Health Care Consumers' Association ACT INC
100 Maitland Street, HACKETT ACT 2602
Phone: 02 6230 7800 Fax: 02 6230 7833
Email: adminofficer@hcca.org.au
ABN: 59 698 548 902
hcca.org.au | hcca-act.blogspot.com |
facebook.com/HCCA.ACT | @HealthCanberra

23 September 2015

Vivien Bevan
Chief Pharmacist
Health Protection Service
Email: hps@act.gov.au

Dear Ms Bevan,

RE: Invitation to comment: Greater flexibility in prescribing controlled medicines.

Thank you for providing opportunity for consumer comment on the discussion paper*, Greater flexibility in prescribing controlled medicines.* The Health Care Consumers' Association (HCCA) of the ACT is a health promotion organisation that provides a voice for consumers on local health issues and provides opportunities for health care consumers in the ACT to participate in all levels of health service planning, policy development and decision making.

In preparation for this feedback we circulated these documents to our members who have an interest in this area, including individual members and our organisational members Canberra Alliance for Harm Minimisation and Advocacy, Pain Support ACT, Canberra and Queanbeyan ADD Support Group, Inc. The feedback provided is the collated responses to the discussion paper.

Thank you for seeking consumer input on these complex issues. We are pleased to provide input. We look forward to seeing how our comments can help shape the regulation of persecution controlled medicines. If any aspect of this response requires clarification please contact Eleanor Kerdo by email eleanorkerdo@hcca.org.au or by phoning the HCCA office on 6230 7800.

Yours sincerely,

Darlene Cox
Executive Director

24 September 2015

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Background

HCCA welcomes the opportunity to provide comment on the *Discussion Paper: Greater flexibility in prescribing controlled medicines*. HCCA recognises the importance of guidelines for prescription of controlled medicines, ensuring that these measures keep us as consumers safe while allowing equitable access to medication and care. The complex issues surrounding access to controlled medicines and safe use is of great interest to our members. These proposed changes directly impact the essential rights of a health care consumer as addressed in the Australian Charter of Healthcare Rights, particularly the charter rights of access and safety.

General Comments

We are broadly supportive of the proposed items for discussion, however we feel the discussion paper is quite vague and it is difficult to get a sense of what the new draft standards will look like and how closely they will resemble the draft Controlled Medicine Prescribing Standards that were circulated for consultation in February 2015, or the previously circulated proposed changes for *Guidelines for prescribing amphetamines for Attention Deficit Hyperactivity Disorder (ADHD)* in June 2014. This makes it difficult for us to make a judgement about the proposed changes.

We suggest holding a consultation forum with the newly proposed standards to ensure that we can explore these changes in detail with the community.

Training & Support for General Practitioners & Controlled Medicine Prescribers

We understand that the previous model proposed in the August consultation around removing the need for Chief Health Officer's sign off was of concern to some. General Practitioners (GPs) lack of confidence with prescribing schedule eight (S8) drugs may mean GPs choose not to provide access to these treatments due to fear of misuse.

> *"It is commendable that the Chief Health Officer will also publish revised standards to assist prescribers and pharmacists in using the proposed new flexible system. Increased training of primary health care prescribers in managing chronic pain would also be a highly desirable addition to this support, as it is known that many healthcare*

> *professionals have received limited training in chronic pain treatment*[1] - Pain Support ACT

We see this an issue that needs to be addressed through educating general practitioners about the safe use of these medications and where they can find more information and support. We are also aware that many GPs feel unable to treat chronic pain. Anecdotally we know this is leading to increased presentations to acute pain management services, a service that is already dealing with significant demand.

We are aware that in Canberra access to pain management and other acute services such as elective surgery is hindered by long waiting lists, leaving people with unmanaged pain for longer periods and sometimes increasing their use prescription medications like S8 drugs to manage pain. We acknowledge that we need an approvals process that is less burdensome for administrators, clinicians, pharmacists and consumers, however we cannot create standing three year approvals and thus create greater responsibility for GPs for their prescribing practice without ensuring there is quality support for GPs providing care.

