LEGISLATIVE COUNCIL BRIEF

Pharmacy and Poisons Ordinance (Cap. 138)

PHARMACY AND POISONS (AMENDMENT) (NO.4) REGULATION 2019

INTRODUCTION

The Pharmacy and Poisons Regulations ("the Regulations") (Cap. 138A) was made under section 29 of the Pharmacy and Poisons Ordinance ("the Ordinance") (Cap. 138). The Pharmacy and Poisons (Amendment) (No.4) Regulation 2019 ("the Amendment Regulation") at **Annex A** is to amend Schedule 1, Schedule 3 and Schedule 10 to the Regulations.

JUSTIFICATIONS

Background

2. The Pharmacy and Poisons Board ("the Board") is established under section 3 of the Ordinance. Under section 29(1B) of the Ordinance, the Board is empowered to make regulations to amend the Poisons List; or any list of articles or substances in the Regulations, subject to the approval of the Secretary for Food and Health and of the Poisons Committee, established under section 31 of the Ordinance.

Proposal of the Pharmacy and Poisons Board

3. Arising from applications for registration of pharmaceutical products, and from an ongoing review of sales control of pharmaceutical products, the Board proposes adding the following 15 drugs to Division A of Schedule 1 (relating to the requirement to keep sales records), Division A of Schedule 3 (relating to the requirements to supply in accordance with a prescription and to keep dispensing records) and Division A of Part

1 of the Poisons List in Schedule 10 (relating to the requirements for sales to be conducted in a pharmacy by a registered pharmacist or in his presence and under his supervision, and for the drugs to be kept in a locked receptacle) to the Regulations –

- (a) "Dacomitinib; its salts";
- (b) "Efinaconazole; its salts";
- (c) "Erenumab";
- (d) "Isavuconazole; its salts; its derivatives; their salts";
- (e) "Latanoprostene bunod; its salts";
- (f) "Lorlatinib; its salts";
- (g) "Neratinib; its salts";
- (h) "Nifuratel; its salts";
- (i) "Nifuroxazide; its salts";
- (i) "Nitrofural; its salts";
- (k) "Nitrofurantoin; its salts";
- (1) "Nitroxoline; its salts";
- (m) "Omega-3 fatty acids; their salts; their esters; when contained in pharmaceutical products intended to be used for the treatment of hypertriglyceridaemia";
- (n) "Piracetam; its salts"; and
- (o) "Sugammadex; its salts; its esters; their salts".
- 4. Details of the above drugs (in paragraph 3) are set out at **Annex B**. The Board considers the proposed amendments appropriate in view of the potency, toxicity and potential side effects of the drugs.

THE AMENDMENT REGULATION

5. The Amendment Regulation is to add the above drugs (in paragraph 3) to the relevant Schedules to the Regulations.

LEGISLATIVE TIMETABLE

6. The legislative timetable will be –

Publication in the Gazette 18 October 2019
Date of Commencement 18 October 2019¹ or 18 October 2020²

IMPLICATIONS OF THE PROPOSAL

7. The proposal will impose appropriate control on pharmaceutical products which consist of the above drugs (in paragraph 3). The proposal allows the pharmaceutical products to be sold in the market upon fulfillment of relevant regulations.

ENQUIRY

8. For any enquiries, please contact Mr. Dan Chan, Assistant Secretary for Food and Health (Health), at 3509 8956.

Food and Health Bureau October 2019

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¹ For the drugs in paragraph 3(a)-(g), (m) and (o).

² For the drugs in paragraph 3(h)-(l) and (n), the Board recommends that the proposed amendments be implemented 12 months after the date of publication in the Gazette. This is to give affected registration certification holders of pharmaceutical products that contain the drugs in paragraph 3(h)-(l) and (n) sufficient time to (a) recall the affected products from the market and (b) re-label the affected products to comply with the labelling requirements due to changes in sales control.

