For discussion on
1 March 2016

Legislative Council Panel on Security

Proposed amendments to the First Schedule to the Dangerous Drugs Ordinance

PURPOSE

This paper seeks Members' views on the Administration's proposal to bring Tapentadol and AH-7921 under control in the First Schedule to the Dangerous Drugs Ordinance (DDO) (Cap. 134).

BACKGROUND

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[1]. Tapentadol presents a risk of addiction, potential illegal diversion and medicinal misuse.

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

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

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 (PPO) (Cap. 138). Currently, there are eight registered pharmaceutical products[2] containing Tapentadol in Hong Kong. Under the PPO, 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 DDO.

9. AH-7921 is currently not controlled under the DDO or PPO in Hong Kong. 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

[2] 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).

enforcement agencies. There is no record of import and export of this substance in trade declarations since January 2012.

PROPOSAL

10. In order to enable law enforcement agencies in Hong Kong to respond effectively to the latest developments as set out above, we propose to include Tapentadol and AH-7921 in the First Schedule to the DDO.

11. Under the DDO, 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. The import and export of these substances will require a licence from the Director of Health. Illicit trafficking, manufacturing, possession, consumption, cultivation, supply, import and export of the substances will be subject to a maximum penalty of life imprisonment and a fine of $5 million.

CONSULTATION

12. The Administration has consulted relevant trades, as well as licensees of the DDO and the PPO. There was no adverse comment.

13. The Administration has also consulted the Action Committee Against Narcotics, which supports the proposed control.

WAY FORWARD

14. Pursuant to section 50(1) of the DDO, the Chief Executive may by order published in the Gazette amend the First Schedule to the DDO.

15. Having consulted Members' views on the above proposal, we plan to table the relevant amendment order in the Legislative Council for negative vetting in May 2016.

ADVICE SOUGHT

16. Members are invited to comment on the Administration's proposal as set out in paragraph 1 above.

Narcotics Division
Security Bureau
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