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From : Clerk to the Legislative Council

To : All Members of the Legislative Council

Council meeting of 20 January 2010

Proposed resolution under the Pharmacy and Poisons Ordinance

I forward for Members' consideration a proposed resolution which the Secretary for Food and Health will move at the Council meeting of 20 January 2010 under the Pharmacy and Poisons Ordinance relating to:

(a) the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2009; and

(b) the Poisons List (Amendment) (No. 5) Regulation 2009.

The President has directed that "it be printed in the terms in which it was handed in" on the Agenda of the Council.

2. The speech, in both English and Chinese versions, which the Secretary will deliver when moving the proposed resolution and the supplementary information provided by the Secretary are also attached.

(Mrs Justina LAM)
for Clerk to the Legislative Council

Encl.

PHARMACY AND POISONS ORDINANCE

RESOLUTION

(Under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138))

RESOLVED that the following Regulations, made by the Pharmacy and Poisons Board on 28 December 2009, be approved –

(*a*) the Pharmacy and Poisons (Amendment) (No. 5) Regulation 2009; and

(*b*) the Poisons List (Amendment) (No. 5) Regulation 2009.

PHARMACY AND POISONS (AMENDMENT) (NO. 5) REGULATION 2009

(Made by the Pharmacy and Poisons Board under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) subject to the approval of the Legislative Council)

1. First Schedule amended

The First Schedule to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) is amended, in Division A –

(*a*) by adding "Lenalidomide; its salts";

(*b*) by adding "Melatonin; its salts; when contained in pharmaceutical products intended to be used for the treatment of insomnia";

(*c*) by adding "Tocilizumab";

(*d*) by adding "Ustekinumab".

2. Third Schedule amended

The Third Schedule is amended, in Division A –

(*a*) by adding "Lenalidomide; its salts";

(*b*) by adding "Melatonin; its salts; when contained in pharmaceutical products intended to be used for the treatment of insomnia";

(*c*) by adding "Tocilizumab";

(*d*) by adding "Ustekinumab".

Chairman,
Pharmacy and Poisons Board

28 December 2009

Explanatory Note

This Regulation adds 4 substances to the Divisions A of the First and Third Schedules to the Pharmacy and Poisons Regulations (Cap. 138 sub. leg. A) ("principal Regulations") respectively so that the sale, supply, labelling and storage of those substances are subject to the restrictions imposed under the Pharmacy and Poisons Ordinance (Cap. 138) and the principal Regulations.

POISONS LIST (AMENDMENT) (NO. 5) REGULATION 2009

(Made by the Pharmacy and Poisons Board under section 29 of the Pharmacy and Poisons Ordinance (Cap. 138) subject to the approval of the Legislative Council)

1. The Poisons List

The Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) is amended, in Part I, in Division A –

(*a*) by adding "Lenalidomide; its salts";

(*b*) by adding "Melatonin; its salts; when contained in pharmaceutical products intended to be used for the treatment of insomnia";

(*c*) by adding "Tocilizumab";

(*d*) by adding "Ustekinumab".

Chairman,
Pharmacy and Poisons Board

28 December 2009

Explanatory Note

This Regulation adds 4 substances to Division A of Part I of the Poisons List set out in the Schedule to the Poisons List Regulations (Cap. 138 sub. leg. B) so that, among other applicable requirements, poisons containing those substances can only be sold on registered premises of an authorized seller of

poisons by a registered pharmacist or in the pharmacist's presence and under the pharmacist's supervision.

SPEECH BY
THE SECRETARY FOR FOOD AND HEALTH
AT THE LEGISLATIVE COUNCIL
ON 20 JANUARY 2010

Pharmacy and Poisons Ordinance (Cap. 138)

Pharmacy and Poisons (Amendment) (No. 5) Regulation 2009
Poisons List (Amendment) (No. 5) Regulation 2009

Mr President,

I move that the motion under my name, as printed on the Agenda, be passed.

