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Primary Health Network Submission

Consultation: Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response

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The Victoria Primary Health Network Alliance (VPHNA) welcomes the opportunity to provide feedback to the consultation paper Prescription strong (Schedule 8) opioid use and misuse in Australia options for a regulatory response. This response has been prepared by Western Victoria PHN on behalf of the Victorian PHN Alliance with input from subject matter experts. It is acknowledged that the Therapeutic Goods Administration provides an important opportunity to advance the regulatory response to opioid use and misuse in Australia.

Overview

The objectives of Primary Health Networks (PHNs) are to increase the efficiency and effectiveness of medical services and improve coordination of care to ensure patients receive the right care, in the right place, at the right time. PHNs apply a regional perspective to examining and supporting:

- the health workforce
- organisational processes
- networked systems of care.

The Alliance purpose is to optimise the collective capabilities of Victorian PHNs as a sector, proactively align efforts with a state-wide purview and advance primary care reform.

VPHNA provides a platform for the six Victorian PHNs and where relevant and appropriate also includes the Tasmanian PHN. The Alliance enables the PHNs to collectively achieve the best possible outcomes for local communities and organisations through leadership, collaboration, coordination and synergy.[1]

Related PHN and partnered efforts with the Victorian Department of Health and Human Services (DHHS) include:

- Primary care workforce development to support the implementation of the Victorian real-time prescription monitoring system, SafeScript.[2] VPHNA is a part of a consortium led by Western Victoria PHN to develop SafeScript training for prescribers and pharmacists from 2018. SafeScript training and education will be delivered within each Victorian PHN and will focus on key training needs identified by prescribers and pharmacists as well as facilitating discussions and collaborations on local issues related to best practice prescribing.

[1] http://vphna.org.au/
[2] https://www2.health.vic.gov.au/public-health/drugs-and-poisons/safescript

- PHN Alcohol and Other Drug (AOD) service commissioning of treatment services, including indigenous-specific services, based on what is necessary and appropriate to the needs of local communities[3]
- General Practice engagement and education[4] to enhance AOD responses in areas including but not limited to codeine scheduling change [5] and pharmacotherapy (including hosting of Pharmacotherapy Area Based Networks within South Eastern Melbourne PHN[6] and Western Victoria PHN)
- Localised clinical and referral pathways for General Practice use (referred to as HealthPathways)[7]

General remarks

The Alliance would like to propose the following general remarks:

- VPHNA believe that the best way to advance the regulatory responses to opioid use and misuse in Australia, is to acknowledge that this is a profession wide problem requiring a multi-facetted approach to a solution.
- VPHNA support strategies that reduce the emphasis on unsystematic clinical experience and pathophysiological rationale alone while increasing the likelihood of improving clinical outcomes. A focus on Evidence Based Healthcare (EBH) regulatory strategies and ongoing training is widely supported.
- VPHNA support the following statement "*Changes in prescriber behaviour and changes in community expectations about the use of opioids in management of chronic non-cancer pain will have greater impact on appropriate prescription and unsanctioned use of opioids*"[8]. VPHNA support better education programs for General Practitioners throughout tertiary training and ongoing Continuous Professional Development (CPD) activities. VPHNA sees the benefit of Primary Health Networks being involved in the development and delivery of CPD events for Prescribers.
- VPHNA support the *National Pharmaceutical Drug Misuse Framework for Action (2012-2015)*, however, it is believed there needs to be greater focus and education on the range of interventions

[3] https://health.gov.au/internet/main/publishing.nsf/Content/PHN-Circular1_AOD
[4] http://vphna.org.au/education/
[5] http://vphna.org.au/codeine-changes/
[6] http://www.pabn.org.au/
[7] http://vphna.org.au/care-pathways-and-referral/
[8] https://www.tga.gov.au/sites/default/files/consultation-prescription-strong-schedule-8-opiod-use-misuse-in-australia-options-for-regulatory-response.pdf, p.11.

available to assist in the management of pharmaceutical misuse, in particular the role that allied health, specialists and the AOD treatment sector can play in addressing this issue.

