RE: LISTING OF IMMEDIATE RELEASE TAPENTADOL ON THE WA STATEWIDE MEDICINES FORMULARY

The WA Drug Evaluation Panel (WADEP) did not approve the applications for listing of immediate release (IR) tapentadol (Palexia®) for the treatment of acute post-operative pain secondary to tramadol or for chronic pain secondary to transvaginal mesh complications. Tapentadol IR is TGA approved for the relief of moderate to severe pain\(^1\). Tapentadol IR is not listed on the Pharmaceutical Benefits Scheme (PBS).

The primary evidence of efficacy for tapentadol IR is derived from a meta-analysis which pooled data from 9 randomised controlled trials in over 4000 patients\(^2\). The trials in the meta-analysis were both acute and chronic pain indications (leaning more towards to acute pain) and concluded that doses of 50mg, 75mg and 100mg of tapentadol IR could provide comparable efficacy to oxycodone 10mg IR. Compared to 50mg IR tapentadol, 75mg doses of IR tapentadol demonstrated significant improvement in pain relief scores (SPID\(_{48}\) and TOTPAR\(_{48}\)). Relative to oxycodone 10mg, no statistically significant reductions in pain intensity were measured relative to 50mg, 75mg 100mg doses of IR tapentadol. 50mg and 75mg IR tapentadol doses were shown to be statistically less significant in terms of nausea incidence relative to oxycodone, and the 50mg IR dose also showed statically significant less vomiting. Evidence was not available comparing tapentadol IR with tramadol IR.

Claims that tapentadol has lower risk of abuse and diversion relative to oxycodone are largely drawn from an American study\(^3\). Shopping behaviour was observed in 0.8% (0.80-0.91) of subjects in the oxycodone group relative to 0.2% (98% 0.16-0.25) in the tapentadol group. Heavier shopping behaviour was observed in the tapentadol group relative to oxycodone, however rates were very low across both groups; 0.07% and 0.01% respectively. This study had editorial support from the drug sponsor and the definitions of shopping behaviour used in the study have not been explicitly linked to abuse. A robust cost effectiveness analysis is required to determine whether the potential for abuse and diversion reduction justifies the additional costs.

Overall, the WADEP could not support the claims of cost-effectiveness and had a number of concerns about its place in therapy. The key concerns were:

1. There is a lack of robust evidence of cost effectiveness. Tapentadol is nearly seven times more costly than currently available formulary alternatives and it remains difficult to confidently state that increased cost will be offset.
2. There is a considerable risk of leakage of tapentadol being prescribed beyond the requested indications.
3. The submissions do not claim superiority of efficacy of tapentadol IR over currently available formulary alternatives.
4. WADEP acknowledge that tapentadol IP appears to have a superior side effect (SE) profile in comparison to oxycodone 10mg IR, although noted that the formulary listing of the MR tapentadol should result in significantly less total opioid usage in the chronic pain setting and therefore decreased tendency for patients to experience these dose related SE’s.

5. The medication safety risks (look alike and sound alike with tramadol) were considered significant and incidences have been reported both internationally and locally in institutions that currently have IR and MR tapentadol on their formulary.

6. Abuse potential is difficult to measure and causality with familiarity of this formulation in Australia cannot be excluded. WADEP noted that the WA Department of Health S8 Prescribing code rates tapentadol at doses of up to 500mg/day as of comparative risk as oxycodone at doses of 60mg/day (equivalent to to 90meq)

7. Tapentadol IR is not listed on the PBS, creating complexities with continuity of care for patients transitioning between the tertiary and primary care setting.

References


4. Department of Health, (2017), Schedule 8 Medicines Prescribing Code, Medicines and Poisons Regulation Branch, Department of Health, Perth, Western Australia

<table>
<thead>
<tr>
<th>Version</th>
<th>Version Date</th>
<th>Document Owner</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>01/2018</td>
<td>WA Drug Evaluation Panel (WADEP)</td>
</tr>
<tr>
<td>2.0</td>
<td>04/2018</td>
<td>WA Drug Evaluation Panel (WADEP)</td>
</tr>
</tbody>
</table>