An Economic Framework to Inform the Scheduling of Medicines

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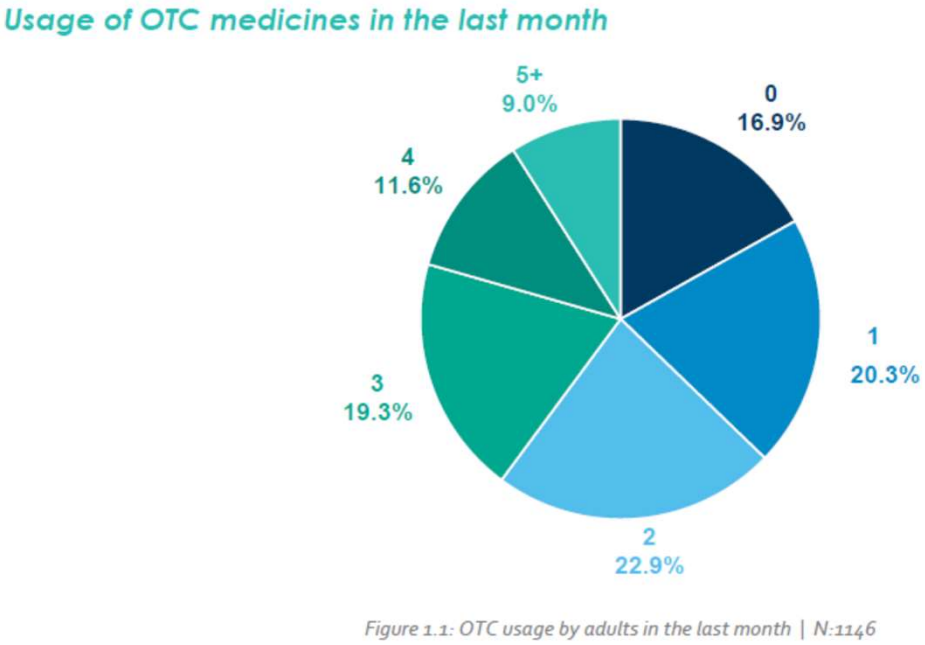
Background

OTC MEDICINES IN AUSTRALIA

Government expenditure on medicines has increased substantially due to ↑ utilisation and prices → concerns regarding sustainability.

Total expenditure on medicines represented ~ 12.3% of all health spending in 2014-15.

Most Australians have used a medicine for self-medication in the past month, including over-the-counter (OTC) medicines and complementary medicines.



Source: MUCHE (2015) Understanding Consumers' Use and Attitudes Towards OTC Medicines, Vitamins, Minerals and Supplements

Background

CURRENT REGULATORY APPROACH TO OTC IN AUSTRALIA

The *Poisons Standard* sets out the degree of control over the availability of medicines to the public.

Initially patients require a prescription to access most new medicines (i.e. **Schedule 4 (Prescription only)** or **8 (Controlled))**

Later regulators may 'switch' or 'down-schedule'

- **Schedule 3 (Pharmacist Only)**: Available behind the pharmacy counter. A pharmacist must be consulted before dispensing
- **Schedule 2 (Pharmacy Medicine)**: May be available on the shelf at pharmacies. If required, advice from a pharmacist or pharmacy assistant should be available

Some medicines are also "**unscheduled**"

- Available in pharmacies + other distributional channels (e.g. supermarkets, online stores and health food stores)

Background

CURRENT REGULATORY APPROACH TO OTC

Who decides?

An advisory committee of the Therapeutic Goods Administration (TGA) provides advice regarding under which schedule should a medicine be listed.

Factors considered?

