立法會 Legislative Council

LC Paper No. CB(2)318/17-18 (These minutes have been seen by the Administration)

Ref: CB2/SS/2/17

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

Minutes of meeting held on Tuesday, 31 October 2017, at 2:30 pm in Conference Room 3 of the Legislative Council Complex

Members: Hon CHAN Han-pan, JP (Chairman)

present Hon James TO Kun-sun

Hon CHAN Kin-por, GBS, JP

Dr Hon KWOK Ka-ki

Dr Hon Helena WONG Pik-wan

Hon SHIU Ka-fai Hon YUNG Hoi-yan Hon LUK Chung-hung

Hon Kenneth LAU Ip-keung, BBS, MH, JP

Hon KWONG Chun-yu

Members : Dr Hon Priscilla LEUNG Mei-fun, SBS, JP

absent Dr Hon Junius HO Kwan-yiu, JP

Public Officers: Mr Howard CHAN

attending Deputy Secretary for Food and Health (Health)1,

Food and Health Bureau

Ms Linda WOO

Assistant Director (Drug), Department of Health

Mr Clive CHAN

Senior Pharmacist (Drug Registration)1,

Department of Health

Mr James LAM

Assistant Secretary for Food and Health (Health)2,

Food and Health Bureau

Clerk in : Mr Colin CHUI

attendance Chief Council Secretary (2) 4

Staff in : Mr Alvin CHUI

attendance Assistant Legal Adviser 3

Ms Catherina YU

Senior Council Secretary (2) 4

Miss Alison HUI

Legislative Assistant (2) 4

Action

I. Election of Chairman

Election of Chairman

Mr James TO, member present who had the highest precedence, presided over the election of Chairman of the Subcommittee. Mr TO called for nominations for the chairmanship of the Subcommittee. Mr CHAN Han-pan was nominated by Mr SHIU Ka-fai and the nomination was seconded by Ms YUNG Hoi-yan. Mr CHAN accepted the nomination.

- 2. As there was no other nomination, <u>Mr TO</u> declared Mr CHAN Han-pan elected as Chairman of the Subcommittee. Mr CHAN then took the chair.
- 3. Members agreed that there was no need to elect a Deputy Chairman for the Subcommittee.

II. Meeting with the Administration

[File Ref.: FHB/H/23/4, L.N. 167 of 2017, LC Paper Nos. LS3/17-18 and CB(2)176/17-18(01)]

- 4. <u>The Subcommittee</u> requested the Administration to provide the following information:
 - (a) the policy and the relevant legislation relating to the handling of cases under which a person was in possession of controlled pharmaceutical products with prescriptions by a non-locally registered medical practitioner for personal use;
 - (b) who applied for the registration of Netupitant and its salts, the date of receiving the application, the mechanism and time taken for assessing the application and the date of approving the application;
 - (c) a list of documents required to be produced by an applicant for registration of a pharmaceutical product; and
 - (d) relevant legislation relating to prohibition on Internet sale of controlled pharmaceutical products.

(*Post-meeting note:* The Administration's response was issued to members vide LC Paper No. CB(2)240/17-18(01) on 3 November 2017.)

III. Any other business

- 5. <u>Members</u> noted that the Subcommittee would report its deliberations to the House Committee on 3 November 2017. The deadline for giving notice of amendment was 8 November 2017 and the expiry date of scrutiny period was 15 November 2017.
- 6. There being no other business, the meeting ended at 3:33 pm.

Council Business Division 2
<u>Legislative Council Secretariat</u>
14 November 2017

Proceedings of the meeting of the Subcommittee on Pharmacy and Poisons (Amendment) (No. 5) Regulation 2017 on Tuesday, 31 October 2017, at 2:30 pm in Conference Room 3 of the Legislative Council Complex

Time marker	Speaker(s)	Subject(s)	Action required
Agenda item I – El	ection of Chairman		
000513 - 000631	Mr James TO Mr SHIU Ka-fai Ms YUNG Hoi-yan Mr CHAN Han-pan	Nominations for the chairmanship of the Subcommittee.	
	Chairman	Election of Chairman	
Agenda item II – M	leeting with the Administra	tion	
000632 - 002049	Chairman Administration Mr James TO	Briefing by the Administration on the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2017 ("the Amendment Regulation") (Legislative Council Brief (File Ref.: FHB/H/23/4) issued by the Food and Health Bureau).	
		Mr James TO's enquiry and the Administration's response regarding the criteria for adding certain substances to Schedule 3 to the Pharmacy and Poisons Regulations (Cap. 138A) and the identification of controlled pharmaceutical products.	
		Mr TO's enquiry and the Administration's response regarding the regulation of controlled pharmaceutical products which were brought to Hong Kong for personal use.	
		Mr TO's enquiry and the Administration's response regarding whether a person who was in possession of controlled pharmaceutical products committed an offence.	
002050 - 002432	Chairman Mr CHAN Kin-por Mr LUK Chung-hung Administration	Views of Mr CHAN Kin-por and Mr LUK Chung-hung that as the Administration's proposed amendments to Cap. 138A were straight-forward, the Subcommittee should not require too much time for examining the Administration's proposal.	
		The Administration advised the Subcommittee that more than 90 substances had been added to relevant Schedules to Cap. 138A by way of negative vetting since 2015. The sooner the inclusion of Netupitant and its salts ("the relevant substance") in Cap. 138A, the earlier patients	

