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2nd March 2018

Dear Therapeutic Goods Administration,

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

I am a Clinical Pharmacist, Advanced currently working in positions as a practitioner in the Interdisciplinary Persistent Pain Centre in the Gold Coast HHS and as an academic at Queensland University of Technology (QUT)'s School of Clinical Science. My clinical background has been as a specialist clinical pharmacist working over the past 30 years in Palliative Care and Persistent Pain Management. I define Persistent Pain using the definitions used by the International Association for the Study of Pain (IASP) as pain that has been present for more than 3-6 months and thereby associated with neural sensitisation after the normal processes of healing have ceased.

I write representing myself not necessarily the position of either Queensland health or QUT.

Opioid analgesics are use in three major clinical areas: Acute postoperative and post trauma pain, Chronic Non-Cancer Pain, and in the management of pain and other symptoms in Palliative Care. I believe it is important that any changes undertaken by the TGA do not affect the management of dying patients (Palliative Care) where the use of opioids is appropriate and not related to the problems of abuse and misuse.

There should be no differentiation between 'Weak' and 'Strong' opioids. This is dependent upon dose and oral morphine equivalency (as demonstrated by recent issues with codeine)

Option 1: Consider the pack sizes for strong (S8) opioids

There is a need for smaller pack sizes to reflect the needs for patients with acute pain where it would not be expected that patients would require medication other than to reflect the pain trajectory associated with tissue healing and hence the short duration necessary until weaker non-opioid analgesics might be effective.

Research conducted by the Centre for Disease Control in USA has demonstrated that the quantity of opioids supplied on initial prescription positively correlates with probability of prolonged use of opioids. Patients receiving initial opioid prescription of one-day supply only had a 6% chance of being on opioids for a year or longer, compared with 10% chance for patients supplied with five-days supply. Patients receiving 14-days supply, which is the standard pack-size for sustained release opioids in Australia, had a 25% chance of remaining on opioids one year later(Shah A, Hayes C.J, & B.C., 2016).

However for Palliative patients a small pack for breakthrough pain management may be inadequate so there would need to be both available. The only way to distinguish and manage the prescribing of an appropriate pack might be though PBS authority.

Option 2: Consider a review of the indications for strong (S8) opioids

Ideally strong opioids would not be used in Persistent Pain as the evidence to support their use is limited. However the application of strong opioids in the management of pain and other symptoms in Palliative Care is not questioned. Similarly the use of opioid analgesia in acute pain enables the types of surgery not being undertaken and it is inconceivable how some operations could be performed without the use of opioids afterwards

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

RACGP guidelines and Persistent Pain guidelines support the use of opioid doses of less than 100mg oral morphine equivalent a day(Practitioners, 2015). Unfortunately we commonly see patients attending the Persistent Pain Clinic taking doses greatly in excess of this. There is also a thought that it is the instant release opioid formulations that encourage the development of drug tolerance and encourage abuse through euphoric effects. In Persistent Pain we might therefore envisage the availability of doses up to 100mg Oral Morphine Equivalent Daily doses (OMEDD) e.g. oral morphine CR 50mg twice daily, oxycodone CR 30mg twice daily, oxycodone/naloxone CR 30/15mg twice daily, fentanyl patch 25mcg/hr, tapentadol CR 100mg twice daily and that higher strengths are only available on PBS authority supported by specialist Persistent Pain Centres or in patients with cancer-related pain.

Option 4: Strengthening of the Risk Management Plans for opioid products

Supported

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

Supported although language would need to be moderated to avoid creating fear in the appropriate use of an opioid in a Palliative setting.

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

All medications requires due diligence in TGA review before accepting products into the Australian market. Therefore I do not agree that there is a need to expedite the TGA review process for any medications

Option 7: Potential changes to use of appendices in the Poisons Standard to provide additional regulatory controls for strong S8 opioids (this could potentially include controls of prescribing for particular populations or classes of medical practitioners, additional safety directions or label warning statements, specific dispensing labels).

The majority of patients taking opioid analgesia only do so in the management of their pain symptoms. I would estimate that the numbers of patients misusing or abusing these agents in the Persistent Pain Clinic is in the region of 3-5%. Persistent Pain patients are often unable to work because of their symptoms and are ill equipped to access Specialist Pain services outside of the public health service. We already see a number of GPs who will not care for patients with Persistent Pain on the Gold Coast or who cease support when the patients' complexity becomes too much. To impose requirements that limit or restrict the access to appropriate health care practitioners cannot be supported.

Option 8: Increase health professional awareness of alternatives to opioids (both S4 and S8 opioids) in the management of chronic pain.