We support providing a telephone hotline service that can provide support to prescribing doctors who are working with patients that require access to controlled medicines. This is a service that could be provided locally or nationally, taking into account the possible cross-jurisdictional issues that could arise. The service could be provided by the Pharmacy Guild of Australia, NPS Medicine Wise or the Primary Health Networks. This is a necessary safeguard should the approvals be extended to three years, as it allows equitable access to controlled drugs while providing safeguards against patients 'doctor-shopping' or being prescribed medications that are inappropriate.

HCCA is supportive of the HealthPathways program currently in use by a number of Primary Health Networks. HealthPathways is an online health information portal used at the point of care by GPs, specialists, nurses and allied health practitioners to assist them in assessing, managing and referring patients in a timely manner to available services. This can help guide integrated care for consumers and standardise referral pathways for best practice and quality care. We are strong supporters of the development of a consumer portal that provides patient information about these pathways. It is only where consumers are informed of what to expect, that they can determine the appropriateness and effectiveness of what is delivered to them. We think it is important to prioritise the development of pathways for medication management for people living with chronic pain.

We also support the proposal as put forward in CAHMA's 2013 submission on controlled medicine prescribing, which advocates for a mentoring and education programs for GPs about controlled medicines and the consumer needs of those who require them. Education is required about the needs of consumers who require controlled medicine such as those with

[1] Pain Australia (2014) "Access to pain management education and training for health professionals in particular as it relates to early intervention, multidisciplinary team practice and the use of opioid medications" Accessed 15/09/2015 : http://www.painaustralia.org.au/images/pain_australia/CampaignForPain_Briefing_Kit_July2014.pdf

chronic non-malignant pain, malignant pain, ADHD, mental ill health, and drug dependency. The needs of these consumers can be quite complex and we encourage ACT Health to work with consumers to identify needs and participate in workforce training. We would be interested to work with ACT Health to coordinate community involvement in workforce training.

Community Education and Communication Plan

We know that as chronic non-cancer pain gains increasing recognition in the community and among professionals, we can expect a greater level of prescribing of controlled medications in response. There are currently one in five Australians living with chronic pain[2]. There is a projection that one in three of people over 65 years will live with chronic pain[3]. We need to make sure that there is active communication and community education about how these changes may affect access to controlled medicine. It would be disappointing given the previous consultation and work around this if this change is not well understood within the community. We want an effective, flexible and safe approval system that will improve the experience of consumers who require controlled medication.

Given that acute pain management services in the ACT are under considerable pressure, community pain management programs should be a priority for ACT Health and the CHN. We encourage ACT Health and CHN to work with the community, especially with organisations like Pain Support ACT to guarantee we are meeting the community need.

Post-Surgical Pain Management

Several HCCA members have raised with us their concern about post-surgical pain management, indicating that is not meeting the needs of some consumers. We know the Health Protection Service and the Medication Advisory Committee is aware of this as a growing area of concern.

> *"A recent experience of a friend in hospital illustrated to me we have problems with post-surgical pain management. She was in hospital having an op and was in pain. She can't take morphine, but she can take Endone. She requested one (as she has had quite a lot of ops and knows how much works), She was given two tablets - which felt a bit sus (sic) about, and then she didn't get any pain relief from the medication. She asked for some more within an hour, and a different senior nurse came and gave her one, and she went out like a light. The next day when she requested pain relief, they gave her three. When she questioned it, they said she had needed that much the night before. She took the dose as advised and proceeded to throw up and be quite ill. It seems highly likely that there was some hanky-panky going on with the two "endones" in the middle of the night. She thinks they were probably Panadol. She was waiting until after she was out, because she felt quite vulnerable on the night shift*

[2] *ibid*

[3] MBF Foundation (2007) The high price of pain: the economic impact of persistent pain in Australia – Pain Management Research Institute, University of Sydney.

thereafter. When she raised it with the overnight nurse, they treated her as if she was a dippy old thing - she was furious, but said she would wait till she was discharged to report anything formally." – Case Study, HCCA Member

Evaluation and Policy Development Process

We note that on page two of the discussion paper there is discussion of community consultation in 2013 about several options around controlled medicine approval systems. It was pointed out by one of our members that the paper does not contain any specific outcomes of this consultation, and it is vague when it comes to explaining how this consultation informs the current proposal.