- A review of Medicare items that support prescribers undertaking additional training and managing patients in a care team arrangement should be undertaken such as:
    - In order to increase the uptake of non-pharmacological options it is suggested that there is a need for a Medicare item number to specifically support health coaching for those with painful medical conditions.
    - In order to encourage prescribers to manage patients identified as high risk within a Real Time Monitoring system, manage the complexity of dependence including encouraging the use of Medication Assisted Treatment for Opioid Dependence, specific item numbers such as Chronic Disease Plans be established or promoted. The listing should account for the chronic nature of opioid dependence as well as the cost and complex nature of providing this support, such as a substance use disorder management plan.
    - There is a need to ensure that hospital discharge opioid prescribing be included in any changes to regulations and training strategies.

Regulatory options for consideration

VPHNA support the commitment to implement an Australia wide Real-Time Monitoring (RTPM) System. Given the work on RTPM systems in both Tasmania and Victoria – SafeScript, it is recommended that any Real-Time Prescription Monitoring System designed should both interact and/or integrate with already developed systems and leverage the learnings of the previous implementations of these systems. In late 2017, Western Victoria PHN undertook a situational analysis to provide an understanding and overview of the training needs of prescribers and dispensers in relation to the implementation of SafeScript RTPM System in Victoria and recommend that a focus on the following be included with any RTPM system design:

- The downstream effects on the AOD Treatment Sector and sector readiness to manage potential additional pressures on capacity.
- Training approaches that include prescribers and pharmacists as a primary audience however have a wider scope to include health professionals that will have contact with and be a part of care plans for patients, as well as whole of practice and whole of Pharmacy approaches.
- Education and training for prescribers and pharmacists that includes:[9] (Refer appendix 1)
    - Communication and engagement skills
    - Collaborative and coordinated engagement between patients, prescribers, pharmacists, allied health and specialists

[9] Western Victoria PHN undertook a situational analysis to provide an understanding and overview of the training needs of prescribers and dispensers in relation to the implementation of SafeScript RTPM System in Victoria. A summary of the training is found in Appendix 1

  - Education and information on best practice use and management of medications when prescribing/de-prescribing and dispensing
  - Maintaining personal and staff safety
  - Streamlining of permit processes by integrating into RTPM systems to ensure current permit regulations are adhered to and ensuring prescribers and pharmacists have access to this information at the point of intervention
  - Clinical Pathway resources for prescribers and pharmacists
  - Patient access to information on high risk medications
  - Ongoing patient monitoring and support.
- VPHNA support accreditation standards for The Royal Australian College of General Practitioners (RACGP) and recommend a review of opioid permit compliance audit which may assist in identifying problems in the system contributing to high rates of prescribing.

Comments on proposed options

Option 1. Consider the pack sizes for Schedule 8 opioids

VPHNA support the introduction of both smaller (such as maximum three-day) pack sizes for treatment of patients with acute pain and suitable pack sizes (14 or 28 days) for treatment of people with chronic pain due to malignancy.

Option 2: Consider a review of the indications for strong opioids

VPHNA support the review of the current indications for strong opioid products and their alignment with current clinical guidelines for the appropriate use of these products, however, there is a need to ensure barriers are not created to the prescribing of opioids where indicated. VPHNA acknowledge the difficulties in the management of non-cancer chronic pain and the disabling effects this can have on patients' lives. Any barriers to prescribing of opioids to this group must be considered in terms of options available to refer this patient group to accessible and timely support. If there continues to be limited referral pathways, there is a likelihood that GPs may prescribe "off label" even if the prescribing indications change.

Option 3: Consider whether the highest dose products should remain on the market, or be restricted to specialist/authority prescribing

VPHNA request further consideration of any evidence that medical specialists currently or in the future are likely to prescribe opioids more appropriately than General Practitioners. Access to Medical Specialists in rural and regional communities is low and limitations of prescribing of opioids may create barriers to accessible services without improving the quality barrier.

VPHNA recommend that any changes related to the restriction of specialist/authority prescribing be developed in consultation with the relevant stakeholders and peak medical bodies to ensure all potential ramifications of such decisions are considered. Other consideration options may include:

- Phone based authority prescribing - recognising that non-PBS prescribing falls outside of this option
- 'Special Permit' options that detail specific 'indication'. This would require collaboration around legislation between the Commonwealth and states and territories
- Requirements that co-prescribing of Naloxone for all patients on more than a short course of opioids
- Specialist oversight of prescribing if multiple scripts issued
- Monitoring of prescribing, particularly post operatively, on discharge from hospital. Further training and oversight of hospital specialists (particularly surgeons and Emergency Department prescribers) is required.

