Ref: NCR 2/1/8 S/F(14)

LEGISLATIVE COUNCIL BRIEF

Dangerous Drugs Ordinance (Chapter 134) DANGEROUS DRUGS ORDINANCE (AMENDMENT OF FIRST SCHEDULE) ORDER 2016

INTRODUCTION

At the meeting of the Executive Council on 26 April 2016, the Council **ADVISED** and the Chief Executive **ORDERED** that the Dangerous Drugs Ordinance (Amendment of First Schedule) Order 2016 (the Order), at the **Annex**, be made under section 50 (1) of the Dangerous Drugs Ordinance (the Ordinance) (Cap. 134), to impose control on Tapentadol and AH-7921[1].

JUSTIFICATIONS

Tapentadol

2. According to the report of the 36th Expert Committee on Drug Dependence (ECDD) of the World Health Organization (WHO) published in June 2014, Tapentadol is a novel analgesic agent which provides analgesia in acute and chronic pain, and demonstrates fewer side effects when compared with strong opioids at doses providing similar analgesia. It may also provide a new therapeutic for the relief of neuropathies.

3. According to the Advisory Council on the Misuse of Drugs (ACMD) of the United Kingdom (UK), the potential for abuse of Tapentadol is similar to that of other opioid analgesics, including hydromorphone and morphine[2]. Tapentadol presents a risk of addiction, potential illegal diversion and medicinal misuse.

---

[1] AH-7921 is the common name of 3,4-Dichloro-N-[[1-(dimethylamino)cyclohexyl]methyl]benzamide.

[2] Hydromorphone and morphine have been included in both Schedule 1 of the Dangerous Drugs Ordinance and Schedule 10 (Poisons List) of the Pharmacy and Poisons Regulations (Cap. 138A).

4. In addition, the Home Office of the UK has assessed that the risks associated with an overdose of Tapentadol are constriction of the pupils, vomiting, loss of consciousness, seizures, difficulty in breathing and a risk of serious complications likely to lead to death. Currently, Tapentadol is subject to the same legislative control as hydromorphone in the United States, the UK and Australia.

5. In Hong Kong, Tapentadol is already subject to control under the Pharmacy and Poisons Ordinance (Cap. 138). Currently, there are eight registered pharmaceutical products[3] containing Tapentadol in Hong Kong. Under the Pharmacy and Poisons Ordinance, these products should only be supplied by an authorized seller of poisons in accordance with a prescription by a registered medical practitioner, dentist or veterinary surgeon.

6. There is no record of seizure of Tapentadol by law enforcement agencies in Hong Kong. There is no record of import and export of this substance in trade declarations since January 2012.

AH-7921

7. According to the report of the 36th ECDD of the WHO, AH-7921 is a synthetic opioid and a central nervous system depressant. In addition to analgesia, relaxation and euphoria, there were also reported cases of occasional itching, nausea and tremors after using AH-7921. The drug effects of AH-7921 are similar to those of morphine.

8. The ACMD of the UK has strongly recommended the permanent control of AH-7921, having considered its potential to cause harm, its potency, fatalities reported in other European countries, and its high addictive potential. During the 58th Session of United Nations Commission on Narcotic Drugs (UNCND) held in March 2015, member states adopted the ECDD's recommendation to place AH-7921 in Schedule I of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol. In Hong Kong, the effect of the UNCND's decision is similar to including AH-7921 in Part I of the First Schedule to the Ordinance.

9. AH-7921 is currently not controlled under the Dangerous Drugs Ordinance or the Pharmacy and Poisons Ordinance in Hong Kong.

[3] The eight registered pharmaceutical products are Nucynta ER extended-release tablets (50, 100, 150, 200 and 250mg) and Nucynta immediate-release tablets (50, 75 and 100mg).

AH-7921 does not have any recognized medical use. There is no registered pharmaceutical product containing AH-7921 in Hong Kong. There is no record of local seizure of AH-7921 by law enforcement agencies. There is no record of import and export of this substance in trade declarations since January 2012.

