

EXPERT ADVISORY COMMITTEE ON DRUGS

Thursday 12 June 2008, 9.00 am– 11.00 am
Ministry of Health, 1-3 The Terrace, Wellington

EACD MEMBERS PRESENT

Dr Ashley Bloomfield (Chair)	Adrienne Fruean
Dr Keith Bedford	Stewart Jessamine
Fiona Roberts (for Rajesh Chhana)	Detective Senior Sergeant Stuart Mills (for Detective Superintendent Win Van der Velde

EACD SECRETARIAT PRESENT

Olivia Stapleton	Mark Heffernan
Chris Laursen	

1 WELCOME AND APOLOGIES

Apologies were received from Dr Tim Maling, Dr Geoffrey Robinson, Professor Doug Sellman, Dr Helen Moriarty, Rajesh Chhana, Paul Campbell and Detective Superintendent Win Van der Velde.

2 CONFIRMATION OF 19 FEBRUARY 2008 MINUTES

The minutes from the 19 February 2008 meeting were confirmed and authorised to be made publicly available on the National Drug Policy website.

One member commented that the minutes did not make it clear whether the evidence suggests tramadol is being abused, or has a potential for abuse. The Committee commented that discussions at the 19 February meeting were informed by the clinical experience of some members, who noted practitioner concerns for the potential of abuse from tramadol.

Action:

It was agreed that the EACD paper on tramadol that was discussed at the 19 February meeting would be made available to this member for information.

3 MATTERS ARISING FROM 19 FEBRUARY 2008 MEETING

2.1 Thalidomide. Item 2.2

Issue: The Minister is to be advised of the issues surrounding thalidomide, and the EACD recommendation from the 30 November 2007 meeting that it should be removed from the Misuse of Drugs Act but remain subject to the strict controls under the Medicines Act that are already in place.

Outcome: The Chair has written to the Minister on this matter. The Minister agreed with the advice of the EACD on thalidomide in April 2008.

It was suggested that the EACD recommendation on thalidomide may have implications for lenolidomide, the next-generation thalidomide-derived drug, as a prescription drug in New Zealand.

2.2 Tramadol. Item 4.

Issue: The Committee agreed to recommend that tramadol be classified as a class C2 controlled drug under the Misuse of Drugs Act 1975.

Outcome: The Secretariat will send a letter to Pharmac and Medsafe emphasising the issues of, adverse effects, and abuse potential around tramadol, particularly if the drug is subsidised and more freely available.

It was suggested that the Ministry of Health consider advising practitioners that tramadol will be classified as a C2 controlled drug under the Misuse of Drugs Act 1975 once this is confirmed. This would be a useful way to inform practitioners of the classification of tramadol as most restrictions under a C2 classification will have no impact or changes in processes for practitioners. This is especially important if tramadol is not added to the list of controlled drugs for which prescriptions must be written by practitioners on a form provided by the Director-General of Health.

2.3 General Business. Item 7.

It was noted that the establishment of the National Consumer Alcohol and Drug Network will be a useful tool for the consumer representative on the EACD to monitor matters relevant to consumers and raise consumer issues at EACD meetings.

4 DECLARATION OF CONFLICTS OF INTEREST

No conflicts of interest were declared. The Committee noted that one member was involved in the Environmental Science and Research Institute (ESR) testing of the BZP-free party pills, which were discussed under agenda item 6.

5 RESTRICTED SUBSTANCES REGULATIONS

Reference: Paper provided by the Secretariat

Issue: The Secretariat requested that the Committee indicate any matters that they would like the Ministry of Health to consider relating to the regulations

proposed under the Misuse of Drugs Amendment Act 2005 to place further controls on restricted substances.

Outcome: The Committee discussed the proposed regulations and noted that the review of the Misuse of Drugs Act 1975 will provide the appropriate forum to discuss the potential for further controls that would not be provided for by regulation under the Misuse of Drugs Amendment Act 2005.