VPHNA support better auditing of current prescribing and permit practices, via state and territories, including:

- Better processes to ensure prescribers are not in breach of permit conditions
- Better access and monitoring of drugs of dependence register. Currently in Victoria the hours of operation are limited on evenings and weekends. Real Time Prescription Monitoring may assist in this process if it becomes the data source
- New patients to a practice to have a phoned authority script in place prior to any opioid prescribing (monitoring maybe administratively difficult). The Authority line would therefore have information available for the prescribing GP of previously prescribed "first time" opioids; the alternative is the SafeScript patient record.

Option 4: Strengthening Risk Management Plans for opioid products

VPHNA would support additional resources for prescribers linked to training. The ability to prescribe opioids could be limited to those who have completed a module around opioid prescribing. The states/territories could require proof of such educational activity prior to approving an application for a permit such as for other medically assisted opioid prescribing.

VPHNA support initiatives that encourage the co-prescribing of Naloxone for all patients on more than a short course of opioids.

Any consideration of training requirements for permits should be reviewed in line with existing opioid prescribing training requirements for medically assisted treatment for opioid dependence (MATOD). This may reduce the barriers for prescribers in relation to General Practitioners prescribing MATOD treatment by seeing these treatments as options for management of people with dependence of opioids.

Option 5: Review of label warnings and revision to the Consumer Medicines Information

VPHNA support the placement of information on opioid product packaging detailing the risks of dependence, and the lack of efficacy in long-term treatment of non-cancer pain. Something obvious such as '*Warning – this is a high risk medication. Please speak with your GP or pharmacist if taking a dose of more than 2 weeks'.* This could be adjusted according to the indication e.g. for disabling cancer pain.

VPHNA support the implementation of the Choosing Wisely Australia program to increase patient health literacy. Choosing Wisely Australia is designed to assist 'healthcare providers and consumers start important conversations about improving the quality of healthcare by eliminating unnecessary and sometimes harmful tests, treatments, and procedures'.[10]

Option 6: Consider incentives for expedited TGA review of improved products for pain relief and opioid antidotes

VPHNA support the expedition of the TGA review of improved products for pain relief and opioid antidotes.

Option 7: Potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong opioids

VPHNA support a review of how current legislation is managed as a first response, with consultation developed with input from the relevant stakeholders and peak medical bodies to ensure all potential ramifications of such decisions are considered; also refer back to discussion in Option 3.

The examples on limitations to prescribing provided may not increase quality prescribing but limit access. Limitations on prescribing may be better addressed by targeted training rather than initial qualifications and specialty.

Restricting S8 prescribing to palliative care and specialist pain care physicians may create further barriers to patients, particularly those in regional and rural areas. Access to pain specialists is currently very difficult and this would create an increased cost for those patients due to specialist fees and transport issues. This highlights the need for further national and/or jurisdictional leadership in relation to pain management.

A review of restrictions may include exceptions where:

- treatment is overseen by a specialist via telehealth
- management plan have be reviewed by a specialist and consolation occurs with the prescriber
- prescribing low dose opioids not including Fentanyl.

[10] http://www.choosingwisely.org.au/home

Option 8: Increase health care professional awareness of alternatives to opioids (both Schedule 4 and Schedule 8) in the management of chronic pain

VPHNA support mandated education via the Medical Board of the prescriber rather than limitations on the original medical qualification of the prescriber. Specific recommendations include:

- Medical students to be provided with provisional registration upon completion of an approved module prior to registration with AHPRA.
- The TGA/NPS to develop a patient portal to outline the de-prescribing clinical pathway. This pathway should be utilised by PHN's HealthPathways for prescribers.

VPHNA support multidisciplinary evidence based pathways related to pain such as those developed by National Health and Medical Research Council (NHMC). The paper references a prime mover for the increasing opioid prescribing in Australia has been addressing patients presenting with osteoarthritic pain.

There is significant evidence based on the efficacy of manual therapy addressing osteoarthritic pain. In 2009, the National Health Service in the UK undertook an extensive review[11] of all evidence relating to the benefits of exercise and therapy. Their conclusions were that there is significant benefit for patients suffering from osteoarthritis via a consultation with any one of a number of allied health practitioners and massage therapies. This approach delivered numerous benefits from manual therapy for patients presenting with an array of classical degenerative conditions. This awareness has led to greater integration of allied health teams into General Practice and even cases where osteoarthritic pain is effectively managed by Consultant Physiotherapists working in parallel with GPs in primary care.