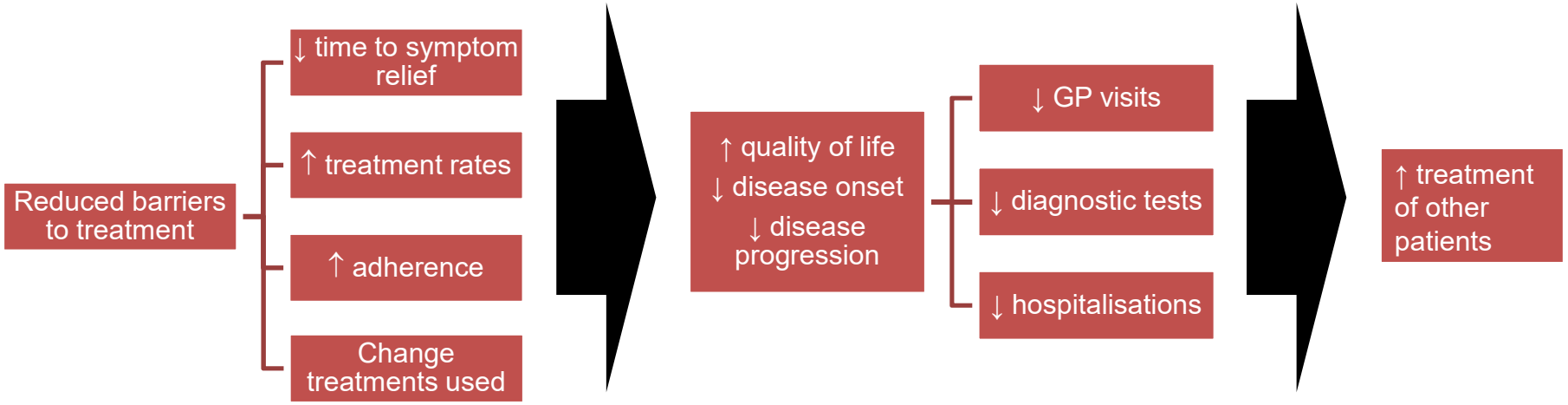
Largely focus on **patient risk**, especially:

- The need for advice from a medical practitioner or pharmacist
- The risk of inaccurate or delayed diagnosis
- The risk of inappropriate use
- The incidence and severity of adverse events (including contraindications and interactions)

Background

CURRENT REGULATORY APPROACH TO OTC

But there are also benefits from listing a medicine on a lower schedule:



Background

CURRENT REGULATORY APPROACH TO OTC

Consideration of the benefits

These benefits may be considered by the advisory committee BUT given less importance as not included in the formal list of factors to be considered.

- Scheduling Policy Framework for Medicines and Chemicals

Risk aversion

Gauld et al (2014 and 2015) found that while Australia was initially previously active in down-scheduling vs rest of the world, in recent years Australia has adopted a more conservative and risk-adverse approach.

Background

EXTERNAL REVIEW

An external review of medicines and medical devices regulation was conducted for the Australian Federal Minister for Health in 2015.

The review recommended that:

> *...the Scheduling Policy Framework be reviewed, in consultation with State and Territory Governments 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 (Recommendation 11).*

An economic evaluation approach

HOW CAN IT HELP?

Not possible to conduct a randomised controlled trial (RCT) to explore the impact of down-scheduling on health outcomes.

Economic modelling can synthesise evidence from a variety of sources, enabling:

- Consideration of a broad range of benefits and risks
- Estimation of the impact on health outcomes and resource use

An economic evaluation approach

HOW CAN IT HELP?

Down-scheduling is likely to result in a wide range of different health outcomes:

- Symptoms reduced or duration shortened
- Different diseases avoided
- Incidence and severity of different adverse events