(Made by the Pharmacy and Poisons Board under section 29(1B) of the Pharmacy and Poisons Ordinance (Cap. 138) subject to the approval of the Secretary for Food and Health)

1. Commencement

- (1) Subject to subsection (2), this Regulation comes into operation on the day on which it is published in the Gazette.
- (2) Sections 3(8), (9), (10), (12) and (13), 4(8), (9), (10), (12) and (13) and 5(8), (9), (10), (12) and (13) come into operation on 18 October 2020.

2. Pharmacy and Poisons Regulations amended

The Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) are amended as set out in sections 3, 4 and 5.

- 3. Schedule 1 amended (substances to which certain restrictions with respect to the sale, supply, labelling and storage apply under regulations 3, 5, 6, 22 and 24)
 - (1) Schedule 1, Division A, after item "Daclizumab"—

Add

- "Dacomitinib; its salts".
- (2) Schedule 1, Division A, after item "Efavirenz; its salts"—

 Add
 - "Efinaconazole: its salts".
- (3) Schedule 1, Division A, after item "Eptifibatide; its salts"—
 Add

Annex A

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2019

Section 3

2

"Erenumab".

(4) Schedule 1, Division A, after item "Irinotecan; its salts"—

Add

"Isavuconazole; its salts; its derivatives; their salts".

- (5) Schedule 1, Division A, after item "Laropiprant; its salts"—Add
 - "Latanoprostene bunod; its salts".
- (6) Schedule 1, Division A, after item "Lorcainide; its salts"—
 Add

"Lorlatinib; its salts".

- (7) Schedule 1, Division A, after item "Nepafenac; its salts"—

 Add
 - "Neratinib; its salts".
- (8) Schedule 1, Division A, after item "Niflumic acid; its salts"—

 Add

"Nifuratel; its salts

Nifuroxazide; its salts".

(9) Schedule 1, Division A, after item "Nitrendipine"—

Add

"Nitrofural; its salts

Nitrofurantoin; its salts".

(10) Schedule 1, Division A, after item "Nitromethaqualone; its salts"—

Add

"Nitroxoline; its salts".

(11) Schedule 1, Division A, after item "Ombitasvir; its salts"—

3

Section 4

1

Add

"Omega-3 fatty acids; their salts; their esters; when contained in pharmaceutical products intended to be used for the treatment of hypertriglyceridaemia".

(12) Schedule 1, Division A, item relating to "Pharmaceutical products for human parenteral administration"—

Repeal

"Piracetam".

(13) Schedule 1, Division A, after item "Pipobroman"—

Add

"Piracetam; its salts".

(14) Schedule 1, Division A, after item "Styramate"—

Add

"Sugammadex; its salts; its esters; their salts".

- 4. Schedule 3 amended (substances required by regulation 9 to be sold by retail only upon a prescription given by a registered medical practitioner, registered dentist or registered veterinary surgeon)
 - (1) Schedule 3, Division A, after item "Daclizumab"—

Add

"Dacomitinib; its salts".

(2) Schedule 3, Division A, after item "Efavirenz; its salts"—

Add

"Efinaconazole; its salts".

(3) Schedule 3, Division A, after item "Eptifibatide; its salts"—

Add

"Erenumab".

Schedule 3, Division A, after item "Irinotecan; its salts"—Add

"Isavuconazole; its salts; its derivatives; their salts".

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2019

(5) Schedule 3, Division A, after item "Laropiprant; its salts"—
Add

"Latanoprostene bunod; its salts".

(6) Schedule 3, Division A, after item "Lorcainide; its salts"—
Add

"Lorlatinib; its salts".

(7) Schedule 3, Division A, after item "Nepafenac; its salts"—

Add

"Neratinib; its salts".

(8) Schedule 3, Division A, after item "Niflumic acid; its salts"—

Add

"Nifuratel; its salts

Nifuroxazide; its salts".

(9) Schedule 3, Division A, after item "Nitrendipine"—

Add

"Nitrofural; its salts

Nitrofurantoin; its salts".

(10) Schedule 3, Division A, after item "Nitromethaqualone; its salts"—

Add

"Nitroxoline; its salts".

(11) Schedule 3, Division A, after item "Ombitasvir; its salts"—
Add

(12) Schedule 3, Division A, item relating to "Pharmaceutical products for human parenteral administration"—

Repeal

"Piracetam".