We would like to know how the *ACT Health Learning and Development Framework Objectives*[4] for learning and development, particularly those around policy evaluation and development are being used to inform this newly proposed work?

It is not clear if this discussion paper and proposals is based on evidence-based practice. We assume this is the case but this requires consideration. For example, there is no reference for the following statements: *"rising rates of controlled medicine abuse, misuse and diversion and calls for greater regulatory oversight"*. Where did this data come from and why was this proposal chosen to address this issue? It would be of value to see a rigorous evaluation and analysis of previous ACT Health work in this area, highlighting why this is appropriate action that meets the need of ACT community. It is unclear how these changes will contribute to *improved public health outcomes* as argued on page two of the discussion paper. As stated, we are supportive of a more flexible and responsive approval system but the discussion paper fails to provide a convincing or clear argument to allow us to make an informed decision about changes in the regulation. The emphasis of the paper appears to be on making regulation less burdensome for prescribing doctors and pharmacists and the CHO, rather than protecting the interests of consumers and the ACT Community.

Stigma and Access to Treatment

On page four of the discussion paper it is stated that these approval changes will only be available to *stable, low-risk patients*. It is not clarified anywhere in the discussion paper what criteria you must meet to be considered stable and low-risk. Does this mean that those who are drug dependant due to long term use for management of chronic pain are unable to benefit from this new approval system? There is a sub-group of people who live with chronic pain who have unfortunately become dependent, to varying degrees, on opioids. These people require the same respect and standard of practical help as all health care consumers.

[4] ACT Health, (2013) *ACT Health Learning and Development Framework 2013-2016; creating a learning organisation to support our business, our consumers and our people* Accessed 21/9/2015 : http://www.health.act.gov.au/sites/default/files/Learning%20and%20Development%20Framework%20(2013%20-%202016).pdf

> *Patients who are deemed to be 'drug dependent' are essentially locked out of being able to access controlled medicines. While we understand that striking a balance between providing legitimate patients with necessary medication and avoiding dispensing controlled medicines to people who may divert or misuse them is a difficult and complex issue, we are concerned that there is an inordinate focus on the dangers of enabling patients to become dependent upon their medication. We fear that this focus may lead to patients with chronic pain being refused medication because of inflated concerns about the hazards and harms of iatrogenic dependence* – CAHMA

Greater Flexibility in Approval Time, Drug Titration and Drug Type

We are supportive of greater flexibility in drug titration and type as we know that many GPs and consumers feel like there is little option for changing treatments that are not effective or causing significant discomfort particularly those consumers who have conditions which are long standing, particularly longer than two months. We think (with proper support for prescribers and consumers) that greater flexibility in approval time, drug type and drug titration is essential in meeting the needs of the ACT community when managing chronic pain and controlled medicine use.

> *I do think there is a case to be made for allowing greater flexibility to titrate the dose of a particular medicine for a particular patient without requiring the prescribing doctor to seek an additional approval each time the dose is changed. This could be addressed by specifying an approved maximum dose for that medicine for that patient as part of the initial approval. This change alone would provide increased flexibility for prescribing doctors and reduce some of the burden on the CHO.* – HCCA member

One of our members felt that the measures currently in place provide enough flexibility to provide safe access to controlled medicine.