Discussion: The Committee discussed several of the proposed regulations and made comparisons with the controls around some medicines. The Committee queried whether the proposed controls would be specific to the regulation of salvia divinorum or applicable to any future substance scheduled as a restricted substance. It was clarified that the proposed regulations are generic and would apply to any substance listed in that Schedule. The Secretariat commented that the proposed regulations would likely be supported by a large portion of the industry, which may facilitate greater compliance.

It was suggested that the harm minimisation approach that is taken with illegal drugs could be applied to the proposed regulations so that labels of all restricted substances might be required to include generic safety advice. For example, a warning to not exceed a maximum specified dose or to advise against taking if pregnant or breastfeeding. It was agreed that the Committee could not offer advice on such matters without first assessing all available evidence on a specific substance.

Regulations to potentially restrict packet sizes were discussed. The Secretariat noted that there is provision for regulations to be made relating to the quantity, dosage, form, or serving of restricted substances, but that such restrictions would need to be substance specific and could not be applied to all restricted substances across the board. It was clarified that it would likely be within the scope of the Misuse of Drugs Amendment Act 2005 to limit the amount of a restricted substance sold at any one time to a 24-hour supply. But that sufficient evidence of matters such as a substances pharmacology and toxicity would need to be provided before a restriction on package size could be progressed.

Members noted that regulatory controls would be enforced by the Ministry of Health but that there is also provision for the Police to enforce the Misuse of Drugs Amendment Act 2005. The timeframe for the implementation of the proposed regulations is dependent on Government priorities but it is hoped that, pending Government approval, the proposed regulations will come into effect within six months.

6 BZP-FREE 'PARTY PILLS'

Reference: paper provided by the Secretariat

Issue: the Secretariat presented the results from ESR's testing of four brands of BZP-free party pills.

Outcome: the Committee agreed that the results from the tests of four brands of BZP-free party pills indicated that they all contained caffeine and that some brands may contain one or more psychoactive amines but a reference standard is required for ESR to confirm these findings. The Committee did not consider it necessary to make any recommendations at this time as there is no evidence suggesting urgent action is required but the EACD will keep a watching brief on any developments.

Discussion: The Committee noted that the party pill industry has indicated that both synephrine and 1,3 dimethylamylamine are being incorporated into BZP-free party pills and that importations of these products, into New Zealand, have also recently increased. However, the results of ESR's testing of four brands of party pills could not confirm the presence of these substances.

The Committee noted that methylhexaneamine and 1,3 dimethylamylamine (Or Geranamine™) are not likely to be covered by the current legislation and that these substances, which are geometric isomers, both have a mild stimulant effect.

One member commented that based on molecular weight caffeine is likely to be a more potent than stimulant than 1,3 dimethylamylamine or methylhexaneamine and there are associated risks of taking a high dose of caffeine. Members commented that caffeine is also highly addictive and there is a potential risk that a user could use BZP-free party pills to alleviate a state of caffeine withdrawal rather than to maintain a 'high'. Members noted that symptoms of reported hospital presentations from BZP-free party pill use are consistent with the effects of caffeine overdose.

Members considered synephrine to be a potent stimulant that can produce cardiovascular effects and that high frequency and chronic use of synephrine has been linked with deaths internationally. One member commented that both the American Food and Drug Administration and the Australian Therapeutic Goods Administration had taken action on synephrine because it has been linked to a number of deaths from use in athletic performance enhancement.

The Committee commented that quality control of these products may be poor and there could be issues regarding the consistency of substances between batches that could account for only caffeine being identified in ESR's testing of these products. However the Secretariat clarified that two rounds of testing of the most popular brand of BZP free party pills were commissioned to potentially account for any batch to batch variation. It was agreed that further testing will be carried out once ESR have sourced an accurate reference standard for the substances purported to be in these products.

Actions:

The Secretariat to facilitate discussion with the party pill industry to assist in providing ESR with a reference standard for further testing of BZP-free party pills. Any further information from testing will be provided to the Police and the Ministry of Health.

The Secretariat to prepare a response to a letter from the Executive Director of the New Zealand Drug Foundation to inform the Foundation of further tests on BZP-free party pills and that the EACD does not consider it necessary to make any recommendations at this time but will keep a watching brief on any developments.

