Australian Health Review
doi:10.1071/AH20208

Supplementary Material for

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

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File S1

Legislation and guidance

Section 52(E) of the Therapeutic Goods Act 1989 specifies the following should be considered when making scheduling recommendations[1]:

a) the risks and benefits of the use of a substance;

b) the purposes for which a substance is to be used and the extent of use of a substance;

c) the toxicity of a substance;

d) the dosage, formulation, labelling, packaging and presentation of a substance;

e) the potential for abuse of a substance; and

f) any other matters considered necessary to protect public health.

Further guidance for the ACMS is provided in the Scheduling Policy Framework for Medicines and Chemicals (see Table 1), and guidance for stakeholders is provided in the Scheduling Handbook.[2, 3]

Table S1: Scheduling Factors

Factor	Pharmacy medicines (schedule 2)	Pharmacist only medicines (schedule 3)	Prescription only medicines (schedule 4)	Controlled drugs (schedule 8)
Patient risk	The use of the medicine is substantially safe for short term treatment and the potential for harm from inappropriate use is low. The risk profile of the medicine is well defined and the risks can be identified and managed by a consumer through appropriate packaging and labelling, including consultation with a health professional if directed by labelling.	The risk profile of the medicine is well defined and the risk factors for adverse effects, interactions and contraindications are known, identifiable and manageable by a pharmacist.	The seriousness, severity and frequency of adverse effects are such that monitoring or intervention by a medical, veterinary or dental practitioner is required to minimise the risk of using the substance. The seriousness or severity and frequency of the interactions of the substance (medicine-medicine, medicine-food, or medicine-disease) are such that monitoring or intervention is required by a medical, veterinary or dental practitioner.	-
Risk of inaccurate or delayed diagnosis	The use of the medicine at established therapeutic dosage levels is not likely to mask the symptoms or delay diagnosis of a serious condition.	The use of the medicine at established therapeutic dosage levels may mask the symptoms or delay diagnosis of a serious condition.	-	-
Inappropriate use (e.g. overuse, misuse or accidental ingestion)	The use of the medicine is very unlikely to produce dependency (at either the established therapeutic dose or supratherapeutic doses) and the medicine is very unlikely to be misused, abused or illicitly used.	The use of the medicine is not expected to produce dependency at either the established therapeutic dose or at supratherapeutic doses. Where risk of misuse, abuse or illicit use is identified, the risk can be minimised through pharmacist consumer consultation.	The use of the substance at established therapeutic dosage levels may produce dependency but has a moderate propensity for misuse, abuse or illicit use. The margin of safety between the therapeutic and toxic dose of the substance is such that it requires medical, veterinary or dental intervention to minimise the risk of using the substance.	The substance has an established therapeutic value but its use, at established therapeutic dosage levels, is recognised to produce dependency and has a high propensity for misuse, abuse or illicit use.

Factor	Pharmacy medicines (schedule 2)	Pharmacist only medicines (schedule 3)	Prescription only medicines (schedule 4)	Controlled drugs (schedule 8)
Frequency of use	-	-	The experience of the use of the substance under normal clinical conditions is limited.	-
The need for advice from a medical practitioner or pharmacist	The quality use of the medicine can be achieved by labelling, packaging, and/or provision of other information; however access to advice from a pharmacist should be available to maximise the safe use of the medicine.	The medicine is substantially safe with pharmacist intervention to ensure the quality use of the medicine. There may be potential for harm if used inappropriately. Where the medicine is intended for recurrent or subsequent treatment of a chronic condition, pharmacist intervention is required to monitor safe use of the medicine following recommendation by a medical practitioner or other authorised prescriber.	The ailments or symptoms that the substance is used for require medical, veterinary or dental intervention.	-
The need for expertise to administer the medicine	-	-	The use of the substance requires adjunctive therapy or evaluation or specialised handling for administration.	-
Other factors	-	-	The use of the substance has contributed to, or is likely to contribute to, communal harm.	The substance is included in Schedule I or II of the United Nations Single Convention on Narcotic Drugs 1961 or in Schedule II or III of the United Nations Convention on Psychotropic Substances 1971.

Source: [2]

References

1. *Therapeautic Goods Act*. 1989, Commonwealth Government of Australia: Canberra.
2. Australian Health Ministers' Advisory Council, *Scheduling Policy Framework for Medicines and Chemicals. Version 1.0*. 2018, TGA: Canberra.
3. Therapeutic Drugs Administration, *Scheduling handbook: Guidance for amending the Poisons Standard*. 2018, Australian Government Department of Health: Canberra.