

Application of an economic evaluation approach to making regulatory decisions regarding access to medicines: advantages, challenges and recommendations

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Abstract. Initially patients require a prescription to access most new medicines. Some medicines may later be reclassified, allowing patients to access them without a prescription. Currently, Australian Therapeutic Goods Administration guidelines regarding reclassification decisions focus on patient risk rather than on potential benefits to patient health and the healthcare system. We conducted two extensive case studies demonstrating an economic evaluation approach to medicine reclassification in Australia, which were presented at various conferences and to key stakeholders. This article discusses the advantages and challenges of using an economic evaluation approach to inform medicine reclassification decisions. Advantages identified include systematically and transparently synthesising evidence from multiple sources; predicting the overall expected impact of reclassification on health outcomes and costs before it occurs; considering a broader range of risks and benefits; aggregation of health impacts into a single measure (quality-adjusted life years); identification of drivers of uncertainty; insight into the effects of different regulatory decisions; and improved consistency of evidence. Challenges include data availability and quality, estimating behavioural changes, model complexity, the lack of an incremental cost-effectiveness ratio threshold, and funding of economic analyses. We recommend that regulatory decision makers use an economic evaluation approach to help inform reclassification decisions, although economic evaluation results should be considered as part of the broader body of evidence. Ultimately, the use of an economic evaluation approach will contribute to helping decision makers maximise population health outcomes in an efficient way.

What is known about the topic? In the past, decisions regarding medicine reclassification have generally been made using a deliberative approach focusing on patient risk. However, there are also potential benefits to patient health and effects on the healthcare system. Increasing awareness of these benefits have led to the development of alternative approaches to decision making, including an economic evaluation approach.

What does this paper add? This article discusses the advantages and challenges of using an economic evaluation approach to inform medicine reclassification decisions compared with alternative approaches.

What are the implications for practitioners? Economic evaluation results should be considered as part of the broader body of evidence regarding the types of health impacts, the extent of the available evidence, who will be affected, and the role of medical practitioners and pharmacists in mitigating any risks. However, awareness of the advantages and challenges of this approach in advance will help mitigate some of the challenges and increase acceptance of the economic evaluation results by decision makers and stakeholders.

Keywords: Australia, behind-the-counter, cost-effectiveness, economic evaluation, medicine reclassification, non-prescription drugs, over-the-counter, prescription drugs.

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Introduction

In Australia, the Poisons Standard sets out the degree of control over the availability of medicines and poisons to the public.¹ The Poisons Standard contains the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), which classifies substances into 10 different schedules. Prescription

medicines are listed under Schedule 4 (prescription only medicine) and Schedule 8 (controlled drug). Over-the-counter (OTC) or behind-the-counter (BTC) medicines are listed under Schedule 2 (pharmacy medicine) and Schedule 3 (pharmacist only medicine) respectively. Some medicines may be exempt from scheduling on the SUSMP (unscheduled) and are available

in pharmacies and through other distribution channels, such as supermarkets. Substance scheduling is implemented through legislation in individual states and territories, which can adopt the SUSMP subject to variations.^{1,2} The SUSMP aims to promote uniform scheduling throughout Australia.¹

Initially patients require a prescription to access most new medicines (Schedule 4 or 8). These medicines may be later reclassified (or 'switched' or 'rescheduled') to being available BTC or OTC at pharmacies (Schedule 2 or 3), or available for general sale (unscheduled). The Advisory Committee of Medicines Scheduling (ACMS), an expert advisory committee of the Therapeutic Goods Administration (TGA), provides advice regarding medicines scheduling, with the Secretary of the Department of Health or their delegate making the final decision.¹⁻³ The ACMS generally uses a deliberative approach.

Section 52(E) of the *Therapeutic Goods Act 1989* (Cth) specifies what should be considered when making scheduling recommendations, with further guidance provided in the Scheduling Policy Framework for Medicines and Chemicals and in the Scheduling Handbook (see Supplementary File S1, Table S1).^{2,4} In general, the guidance focuses on: (1) risk, such as adverse events (AEs), inaccurate or delayed diagnosis, and inappropriate use (e.g. overuse, misuse or accidental ingestion); (2) the need for medical advice; and (3) the need for expertise to administer the medicine.

