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Introduction & Aims

In Australia, opioid prescribing has increased an estimated 4 to 15 fold over the last two decades, linked to analgesic use for chronic non-cancer pain. However, many harms are associated with prescription opioid use e.g. 70% of fatal overdoses involve pharmaceutical opioids. Harms are exacerbated with extramedical use of opioids and diversion to the illicit market.

The aim of this project was to:

- establish a detailed understanding of the regulatory and policy landscape in which pharmaceutical opioid use occurs, and
- to develop a systematic way to consider how the illicit market may shift in response to activities for a specific event, focusing on indicators such as **pricing**, availability, and drug type.

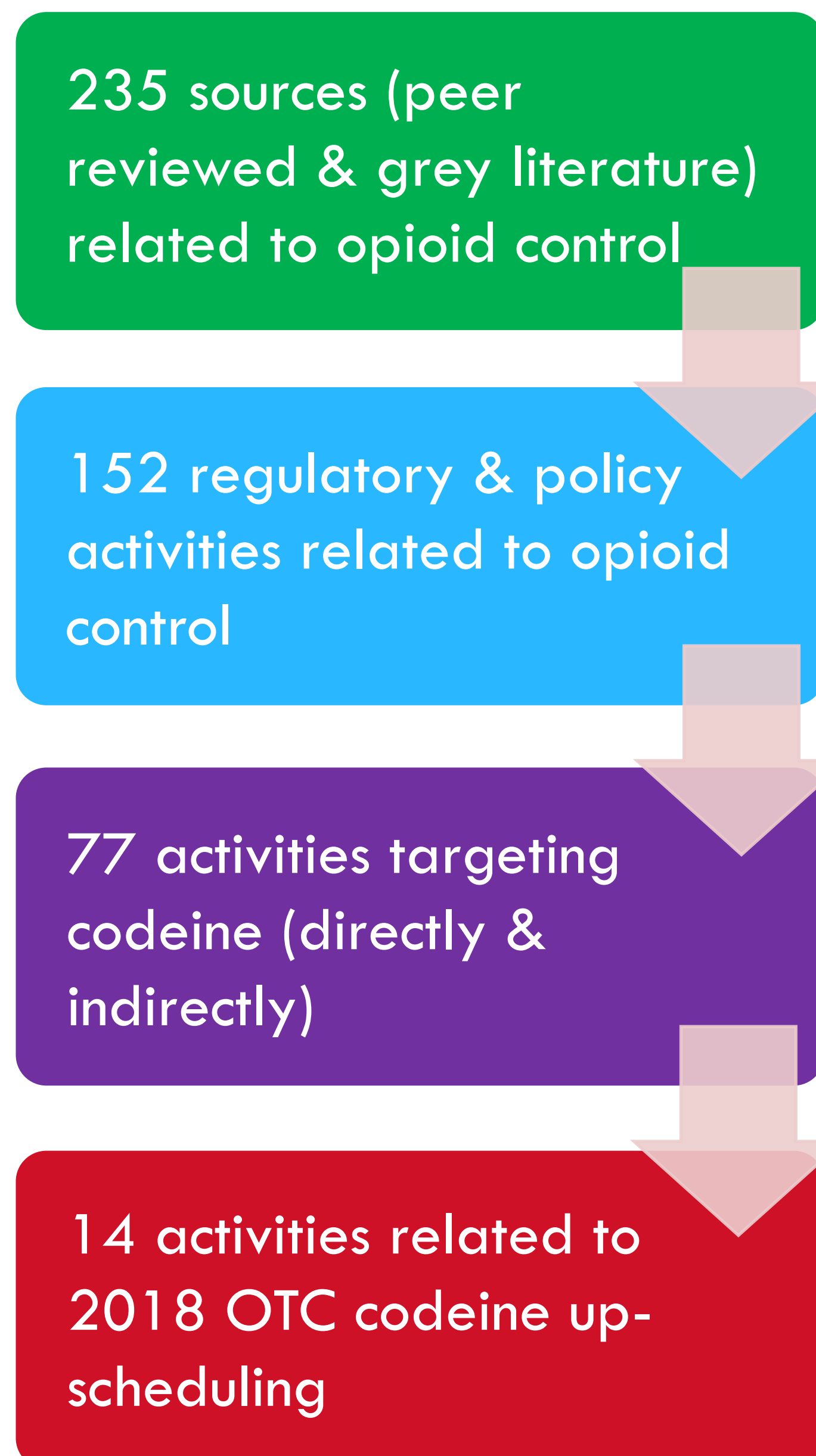
These indicators of the illicit pharmaceutical market can be monitored using the novel platform, StreetRx.*

Methods

1. A literature review was conducted for studies on changes to opioid-related policy and prescribing regulation in Australia from 2010 to 2021.
2. Grey literature was searched to gather details of regulatory and policy-related activities that either directly or indirectly targeted opioid use in Australia. All activities were compiled in a timeline.
3. Codeine was selected for deeper exploration due to significant recent attention. All codeine-related activities were compiled in a timeline.
4. A literature review was conducted on changes to illicit market indicators after codeine up-scheduling in 2018. No studies were found; therefore focused on codeine use and harms following up-scheduling.
5. Activities on codeine timeline were coded to hypothesise impact on illicit market indicators.