(13) Schedule 3, Division A, after item "Pipobroman"—

Add

"Piracetam; its salts".

(14) Schedule 3, Division A, after item "Styramate"—

Add

"Sugammadex; its salts; its esters; their salts".

5. Schedule 10 amended (Poisons List)

(1) Schedule 10, section 2, Table, Part 1, Division A, after item "Daclizumab"—

Add

"Dacomitinib; its salts".

(2) Schedule 10, section 2, Table, Part 1, Division A, after item "Efavirenz; its salts"—

Add

"Efinaconazole; its salts".

(3) Schedule 10, section 2, Table, Part 1, Division A, after item "Eptifibatide; its salts"—

Add

"Erenumab".

4) Schedule 10, section 2, Table, Part 1, Division A, after item "Irinotecan; its salts"—

Add

Section 5

"Isavuconazole; its salts; its derivatives; their salts".

Pharmacy and Poisons (Amendment) (No. 4) Regulation 2019

(5) Schedule 10, section 2, Table, Part 1, Division A, after item "Laropiprant; its salts"—

Add

"Latanoprostene bunod; its salts".

(6) Schedule 10, section 2, Table, Part 1, Division A, after item "Lorcainide; its salts"—

Add

"Lorlatinib; its salts".

(7) Schedule 10, section 2, Table, Part 1, Division A, after item "Nepafenac; its salts"—

Add

"Neratinib; its salts".

(8) Schedule 10, section 2, Table, Part 1, Division A, after item "Niflumic acid; its salts"—

Add

"Nifuratel; its salts

Nifuroxazide; its salts".

(9) Schedule 10, section 2, Table, Part 1, Division A, after item "Nitrendipine"—

Add

"Nitrofural; its salts

Nitrofurantoin; its salts".

(10) Schedule 10, section 2, Table, Part 1, Division A, after item "Nitromethaqualone; its salts"—

7

Add

"Nitroxoline; its salts".

(11) Schedule 10, section 2, Table, Part 1, Division A, after item "Ombitasvir; its salts"—

Add

- "Omega-3 fatty acids; their salts; their esters; when contained in pharmaceutical products intended to be used for the treatment of hypertriglyceridaemia".
- (12) Schedule 10, section 2, Table, Part 1, Division A, item relating to "Pharmaceutical products for human parenteral administration"—

Repeal

"Piracetam".

(13) Schedule 10, section 2, Table, Part 1, Division A, after item "Pipobroman"—

Add

"Piracetam; its salts".

(14) Schedule 10, section 2, Table, Part 1, Division A, after item "Styramate"—

Add

"Sugammadex; its salts; its esters; their salts".

Chairman,
Pharmacy and Poisons Board

9 October 2019

Explanatory Note

This Regulation amends the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) to add 15 items to—

- (a) Division A of Schedule 1;
- (b) Division A of Schedule 3; and
- (c) Division A of Part 1 of the Poisons List set out in Schedule 10.
- 2. The amendments relate to requirements concerning sale, supply, labelling and storage. Main effects of the amendments include—
 - (a) that the sale, by retail, of substances specified in the 15 items—
 - (i) may only be effected on registered premises of an authorized seller of poisons by a registered pharmacist or in the presence and under the supervision of a registered pharmacist; and
 - (ii) may only be effected on and in accordance with a prescription by a registered medical practitioner, registered dentist or registered veterinary surgeon; and
 - (b) that the substances, if stored in retail premises, must be stored in a part of the premises to which customers are not permitted access.
- 3. This Regulation also consequentially amends the Divisions referred to in paragraph 1 to remove a sub-item from the item relating to "Pharmaceutical products for human parenteral administration".

Pharmacy and Poisons (Amendment) (No.4) Regulation 2019

Supplementary Information to the Legislative Council

《2019年藥劑業及毒藥(修訂)(第4號)規例》

提交立法會的補充資料

Numb	er Drug Name	Proposed	Remarks
序號	藥名	Classification 建議類別	備註
1	Dacomitinib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	The drug is used for first-line treatment of adult patients with metastatic non-small cell lung cancer with epidermal growth factor receptor exon 19 deletion or exon 21 L858R substitution mutations. Side effects include diarrhoea, rash, decreased appetite, decreased weight and pruritus. The use of the drug should be decided by a doctor based on the patient's conditions.