However, there are also potential benefits to patient health and healthcare system costs from medicine reclassification. Reducing treatment barriers may reduce the time to symptom relief and improve treatment rates and adherence. Reducing treatment barriers may also encourage patients to switch to more effective or safer treatments, subsequently improving health-related quality of life through improved symptom relief, and preventing disease onset or delaying progression. Allowing patients to access a medicine without a prescription may reduce consultations with medical practitioners to obtain prescriptions, while improved health outcomes may reduce demand for health care, such as diagnostic tests and hospitalisations. Saved resources could be used to diagnose and treat other patients. The Scheduling Policy Framework does not include the benefits of using a medicine², despite being listed in Section 52(E) of the Therapeutic Goods Act, and the Scheduling Handbook states that 'relevant benefits for a substance proposed to be down-scheduled [or reclassified] are only in relation to public health outcomes'.⁴ Thus, healthcare system costs are excluded from consideration. Conversely, healthcare system costs must be considered when considering listing medicines on the Pharmaceutical Benefits Scheme (PBS; Section 101(3A) of the *National Health Act 1953* (Cth)).

Increasing awareness of potential benefits led to the development of the Brass model, a benefit-risk assessment framework for non-prescription medicines.⁵ The Brass model included a modified value-tree framework to identify important benefit and risk attributes, including economic benefits.⁵ Application of the value-tree framework involves identifying the product-specific benefit or risk attributes under each major domain. The authors proposed the application of the International Risk Governance Council framework and multiple criteria analysis (MCA) to guide the overall evaluation process.⁵

An external review of medicines and medical devices regulation was conducted for the Australian Federal Minister for Health in 2015.⁶ That review noted that a formalised methodology for assessing benefits and risks to inform scheduling decisions would: (1) facilitate a structured and systematic approach, ensuring that multiple benefits and risks are explored and promote consistency of decision making; (2) increase transparency, making it easier for sponsors to frame a case for reclassification, or for other interested parties to input into the process; and (3) make the formulation of recommendations and/or statements of reason for a decision easier, as well as providing a consistent format to such documents, making them easy to read, digest and understand.⁶

The review recommended that:

...the Scheduling Policy Framework be reviewed... to provide for the development and adoption of a formal risk-benefit methodology to assess scheduling applications, and opportunities to enhance input from interested parties into the scheduling process.⁶ (Recommendation 11)

Although the review did not recommend a specific formal risk-benefit methodology, it noted that the Brass model was a potential approach. The Brass model was subsequently mentioned in the revised Scheduling Handbook as a potentially useful tool to 'identify potential risks to a down-scheduling [or reclassification] proposal'.⁴

Traditionally, economic evaluation has been used to inform funding decisions, but it can also be applied to medicine reclassification.⁷⁻¹⁶ The TGA did commission a cost-benefit analysis as part of a regulatory impact statement before the recent decision to reclassify codeine to Schedule 4 from Schedule 2 and 3.^{17,18} However, not all aspects of the modelling, including social and economic burdens, could be considered, as per the Therapeutic Goods Act.¹⁸

We conducted two extensive case studies demonstrating an economic evaluation approach to reclassifying triptans and the oral contraceptive pill (OCP), from available with a prescription (Schedule 4) to being available BTC (Schedule 3), in Australia (Table 1).^{19,20} We presented these case studies at various conferences and at a roundtable with key stakeholders, including senior figures from the TGA, Medicines Australia, the Australian Self-Medication Industry, major pharmaceutical companies and the Pharmacy Guild. This article discusses the advantages and challenges of using an economic evaluation approach to inform medicine reclassification decisions compared with deliberation alone or the Brass model combined with MCA, which were identified through the two case studies and by conference attendees and stakeholders.