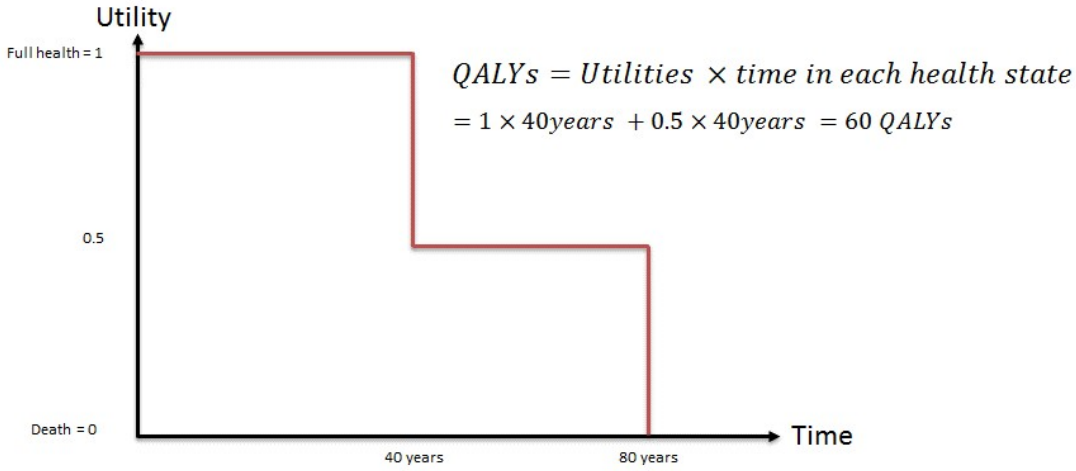
Can be aggregated to a single measure – **Quality Adjusted Life Years**.

An economic evaluation approach

HOW CAN IT HELP?

Quality adjusted life years (QALYs)

- Incorporate survival and quality of life
- Utility values = strength of preference between health states, anchored at perfect health (1) and death (0)
- Utility values reflect strength of community preferences across survival and quality of life
- Measured using approaches that ask respondents to trade off survival and quality of life (e.g. standard gamble or time trade-off)



An economic evaluation approach

HOW CAN IT HELP?

Inappropriate scheduling decisions result in:

- Poorer health outcomes
- Wastage of health care resources

Presence of uncertainty ≠ inappropriate scheduling decision.

- If decision is unchanged regardless of the parameter value, then decision is likely to be appropriate regardless of the presence of uncertainty.
- But if there is a risk that scheduling decision is inappropriate, then there may be value in waiting and collecting more evidence.

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HOW CAN IT HELP?

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Sensitivity analyses can help assess whether the presence of uncertainty in the evidence = uncertainty in the regulatory decision.

Type of uncertainty analysis	Questions answered
Univariate sensitivity analysis and threshold analysis	How important is an attribute? Is further research is required?
Sub-group analysis	Should access differ by patient group?
Scenario analysis	Impact of different regulatory scenarios (e.g. require screening questionnaire, or require 1st GP visit)?
Probabilistic sensitivity analysis	What is the probability that down-scheduling is cost-effective?

Research Project

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To develop an extended framework using an economic evaluation approach that could be used by sponsors and decision makers to inform whether a medicine should be down-scheduled from prescription only (Schedule 4 in Australia) to Pharmacist Only (Schedule 3 in Australia), and vice versa.

Research Project

MACQUARIE University

The economic framework was based on current best practice guidelines, but with some adjustment to scheduling decisions.

It's application was illustrated using 2 case studies:

- Down-scheduling triptans for the treatment of migraines
- Down-scheduling the oral contraceptive pill to avoid unintended pregnancies

→ demonstrated that an economic evaluation approach is possible and can be insightful for regulators.

Report will be launched in Canberra in early 2018.

An economic evaluation approach

APPLICATION

Clearly our framework is not the final version.

Final framework would need to be driven by the TGA following extensive consultation with:

- TGA and committee members
- Industry
- Patient groups
- Medical practitioners
- Pharmacists
- Health researchers
- Health economists

An economic evaluation approach

APPLICATION

The results of economic evaluations should be considered by regulators as part of the broader body of evidence regarding:

- Expected health impacts
- Extent of the available evidence
- Who will be affected
- The role of medical practitioners and pharmacists

Summary

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An economic framework to inform down-scheduling decisions can assist regulators:

- Synthesise a wide variety of evidence
- Consider a broader range of benefits and risks
- Ensure consistency across submissions
- Assess the uncertainty and whether further research is required

→ help reduce some of the recent conservatives shown by regulators regarding down-scheduling drugs in Australia.

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Thank you

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