Alcohol dependence is a common, disabling and costly medical condition that affects 4% of Australian adults. Several pharmacological therapies are now available in Australia to treat alcohol dependence, including disulfiram, acamprosate and naltrexone. While all three medicines are registered in Australia by the Therapeutic Goods Administration (TGA), only acamprosate and naltrexone are listed on the Pharmaceutical Benefits Scheme (PBS). Recent reviews show that supervised administration of disulfiram is both effective and safe. Accordingly, disulfiram should be made more available and accessible through PBS listing.

Disulfiram helps to achieve abstinence by inhibiting aldehyde dehydrogenase. This leads to the temporary accumulation of acetaldehyde, which causes a potentially severe aversive reaction with nausea, flushing, agitation and dizziness, thereby usually deterring future drinking. Although the treatment has a logical basis, early studies found only mixed evidence for its efficacy. Consequently, disulfiram fell into disfavour.

Recently, however, the original studies of the efficacy of disulfiram were reviewed. When studies of supervised and unsupervised dispensing of disulfiram were compared, well supervised treatment was far more effective, often achieving excellent results. Indeed, the few available direct comparisons of supervised disulfiram and other medications for alcohol dependence found disulfiram to be more effective.

At first glance, this would seem like unqualified good news: a well known, registered, and relatively inexpensive medicine (costing about $70 per month, including pharmacy dispensing fees) has been found to be effective for a condition that is often ineffectively treated and is estimated to cost Australia as much as $36 billion per annum. But the definition of “inexpensive” is a relative one — many of the patients who need disulfiram cannot easily afford even $70 per month, especially on a continuing basis. At present, these patients can access subsidised disulfiram only through ad hoc mechanisms, such as appealing to hospital drug committees. Listing disulfiram on the PBS is the obvious solution — not only because the drug is effective and inexpensive, but because there is reasonable evidence that it is more effective and less expensive than other treatments listed for alcohol dependence.

But therein lies the problem: because disulfiram is an inexpensive and old drug, there is little incentive for a pharmaceutical industry sponsor to underwrite the expensive process of applying to the PBS for listing. While professional associations (such as the Australasian Chapter of Addiction Medicine of the Royal Australasian College of Physicians) could submit an application, they too are likely to be deterred by the costs involved. The PBS is also unlikely to take this on, because it has an interest in controlling expenditure and because the cost of applications to the PBS is usually recovered by charges collected from the sponsor of the drug. We are left with a situation in which a treatment is not listed on the PBS despite being effective, relatively inexpensive, likely to save health care resources and, somewhat ironically, recommended for use in government-funded treatment guidelines.

There is, however, a mechanism by which disulfiram could potentially be listed on the PBS that is analogous to the TGA’s “orphan drug” provisions: the PBS is willing to list certain drugs in the public interest and waive the associated application costs. For disulfiram to be listed in this way, an economic justification (however crude) would need to be made, support from the relevant clinical organisations would be required, and the sponsor would need to be willing to supply the drug under arrangements proposed by the Pharmaceutical Benefits Advisory Committee that might or might not be commercially appealing.

PBS listing of disulfiram would have to be contingent on its proper clinical use. Disulfiram is not a first-line therapy; it should not be used in the elderly or in patients with cerebrovascular or cardiovascular disease; and patients must be able to understand the consequences of drinking alcohol when taking disulfiram. Most importantly, disulfiram is effective only when administered daily under strict supervision (by a health professional, family member, employer, police officer or probation and parole officer) for at least 12 months. While we would not wish to discourage the prescribing of disulfiram in general practice and in rural areas, prescribers would need to be familiar with its side effects and able to provide the necessary counselling.
We believe that current evidence is more than sufficient to justify listing disulfiram on the PBS, but continued PBS listing of disulfiram would need to be contingent on further evidence demonstrating relative efficacy and cost-effectiveness.

Improving treatment outcomes for patients with alcohol dependence is a very worthwhile goal — especially for critical populations such as Indigenous Australians, recidivist drink-drivers, and people with a long history of repeated alcohol-related violence. Increasing the affordability and use of disulfiram, by listing it on the PBS, would be an important step towards this goal.

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