Advantages of an economic evaluation approach

It is often not possible to conduct a randomised control trial of medicine reclassification. Because this is generally a policy decision applied nation-wide, a trial would have some practical limitations (e.g. blinding and restricting access). As a solution, economic modelling can be used to systematically and transparently synthesise evidence from multiple sources and predict the overall expected effects of medicine reclassification on health outcomes and resource use before they occur. Economic modelling enables consideration of a broad range of risks and

Table 1. Summary of case studies

AE, adverse event; BTC, behind-the-counter (pharmacist only); CI, confidence interval; ICER, incremental cost-effectiveness ratio; LARC, long-acting reversible contraceptives; OCP, oral contraceptive pill; OR, odds ratio; QALY, quality-adjusted life years

	Case study 1 ¹⁹	Case study 2 ²⁰
Medicine	Triptans	OCP
Reclassification	From available with a prescription (Schedule 4) to being available BTC (Schedule 3)	From available with a prescription (Schedule 4) to being available BTC (Schedule 3)
Population	Australian adults aged ≥ 15 years	Australian women aged 15–49 years
Impact on health outcomes and resource use	Reclassification resulted in 337 QALYs gained at an increased cost of A\$5.9 million over 10 years (ICER = A\$17 412 per QALY gained)	Reclassification resulted in 17 159 QALYs gained and saved A\$3365 million over 35 years
Sensitivity analysis results: parameters that most affected the results	Univariate sensitivity analysis <ul style="list-style-type: none"> • OR of being pain-free at 2 h with triptans (ICER = A\$42801/QALY gained using lower 95%CI) • OR of chronic headache with triptans (ICER = less effective and costlier using upper 95% CI) • OR of chronic headache with other OTC medicines (ICER = less effective and costlier using lower 95% CI) Scenario analysis <ul style="list-style-type: none"> • Exclusion of gastrointestinal AEs (ICER = A\$44 604 per QALY gained) • Not implementing the Migraine Questionnaire (ICER = A\$39 692 per QALY gained) 	Univariate sensitivity analysis <ul style="list-style-type: none"> • Probability of pregnancy when not using contraception and not trying to conceive (ICER = less effective and costlier using lower 95% CI) Scenario analysis <ul style="list-style-type: none"> • Including future QALYs lost from unborn children (ICER = less effective and not cost-effective)
Sensitivity to patient switching rates	Not sensitive <ul style="list-style-type: none"> • Migraineurs switching from prescription-only triptans to BTC triptans: ICER always <A\$60 000 per QALY gained • Migraineurs switching from other OTC medicines to BTC triptans <0.009% (ICER = less effective) • Non-migraineurs using BTC triptans >1.534% (ICER >A\$60 000 per QALY gained) Values for latter two parameters lay outside the 95% CIs for these parameters	Not sensitive <ul style="list-style-type: none"> • Women switching from prescription-only OCPs to BTC OCPs: ICER always <A\$60 000 per QALY gained • Women switching from no contraception to BTC OCPs: ICER always <A\$60 000 per QALY gained • Women switching from other contraceptives to BTC OCPs: ICER always <A\$60 000 per QALY gained
Parameters of concern to the ACMS that did not affect the results	Serotonin syndrome was a key factor in rejecting reclassification of sumatriptan and zolmitriptan, ^{21–24} but had little effect on the results	AEs such as venous thromboembolism, myocardial infarction, stroke and depression were the key reason reclassifying OCPs was rejected, ^{20,25} but had little effect on the results LARC use will decrease, but the impact is small because a small proportion of women currently use LARCs in Australia (23.2%) and the estimated switch rate from LARCs to BTCs OCPs was low
Probability reclassification cost-effective	Probabilistic sensitivity analysis <ul style="list-style-type: none"> • 70% at a threshold of A\$60 000 per QALY gained) 	Probabilistic sensitivity analysis <ul style="list-style-type: none"> • 95% at a threshold of A\$60 000 per QALY gained
Parameters needing further research	OR of pain-free and pain relief with other OTC medicines, cardiovascular risk with triptans, chronic headache with triptans	Probability of pregnancy when not using contraception and not trying to conceive
Impact of valuing QALY losses twice that of QALY gains	Reclassification resulted in 266 QALYs gained at an increased cost of A\$5.9 million over 10 years (ICER = A\$22 057 per QALY gained)	Reclassification resulted in 16 371 QALYs gained and saved A\$3365 million over 35 years

benefits, including evidence of the incidence, magnitude and duration of those risks and benefits. It can incorporate evidence regarding patient, pharmacist and medical practitioner behavioural change. Finally, it makes any assumptions explicit. These advantages are known key benefits to conducting economic modelling to inform funding decisions.²⁶

