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/23/4
Your ref: CB2/SS/2/17

Tel no: 3509 8956
Fax no: 2840 0467

3 November 2017

Mr Colin CHUI
Clerk to Subcommittee on Pharmacy and Poisons (Amendment) (No. 5) Regulation 2017
Legislative Council Complex
1 Legislative Council Road
Central, Hong Kong

Dear Mr CHUI,

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

At the meeting on 31 October 2017, the Subcommittee on Pharmacy and Poisons (Amendment) (No. 5) Regulation 2017 requested for the following –

(i) 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;
(ii) 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;
(iii) a list of documents required to be produced by an applicant for registration of a pharmaceutical product; and
(iv) relevant legislation relating to prohibition on Internet sale of controlled pharmaceutical products.

The Government has set out the relevant reference materials for Member's information.

According to regulation 36 of the Pharmacy and Poisons Regulations (PPR) (Cap. 138A), products that fall within the definition of "pharmaceutical product" as stipulated in section 2 of the Pharmacy and Poisons Ordinance (PPO) (Cap. 138) must fulfill the requirements of the PPO on safety, quality and efficacy, and be registered with the Pharmacy and Poisons Board of Hong Kong (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 that the pharmaceutical product can fulfill 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 (PIC/S) good manufacturing practice (GMP) 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 of the Drug Office of the Department of Health (DH) (http://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/guid.pdf?v=72jz3h).

Please refer to Annex for the sequence of event for the application containing the new drug ingredient Netupitant.

The PPO imposes different levels of restriction on the sale and supply of registered pharmaceutical products that are classified as Part 1 poisons, Part 2 poisons, Schedule 1 poisons and Schedule 3 poisons and the corresponding retailers or wholesalers should also obtain relevant licences.

Regulation 9 of the PPR stipulates that pharmaceutical products containing Schedule 3 poisons are "prescription-only medicines" and they must be dispensed and sold on doctor's prescriptions in licensed pharmacies (Authorized Seller of Poisons) under the direct supervision of a registered pharmacist.

Under section 21 of the PPO, pharmaceutical products containing Part 1 poisons (which includes Schedule 1 poisons) are "pharmacy-only medicines". Their sale does not require doctor's prescription but they have to be sold in licensed pharmacies under the direction and supervision of a registered pharmacist.

Pharmaceutical products containing Part 2 poisons or non-poisons are "over-the-counter medicines". Their sale does not require doctor's prescription. Pharmaceutical products containing non-poisons can be sold in licensed pharmacies, licensed medicines stores (Listed Sellers of Poisons) or any unlicensed retail shops, while under section 26 of the PPO, pharmaceutical products containing Part 2 poisons can be sold in licensed pharmacies or licensed medicines stores.

According to sections 23 and 28 of the PPO, no person shall have in his possession any Part 1 poisons otherwise than in accordance with the provisions of the PPO (including the aforementioned provisions). Nevertheless, the PPO does not prohibit any person from possession of Part 1 poisons where medicines containing Part 1 poisons are supplied in accordance with the 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 Part 1 poisons are dispensed or supplied in accordance with the relevant provisions under the PPO by a licensed pharmacy on the registered premises.

On the other hand, importation and exportation of pharmaceutical products are controlled under the Import and Export Ordinance (Cap. 60). Under sections 6C and 6D of the Import and Export Ordinance, importation and exportation of pharmaceutical products must be covered by licences issued by the DH under delegated authority of the Director-General of Trade and Industry Department. Contravention of such provisions is a criminal offence and may be subject to a maximum penalty of a fine of $500,000 and imprisonment of 2 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 or leaving Hong Kong for his or her personal use and in reasonable quantity may be exempted from 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. The Import and Export Ordinance is enforced by the Customs and Excise Department.

Any person who is involved in illegal sale (including internet sale) or possession of unregistered pharmaceutical products or Part 1 poisons contravenes the PPO and is subject to a maximum penalty of a fine of $100,000 and imprisonment of 2 years upon conviction of each offence.

The 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. Unregistered pharmaceutical products have not been assessed by the Board, thus 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 of the Drug Office (http://www.drugoffice.gov.hk/eps/do/en/consumer/search_drug_database.html) 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 medicines.

Yours sincerely,

(James LAM)
for Secretary for Food and Health

Encl.

c.c. Department of Health (Attn: Ms Linda WOO)

Annex

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