

Advisory Council on the Misuse of Drugs

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James Brokenshire MP 2 Marsham Street London SW1P 4DF

Dear Minister,

Re: Amineptine advice

I am writing to provide you with the Advisory Council on the Misuse of Drugs' (ACMD) consideration of the compound Amineptine (7-[(10,11-dihydro-5*H*-dibenzo[*a,d*]cyclohepten-5-yl)amino]heptanoic acid)

Amineptine (common brand names include Survector, Viaspera, Maneon and Directin) has antidepressant and psychostimulant properties that selectively inhibit the reuptake of dopamine, and to a lesser extent norepinephrine, exerting a powerful and fast-acting antidepressant effect. The antidepressant effect is similar to other tricyclic antidepressants, however, Amineptine has little cardiovascular, analgesic or anorectic effects.

According to the WHO Expert Committee on Drug Dependence (ECDD); 'Amineptine abuse has been reported mainly in Asia and Europe. The drug has been withdrawn from the market in France, where it was developed a few decades ago, because of its considerable hepatotoxicity and abuse. However, its medical use in developing countries, as well as its abuse continue. The reports of adverse drug reactions collected by the international drug monitoring programme indicated a larger number of case reports of abuse and dependence for amineptine than for other anorectic stimulants currently placed in Schedule IV of the 1971 Convention, such as amfepramone. The responses of governments to the WHO questionnaire also indicated limited

diversion and abuse of the drug although some reported hospital admissions have been linked to the use or abuse of amineptine'. 1

The WHO Expert Committee on Drug Dependence (ECDD) has reported that there had been few animal studies on the potential for dependence or abuse of Amineptine. However, some clinical studies have indicated that Amineptine has the potential both for dependence and abuse, predominantly in patients with a previous history of substance abuse. The withdrawal symptoms include anxiety, psychomotor agitation and insomnia. Instances of dependence have been reported in Asia and Europe.

On 8th April 2003, the Commission on Narcotic Drugs, on the recommendation of the World Health Organization, decided by 41 votes to none, with 2 abstentions, to include amineptine (7-[(10,11-dihydro-5*H*dibenzo[*a,d*]cyclohepten-5-yl)amino]heptanoic acid) in Schedule II of the Convention on Psychotropic Substances of 1971.²

The ACMD have considered the status of Amineptine and acknowledge that there is little evidence concerning its licit or illicit use in the United Kingdom as Amineptine is currently off-patent and difficult to obtain. However, considering its potential for harms and the UK's obligations under the Convention on Psychotropic Substances of 1971, the UK is legally obliged to schedule Amineptine, under domestic legislation, i.e. the Misuse of Drugs Act 1971 following the decision of the Commission on Narcotic Drugs (2003). Therefore the ACMD supports Amineptine being controlled under the Misuse of Drugs Act 1971 and would recommend that it is done so as a Class C substance and scheduled as a schedule II substance under the Misuse of Drugs Regulations 2001.

Yours sincerely,

Professor Les Iversen FRS

¹ http://whqlibdoc.who.int/trs/WHO TRS 915.pdf

² http://www.unodc.org/documents/commissions/CND-session46/CND-Decision-46-01.pdf