or Hong Kong registration number. Member of the public are advised to consult healthcare professionals prior to using any pharmaceutical products.

Recommendation

15. The Subcommittee raises no objection to the Amendment Regulation and will not propose any amendment to it.

Advice Sought

16. Members are invited to note the deliberations of the Subcommittee.

Council Business Division 2
Legislative Council Secretariat
8 November 2017

[6] The address of the website is http://www.drugoffice.gov.hk/eps/do/en/consumer/search_drug_database.html.

Appendix I

附錄 I

Details of Netupitant and its salts

奈妥匹坦及其鹽類的詳情

Netupitant; its salts	Part 1 of the Tenth Schedule, First and Third Schedules poison	This drug is used in adults and in combination with palonosetron for the prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based and moderately emetogenic cancer chemotherapy. Side effects include headache, constipation and fatigue. Its use should be decided by a doctor based on the patient's conditions.
奈妥匹坦；其鹽類	附表十的第一部，附表一及附表三毒藥	此藥物與帕洛諾司瓊聯合使用於成年患者，預防與高致吐性順鉑基礎及中度致吐性癌症化療相關的急性和延遲性噁心和嘔吐。 副作用包括頭痛、便秘和疲勞。 使用此藥物與否，須由醫生按病人情況決定。

Source: *Annex B to the Legislative Council Brief entitled "Subcommittee on Pharmacy and Poisons (Amendment) (No.5) Regulation 2017" issued in October 2017 (File Ref.: FHB/H/23/4)*

資料來源： *在 2017 年 10 月發出的題為"《2017 年藥劑業及毒藥(修訂)(第 5 號)規例》"的立法會參考資料摘要附件 B (檔號：FHB/H/23/4)*

Appendix II

Subcommittee on Pharmacy and Poisons (Amendment) (No.5) Regulation 2017

Membership list

Chairman	Hon CHAN Han-pan, JP
Members	Hon James TO Kun-sun Hon CHAN Kin-por, GBS, JP Dr Hon Priscilla LEUNG Mei-fun, SBS, JP Dr Hon KWOK Ka-ki Dr Hon Helena WONG Pik-wan Dr Hon Junius HO Kwan-yiu, JP Hon SHIU Ka-fai Hon YUNG Hoi-yan Hon LUK Chung-hung Hon Kenneth LAU Ip-keung, BBS, MH, JP Hon KWONG Chun-yu (Total : 12 members)
Clerk	Mr Colin CHUI
Legal adviser	Mr Alvin CHUI

Product Name: Akynzeo Capsules 300mg/0.5mg
Composition: Each capsule contains netupitant 300mg and palonosetron 0.5mg
Applicant: Mundipharma (Hong Kong) Limited

SEQUENCE OF EVENT FOR THE APPLICATION OF AKYNZEO CAPSULES 300MG/0.5MG

Date	Actions by the Applicant	Actions by the DH
17.10.2016	Submission of application	
20.10.2016		The DH conducted preliminary screening of the application and informed the applicant on the outstanding documents
30.12.2016	Applicant re-submitted the application with the outstanding documents	
5.1.2017		The DH accepted the application and informed the applicant to pay the application fee
6.1.2017	Applicant paid the application fee	
10.1.2017		The DH conducted evaluation and informed the applicant on the following outstanding documents: 1. certified true copy of the US CPP 2. comparison of package inserts 3. information on any withdrawal or refusal of application in other places 4. clarification of the RMP 5. clarification on the risks of TSE by the gelatin capsule 6. declaration for the gelatin capsule to comply with pharmacopoeial standards 7. amending the sales pack 8. amending the package insert 9. photo of the product 10. justification of product specifications 11. copy of the Quality Overall Summary
14.2.2017	Applicant replied with the outstanding documents	
28.2.2017		The DH conducted evaluation on the submitted documents and informed the

Date	Actions by the Applicant	Actions by the DH
		applicant on the following outstanding documents: 1. certified true copy of the US CPP 2. clarifications on the posology 3. clarifications on the package insert
20.3.2017	Applicant replied with the outstanding documents	
30.3.2017		TheDH conducted evaluation on the submitted documents and informed the applicant on the following outstanding document: 1. request for the final package insert
31.3.2017	Applicant replied with the final package insert	
3.4.2017		Documents were satisfactory for the meeting of Registration Committee
1.6.2017		Internal meeting on the application by DH senior colleagues
2.6.2017		After the internal meeting, DH informed the applicant to include additional safety warnings in the package insert of the product.
5.6.2017	Applicant replied with the additional safety warnings in the package insert of the product.	
30.6.2017		The Registration Committee approved the application.
3.7.2017 - 25.7.2017		The DH internal administration to prepare the registration certificate
26.7.2017		The DH informed the applicant to pay the registration certificate fee
31.7.2017	Applicant paid the registration certificate fee	
8.8.2017		The DH sent the registration certificate to the applicant by post

Source: *Annex to the Administration's response for the meeting of the Subcommittee on Pharmacy and Poisons (Amendment) (No. 5) Regulation 2017 on 31 October 2017 (LC Paper No. CB(2)240/17-18(01) issued on 3 November 2017).*