> *There are good reasons for the checks and balances in the existing system. The Paper itself points to the "rising rates of controlled medicine abuse, misuse and diversion and calls for greater regulatory oversight". It is important to note that the current regulatory approach is not entirely lacking in flexibility. The existing short-term standing approval provision already provides a degree of flexibility for prescribing doctors - prescribing doctors are not currently required to seek approval from the CHO to prescribe a controlled medicine for up to 2 months under a short-term standing approval. Extending the life of an approval from one year to 3 years seems excessive in the absence of good evidence to support the proposed extension.* – HCCA member

Use of Drugs and Poisons Information System (DAPIS) and the need for Real Time Electronic Medication Management

HCCA supports the use of the new Drugs and Poisons Information System (DAPIS), and believe that real time electronic management is needed as one of many safeguards for consumers who require controlled medication as part of their care. We note that the paper states it will *improve monitoring activities through the use of DAPIS data*, however, the paper fails to explain exactly what data will be used or how it will be analysed. We would also like to know how this data is reported and used to ensure consumer safety. We understand that HPS currently checks approvals against dispensing records. Presumably that will need to continue - it's just that the individual approvals would endure for longer? How will "electronic, real-time reporting of ACT pharmacy dispensing data" compensate for the proposed relaxation of regulatory controls? It would be helpful if the paper provided a more meaningful explanation of this point.

We believe that real time reporting has the potential to streamline the process of pharmacies reporting the dispensing of S8 medicines. A fully automated monitoring system could also expedite any investigations into impropriety. We are aware that ACT Health have been unable to produce a so-called “Living List” that would ensure that all opioid pharmacotherapy clients dosing information is available and up-to-date despite ongoing funding. With this in mind, we would like to know how we can be assured that ACT Health has the capacity to effectively manage DAPIS and real time medication management to ensure safe dispensing and access to controlled medication.

> *The new DAPIS is an important step forward in monitoring and controlling, but to reduce the impact of this disbelief on patients, a system such as the Commonwealth Electronic Recording and Reporting of Controlled Drugs (ERRCD) project is necessary. In other words, a system whereby prescribers (not just pharmacists) can see in real time a patient’s history with controlled medications is also an important step. – Pain Support ACT.*

Cross Jurisdictional Issues

We are aware that cross-jurisdictional issues continue to present significant challenges to consumers when accessing controlled medication.

It is essential that the discussion paper clearly outlines how the ACT Health and other state and territory health departments intend to coordinate care and support these consumers and their families as they move between local and interstate services. How it can be ensured that people who do receive treatment from treating teams locally and interstate have seamless holistic care, with coordination of both treating teams and services including access to necessary medication that may be a controlled substance?

It is not clear in the discussion paper how these proposed changes compare to those in other jurisdictions. We would like know how the proposed regulations compares to other states and territories. The paper states that "removing the requirement for approval details to be

recorded on prescriptions for controlled medicines" would bring the ACT into line with other jurisdictions. This is not referenced so it hard to verify or understand which jurisdictions you are referring to and which aspect of the proposed regulatory changes would align with other jurisdictions.

Concluding comments.

HCCA advocates for an effective, flexible and safe approval system that will improve the experience of consumers who require controlled medication. We are broadly supportive of the changes proposed in the discussion paper *Greater flexibility in prescribing controlled medicines*, however we have concerns that the discussion paper is too vague to allow informed decisions about the regulatory changes.

We believe that any changes must be accompanied with education for health professionals including GPs, pharmacists and consumers. We are also concerned that these changes are more focused on lessening bureaucratic burdens to government and less about improving access to controlled medications for those who need them.

We would like to see an in-depth evaluation and review of the current policies and regulations around controlled medicine and detail about how previous consultation has informed the proposed changes. We also emphasise the importance of real-time medication management lists as an important consumer safeguard. Real-time management is only of use if it is clear how this data will be analysed and used to improve prescribing and dispensing in the ACT community. The complex issues surrounding access to controlled medicine and safe use is of great interest to our members and we will continue to advocate for improvements to current regulatory requirements and service delivery for all consumers.

References

- ACT Health, (2013) ACT Health Learning and Development Framework 2013-2016; creating a learning organisation to support our business, our consumers and our people Accessed 21/9/2015 : http://www.health.act.gov.au/sites/default/files/Learning%20and%20Development%20Framework%20(2013%20-%202016).pdf
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