Time marker	Speaker(s)	Subject(s)	Action required
		could benefit from any new drugs containing such substance. Mr LUK Chung-hung's enquiry regarding the recall mechanism for pharmaceutical products which contained the relevant substance before its inclusion in relevant Schedules to Cap. 138A. The Administration's response that the relevant substance had not been registered and sold in Hong Kong before.	
002433 - 003739	Chairman Mr James TO ALA3 Administration Mr CHAN Kin-por	In response to Mr James TO's enquiry, ALA3 referred members to section 23 of the Pharmacy and Poisons Ordinance (Cap. 138) which concerned possession of poisons included in Part I of the Poisons List set out in Schedule 10 to Cap. 138A. ALA3's advice that the relevant substance would be subject to regulation of section 23 of Cap. 138 as it had been added to the relevant Schedules to Cap. 138A by virtue of the Amendment Regulation. At the request of the Chairman and Mr James TO, ALA3 explained the exemptions with regard to a poison that was obtained in the circumstances set out in section 28(1) of Cap. 138. Mr James TO's concern about the legal implications on a person who brought controlled pharmaceutical products to Hong Kong for personal use. Mr TO's enquiry and the Administration's response regarding whether a person committed an offence if he/she was in possession of controlled pharmaceutical products with a prescription by a non-locally registered medical practitioner. At Mr TO's request, the	Admin
		Administration undertook to provide information on the policy and the relevant legislation relating to the handling of cases under which a person was in possession of controlled pharmaceutical products with prescriptions by a non-locally registered medical practitioner for personal use. Mr CHAN Kin-por's view that members should first accept the Administration's proposed amendments for the interests of patients and allow time for the Administration to take steps to address members' concerns.	(paragraph 4(a) of the minutes)
003740 - 004211	Chairman Mr James TO Administration	In response to Mr James TO's concern that a patient might purchase controlled medicines from places outside Hong Kong so as to save the	

Time marker	Speaker(s)	Subject(s)	Action required
		consultation fees, the Administration advised that the patient should consult a registered doctor for treatment and prescription of medicine. But it would be up to the individual to decide where he would wish to seek medical consultation.	
004212 - 005354	Chairman Dr KWOK Ka-ki Administration	Dr KWOK Ka-ki's concern that spinal muscular atrophy patients were unable to use a certain drug because it had not yet been registered in Hong Kong. Dr KWOK's enquiry and the Administration's response regarding the reasons why such drug was not introduced to and registered in Hong Kong. The Administration advised that a mechanism had been put in place to provide patients with drugs which had not been registered under special circumstances.	
		Dr KWOK's enquiry and the Administration's response regarding 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. Dr KWOK's request for a written response in this regard. He also requested for a list of documents required to be produced by an applicant for registration of a pharmaceutical product.	Admin (paragraph 4(b) and (c) of the minutes)
		Dr KWOK's enquiry and the Administration's response regarding whether there was a mechanism to ensure patients would be provided with suitable drugs before new pharmaceutical products were registered in Hong Kong. The Administration advised that the Hospital Authority had mechanism in place for access of unregistered drugs by individual patients on a need basis.	
005355 - 010115	Chairman Mr James TO Administration	Mr James TO's concern about the implications of adding pharmaceutical products to Cap. 138A on members of the public. Mr James TO's enquiry and the Administration's	
		response regarding whether a person committed an offence if he/she purchased pharmaceutical products containing the relevant substance from the Internet with a prescription from a locally registered medical practitioner after the substance had been included in the relevant Schedules to Cap. 138A. At Mr TO's request, the Administration undertook to provide information on relevant legislation relating to prohibition on Internet sale of controlled pharmaceutical products.	Admin (paragraph 4(d) of the minutes)

Time marker	Speaker(s)	Subject(s)	Action required	
010116 - 010605	Chairman Administration Ms YUNG Hoi-yan	Section-by-section examination of the Amendment Regulation Completion of scrutiny.		
Agenda item III - Any other business				
010606 - 010610	Chairman Ms YUNG Hoi-yan	Members noted the legislative timetable.		
		Members agreed that it was not necessary for the Subcommittee to meet with deputations and hold		
		further meetings.		

Council Business Division 2 <u>Legislative Council Secretariat</u> 14 November 2017