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2nd March, 2018 PH1247

Dear Sir

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

I write regarding this consultation process.

Like many clinicians, I have been greatly concerned by the inexorable growth in pharmaceutical opioid use and related complications. The regulatory and service level responses have been disappointing to date. In this light the TGA paper is of great interest. However, the challenges lie at multiple levels of the health system, and the actions proposed by the TGA appear likely to have a limited impact.

It would be important to identify the likely costs and cost effectiveness of the proposed actions. For example, reducing pack sizes will increase cost to those who use S8 drugs regularly. The review of clinical indications is likely to also be fairly costly and it is not immediately obvious that this will make much impact on use.

The suggested regulation of high dose agonist preparations is worth exploration due to the associated risk of these products. Most are already PBS Authority items so regulation beyond Authority listing would be required. The use of Fentanyl for non-malignant pain might be reviewed as this preparation is particularly high risk. State-based regulations introduce an additional level of complexity and existing processes at least in NSW are highly unsatisfactory. It is cumbersome to apply to both state and Commonwealth services for medications and a single level of authority that addressed the clinical indications and the financial issues would surely be preferable.

Not all opioids are the same. Full agonists present the highest risk and the partial agonist buprenorphine and the atypical opioids tapentadol and tramadol appear to be less risky. The differential risk should inform decision making such that the higher risk products might be managed more assertively.

The greatest risk comes from pharmacodynamic interactions when multiple sedatives are combined particularly benzodiazepines (mostly within S4), gabapentinoids, and some centrally acting anticholinergics. Thus, regulations affecting one class of drugs and not the other drugs are less likely to be effective. The proposed ERCCD should cover all psychoactive drugs susceptible to abuse.

Real time prescription monitoring could reintegrated with the PBS given this system records all reimbursed medication already, albeit with delayed response times. It is sad to see that we have robust nationwide systems for funding of medications but not for their safety.

It is great to see action being considered by the TGA and overall, closer integration with state authorities and more comprehensive actions will be required to significantly impact on this growing problem.

Kind regards

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