Mental Health Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC)

Meeting held on 12 June 2018

(minutes for web publishing)

Mental Health Subcommittee minutes are published in accordance with the *Terms of Reference for the Pharmacology and Therapeutics Advisory Committee (PTAC) and PTAC Subcommittees 2016.*

Note that this document is not necessarily a complete record of the Mental Health Subcommittee meeting; the relevant portions of the minutes relating to Mental Health Subcommittee discussions about an Application or PHARMAC staff proposal that contain a recommendation are generally published.

The Mental Health Subcommittee may:

(a) recommend that a pharmaceutical be listed by PHARMAC on the Pharmaceutical Schedule and the priority it gives to such a listing;

(b) defer a final recommendation, and give reasons for the deferral (such as the supply of further information) and what is required before further review; or

(c) recommend that PHARMAC decline to list a pharmaceutical on the Pharmaceutical Schedule.

These Subcommittee minutes will be reviewed by PTAC at its meeting on 1 & 2 November 2018, the record of which will be available in due course.

Record of the Mental Health Subcommittee Meeting held on 12 June 2018

1. Record of previous minutes

1.1 The Subcommittee noted the previous minutes of the meeting that took place on 23 November 2016. The Subcommittee considered that the record was an accurate representation of the meeting and accepted the minutes as a true record.

2. Correspondence and Matters arising

Paliperidone 3-monthly depot

2.1 The Subcommittee noted correspondence about paliperidone palmitate 3-monthly depot injection (Invega Trinza), including the April 2018 letter the supplier, Janssen New Zealand Limited, sent to psychiatrists asking them to petition PHARMAC to have this pharmaceutical funded.

2.2 Members noted the PTAC February 2017 recommendation that the 3-monthly paliperidone depot injection be funded, with a low priority, subject to Special Authority criteria. This was only if the 3-monthly depot was no more expensive on a mg to mg basis compared with paliperidone 1-monthly depot injection, and if the longer-term financial risks could be addressed.

2.3 The Subcommittee noted that the formulation patent on the paliperidone 1-monthly depot injection expires in late 2018, as notified by the supplier in their May 2010 funding application. This would provide PHARMAC with the opportunity to consider a competitive tender process. However, members noted the 3-monthly formulation of paliperidone has data protection granted by Medsafe, which means a generic 3-monthly formulation will not be able to be registered until August 2021.

2.4 The Subcommittee supported the PTAC February 2017 view that use would shift quite quickly from the 1-monthly to the 3-monthly formulation and that the number of patients being treated overall would quickly exceed the current number of patients being treated. As a consequence, while it may be possible to negotiate equivalent mg to mg pricing in the short term, the Subcommittee noted this is highly unlikely to be the case in the long term if usage shifts from the 1-monthly to the 3-monthly and there is overall market growth.

2.5 The Subcommittee considered that a 3-monthly formulation may confer convenience in terms of less frequent dosing but this would potentially only benefit clinically stable patients. Members considered that on the basis of the evidence provided by the supplier and reviewed by PTAC in February 2017, there is insufficient information to demonstrate clinical benefit for a 3-monthly formulation over the currently funded alternatives.

Nurse Practitioner prescribing

2.6 The Subcommittee noted correspondence from the NZ Nurses Organisation requesting changes to the funding rules to increase nurse practitioner access to various medicines, including some listed in the mental health therapeutic group. Members considered that the issues raised in the letter are longstanding and have not resulted from any recent changes to the Pharmaceutical Schedule rules.

2.7 The Subcommittee noted that Nurse Practitioners, as Authorised Prescribers, are independently able to legally prescribe within their scope of practice and can apply for a Special Authority (initial applications and renewals) where the prescriber fits the criteria of “relevant practitioner” or “nurse practitioner”.

2.8 Members noted that at the 2015 meeting of the Mental Health Subcommittee, PHARMAC sought advice about amending the methylphenidate Special Authority to allow nurse practitioners to apply. The Subcommittee noted that nurse practitioners were not able to initiate a patient on funded methylphenidate, although they are able to write subsequent prescriptions for funded methylphenidate once a Special Authority approval had been granted. The Subcommittee considered this was appropriate, and the Special Authority should not be amended at that time.