Medicine reclassification may affect many health outcomes through changing the mix of disease types and symptoms, as well as the incidence and severity of AEs. Considering all potential health outcomes can be complex, especially if reclassification improves some health outcomes but makes others worse. Within an economic evaluation multiple health outcomes

can be aggregated into a single measure, namely quality-adjusted life years (QALYs), which incorporates life expectancy and quality of life.²⁷ QALYs are based on information regarding how the community trades-off different health outcomes, and thus avoids the need for decision makers to decide on the relative importance of each type of health outcome.

An economic evaluation approach would explicitly include healthcare costs. Healthcare resources are both valuable and scarce. Their use generates opportunity costs because they could improve health outcomes in other patients. An economic evaluation approach also incorporates choices at the margin to ensure the benefit from one additional unit of resource is maximised while the cost from reducing one additional unit of resource is minimised. Evaluating medicine reclassification through the lens of opportunity cost and choices at the margin must occur to maximise social welfare, lending weight to using an economic evaluation approach.

Reclassification decisions are often based on limited evidence. Consequently, the ACMS may have taken a risk-adverse approach to decision making.^{28,29} However, differentiating between uncertainty in the evidence and the risk of an inappropriate reclassification decision is essential. If medicine reclassification from prescription to BTC or OTC is inappropriately implemented, patients may experience poorer health outcomes (e.g. AEs) and valuable healthcare resources (e.g. to treat AEs) may be diverted from treating other patients. If medicine reclassification from prescription to BTC or OTC is appropriate but not implemented, patients may be denied valuable health benefits, and the potential to save valuable resources (e.g. consultations) may be missed. Similar effects apply to reclassifying a medicine from BTC or OTC to prescription, depending on whether it is appropriate and reclassified.

Sensitivity analyses within an economic evaluation can facilitate the assessment of whether evidence uncertainty results in decision uncertainty. Univariate and multivariate sensitivity analysis enables the identification of drivers of uncertainty and whether reclassification should be delayed until further research is conducted. This reduces the risk of placing too much or too little importance on risks or benefits, where the clinical impact or events frequency is unknown due to limited data. Probabilistic sensitivity analysis can help estimate the probability that reclassifying a medicine is appropriate.

Scenario and subgroup analysis can provide further insight into the impact of different regulatory decisions on health outcomes and healthcare resource use. Scenario analysis can explore the effect of a patient-screening questionnaire or the requirement for a diagnosis by a medical practitioner. Subgroup analysis can help better target patients expected to receive a net benefit from medicine reclassification and avoid patients where risks are likely to outweigh benefits. For example, the patient-screening questionnaire for BTC sildenafil for erectile dysfunction in New Zealand requires the patient to be aged 35–70 years.³⁰

The two extensive case studies we undertook illustrated that an economic evaluation of reclassification decisions is viable and can provide decision makers with new insights beyond deliberation alone or the Brass model combined with MCA. In the two case studies, the total QALYs gained from improved patient access to the reclassified medicines outweighed the total QALYs

lost from increased AEs.^{19,20} The case studies also found several parameters of concern to the ACMS when rejecting recent reclassification applications did not affect the results. The concerns of the ACMS may have been alleviated if an economic evaluation had been conducted. However, the economic evaluations also identified other parameters with a significant effect that were not considered by the ACMS (see [Table 1](#)).

Finally, an economic evaluation approach can ensure evidence presented across applications when making reclassification decisions is consistent.

Challenges of an economic evaluation approach

Several valid concerns were raised at conferences and by stakeholders regarding the application of an economic evaluation approach to inform reclassification decisions, as discussed below.

