CSIRO PUBLISHING

Australian Health Review, 2021, 45, 261–262
https://doi.org/10.1071/AH20060

Letter to the Editor

Time to rethink our approach to the Pharmaceutical Benefits Scheme (PBS) listing of medicines: the case of pregabalin

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Received 6 April 2020, accepted 14 April 2020, published online 3 September 2020

We write to highlight a potential inefficiency in the process of off-patent medicines being subsidised on the Pharmaceutical Benefits Scheme (PBS). We advocate that an approach that considers future costs, in addition to the current approach of applications initiated by pharmaceutical companies, can yield substantial cost savings for the government, and use pregabalin as an example.

Prior to the listing of pregabalin on the PBS for neuropathic pain in 2013, gabapentin was widely prescribed privately (i.e. not subsidised on the PBS) to treat neuropathic pain; gabapentin has been subsidised on the PBS since 1999 to only treat epileptic seizures. Gabapentin has been subsidised since 2002 to treat neuropathic pain but only on the Repatriation PBS. Pregabalin and gabapentin are similar medicines with limited but comparable efficacy in treating neuropathic pain.[1] Both medicines are manufactured by Pfizer. Pfizer applied to the Pharmaceutical Benefits Advisory Committee (PBAC) for PBS listing of pregabalin for neuropathic pain in 2011, but the PBAC rejected the application. The PBAC concluded there was no difference in efficacy between pregabalin and gabapentin and that the estimated cost of listing pregabalin was A$100 million over 5 years.[1] Pfizer applied again in 2012, and pregabalin was subsequently listed on the PBS.[2] Pfizer did not apply to the PBAC for subsidy of gabapentin for neuropathic pain, based on publicly available data.

These anomalies represent additional expenditure for the Australian government. We have estimated the savings to government over 6 years (2013–18; http://medicarestatistics.humanservices.gov.au/statistics/pbs_item.jsp, accessed 18 August 2020) had gabapentin been listed on the PBS for neuropathic pain and prescribed instead of pregabalin. We used the average price per milligram for each dose formulation, the number of dispensed prescriptions, the cost to government and a dose equivalence of 6 : 1 of gabapentin to pregabalin.[3] The savings totalled A$177.7 million over 6 years (mean cost saving, A$29.6 million per year).

We note growing evidence of non-medical use of pregabalin in Australia and risks of respiratory depression as a sole agent, exacerbated when used concomitantly with opioids.[4,5] Although therapeutic doses of gabapentin have some risk of respiratory depression in those who use opioids,[6] combinations of opioids with supratherapeutic doses of gabapentinoids is, theoretically, less risky with gabapentin than pregabalin. The bioavailability of gabapentin, but not pregabalin, is limited by a saturable active transport mechanism. This makes pregabalin more attractive, but potentially riskier, than gabapentin in those who use opioids illicitly,[4] especially heroin users.[7]

We may have 'missed the boat' with pregabalin; the costs have decreased substantially now it is off patent, but the risks have not, and this is not an isolated example.[8,9] We believe it is time that the PBAC considers a process whereby off-patent medicines can be listed on the PBS without the need for a pharmaceutical company sponsor where this has the potential to save the PBS large amounts of money and/or reduce harm to the population.

Competing interests

MD has received speaker's fees from Indivior, Lundbeck, Servier and Janssen-Cilag and consultancy fees from Indivior

and Mundipharma for unrelated work. The other authors have no competing interests to declare.

Acknowledgement

This research did not receive any specific funding.

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