Opioid use and harms associated with a sustained-released tapentadol formulation: a post-marketing study

AMY PEACOCK1, NATASA GISEV1, SONJA MEMEDOVIC1, BRIONY LARANCE1, JARED BROWN2, MICHAEL FARRELL1, ROSE CAIRNS3,4, NICHOLAS BUCKLEY3,4, & LOUISA DEGENHARDT1

1 National Drug and Alcohol Research Centre, University of New South Wales, Sydney, NSW, Australia, 2 NSW Poisons Information Centre, Sydney Children’s Hospital Network (Children’s Hospital at Westmead), Sydney, NSW, Australia 3 NSW Poisons Information Centre, The Children’s Hospital at Westmead, Sydney, NSW, Australia, 4 School of Medical Sciences, University of Sydney, Sydney, NSW, Australia

Presenter’s email: amy.peacock@unsw.edu.au

Introduction: It has been argued that tapentadol may have lower abuse potential than other pharmaceutical opioids. A sustained-release formulation (SRF) of tapentadol (Palexia®) was released in Australia in 2011 and listed for public subsidy in 2013. The aim of this post-marketing study was to describe i) population level availability, ii) extra-medical use and diversion, iii) attractiveness for extra-medical use, and iv) associated harms, comparing tapentadol SRF compared against other pharmaceutical opioids.

Method: We conducted analyses of national pharmaceutical opioid community sales from 2011-2017; self-reported pharmaceutical opioid extra-medical use, attractiveness, and harms from interviews with people who inject drugs (n=888) as part of the Illicit Drug Reporting System (IDRS) 2017; and pharmaceutical opioid poisonings reported to Australian Poison Information Centres and coded as recreational (intentional self-poisoning, abuse or misuse) from 2011-2017.

Results: Tapentadol SRF comprised a small but increasing percentage of pharmaceutical opioid sales nationally. Few IDRS participants reported non-prescribed use or injection of tapentadol SRF; due to small numbers, perceived attractiveness for extra-medical use (e.g., enjoyment/interest in injecting) could not be ascertained. Less than one-percent of the IDRS sample reported a non-fatal overdose following tapentadol SRF use. A small number of pharmaceutical opioid cases involving tapentadol SRF had been reported to Poison Information Centres.

Conclusions: Few participants in a sentinel sample who regularly inject drugs reported non-prescribed use and tampering with tapentadol SRF, and analysis of Poison Information Centre calls showed few cases involving tapentadol. These findings should be considered in the context of a limited number of data sources distinguishing tapentadol from other pharmaceutical opioids, and the smaller market share and shorter period of availability relative to other pharmaceutical opioids.

Implications for Practice or Policy: Tapentadol is typically not differentiated from other pharmaceutical opioids in most routinely collected administrative data systems. This is important to address in monitoring trends in extra-medical use and associated harms with any increases in tapentadol prescribing.

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