HCASA
Health Consumers Alliance of SA Inc

Consumers at the centre of health in South Australia

Response to Therapeutic Goods Administration (TGA) Consultation Paper: 'Prescription strong (Schedule 8) opioid use and misuse in Australia - options for a regulatory response'

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Prescription strong (Schedule 8) opioid use and misuse in Australia

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HCA acknowledges the Traditional Custodians of Country. We pay respect to Elders past and present, and recognise that their cultural heritage, beliefs and relationship to Country are important for sustaining health and wellbeing.

Background

Health Consumers Alliance of South Australia (HCA) hcasa.asn.au

HCA is the peak body for health consumers in South Australia. We work with consumers and health services to position consumers at the centre of care. This work includes training and support to enable consumers and health professionals to collaborate in the design, delivery and evaluation of health policy, services and research.

HCA supports the National Medicines Policy (Commonwealth of Australia 1999), which seeks, in part, to 'provide quality care responsive to people's needs'. The policy is based on the central importance of a partnership approach between government, health professionals, industry, the media – and consumers.

General Comments

Consumer values, perspectives and reported experience are absent from this paper; there is a distinct lack of any acknowledgement of people; their life circumstance; and the impact these regulatory changes will have on them and their families, their health and wellbeing.

The up-scheduling of low dose products containing opioids has left consumers confused about the information they are receiving, the inconsistency with their own experience of the use of these products, and the lack of alternatives to assist them in managing their chronic pain. Changes without appropriate consultation with consumers will add to confusion and concern.

Consumers are right to be concerned; the TGA paper puts the view that:

- Chronic pain has not been treated appropriately or effectively over many years
- Many health practitioners have been wrongly dispensing/prescribing opioids for chronic pain against growing evidence to the contrary
- Health consumers cannot be relied upon to appropriately use S8 opioids (or S4 opioids) to manage chronic pain
- Greater regulatory control, rather than improved prescribing and consumer health literacy, is the most effective first response.

General Recommendations

Any further changes in regulation, policy and practice that increases regulatory control of Schedule 8 opioids must be determined in partnership with health consumers. In parallel, and as a priority, non-regulatory strategies must include:

1. Implementation of the National Pain Strategy
2. Improved patient pain assessment tools (including the language tools to describe pain) to assist them in discussions with their treating health practitioner
3. Appropriate resources for consumers about indicators for misuse/ abuse/ addition and risk management protocols

4. Appropriate resources for consumers to assist them to better understand, assess and manage their pain
5. Addressing the stigma people with chronic non-cancer pain experience.

Response to Options

Option 1: Consider the pack sizes for Schedule 8 opioids

Whilst a reduction in pack size has the potentials in reduction of misuse and diversion, any reduction in pack size should consider and balance the potential cost and issues of access for consumers, including consideration of:

- medical appointments (GP and specialist)
- delays in getting an appointment with GP (and often extended delays in getting appointment with specialist)
- issues of communication between GPs and specialists
- higher levels of presentation at emergency departments where consumers experience prolonged pain (beyond pack size).

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

Health consumers expect that health providers demonstrate best practice and would assume practice was aligned with current clinical guidelines for appropriate prescription of Schedule 8 opioids. HCA recommends consideration be given to the following:

- adoption of a clear, agreed/accepted definition of *chronic, severe disabling pain* (unresponsive to non-opioid analgesics) in Australia
- tools for consumers to self-assess pain under this definition
- adoption of Patient reported outcomes measures (PROMs), Patient reported experience measures (PREMs) and Patient reported adverse events as part of the accepted tools for assessing pain
- recognition that any shift in pain management toward non-pharmacological, functional improvement rather than pain level may still require pharmacological support whilst/to aid improving function

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

Consumers expect any such decision to be based on evidence relating to both the products and the proposed alternatives and for this to include patient data (PROMs, PREMs and adverse events) and Australian as well as international data. Any shift to greater restrictions on prescribing should consider and balance the potential cost and issues of access for consumers, including consideration of:

- access and cost related to GP vs medical specialist appointments
- access and cost for consumers in rural and remote regions where access to specialists (and GPS) is limited and may result in difficulty/delays in treatment;

- impact on prescribing nurse practitioners / remote areas nurse who currently dispense medicines against standard guidelines
- improved communication/referral pathways between GPS and specialists how and other health professionals can work better together to support consumers and expedite pain management plans.

