



1 March 2018

Technical and Safety Improvement Section
Pharmacovigilance and Special Access Branch
Therapeutic Goods Administration
P.O. Box 100
Woden ACT 2606

To Whom It May Concern

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

Thank you for providing Indivior Pty Ltd with the opportunity to comment on the options being considered for a regulatory response to prescription opioid use and misuse in Australia. Indivior is a global specialty pharmaceuticals company focused on delivering treatments for the chronic condition and co-occurring disorders of addiction.

Indivior support this initiative in principle however recommends that the possible measures are considered in a wider context of government initiatives including funding of opioid use disorder (OUD) treatment programs and updates to therapeutic guidelines for pain management.

Indication-specific changes

Indivior would like to recommend that any such regulatory changes are **indication-specific**, allowing distinction between S8 opioids used for the treatment of OUD vs those used for the treatment of pain. Indeed, due to their different pharmacological properties, certain strong S8 prescription opioids such as buprenorphine and methadone are used for the treatment of dependence to short-acting opioids, be they illicit such as heroin, or licit such as opioid painkillers themselves. The 2016 National Opioid Pharmacotherapy Statistics Annual Data (NOPSAD) collection identified 48,900 people treated for OUD with methadone or buprenorphine-based products in Australia. Treatment modalities and delivery for this indication are different from those for pain. It is therefore recommended that the proposed changes are considered in a way that allows appropriate distinction between both indications in order not to adversely affect OUD treatment delivery.

Furthermore Indivior would like to contribute the following additional comments about the specific measures proposed for discussion:

Risk Management Plans

Buprenorphine products used for opioid dependence treatment currently have an RMP. While Indivior support the introduction of RMPs for all S8 opioids as a means to collect information and provide education on these safety risks, in the Company's experience these are of limited effectiveness in controlling diversion and misuse.

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Incentives for expedited review of improved non-opioid pain relievers and opioid antidotes

Indivior supports this initiative, and would like to recommend going beyond what is currently proposed to include regulatory submissions improving the treatment of OUD, be they new chemical entities or changes to existing medicines which improve treatment outcome and delivery. A possible way to achieve this could be to make the above list of indications an eligibility criterion for priority review designation.

Changes to SUSMP

A State-based system restricting prescription of opioids used in OUD treatment to accredited prescribers who have undergone a training program already exists.

Indivior notes that Appendix D does not allow for an indication-specific approach. In view of the recommendation made at the outset of this submission to consider proposed changes in an indication-specific manner, Appendix D would therefore not be a suitable solution.

Owing to differences in pharmacological profile with other S8 opioids such as ceiling effect on respiratory depression and euphoria, buprenorphine is suitable for and used in OUD treatment. The USA recognise this difference and as a result it has a less restrictive poison classification than other S8 opioids. Indivior recommend that this aspect is taken into account in any consultation aiming to makes changes to the SUSMP.

Tamper evidence

Diversion occurs mostly after dispensing so tamper evidence will be of little effect. Indivior however would support making child resistant packaging a mandatory standard for all S8 opioids.

Thank you again for the opportunity to contribute to this consultation. Indivior Pty Ltd is available at any time to provide further information to TGA, as required.

Yours faithfully,

Indivior Pty Ltd