Number	Drug Name	Proposed Classification	Remarks
序號	藥名	建議類別	備註
	現時沒有中文名稱 ¹	附表一及附表三毒	此藥物用作一線治療患有轉移性非小細胞肺癌,並且有表皮生長因子受體外顯子19缺失或外顯子21 L858R取代型突變的成年患者。
			副作用包括腹瀉、皮疹、食慾下降、體重減輕及瘙癢。
			使用此藥物與否,須由醫生按病人情況決定。
2	Efinaconazole; its salts		The drug is an azole antifungal used for topical treatment of onychomycosis of toenail(s) due to Trichophyton rubrum and Trichophyton mentagrophytes in adult patients.
			Side effects include ingrown toenails, application site dermatitis, application site vesicles and application site pain.

¹ 根據世界衞生組織「國際非專利藥品名稱」(International Nonproprietary Name for Pharmaceutical Substances),「Dacomitinib; its salts」現時沒有正式的中文名稱。

Number	Drug Name	Proposed	Remarks
序號	藥名	Classification 建議類別	備註
			The use of the drug should be decided by a doctor based on the patient's conditions.
	艾非康唑;其鹽類		此藥物是一種唑類抗真菌藥,作為局部治療用於因深紅色髮癬菌及鬚髮癬菌引起的趾甲甲癬的成年患者。
		禾	副作用包括嵌甲、使用部位皮炎、使用部位小泡及使用部位 疼痛。
			使用此藥物與否,須由醫生按病人情況決定。
3	Erenumab	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	The drug is used for the preventive treatment of migraine in adults. Side effects include injection site reactions, constipation, muscle spasms.
			The use of the drug should be decided by a doctor based on the

Number	Drug Name	Proposed	Remarks
序號	藥名	Classification 建議類別	備註
	依瑞奈人單抗	附表一及附表三毒 藥	patient's conditions. 此藥物用於成人作為偏頭痛的預防性治療。 副作用包括注射部位反應、便秘及肌肉痙攣。 使用此藥物與否,須由醫生按病人情況決定。
4	Isavuconazole; its salts; its derivatives; their salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	The drug is used in adults for the treatment of invasive aspergillosis and mucormycosis in patients for whom amphotericin B is inappropriate. Side effects include nausea, vomiting, dyspnoea, abdominal pain and diarrhoea. The use of the drug should be decided by a doctor based on the patient's conditions.

Number 序號	Drug Name 藥名	Proposed Classification 建議類別	Remarks 備註
	艾沙康唑;其鹽類; 其衍生物;它們的鹽 類	附表一及附表三毒 藥	此藥物用於治療入侵性曲霉病和毛霉菌病而不適合使用兩性霉素B的成年患者。 副作用包括噁心、嘔吐、呼吸困難、腹痛及腹瀉。 使用此藥物與否,須由醫生按病人情況決定。
5	Latanoprostene bunod; its salts	10, Schedule 1 and Schedule 3 poison	The drug is used for the reduction of intraocular pressure in adult patients with open-angle glaucoma or ocular hypertension. Side effects include conjunctival hyperaemia, eye irritation, eye pain, and instillation site pain. The use of the drug should be decided by a doctor based on the patient's conditions.

