EXPERT ADVISORY COMMITTEE ON DRUGS

Thursday 29 November 2007, 8.30am – 1.30pm Medsafe Conference Room, Level 6, Deloitte House, 10 Brandon Street, Wellington

EACD MEMBERS PRESENT

Dr Ashley Bloomfield (Chair)	Adrienne Fruean
Dr Tim Maling	Dr Keith Bedford
Dr Helen Moriarty	Paul Campbell
Professor Doug Sellman	

EACD SECRETARIAT PRESENT

Olivia Tuatoko	Martin Woodbridge
Bruce Atmore	Mark Heffernan
Mick Alexander (NDIB)	

1 WELCOME AND APOLOGIES

The Chair welcomed members. He welcomed Justine Cornwall from Justice who attended on behalf of Rajesh Chhana.

Apologies were received from Dr Geoff Robinson, Detective Superintendent Win Van der Velde, Dr Stewart Jessamine, and Rajesh Chhana.

Paul Campbell apologised for late arrival.

2 CONFIRMATION OF 30 AUGUST 2007 MINUTES

The minutes from the 30 August 2007 meeting were confirmed and are to be placed on the National Drug Policy website once the Minister has been advised on salvia divinorum.

3 MATTERS ARISING FROM 30 AUGUST 2007 MEETING

3.1 Ketamine. Item 5

Issue: That the EACD would recommend that the presumption for supply amount for ketamine be set at 10 grams, whether or not contained in a substance, preparation or mixture.

Outcome: It has been agreed by Cabinet and is to go through an Order in Council process.

3.2 Salvia Divinorum. Item 6

Issue: That the EACD would recommend salvia divinorum as a Schedule 4 Restricted Substance in the Misuse of Drugs Amendment Act 2005.

Outcome: Chair to write a letter to the Minister updating him of the EACD recommendation.

3.3 Update on Drugs for Review. Item 7

Issue: The Secretariat to follow up, by the next EACD meeting, with the suppliers of pentazocine, on the impact the possible classification of pentazocine would have.

Outcome: Pentazocine (Fortral range) has been discontinued. Therefore any change to the classification of this substance would not affect previous suppliers. Members requested to look at a previous paper on pentazocine and what their initial recommendation was for classification.

Discussion: Members advised that the last known use of this substance was administration by ambulance drivers. Although it is not currently available in New Zealand, there is concern that is could be imported and members were concerned with the abuse potential of the substance, therefore discussion around scheduling the product would still be necessary.

At this stage, it was agreed that this discussion could be deferred while the MDOA review is underway.

3.4 General Business. Item 8

Issue: The Secretariat to prepare a paper for the next meeting on buprenorphine and tramadol.

Outcome: Buprenorphine on the Agenda as Item 6. Tramadol is currently being assessed and will be available for discussion at the next EACD meeting.

Note: EACD requested that the Secretariat contact several anaesthetists and pain clinics for a wider spectrum of information when collecting information for this paper.

4 DECLARATION OF CONFLICTS OF INTEREST

No conflicts of interest were declared.

UPDATE ON BZP

Discussion: Chair updated the Committee on BZP legislation, advising that the Misuse of Drugs (Classification of BZP) Amendment Bill had been reported back to the House by the Health Select Committee with no recommended changes. The Committee discussed new substances that have emerged to possibly replace BZP. The Secretariat advised that one such product contained a substance considered to be a controlled drug analogue and the Ministry of Health is actively monitoring the 'party pill' market for new developments.

The Committee were also advised of current research studies in progress investigating the use, and effects, of BZP. Members requested that a priority area

for further research should be to investigate how the pending change in legal status might influence people's attitudes towards purchasing and using BZP and related substances.

The Committee also discussed pill presses and encapsulaters as manufacturers of 'party pills' may no longer require them once the classification of BZP and related substance take effect. The Committee noted that there is a potential for this equipment to be diverted for illicit purposes such as the manufacture of 'ecstasy' pills. The Committee identified a need to monitor where this equipment goes and who it is sold to. The Committee also agreed they could be used for licit as well as illicit means, and could potentially drive the importation of substances in their powdered form.

5 THALIDOMIDE

Reference: Paper provided by EACD Secretariat

Issue: The Committee requested that thalidomide be discussed as part of a possible anomaly in the Misuse of Drugs Act 1975 Schedules.

