TGA consultation paper - Prescription strong (Schedule 8) opioid use and misuse in Australia – options for a regulatory response, January 2018

Section	Comments
General comments on the paper/additional recommendations	
Introduction	
Purpose	
Substances in scope	
Background	
National Pharmaceutical Drug Misuse Framework for Action (2012-2015)	
The Opioids Roundtable	
Can some of the problems with opioids potentially be addressed – at least in part –through regulatory measures?	
Regulatory options for consideration	
Option 1: Consider the pack sizes for Schedule 8 opioids	
Option 2: Consider a review of the indications for strong opioids	
Option 3: Consider whether the highest dose products should remain on the market, or be restricted to specialist/authority prescribing	
Option 4: Strengthening risk management plans for opioid products	

Option 5: Review of label warnings and revision to the Consumer Medicines Information	Label warnings are aimed at providing important safety information to complement information provided by prescribers and pharmacists. With the diversity of opioids available of vastly differing potency, in my experience as a specialist pain medicine physician consumers rarely have insight into the relative Mg Morphine Equivalent (MME) of the opioid dose they have been prescribed. Surprise is frequently expressed when MME is explained and engagement with less risky non-pharmacological strategies and/or dose tapering becomes more straightforward. MME dose is now our strongest indicator of risk, with 50mg MME being a "flag" of increased risk and doses of 90mg MME linking to significantly higher risk. The concept is akin to the use and acceptance of "standard drinks" as a means of risk limitation when alcohol is consumed. I propose that each prescription label includes the MME of the prescribed opioid formulation and dose. This may allow 1. Increased consumer understanding and health literacy of medication potency and risks 2. Increased prescriber knowledge and focus on risk mitigation and evidence-based alternative pain management strategies
Option 6: Consider incentives for expedited 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	
Option 8: Increase health care professional	

awareness of alternatives to opioids (both Schedule 4 and Schedule 8) in the management of chronic pain	
Possible role of Pharmaceutical Benefits Scheme prescribing controls	
Advisory Committee for Medicines recommendations	
Appendices	
Appendix 1	
Appendix 2	
Appendix 3	