Number	Drug Name	Proposed	Remarks
序號	藥名	Classification 建議類別	備註
	拉坦前列烯酯;其鹽類	附表一及附表三毒 藥	此藥物用於患有開角型青光眼或高眼壓的成年患者,降低其 眼內壓。 副作用包括結膜充血、眼睛刺激、眼睛疼痛及滴注部位疼 痛。 使用此藥物與否,須由醫生按病人情況決定。
6	Lorlatinib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	The drug is used for treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer whose disease has progressed on — • crizotinib and at least one other ALK inhibitor for metastatic disease; or • alectinib as the first ALK inhibitor therapy for metastatic disease; or • ceritinib as the first ALK inhibitor therapy for metastatic

Number	Drug Name	Proposed	Remarks
序號	藥名	Classification 建議類別	備註
	洛拉替尼;其鹽類	附表十的第一部, 附表一及附表三毒 藥	disease. Side effects include dyspnoea, fatigue, weight gain, arthralgia, and diarrhoea. The use of the drug should be decided by a doctor based on the patient's conditions. 此藥物用於治療患有間變性淋巴瘤激酶呈陽性,轉移性非小細胞肺癌,而且曾於接受以下的療程後仍出現病情惡化的成年患者: • 克唑替尼和至少另外一種間變性淋巴瘤激酶抑制劑作轉移性疾病的治療;或 • 阿來替尼作為第一種間變性淋巴瘤激酶抑制劑作轉移性疾病的治療;或 • 塞瑞替尼作為第一種間變性淋巴瘤激酶抑制劑作轉移性疾病的治療。

Number	Drug Name	Proposed	Remarks
序號	藥名	Classification 建議類別	備註
			副作用包括呼吸困難、疲勞、體重增加、關節痛及腹瀉。使用此藥物與否,須由醫生按病人情況決定。
7	Neratinib; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	The drug is used for extended adjuvant treatment of adult patients with early stage HER2-overexpressed or amplified breast cancer, to follow adjuvant trastuzumab-based therapy. Side effects include diarrhoea, nausea, abdominal pain, fatigue and
			vomiting. The use of the drug should be decided by a doctor based on the patient's conditions.
	奈拉替尼;其鹽類		此藥物用於患有早期第二型人類表皮生長因子受體過度表現 或擴增乳癌的成年患者,在接受以曲司珠單抗為基礎的輔助

Number	Drug Name	Proposed	Remarks
序號	藥名	Classification 建議類別	備註
		藥	性療程後,作為延長輔助性治療。 副作用包括腹瀉、噁心、腹痛、疲勞及嘔吐。 使用此藥物與否,須由醫生按病人情況決定。
8	Nifuratel; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	The drug is used for the treatment of susceptible infections of genito-urinary tract. Side effects include gastrointestinal disturbances, peripheral neuropathy and thrombocytopenic purpura. The use of the drug should be decided by a doctor based on the patient's conditions.
	硝呋太爾;其鹽類	附表十的第一部, 附表一及附表三毒	此藥物用於治療易於生殖泌尿道發生的感染。

Number	Drug Name	Proposed	Remarks
序號	藥名	Classification 建議類別	備註
		藥	副作用包括腸胃失調、周邊神經病變及血小板減少性紫癜。使用此藥物與否,須由醫生按病人情況決定。
9	Nifuroxazide; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	The drug is used for the treatment of colitis and diarrhoea. Side effects include allergic reactions. The use of the drug should be decided by a doctor based on the patient's conditions.
	硝呋齊特;其鹽類	附表十的第一部, 附表一及附表三毒 藥	此藥物用於治療結腸炎及腹瀉。 副作用包括過敏反應。 使用此藥物與否,須由醫生按病人情況決定。

Number	Drug Name	Proposed	Remarks
序號	藥名	Classification 建議類別	備註
10	Nitrofural; its salts	Schedule 3 poison	The drug is topically used for wounds, burns, ulcers, and skin infections; and for the preparation of surfaces before skin grafting. Side effects include sensitization and generalized allergic skin reactions. The use of the drug should be decided by a doctor based on the patient's conditions.
	呋喃西林;其鹽類	附表一及附表三毒藥	此藥局部使用於傷口、燒傷、潰瘍和皮膚感染,以及植皮手術前的表面處理。 副作用包括致敏及全身性皮膚過敏反應。 使用此藥物與否,須由醫生按病人情況決定。