2. Currently, we regulate the sale and supply of pharmaceutical products through a registration and monitoring system set up in accordance with the Pharmacy and Poisons Ordinance. The Ordinance maintains a Poisons List under the Poisons List Regulations and several Schedules under the Pharmacy and Poisons Regulations. Pharmaceutical products put under different parts of the Poisons List and different Schedules are subject to different levels of control in regard to the conditions of sale and keeping of records.

3. For the protection of public health, some pharmaceutical products can only be sold in pharmacies under the supervision of registered pharmacists and in their presence. For certain pharmaceutical products, proper records of the particulars of the sale must be kept, including the date of sale, the name and address of the purchaser, the name and quantity of the medicine and the purpose for which it is required. The sale of some pharmaceutical products must be authorized by prescription from a registered medical practitioner, dentist or veterinary surgeon.

4. Arising from an application for registration of four pharmaceutical products, the Pharmacy and Poisons Board proposes to add the following four substances to Part I of the Poisons List and

the First and Third Schedules to the Pharmacy and Poisons Regulations:

(a) Lenalidomide; its salts

(b) Melatonin; its salts; when contained in pharmaceutical products intended to be used for the treatment of insomnia

(c) Tocilizumab

(d) Ustekinumab.

5. Pharmaceutical products containing the above substances must then be sold in pharmacies under the supervision of registered pharmacists and in their presence, with the support of prescriptions.

6. We propose that these amendment regulations take immediate effect upon gazettal on 22 January 2010 to allow early control and sale of the relevant medicine.

7. The two Amendment Regulations are made by the Pharmacy and Poisons Board, which is a statutory authority established under the Ordinance to regulate pharmaceutical products. The Board comprises members engaged in the pharmacy, medical and academic professions. The Board considers the proposed amendments necessary in view of the potency, toxicity and potential side effects of the medicine concerned.

8. With these remarks, Mr President, I move the motion.

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Poisons List (Amendment) (No.5) Regulation 2009

Pharmacy and Poisons (Amendment) (No.5) Regulation 2009

Supplementary Information to the Legislative Council

《2009年毒藥表（修訂）(第五號) 規例》
《2009年藥劑業及毒藥（修訂）(第五號) 規例》
提交立法會的補充資料

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Lenalidomide; its salts (來那度胺; 其鹽類)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is an anticancer medicine. It is used in combination with dexamethasone (an anti-inflammatory medicine) to treat adult patients with multiple myeloma whose disease has been treated at least once in the past. Multiple myeloma is a cancer of the plasma cells in the bone marrow. The most common side effects are neutropenia (low neutrophil counts), fatigue (tiredness), asthenia (weakness), constipation, muscle cramp, thrombocytopenia (low platelet counts), anaemia (low red blood cell counts), diarrhoea and rash. This drug is expected to be harmful to the unborn child. Therefore, it must not be used in women who are pregnant. It must also not be used in women who could become pregnant, unless they take all of the necessary steps to ensure that they are not pregnant before treatment and that they do not become pregnant during or soon after treatment. A doctor's decision is required as to whether or not this medicine should be used, medical monitoring is also required during administration. 此藥物爲一種抗癌藥物，與地塞米松(消炎藥)混合使用，以治療患有多發性骨髓瘤，並且過去已接受過至少一次治療的成年病人。多發性骨髓瘤是骨髓漿細胞的癌症。 最常見的副作用是中性血細胞減少症(中性白細胞計數偏低)、疲勞(倦怠)、虛弱 (無力)、便秘、肌肉抽搐、血小板過少(血小板數量偏低)、貧血(紅血球數量偏低)、腹瀉以及紅疹。 此藥物預計會對胎兒造成傷害，因此絕不可以用於孕婦身上。它亦不可用於可能懷孕的女性身上，除非她們採取一切必要步驟，以確保在治療之前沒有懷孕，亦不會在治療期間或治療後不久懷孕。此藥需經醫生確診後才使用，用此藥時亦需要醫生小心觀察病人。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Melatonin; its salts; when contained in pharmaceutical products intended to be used for the treatment of insomnia. (Melatonin；其鹽類；但限於包含在擬用於治療失眠症的藥劑製品內者)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used for the short-term treatment of insomnia in patients aged 55 years or over. This drug should only be used by patients upon a correct medical diagnosis of insomnia. (Note: Melatonin is a hormone produced in the pineal gland. Due to its possible role in influencing circadian rhythm, it is also present, in some health food for alleviation of symptoms such as jet lag and sleep disturbances) 此藥物用於患有失眠症的55歲或以上病人作短期治療。 用此藥物的病人，需經醫生正確診斷爲患有失眠症，才能使用。 (按:Melatonin是從松果腺生產的一種激素。由於它可能影響晝夜節律的作用，有些健康食品用Melatonin作減輕時差和睡眠障礙的症狀。)

