Melbourne Pain Group

Date Typed: 27 February 2018

TGA
PO Box 100
WODEN ACT 2006

Dear Sir/Madam

RE: Prescription strong (schedule 8) opioid use and misuse in Australia - options for a regulatory response consultation paper.

I wish to respond as a pain rehabilitation specialist, who has extensive clinical experience in use (and abuse) of opioid analgesia over a prolonged period of time. I work as a director of medical services for two rehabilitation facilities in Melbourne and established the Melbourne Pain Group in 2007, in order to provide a more comprehensive service to pain patients.

I would like to go through the issues you raise sequentially.

Option 1. Consider the pack size for schedule 8 opioids.
The larger issue is patients who are discharged postsurgically are not put on a reduction regime for their analgesia at discharge on the whole. In public hospitals, the discharges are usually done through the junior medical staff. The prescriptions are based on the medication the patients are having as inpatients and transcribed to their discharge summary. Prescriptions done for inpatients are often done to minimise problems for both nursing staff and doctors and hopefully cover their patients pain. To allow as greater flexibility as possible a prescription as an inpatient might be Endone 5 mg 1 to 2 four hourly prn which implies a maximum per day of 12 per day. This is more done for flexibility but when this is then transcribed to the discharge list of medication, it implies to the patient they can take up to 12 per day. In my view, changing the dose of the medication to give more flexible dosing would be reasonable, if only to minimise large amounts being discharged when smaller amounts are more appropriate or to highlight the fact that the medication should be reviewed fairly early post discharge. Whether this would in reality change discharge medication prescribing is difficult to know.

As far as outpatients with acute pain are concerned, given that acute pain episodes can last for a number of weeks, having larger amounts is probably not the issue but the way the medication is used is the issue. If there is a concern about the use of the medication, doctors are not empowered enough to be able to indicate on the script, for instance in someone who they may consider to be at high risk of misuse of the medication, for arguments sake to outline weekly pickups of a certain quantity as opposed to giving a large script for many tablets, expecting that it might last for four weeks, but knowing that patients will take more than allowed.

Option 2. Consider a review of the indications for strong opioids.
There are expectations amongst the community that analgesics are effective for pain. In a similar way that antibiotics were expected to be dispensed by general practitioners, opioids are now expected to

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be dispensed by general practitioners when pain relief is problematic. I think this is more of a broader public health issue and requires further education to patients that opioids have a role for short periods of time only and that the evidence relating to the prescription of opioids in the chronic pain states is poor and the risk of dependency is high. Encouraging patients to discuss alternate options rather than schedule 8 medications would be the key here. Patients commenced on medications which are not adjusted three months later may well remain on that medication indefinitely, with the expectation that the dose would increase slowly with time.

Cannabis has broad support in the public despite lack of evidence and indeed potential for severe adverse outcomes.

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

In the case of nonmalignant pain, I think this is quite reasonable. In the state of Victoria, Drugs and Poisons monitor dispensing as much as they can (when they are informed) and when they reach certain triggers, the doctors are required to seek second opinions. That second opinion is usually requested to come from the specialist but the nature of that specialist is usually unspecified. As such, seeing a gastroenterologist might have a different view to seeing a pain specialist or even a rheumatologist likewise.

There is significant malalignment of state policies of maximum levels of opioids and monitoring of opioids. Alignment of states would be helpful, not the least in order to educate doctors where a consistent policy across Australia is maintained.

We I see a new patient on classical opioids, oxycodone fentanyl and in particular and secondarily, morphine followed by the other opioids, I am not certain as to what I am dealing with. Am I treating a pain problem, a dependency problem or both. The first thing I address is getting them off the classical opioids to give me an indication as to what we are actually treating here. I think high-dose opioids are problematic and I think they do need to be restricted.

Option 4. Strength in the risk management plans for opioid products.

I think this is covered in Victoria by Drugs and Poisons, Department of Human Services Victoria, limiting maximal levels without specialist consultation. Although, as indicated, specialist consultation should be with doctors who have expertise in opioid prescribing and not other specialists. This is practically problematic given the relative lack of availability of pain specialists in both public and private settings.

Option 5. Review of label warnings/revision of the Consumer Medicines Information.

How often do patients read the small print on product information outlining their prescription of the medication. I suspect that this would not be useful. Maybe if three clear take home messages such as:

1. To avoid alcohol and other sedative drugs whilst using this medication.
2. To avoid driving and operating heavy machinery.
3. To return unused medications to the pharmacy, may be enough.

Option 6. Consider an incentive for expedited TGA review of improved products for pain relief and opioid antidotes.

Two years ago, I commenced using Suboxone (buprenorphine plus naloxone) for high-dose opioid patients. This was simply on the basis of the deaths of my patients over years. When you review the files, you realise that the patients were clearly drug dependent, unable to reduce their medication even in inpatient settings and were high risk. Buprenorphine has a safety profile preferable to the classical opioids with less respiratory depression.

All products that are available, which are abuse deterrent, can be overcome in some way. The drugs may not be injectable but they can still be misused. The addition of naloxone to oxycodone does not stop drug dependency and dose escalation.

I think having patients be allowed to use an opioid antidote at home should be encouraged. This is primarily for their family, not for themselves, to use when they realise the patient is oversedated or having difficulty breathing, for instance.

Option 7. Potential changes to use of appendices in the poisons standard to provide additional regulatory controls of strong opioids.
I think this is done in Victoria as it is. Clearly not ideal. Some patients are on high-dose opioid therapy with no permit in situ. Some patients are in this situation some times for many years. It is only when you see the patient and you contact Drugs and Poisons that this comes to light. The only time that doctors prescribing are than cautioned or disciplined on the whole is if there are either a repeat offender or a catastrophic outcome occurs with that particular patient.

Realtime prescribing and monitoring may assist in this regard.

Option 8. Increased health care professional awareness of alternatives to opioids in the management of chronic pain.
I think I have touched on this as above.

I think public education is very important and I have publicly advocated public education campaigns, outlining opioid use and other options previously in this document.

Likewise, there are opioids which are generally safer in the context of chronic pain, less likely to lead to dose escalation and misuse and there are opioids which are far more likely to lead to dependency and misuse. The education outlining which are the preferred opioids, which ones are the safer opioids, which ones are the opioids that are easier to withdraw from and wean off requires continual refinement for general practitioners.

On the whole, easy patients are easy to deal with, complex patients are far more difficult. Complex patients with significant psychopathology and dependency issues can be very difficult patients to cater for.

GPs who have such patients need significant support from specialist pain services, either public or private but access is either limited by cost in the private setting or by vulnerability in the public setting.

Yours sincerely

(Dictated but not sighted or signed)