Continued development of adjunct/alternative to opioid prescription strategies should be utilised including:

- Chronic Disease Management item numbers under the Medical Benefits Scheme for Allied Health referral through the Chronic Disease Management Care plans, and
- Regular medication reviews by Pharmacists.

PHNs are well placed to contribute advice regarding best practice and emerging issues to achieve a more supported, integrated and cohesive service focused on improving patient care, build awareness and provide training to support the move to manual therapy for patients presenting with such conditions.

Other Feedback

Regarding the "previous recommendations" section of the document; the suggestion that *"specialist medical review for non-cancer patients occurs after time x"* needs clarity particularly in terms of which specialist group would provide the review.[12]

[11] Bronhort et al., (2010) Effectiveness of manual therapies: the UK evidence report

[12] https://www.tga.gov.au/sites/default/files/consultation-prescription-strong-schedule-8-opiod-use-misuse-in-australia-options-for-regulatory-response.pdf ,p. 22.

Summary recommendations

In summary, the recommendations of Victorian PHNs are:

1. PHNs to be considered as a key resource to provide overarching support in the area of quality opioid prescribing. PHNs are well placed to provide opioid prescribing support to General Practices in auditing tools and subsequent whole of practice training. The SafeScript training approach will complement past training for prescribers and pharmacists. PHNs could expand their current role supporting General Practice that includes:
    - General Practitioner Champions to support peers in area of prescribing
    - Support for General Practice to implement audit tools to consider opioid prescribing policies and practices
    - Professional development
2. VPHNA support additional training for all prescribers and pharmacists. VPHNA would support mandatory education for health professionals in regard to best practice opioid prescribing, particularly targeting prescribers who have been identified as over-prescribing.

3. VPHNA recommend that any changes related to the restriction of specialist/authority prescribing be developed in consultation with the relevant stakeholders and peak medical bodies to ensure all potential ramifications of such decisions are considered. A more nuanced way of considering this issue is around specific training of the prescriber rather than the original medical qualification of the prescriber.

4. VPHNA support initiatives that encourage the co-prescribing of Naloxone for all patients on more than a short course of opioids. With the introduction of SafeScript, dispensing data will be available in real time to inform prescribers regarding the patient's opioid use. A comprehensive GP, pharmacist and community education program that extends beyond the injecting drug use population should also be developed.

Appendix 1 – Training Needs

A multifaceted needs assessment and consultation process targeting primary care prescribers, pharmacists, Subject Matter Experts and people with lived experience of chronic pain and/or dependence has revealed key themes for Victorian SafeScript training:

Communication and engagement skills	A non-judgmental non-discriminatory approach and the ability to manage difficult conversations is identified as a critical success factor across all workforce streams and by consumers. Respectful and empathetic communication, effective counselling skills and the ability to clearly articulate alternative treatment options and potential risks associated with dependence and withdrawal are identified as the most important skills and the most difficult to get right.
Collaborative approach	Collaborative and coordinated engagement between patients, prescribers, pharmacists and specialists is identified as essential to achieving positive outcomes. This continuity of care approach requires proactive and constructive follow up with active feedback loops.
Education and information	A high level of practitioner knowledge about best practice use and management of medications they are prescribing/de-prescribing and dispensing is very important to practitioners and expected by patients. Greater education about potential risks associated with long-term use of and withdrawal from medications is required, along with increased understanding of non-pharmacological options, pain management; and access to and applicability of local services, and referral options. Practitioners also need to be able to communicate this information effectively and respectfully to patients.
Safety	Maintaining personal and staff safety in situations where it is necessary to refuse to prescribe or dispense a medicine is important to practitioners, along with the need to better understand the implications for workflow (eg appointment length) and set up of spaces to maintain the privacy and emotional safety of patients.
Training accessibility and blended learning	To maximise participation, training needs to be available at a time and place that suits the prescriber and pharmacist. It must follow adult learning principles and cater for multiple learning needs and delivery mode preferences. It must be responsive to local needs and be culturally safe and appropriate. Access to information in real time is valued, with links to localised HealthPathways and other clinical information being accessible in consultations.