THE PROPOSAL

10. We propose to amend Part I of the First Schedule to the Ordinance to impose control on Tapentadol and AH-7921.

11. Under the Ordinance, substances included in Part I of the First Schedule are dangerous drugs and are subject to the control of a licensing scheme administered by the Department of Health. As stipulated under the Ordinance, the manufacture, import, export, as well as supply of these substances will require respective licences issued by the Department of Health. Trafficking and manufacturing of the substances in contravention of the Ordinance will be subject to a maximum penalty of life imprisonment and a fine of $5 million. Possession, consumption and supply of the substances in contravention of the Ordinance will also constitute criminal offences.

THE ORDER

12. The Order, at the **Annex**, seeks to add Tapentadol and AH-7921 to Part I of the First Schedule to the Ordinance.

LEGISLATIVE TIMETABLE

13. The legislative timetable will be –

Gazettal of the Order	6 May 2016
Tabling at the Legislative Council for negative vetting	11 May 2016
Commencement date of the Order	8 July 2016

IMPLICATIONS OF THE PROPOSAL

14. The proposal is in conformity with the Basic Law, including the provisions concerning human rights. It will not affect the current binding effect of the Ordinance. It has no economic, productivity, environmental or gender implications. The proposal is also in line with the sustainability principle of pursuing policies which protect the health of the people of Hong Kong. Apart from inflicting health damage to the abuser, drug abuse is also often found to have a profound impact on an abuser's family, e.g. causing mixed emotions such as anger and frustration among family members, and giving rise to family financial crisis after paying off relevant drug debts. The proposal represents our ongoing efforts to closely monitor emerging new synthetic drugs and ensure that these are brought under control in a timely manner. This would help prevent possible family problems and tension that may be aroused by drug-abusing family members. The additional workload and financial implications arising from the implementation of the proposal are expected to be minimal and any additional requirements will be absorbed by the relevant bureaux and departments with existing resources.

PUBLIC CONSULTATION

15. We have consulted relevant trades, as well as licensees of the Dangerous Drugs Ordinance and the Pharmacy and Poisons Ordinance. They raised no objection to the proposal.

16. We have also consulted the Action Committee Against Narcotics and the Panel on Security of the Legislative Council on 17 December 2015 and 1 March 2016 respectively. They supported the proposal.

PUBLICITY

17. The Order will be published in the Gazette on 6 May 2016. A press release will be issued on 4 May 2016, and a spokesperson will be available for answering media enquiries.

BACKGROUND

18. The growing predominance of psychotropic substance abuse and the continuous emergency of new synthetic drugs pose new challenges to legislative control and law enforcement globally. We need to remain vigilant in closely monitoring the drug trends both overseas and locally and take timely action to bring new drugs under legislative control.

ENQUIRIES

19. Any enquiries concerning this brief can be directed to the following officer –

Miss Rosalind Cheung
Principal Assistant Secretary for Security (Narcotics)1
Tel. No.: 2867 5676

Narcotics Division
Security Bureau
May 2016

Dangerous Drugs Ordinance (Amendment of First Schedule) Order 2016

(Made by the Chief Executive under section 50(1) of the Dangerous Drugs Ordinance (Cap. 134) after consultation with the Executive Council)

1. Commencement

This Order comes into operation on 8 July 2016.

2. Dangerous Drugs Ordinance amended

The Dangerous Drugs Ordinance (Cap. 134) is amended as set out in section 3.

3. First Schedule amended

(1) First Schedule, Part I, paragraph 1(a), after item "Salvinorin-A"—

Add

"Tapentadol".

(2) First Schedule, Part I, paragraph 1(a), after item "4-Cyano-1-methyl-4-phenylpiperidine"—

Add

"3,4-Dichloro-N-[[1-(dimethylamino)cyclohexyl]methyl]benzamide".

Chief Executive

9th April 2016

Explanatory Note

This Order amends Part I of the First Schedule to the Dangerous Drugs Ordinance (Cap. 134) in order to impose control on Tapentadol and 3,4-Dichloro-N-[[1-(dimethylamino)cyclohexyl]methyl]benzamide (commonly known as AH-7921).