Outcome: The Committee agreed to inform the Minister on thalidomide with the possibility to change its classification in the Misuse of Drugs Act.

Discussion: The Committee discussed the historical circumstances surrounding the placement of thalidomide into the Misuse of Drugs Act 1975. All members agreed that it is an anomaly and that, in retrospect, it should not have been scheduled in the Act. The Committee agreed that the fear of this substance is genuine, but there is now very good monitoring of and advice about the use of this substance and notwithstanding that individuals may ignore this advice, history is highly unlikely to repeat itself.

During the discussion of scheduling the Committee considered whether there are any other comparable examples of substances with virtually no abuse potential but severe, specific adverse effects, and therefore, whether the Misuse of Drugs Act Class A classification was the most appropriate framework for managing this situation?

One example came to mind which was MPTP (also Class A). MPTP became infamous in the 1980s after it was distributed in illicit drug circles in the USA as a major contaminant in the product from a botched attempt to synthesize MPPP. MPPP is the "reverse ester" of pethidine meperidine). MPTP is a potent neurotoxin, selectively damaging the substantia nigra and producing symptoms closely resembling Parkinson's disease in users. MPPP and pethidine are scheduled as Class B3 controlled drugs. Unlike thalidomide, MPTP has no recognised therapeutic use.

The Committee agreed that thalidomide should be removed from the Misuse of Drugs Act and placed in the Medicines Act 1981; however the availability and distribution and use of thalidomide requires stringent monitoring. The Committee agreed that the current Pharmion® registration procedure will need to continue,

which was a condition of gazetting during the products registration. Therefore the rules currently governing access cannot be loosened or removed.

The Committee noted that in light of the recommended reclassification of thalidomide from a controlled drug to a medicine, other terotogens should be also considered; this would include retenoic acid (high dose vitamin A). In removing thalidomide from the MODA such that thalidomide is controlled solely under the Medicines Act 1981, it would be important that an outline of standard requirements for access and distribution be confirmed. The current limited access requirements that were gazetted for thalidomide are a suitable and credible benchmark for this purpose; as such access to other teratogens could also be monitored and controlled under such arrangements. These access requirements/restrictions should not go beyond what has already been established for thalidomide as they would likely become overly restrictive and nonsensical.

Action: The Chair to advise the Minister of the issues surrounding thalidomide and the recommendation that it should be removed from the MODA, and that this should be considered during the review of the MODA.

6. DISCUSSION WITH LAW COMMISSION

Initial EACD discussion on the MODA Review

The Committee discussed issues that may come up during the review of the Misuse of Drugs Act (MODA) with the Law Commissioners. Points of notice that the Committee wished to bring up were as follows:

- Medicines that are also classified under the MODA
- Psychoactive substances that are not pharmaceutical medicines but are scheduled in the MODA due to historical reasons
- Assessment of all substances on rational harm assessment criteria, including the possibility of comparing alcohol and tobacco, and determining appropriate supply controls
- Possible change to the name of the Act
- Defining the meaning of harm
- The ability to monitor all controlled drugs, not just those in Schedule One.

6.1 Consultation on Guidelines for Drug Offences

The Chair welcomed to the meeting Warren Young, Judge Jeff Ray, Fiona Wright and Andrea King from the Law Commission.

Reference: Discussion paper provided by the Law Commission

Background: The Law Commission was asked to review the Misuse of Drugs Act by the Associate Minister of Health during Cabinet discussion on BZP. The discussion with the Committee arose as part of drafting up guidelines for the proposed Sentencing Council that is to be established by mid 2008.

Discussion: The Law Commission referred to the list of questions at the back of the discussion paper outlining issues in sets of questions, including:

- 1) Drugs that should be included in the guidelines;
- Guidelines proposed and relativity between the guidelines;
- Separate treatment of methamphetamine;
- Treatment of purity of drugs;
- Relative seriousness of manufacturing;
- 6) Sentence levels; and
- Large scale offending.

The Committee discussed each one of these, raising points that would need to be developed to help assess the issues covered, such as defining what is meant by harm. Harm does not just incorporate physical morbidity but social, physical, mental, and addictive harms.

The Committee also outlined that it was not possible to easily compare the substances within the current Schedule as many were classified due to historical reasons or consequences, or sometimes 'mass hysteria' in other countries.