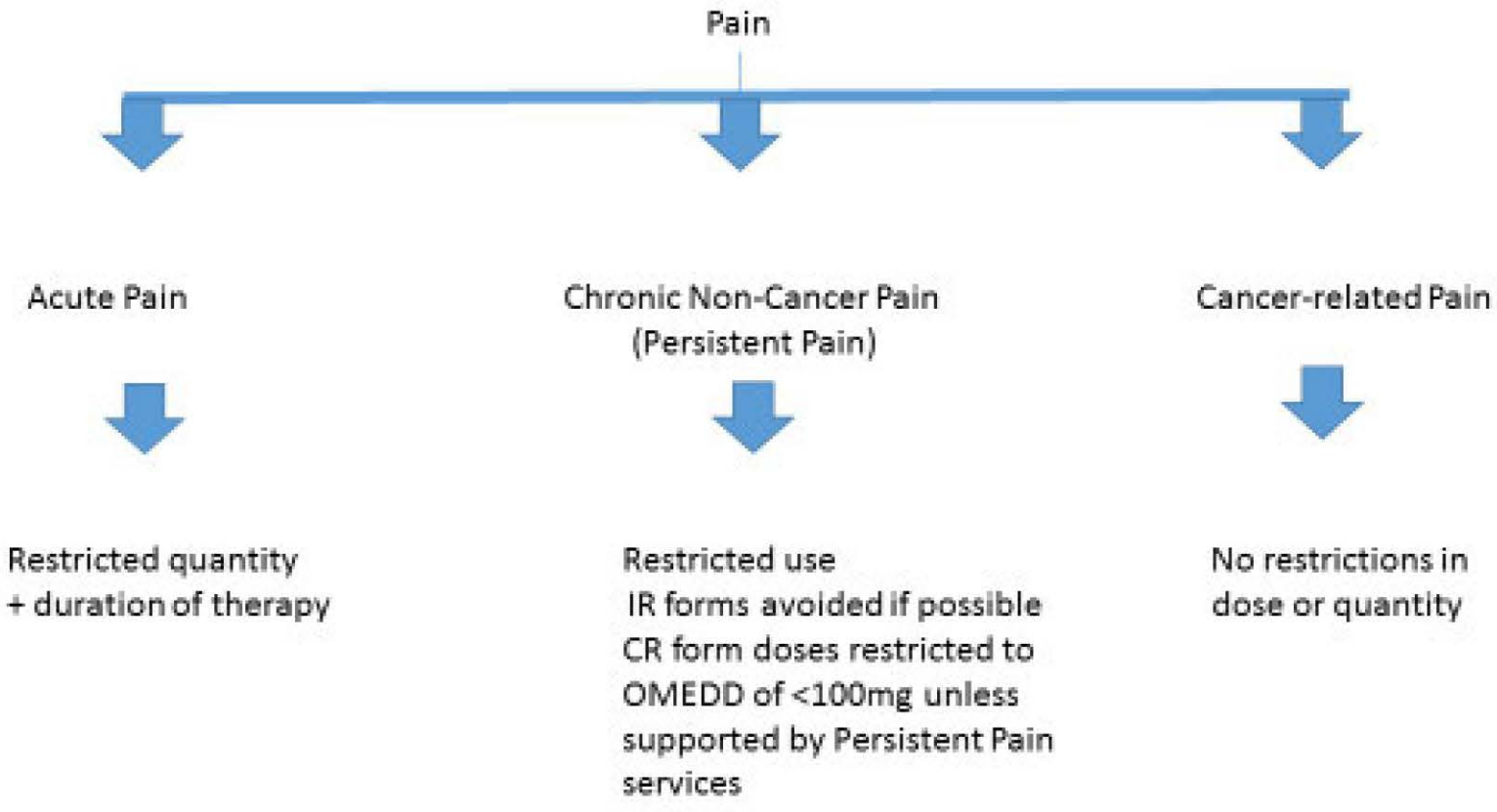
Supported although education as a change agent is not very effective. The management of pain is often not considered a major element in many health practitioner graduate educational curricula. Ideally the management of Persistent Pain would be best taught in an interdisciplinary educational environment and this is not the usual context in any allied health disciplinary education.

Sincerely

References

Royal Australian College of General Practitioners, (RACGP). (Apil 2015). *"Prescribing drugs of dependence in General Practice, Part A: Clinical Governance Framework."* ISBN 978-0-86906-429-0

Shah A, Hayes C.J, & B.C., M. (2016). *"Morbidity and Mortality Weekly Reports - Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015.* Retrieved from www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm#F1_up


Pain
Acute Pain
Chronic Non-Cancer Pain
(Persistent Pain)
Cancer-related Pain
Restricted quantity
+ duration of therapy
Restricted use
IR forms avoided if possible
CR form doses restricted to
OMEDD of <100mg unless
supported by Persistent Pain
services
No restrictions in
dose or quantity