There may be limited evidence available to inform reclassification decisions. There is likely to be substantial evidence regarding usage patterns, efficacy and safety preceding reclassification, but evidence regarding patient, pharmacist and medical practitioner behavioural changes may be challenging. Potential data sources include observational data following reclassification of similar medicine(s), potentially including regression analysis to control for confounders, observational data following reclassification of the same medicine(s) in overseas markets (also including regression analysis), stated preference studies (including surveys and discrete choice experiments), pilot studies or trials, and expert opinion. Because states and territories can adopt the SUSMP subject to variations, one may be willing to conduct a pilot to assess behaviour change before reclassification is implemented nationally.

There may be more evidence regarding patients switching from prescription to BTC or OTC, or vice versa, than for patients switching between medicines, or patients with other conditions using the reclassified medicine inappropriately, although economic evaluations are less likely to be sensitive to patients switching from prescription to BTC or OTC (see [Table 1](#)).

The available evidence used in economic modelling may be of varying quality (e.g. due to study design), may be inconsistent across studies (e.g. different methods to estimate QALYs) and assumptions may be required. The accuracy of the economic model is only as good as the parameter inputs. Assessing the quality of an economic model can be difficult and depends on the reviewer experience and transparency regarding the modelling methods. Currently, the ACMS includes no health economists.

Modelling complexity and the need for evidence increases exponentially with the number of conditions that the medicine can treat; these also increase when related reclassification decisions overlap. For example, the economic evaluation of reclassifying triptans (Case Study 1) was conducted concurrently with the codeine reclassification to Schedule 4 (prescription) in February 2018.^{19,31} Consequently, current medication use by migraineurs was based on data preceding codeine reclassification. Codeine reclassification would affect the economic evaluation of reclassifying triptans. First, codeine reclassification encouraged more patients to use non-steroidal anti-inflammatory drugs, increasing the risk of gastrotoxicity and thus the health benefits from reclassifying triptans.³² Second, consultations for codeine prescriptions may increase, which would increase consultations avoided from reclassifying

triptans. Finally, codeine reclassification reduced codeine overdoses,³³ which would reduce the health benefits from reclassifying triptans. Unless data can be used to separate the effect of each reclassification on behaviour, overlapping reclassification decisions will reduce the accuracy of the economic model. Increased modelling complexity increases uncertainty in the results, and thus may reduce their acceptance by decision makers.

Poor quality or a lack of evidence and overlapping reclassification decisions are also issues when using a deliberative approach or applying the Brass model combined with MCA, but, again, an economic evaluation approach makes this issue more transparent.

Medicine reclassification may affect health outcomes and costs. If reclassification reduces health outcomes, then it is questionable whether the change should go ahead. Alternatively, if reclassification improves health outcomes and decreases costs, then there is strong support for the change. But the appropriate decision is less clear if reclassifying a medicine improves health outcomes and increases costs. When an economic evaluation is conducted to inform funding decisions in this situation, the incremental cost-effectiveness ratio (ICER) must be estimated and compared with some threshold to assess whether funding the intervention is 'value for money'. However, costs relating to medicine reclassification are excluded from consideration when making recommendations,^{2,4} and so understandably the TGA does not currently have a pre-existing cost-effectiveness threshold. In settings where the government bears the majority of healthcare costs,³⁴ it could be argued that using similar thresholds to other decision makers (e.g. the Pharmaceutical Benefits Advisory Committee (PBAC)) would ensure consistency in decisions. There continues to be some debate regarding what is the appropriate threshold, and more research is needed.³⁵

Data gathering and economic modelling can require substantial resources. The ACMS considered rescheduling 20 medicines (e.g. from Schedule 4 to 3 or 2, or vice versa) and approved 11 changes to the Poisons Standard in 2020.³⁶ However, this likely reflects a backlog of decisions following the external review of medicines and medical devices regulation.⁶ For example, the ACMS considered rescheduling five medicines and approved two changes to the Poisons Standard in 2014.³⁶ Potentially, economic evaluation could have informed all these decisions.