Option 4: Strengthening Risk Management Plans for opioid products

Health consumers would assume current risk management plans for opioids reflect best practice in opioid prescribing. Consumers need optimal pain management and optimal management of adverse events related to medicines and the impact on their life. Considerations should include:

- early identification, recognition and support for people with codeine dependence
- education and professional development for prescribers – and for this to be informed by/developed with consumers and include:
    - language and tools for consumers to describe and assess their pain patterns and experience
    - partnering with consumers in determining pain and pain management goals and risk
    - development of risk management resources for consumers
    - development of risk management resources for health providers
    - reducing impact of negative stigma experienced by people with chronic pain.

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

Access to health care information is a health care right. Consumer Medicines Information is a part of this. Consumers would appreciate co-designed (ie developed with consumers):

- access to information regarding for all products containing opioids (including Schedule 4 products containing opioids)
- a public information campaign and additional information (leaflets, webpages on kiosks, fact sheets etc) in pharmacies and medical clinics
- NPS MedicineWise online information (and on their app).

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

Consumers would be concerned to learn that, as the paper states: …*while there are some potential novel compounds under development there are few contenders for regulatory approval in the immediate future. So, while this option should remain 'on the table' there are few therapeutic alternatives on the immediate horizon.*

From a consumer perspective it is important to:

- investigate products for chronic non-cancer pain
- focus on improved pain management planning and accessible, affordable services
- better use of Chronic Management Plans to reduce cost to consumer (eg reduced cost access to physiotherapist as part of Plan)

- improved access/availability of alternative, non-pharmaceutical support and services (eg physiotherapists in rural and remote areas / improved access to pain management clinics etc to improve function)
- introduction of abuse-deterrent formulations should be done in parallel with increases access to opioid addiction support services and early identification of opioid addiction

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

Consumers would be best supported where any regulatory control of prescribing of Schedule 8 opioids was aligned with specific health populations (eg rural and remote) rather then classes of medical practitioners. This would see prescribers working with 'in need' populations (eg older people with complex health condition and chronic pain) would be better placed to manage prescription of Schedule 8 opioids as part of the person's Pain Management Plan

Consumers expect consideration to be given to:

- identifying prescribers who require additional Pain Management Plans and complex pain management support
- identifying health consumers are assessed under an agreed/accepted definition of *chronic, severe disabling pain* (unresponsive to non-opioid analgesics) in Australia
- access and cost related to GP vs medical specialist appointments
- access and cost for consumers in rural and remote regions where access to specialists (and GPS) is limited and may result in difficulty/delays in treatment;
- impact on prescribing nurse practitioners / remote areas nurse who currently dispense medicines against standard guidelines
- improved communication/referral pathways between GPS and specialists how and other health professionals can work better together to support consumers and expedite pain management plans.

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

Consumers would support the TGA working with NPS MedicineWise and clinical colleges/ societies to promote active uptake of the current guidelines by health practitioners. Consumer organisations should also be involved.

Consumers are concerned:

- greater controls of opioids without significant improvement in health practitioner knowledge and implementation of current clinical for the management of acute and chronic pain leaves consumers without alternative options to manage their pain.
- any additional level of regulation for prescribers of Schedule 8 opioids should include regulatory requirements, by their Board, for mandatory professional development
- health practitioners who have limited awareness and uptake of current existing pain management and prescribing/risk management protocols are arguably acting in an unprofessional manner and should be accountable to their profession and the public.

Schedule 4 opioids

Consumers are concerned about the risks of potential for increased/overuse of paracetamol, ibuprofen and combinations products as the alternatives to management of acute/chronic pain given these issues raised. Overuse and misuse of paracetamol and ibuprofen is already well reported (in Australian and the United Kingdom) [1] [2] [3] and that there are already reported concerns about the increased use of paracetamol/ibuprofen combinations as an alternative access to these products containing codeine.

Community pharmacies are actively advertising paracetamol/ibuprofen combination products, advising consumers that these products are much more effective than products containing codeine. The reporting that '*some evidence'* and '*it would appear'* suggest far from definitive evidence for increased use or recommendations by the health system that these products are more effective for the management of acute/chronic pain. NPS MedicineWise reported (in June 2017)[4];

- *Since the products became available the NSW Poisons Information Centre has received around 70 telephone calls from consumers worried they have overdosed on the combinations. Interestingly, the rate of calls jumped markedly from mid-2016, and the Centre reports they are currently receiving, on average, more than one call each week.*

Significant consideration must be given to the risks of potential for increased/overuse of paracetamol, ibuprofen and combination products as the alternatives to management of acute/chronic pain given these issues raised.

[1] https://www.tga.gov.au/media-release/paracetamol-changes-pack-size
[2] https://www.tga.gov.au/book-page/16-ibuprofen
[3] https://www.howtotreat.com.au/how-treat/how-manage-upscheduling-codeine
[4] https://www.nps.org.au/medical-info/clinical-topics/news/dose-confusion-with-paracetamol-ibuprofen-combinations