Results

Figure 1: Sources and activities related to pharmaceutical opioid and codeine control.



A simple colour-coded system was used to categorise the level of potential impact of codeine up-scheduling activities on the illicit market (Figure 2). Potential impact was assessed by weighing outcomes from the literature review against the strength of the regulatory activities.

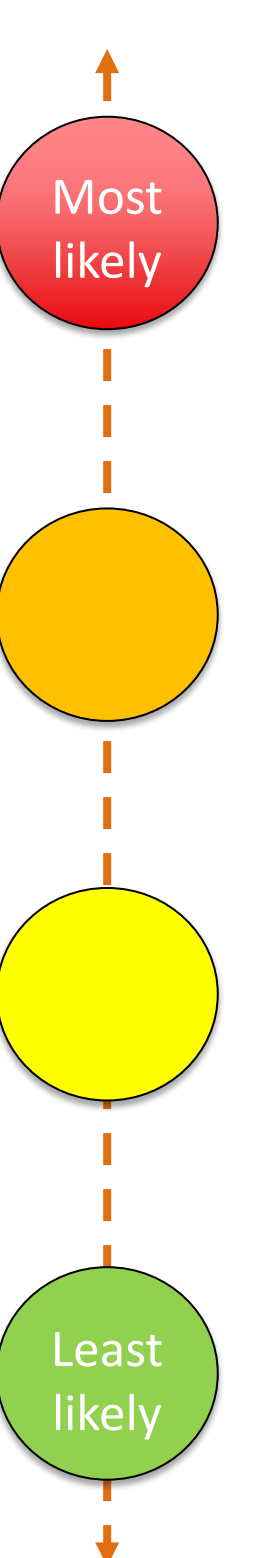
It was hypothesised that the illicit pharmaceutical opioid market may be *moderately* impacted by 2018 over-the-counter (OTC) codeine up-scheduling events, driven by the significant restriction to availability of low-dose codeine and therefore the decreased potential for diversion. The key mechanisms of action were hypothesised as follows:

- Decreasing access to a product formerly easily accessible may change illicit market pricing for codeine.
- Potential price increases to codeine-containing products may influence the pricing of other opioids (e.g. tapentadol) and increase their popularity as an alternative.
- Restricted low-dose codeine in the medical market may result in a greater market share for higher strength opioid formulations.

Table 1: Activities related to 2018 up-scheduling of over the counter (OTC) codeine

Month	Year	Action/Event	Summary info	Impact rating
1	2015	Meeting/ review	TGA initiated further codeine safety & efficacy review of OTC codeine to identify any new evidence	Green
4	2015	Public announcement; Public consultation	TGA announced public consultation on plan to up-schedule OTC codeine products	Yellow
10	2015	Decision; public consultation	Interim decision by TGA in favour of up-scheduling OTC codeine	Yellow
11	2015	Public consultation; Public announcement	TGA deferred final decision on OTC codeine up-scheduling; TGA sought additional advice and public consultation	Yellow
3	2016	Policy initiative/ change	Pharmacy Guild introduced voluntary MedsASSIST real-time OTC clinical decision and monitoring tool	Yellow
12	2016	Meeting/ review	TGA review meeting recommending up-scheduling of OTC codeine	Green
12	2016	Public announcement	TGA decision to up-schedule OTC codeine	Yellow
3	2017	Public announcement	Pharmacy Guild plan to discontinue MedsASSIST real-time OTC clinical decision and monitoring tool prior to up-scheduling comes into effect	Green
3	2017	Public announcement	Federal Health Minister Greg Hunt requested delay to discontinue MedsASSIST until OTC codeine up-scheduling comes into effect	Green
1	2018	Public announcement	Pharmacy Guild plan to discontinue MedsASSIST real-time OTC clinical decision and monitoring tool when up-scheduling comes into effect	Green
1	2018	Policy initiative/ change	Pharmacy Guild discontinued MedsASSIST real-time OTC clinical decision and monitoring tool	Green
2	2018	Regulation	Up-scheduling of OTC codeine to Schedule 4 prescription-only medicine	Red
4	2019	Meeting/ review; public announcement	TGA analysis indicates significant decrease in wholesale codeine supply	Green
6	2020	Meeting/ review; public announcement	TGA analysis of dispensing trends after up-scheduling showed initial increase and then decline of low-dose codeine prescribing since then	Green

Figure 2: Coding of categories for likely impact to illicit market indicators



Conclusion & Next steps

Broadly, it appears that regulatory action has been achieving the desired effect in decreasing codeine use and related harms. A systematic method can be used to hypothesise subsequent effects on the illicit opioid market. We will be utilising data collected via the novel online platform, StreetRx,* as one indicator of changes to illicit markets following regulatory changes to opioids.

*Scan here to explore the StreetRx platform used to anonymously report illicit pharmaceutical purchases.

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StreetRx is part of the RADARS system, owned by the Denver Health and Hospital Authority, USA.