2.9 At this meeting (June 2018), the Subcommittee expressed reservations about amending the methylphenidate Special Authority to include nurse practitioners as it may increase overall prescribing of methylphenidate, including in adults where there is a well-recognised, growing and significant diversion risk. Members considered that there are unlikely to be eligible paediatric patients currently missing out on access to funded methylphenidate under the present Special Authority restrictions.

2.10 The Subcommittee noted that in their clinical experience, ADHD is a diagnosis often made and, when combined with poor follow-up of methylphenidate treatment, can lead to long-term management issues. Members considered that amending “medical practitioner” to “any relevant practitioner” in the Special Authority criteria would not be appropriate as this would widen access to a large group of prescribers (broader than nurse practitioners), adding to the growing burden of methylphenidate management issues. The Subcommittee was of the view that the current methylphenidate funding restrictions were intended to help manage the risk of harm, appropriateness of access and responsible prescribing.

2.11 The Subcommittee also considered that the diagnosis of ADHD should be clinically re-evaluated every two years to determine whether ongoing treatment with methylphenidate remains appropriate. Members advised that consideration should be given to regular breaks on no treatment, and a greater emphasis on Cognitive Behavioural Therapy. Members also noted that access to psychiatrists and psychologists is a resource limitation. On balance, the Subcommittee considered that it would be appropriate for PHARMAC to consult with both the Royal New Zealand College of General Practitioners, and the Royal Australian and New Zealand College of Psychiatrists to seek their views on the impact of amending the methylphenidate Special Authority to include nurse practitioners. Members asked that the risk of harm, appropriateness of access and responsible prescribing of methylphenidate be taken into account when considering this matter.

2.12 The Subcommittee next considered the matter of whether nurse practitioners could be enabled to apply for a Special Authority for buprenorphine with naloxone; currently applications are restricted to “any medical practitioner”. Members considered that it would be reasonable for a nurse practitioner who is legally entitled to prescribe buprenorphine with naloxone and who works within a community alcohol and drug service (CADS) to be able to make Special Authority applications if the patient otherwise meets the criteria.

2.13 The Subcommittee **recommended** that the funding criteria for buprenorphine with naloxone be changed to allow Special Authority applications from any nurse practitioner working with a CADS. This could be achieved by amending “any medical practitioner” to “any relevant practitioner” given that in the current Special Authority there is already the requirement that the applicant works in an opioid treatment service approved by the Ministry of Health, so this would incorporate the CADS requirement.

2.14 The Subcommittee also considered the Special Authority criteria for melatonin, which currently limit prescriber types to “psychiatrists, paediatricians, neurologists, respiratory specialist, or medical practitioners on the recommendation of a psychiatrist, paediatrician, neurologist or respiratory specialist”. Members noted that prescribing of melatonin is significantly higher than was estimated when funding commenced in July 2017, and noted that PHARMAC is commissioning audits of Special Authority applicants to ensure the criteria are being met.

2.15 The Subcommittee noted that the current criteria includes “on the recommendation of” defined specialists and this would help to ensure melatonin is prescribed appropriately. The Subcommittee **recommended** that the Special Authority for melatonin be changed to include “nurse practitioner on the recommendation of a psychiatrist, paediatrician, neurologist or respiratory specialist”.

3. Therapeutic Group Review

Treatments for Substance Dependence

Nicotine inhalers or oral sprays

3.1 The Subcommittee was asked to consider whether there is an unmet clinical need for a nicotine inhaler or nicotine oral spray in smoking cessation and if so, which patient groups would benefit. Members noted that, in August 2014, PTAC considered there was no strong evidence that these preparations were more effective than the fully funded forms of NRT. The Subcommittee supported this view and advised that there remains no available evidence to the contrary.

3.2 Members noted that speed of onset of nicotine effect is sufficiently met by the lozenges; and those patient groups with the greatest clinical need for the inhaler or oral spray already have access under the current criteria. In the absence of new evidence, the Subcommittee **recommended** that consideration of widening access to funded nicotine inhaler or oral spray is not warranted at this time.