7 CLARIFICATION OF EACD ADVICE ON SALVIA DIVINORUM

Reference: paper provided by the Secretariat

Issue: the Secretariat proposed that the Committee agree their previous advice that “salvia divinorum be scheduled as a restricted substance under the Misuse of Drugs Amendment Act 2005,” be interpreted as “Preparations of salvia divinorum” and that this scheduling is not applied to the unprocessed salvia divinorum plant.

Outcome: the Committee agreed, pending out of session confirmation from Committee members not present at the meeting, that it was appropriate to clarify that the scheduling of salvia divinorum should apply only to the processed extracts of salvia divinorum, and not the raw salvia divinorum plant.

Discussion: the Secretariat has received legal advice suggesting that as salvia divinorum is a plant, it is unlikely to fit the definition of a restricted substance under the Misuse of Drugs Amendment Act 2005.(MoDAA) This Act states that a restricted substance is defined as “any mixture, preparation, or article that is manufactured for the primary purpose of being administered, ingested, inhaled, or injected in order to induce a psychoactive response” and that based on this definition, it would not be possible to progress the scheduling of salvia divinorum as a restricted substance.

The Committee noted that no vendors in New Zealand are thought to market the salvia divinorum plant as a raw product. Instead, salvia divinorum is sold in commercially prepared extracts in which the plant leaf is re-infused with an elevated content of the main psychoactive compound Salvinorin-A. This process multiplies the potency of the raw salvia divinorum leaf by a factor between 10x to 25x depending on the strength of extract chosen. The unprocessed salvia divinorum leaf contains only weak levels of Salvinorin-A. Due to this low potency the raw leaves of the salvia divinorum plant are rarely used to achieve a psychoactive effect and are not considered to pose a public health risk.

Concentrated extracts of salvia divinorum pose a significantly greater risk than the unprocessed plant. Furthermore, while it will be possible to progress the Scheduling of preparations of salvia divinorum as a restricted substance, it is not considered feasible to schedule the raw salvia divinorum plant under the definition of a restricted substance in the MoDAA.

The Committee agreed that the Scheduling of the salvia divinorum plant as a restricted substance under this definition is not feasible. The recommended approach of scheduling only preparations of salvia divinorum or preparations of

Salvinorin-A targets the more potent concentrated extracts of salvia divinorum, which pose a significantly greater risk than the unprocessed plant.

Action:

The Chair is to obtain out of session confirmation from members not present at the meeting that it is appropriate to clarify that the scheduling of salvia divinorum should apply to the processed extracts of salvia divinorum, and not the raw salvia divinorum plant.

Following confirmation out of session, the Chair will write to the Minister clarifying the Committee's revised advice

8 GENERAL BUSINESS

The Secretariat provided an update on the review of the Misuse of Drugs Act 1975. The Law Commission is leading the review, which is being supported by a Steering Group and Working Group. The Law Commission will provide an interim report in December 2008 and the final report in 2009. There has been some interest from Ministers to fast track the reverse onus of proof regarding who should prove the safety of unregulated psychoactive substances as a separate issue and this option is currently being investigated.

The Secretariat clarified that the review is a first principles review and will *inter alia* examine the links between the Misuse of Drugs Act 1975 and the *National Drug Policy 2007-2012* and UN Conventions. The Committee commented that there is a broader expectation that the review will address some of the limitations of the current Misuse of Drugs Act 1975 but noted that implementing any legislative changes to the Act will be some time in the future and will depend on the policies and priorities of the government of the day.

9 DATE OF NEXT MEETING

The next meeting is scheduled on Thursday, 21 August 2008, 9.00 am – 12.00 pm, at the Ministry of Health, 1-3 The Terrace, Wellington.

Action:

The Secretariat is to update the EACD's working schedule of substances to include most recent reviews/recommendations, with the aim to incorporate this information into a discussion paper for the EACD to review and develop their strategic plan.

The meeting closed at 10.30 am.