Number	Drug Name	Proposed	Remarks
序號	藥名	Classification 建議類別	備註
11	Nitrofurantoin; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	The drug is used for the treatment of uncomplicated lower urinary-tract infections, including prophylaxis or long-term suppressive therapy in recurrent infection. Side effects include nausea, vomiting, and anorexia. The use of the drug should be decided by a doctor based on the patient's and divisions.
	呋喃妥因;其鹽類	·	patient's conditions. 此藥用於治療非複雜性的下泌尿道感染,包括對復發性感染的預防或長期抑制性治療。 副作用包括噁心、嘔吐及缺乏食慾。 使用此藥物與否,須由醫生按病人情況決定。

Number	Drug Name	Proposed	Remarks
序號	藥名	Classification 建議類別	備註
12	Nitroxoline; its salts 硝羥喹啉;其鹽類	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison 附表十的第一部, 附表一及附表三毒藥	The drug is used for the treatment of urinary-tract infections. Side effects include gastrointestinal disturbances. The use of the drug should be decided by a doctor based on the patient's conditions. 此藥用於治療泌尿道感染。 副作用包括腸胃失調。 使用此藥物與否,須由醫生按病人情况決定。
13	Omega-3 fatty acids; their salts; their esters; when contained in pharmaceutical products intended to	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	The drug is used in adult patients for the treatment of endogenous hypertriglyceridaemia as a supplement to diet when dietary measures alone are insufficient to produce an adequate response — • type IV hyperlipidemia in monotherapy; and

Number	Drug Name	Proposed	Remarks
序號	藥名	Classification 建議類別	備註
	be used for the treatment of hypertriglyceridaemia		 type IIb/III hyperlipidemia in combination with statins, when control of triglycerides is insufficient. Side effects include gastrointestinal disorders, hyperglycaemia, dizziness, headache and rash. The use of the drug should be decided by a doctor based on the patient's conditions.
	奧米加-3脂肪酸;其 鹽類;其酯類;但限 於包含在擬用於治療 高甘油三酯血症的藥 劑製品內者	·	此藥物用於成年患者當其單獨使用飲食措施未能產生合適效果時,作為飲食控制的輔助,治療以下的內源性高甘油三酯血症: IV型高血脂症(作為單一療法);及 IIb/III型高血脂症(當未能足夠控制甘油三酯水平時與他汀類藥物結合使用時) 副作用包括腸胃道疾病、高血糖症、眩暈、頭痛及皮疹。

Number	Drug Name	Proposed	Remarks
序號	藥名	Classification 建議類別	備註
			使用此藥物與否,須由醫生按病人情況決定。
14	Piracetam; its salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	The drug is used for the symptomatic improvement of memory and intellectual impairment of a pathological nature in the absence of a diagnosis of dementia. The drug can also reduce myoclonus of cortical origin in some patients.
			Side effects include nervousness, hyperkinesia and weight increased. The use of the drug should be decided by a doctor based on the
	吡拉西坦;其鹽類		patient's conditions. 此藥物用於在未有被診斷為認知障礙症的情況下,改善病理性的記憶與智力障礙的徵狀。
		藥	

Number	Drug Name	Proposed	Remarks
序號	藥名	Classification 建議類別	備註
			此藥物亦能減少部份病人的皮質性陣發性抽搐。
			副作用包括神經緊張、多動症及體重增加。
			使用此藥物與否,須由醫生按病人情況決定。
	Sugammadex; its salts; its esters; their salts	Part 1 of Schedule 10, Schedule 1 and Schedule 3 poison	The drug is used for reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults.
		zeneaure e penson	Side effects include cough, airway complication of anaesthesia, anaesthetic complication, procedural hypotension and procedural complication
			The use of the drug should be decided by a doctor based on the patient's conditions.
	舒更葡糖;其鹽類;	附表十的第一部,	此藥物用於成人,用作逆轉羅庫銨或維庫銨誘導的神經肌肉

Number	Drug Name	Proposed Classification	Remarks
序號	藥名	建議類別	備註
	其酯類;它們的鹽類	附表一及附表三毒 藥	阻斷。
			副作用包括咳嗽、麻醉中呼吸道併發症、麻醉併發症、手術 性低血壓及手術併發症。
			使用此藥物與否,須由醫生按病人情況決定。