The Committee supported the table that listed the drugs to be covered by the guidelines. The Committee explained why many of the substances were scheduled as they are, and why some drugs with similar effects have different classifications. Members also outlined that there were many anomalies within the MODA and that guidelines for sentencing should take this into consideration. Proposals will be unlikely to include any guidelines around imprisonment for possession or use of substances, as the main issues would be around supply and manufacturing offences.

The Committee also discussed precursors and how their 'weighting' is misleading, due to their potential to be made into very harmful final products. The Committee then agreed that a hybrid response is better and agreed with the guidelines that changed from net quantities to gross quantities of product depending on the substance.

The Committee discussed the assessment of the guidelines around the separate treatment of manufacturing. This issue is driven primarily by methamphetamine and the damages it causes not just to the individual but to society. Sentence levels proposed are to be based on both the quantity/weight of and the intention for use of the substance manufactured.

The Committee also discussed the possible introduction of these expectations in rehabilitation and treatment clinics. A compulsory treatment would be needed not only for the users but dealers as well, which the current legislation does not allow for.

6.2 Review of the Misuse of Drugs Act (MODA)

Discussion: A progress report on this review is to be provided to Cabinet by the end of 2008.

The Committee discussed possible constraints provided by the international environment and that New Zealand should be taking a more rational approach to classifying substances.

The Committee emphasised to the Law Commission that any review of the MODA would impact on the Medicines Act 1981 and possibly the Hazardous Substances and New Organisms Act 1996 (HASNO). This would incorporate substances that are not captured under the Medicines Act or Food Act and that have a psychoactive effect.

The Committee was keen that the review includes consideration of being able to outline to importers, suppliers and manufacturers that substances should be deemed to be safe before they are marketed and sold marketing New Zealand. Such a move effectively 'reverses the onus of proof', pacing the responsibility of proving safety onto the supplier.

Members of the Committee were interested in whether it was possible to 'plot' the drugs currently included in the Misuse of Drugs Act 1975 Schedules and their relative levels of harm.

Action: Secretariat to invite Val Sim and Warren Young to the next EACD meeting to continue discussions on the review of the MODA.

7. BUPRENORPHINE

Reference: Paper provided by EACD Secretariat

Issue: Possible reclassification of buprenorphine from Class C to Class B to provide greater control over its use and provide for increased monitoring capabilities over its distribution and use. This would also assist in establishing the effectiveness of treatment regimens and settings, and reduce the potential for diversion.

Outcome: The Committee agreed to leave buprenorphine at its current classification. However, the EACD will re-visit this paper if PHARMAC decide to fund buprenorphine for opioid addiction treatment, as subsidies generally increase product's use and overall availability (and potential for diversion). Reclassification to Class B would then be more relevant. The Committee were informed that enforcement of the misuse of buprenorphine would not likely change unless there is a significant change in supply and notified misuse/abuse; the cost of compliance would be too large to warrant greater enforcement activity.

Discussion: The Committee noted that buprenorphine is not being used in New Zealand currently as PHARMAC does not subsidise it for opioid substitution treatment. It was noted that buprenorphine is a valuable drug product in this role and that it is used widely overseas for this purpose.

There is a degree of pressure on PHARMAC by prescribers and consumer groups to subsidise buprenorphine so that is made available alongside methadone for substitution programmes.

8. SATIVEX

Reference: Paper provided by EACD Secretariat

Issue: For the Committee to consider if Sativex should be reclassified after further information on the New Zealand situation is reviewed. The paper was intended to alert the Committee of the potential for a reclassification so as to ensure future action is swift and help to guarantee that access to this product is as wide as possible within the established guidelines.

Outcome: This issue is to be reviewed once the use of Sativex in New Zealand has been reviewed and assessed.

Discussion: The Committee noted that it was unlikely that dispensing pharmacies would recover the costs of installing a refrigerated safe if Sativex was required to be stored in a refrigerated safe, as it will likely be a low volume product.

7. GENERAL BUSINESS:

Note: Invitations to Beyond 2008 Regional Consultation for Australasia and 2008 Parliamentary Drug Policy Roundtable forum are being sent out to all EACD members and the next EACD meeting is to be arranged around these.

8. DATE OF NEXT MEETING:

The next meeting is scheduled for Tuesday 19 February 2008, 1pm – 4.30pm, Ministry of Health Rooms 2.06 & 2.07, 1 The Terrace, Wellington.

The meeting closed at 1.33pm.