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Tocilizumab (托珠單抗)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	This drug is used to treat adults with moderate to severe active rheumatoid arthritis (an immune system disease causing inflammation of the joints). It is used in combination with methotrexate (another medicine used in rheumatoid arthritis) in patients who have not responded adequately to or who could not tolerate other treatments, including conventional medicines for rheumatoid arthritis (such as methotrexate) or tumour necrosis factor (TNF) blockers. This drug can also be used on its own in patients who cannot take methotrexate. Most common side effects: upper respiratory tract infections (colds). It must not be used in patients who have an active, severe infection. Doctors should monitor patients carefully for signs of infection during treatment, and should prescribe this drug with caution in patients who have had recurring or long-term infections, or diseases that could increase the risk of infections, such as diverticulitis (a disease affecting the gut) or diabetes. Its use should be decided by a doctor based on the patient's condition. 此藥物用以治療患有中度至嚴重活動性風濕性關節炎(一種令關節發炎的免疫系統病)的成人。此藥物與甲氨蝶呤(另一種治療風濕性關節炎的藥物)混合使用於對其他藥物 (包括治療風濕性關節炎的傳統藥物如甲氨蝶呤，或腫瘤壞死因子(TNF)阻斷劑) 沒有足夠反應或不耐受的病人。不能服用甲氨蝶呤的病人可單獨服用此藥物。 最常見的副作用是上呼吸道感染(感冒)。此藥物不得用於受到活動性及嚴重感染的病人。醫生在進行治療時應小心監察病人有否出現感染的病徵，並在配處此藥物給有以下疾病的病人時應小心謹慎：有復發或長期感染、或所患疾病會增加感染的風險，例如憩室炎(一種影響腸道的疾病)或糖尿病。 使用該藥與否，須由醫生按病人的病情決定。

Drug Name **藥名**	**Proposed Classification** **建議類別**	**Reason** **原因**
Ustekinumab (無中文名)	Part I, First and Third Schedules poison 第一部附表一及附表三毒藥	It is used to treat adults with moderate to severe plaque psoriasis (a disease causing red, scaly patches on the skin) who are suitable for phototherapy or systemic (whole-body) therapy. Side effects include upper respiratory tract infection (colds) and nasopharyngitis (inflammation of the nose and throat). It must not be used in patients who have an active infection that the doctor considers important. The doctor may interrupt treatment in patients who develop a serious infection. This drug should only be used upon medical judgment. 此藥物用以治療患有中度至嚴重斑狀牛皮癬(一種令皮膚出現紅色鱗狀斑塊的疾病)，並適宜接受光線療法或全身療法的成人。 副作用包括上呼吸道感染(感冒)及鼻咽炎(鼻子和喉嚨發炎)。此藥物不得用於醫生認爲受到重要的活動性感染的病人。醫生可在病人出現嚴重感染時中斷治療。 需經醫生清楚診斷，才能使用此藥物。