Large pharmaceutical companies with many on-patent medicines may already have in-house expertise to undertake economic evaluations, but it is unlikely that pharmaceutical companies that sell generic medicines will. It is also unclear who would fund an economic evaluation. Pharmaceutical companies or pharmacies may consider such an investment worthwhile if their brand of medicine is the only one reclassified. However, substances are listed in the SUSMP, not brands. Furthermore, pharmaceutical companies or pharmacies may be reluctant to reclassify medicines if it reduces revenue. This may occur if more patients discontinue treatment due to delisting from the PBS than patients commencing treatment because they no longer require a prescription. Reclassifying a single brand of simvastatin in the UK was not considered commercially viable for this reason.³⁷ In contrast, a pharmacy retail group drove many medicine reclassifications in New Zealand.²⁹ Pharmacies could be better off if patients are encouraged to use a particular brand of BTC or OTC medicine with higher margins, especially

if dispensing fees received by pharmacies for prescription medicines are small.

Policy recommendations and conclusion

Economic evaluation of medicine reclassification decisions has several advantages compared with deliberation alone or the Brass model combined with MCA, but challenges exist. Economic evaluation results should complement the broader body of evidence regarding the types of health impacts, the extent of the available evidence, who will be affected and the role of medical practitioners and pharmacists in mitigating any risks. Decisions should not be made on the results of the economic evaluation alone. This approach is like economic evaluation being considered the 'fourth hurdle' for a medicine to receive public funding through the PBS.

The Therapeutic Goods Act and the Scheduling Policy Framework will need to be amended to include resource use and costs so that economic evaluation results can be considered by the ACMS. The Scheduling Policy Framework should also be amended to include benefits such as reduced time to symptom relief, improved treatment rates and adherence, and switching to more effective or safer treatments.

A patient cannot receive a PBS subsidy without a prescription written on a PBS prescription form. Some Schedule 2 and 3 medicines are listed on the PBS for certain populations, at higher doses or in larger pack sizes, and are eligible for public subsidy; however, most OTC medicines are not listed on the PBS and patients must pay for these medicines out of pocket. Medicine costs can create a financial barrier and reduce their use.³⁸ Decisions to de-list medicines from the PBS are separate from reclassification decisions. Medicines should not be automatically de-listed from the PBS if reclassified as Schedule 2 or 3 so that patients can still obtain a PBS prescription from their medical practitioner and receive a PBS subsidy. There would be no effects on the costs or benefits of reclassification for these patients.

Although the patient is the payer of the OTC medicine, the Australian Government would likely bear most healthcare costs resulting from medicine reclassification (e.g. due to symptom relief, disease onset and progression, AEs).³⁴ Adopting a health-system perspective for economic evaluations of reclassification accounts for all healthcare costs regardless of who incurs them, thus reducing the incentive to cost-shift between payers and ensure consistency in decisions (e.g. with the PBAC).³⁹ The Office of Best Practice Regulation recommends that 'the costs and benefits to all people residing in Australia' should be considered,⁴⁰ suggesting that non-health-system costs also be included, such as travel and productivity costs. However, there is significant debate whether and how productivity costs should be included within economic evaluations due to the risk of double-counting lost productive (paid and unpaid) time with QALYs, debate regarding how to value lost time and equity implications.⁴¹ Unless productivity costs can be reliably estimated, the primary economic evaluation should apply a health-system perspective, and productivity costs should be presented as a supplementary analysis with sensitivity analysis applied to the results.

When conducting economic evaluation for reimbursement purposes, QALYs gained are often treated as equal in value to a QALY loss. However, studies have identified the presence of

loss aversion, with individuals valuing QALY losses between 1.5- and 2-fold more than gains.^{42–45} Valuing QALY losses twice that of QALY gains had minimal effect on the results of the case studies, although this may not hold true in all cases (see Table 1). Consequently, the TGA should consider applying a greater weight to QALY losses when conducting economic evaluation to inform reclassification decisions.

More research is required on what the appropriate ICER threshold may be for medicine reclassification, and how to best measure behavioural change following reclassifying a medicine.

The development of guidelines for economic evaluations for reclassification decisions should be driven by the TGA with extensive consultation with stakeholders. It is encouraging to see the TGA considering more innovative approaches to reclassification decisions. Ultimately, the use of an economic evaluation approach will contribute to helping decision makers maximise population health outcomes in an efficient way.

Competing interests

None.

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