Australian Government
Department of Health
Therapeutic Goods Administration

Consultation: The scheduling policy framework and advertising of pharmacist-only medicines (Schedule 3 substances)

Version 1.0, March 2017

TGA Health Safety Regulation

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Abbreviations

Abbreviation	Meaning
ACCS	Advisory Committee on Chemicals Scheduling
ACMS	Advisory Committee on Medicines Scheduling
AHMAC	Australian Health Ministers' Advisory Council
AHMC (former)	Australian Health Ministers' Conference
APVMA	Australian Pesticides and Veterinary Medicines Authority
COAG	Council of Australian Governments
DoHA	(former) Department of Health and Ageing
NCCTG (former)	National Co-ordinating Committee on Therapeutic Goods
NDPSC (former)	National Drugs and Poisons Schedule Committee
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
OTC	Over the counter
PC report	Productivity Commission report
SPF	Scheduling Policy Framework for Medicines and Chemicals
TGA	Therapeutic Goods Administration
The Act	*Therapeutic Goods Act 1989*

Executive summary

In response to Government's endorsement of Recommendations 11 and 12 of the Expert Panel Review of Medicines and Medical Devices Regulation, the Scheduling Policy Framework has been reviewed in conjunction with representatives of the State and Territory Governments and a number of stakeholders involved in the medicines and chemicals scheduling process, including other regulators, industry and healthcare professionals.

The major issues identified by stakeholders included governance of the SPF, timing, flexibility and principles associated with scheduling decisions, transparency, interim decision, how to encourage or support rescheduling considerations and approaches to regulation of the advertising of pharmacist-only medicines (Schedule 3 substances).

In this paper, possible reform options relating to these issues have been classified either as policy recommendations, ongoing improvements and development of guidance materials. In addition there are business improvement measures which could be undertaken internally within the TGA, without the requirement for policy change, and these could also result in improved processes.

The table below summarises the proposed reform options. Throughout this consultation paper, stakeholders will be asked to provide comment on these options and suggest any alternatives.

Policy recommendations		
Governance	1	Split the SPF into a policy document and a guidance handbook.
	2	Establish an informal working group comprising state and territory representatives, industry, healthcare professionals and consumers to meet as required to provide advice on possible amendments to the SUSMP
Interim decision	3	Amend the Therapeutic Goods Regulations to allow general public consultation on the interim decision and where appropriate, enable the time available for submissions to be extended.
Timing of decision	4	Explore options for establishing a chemicals scheduling delegate in APVMA to streamline scheduling and marketing authorisation considerations.
Tools for better management of rescheduled substances	5	Create a new Appendix in the Poisons Standard (SUSMP) to enable additional controls or requirements for Schedule 3 substances to be specified, in particular for substances that have been down-scheduled from Schedule 4 (prescription only).

Business improvements to TGA processes		
Decision-making principles	1A	A clearer explanation of the cascading principle and how it is applied should be included in the SPF.

Business improvements to TGA processes		
	1B	The structure and the content of the Committee's advice, and the delegate's reasons should be revised to ensure they are meeting the needs of stakeholders.
Transparency	2A	A public summary should be provided by the applicant that will be published as part of the public consultation process.
	2B	Develop a mechanism to alert stakeholders of items being considered for re-scheduling.
	2C	Develop communication milestones and application tracking to improve communication between the scheduling secretariat and applicants.
Risk:benefit value tree	3	When updating the SPF guidance, consider how greater emphasis can be placed on potential benefits as well as risks for substances proposed for rescheduling.
Interim Decision	4	Include an explanation in the SPF of the legislative nature of scheduling decisions and why they are not appealable.
Timing of decision	5A	Include an explanation in the SPF of the jurisdictional requirements for decisions to enhance stakeholder understanding.
	5B	Identify an early alert mechanism to ensure the initial applicant, the jurisdictions, and stakeholder groups have the maximum time available for activities associated with a decision.
	5C	Develop a mechanism to allow early information sharing between the APVMA and the Secretariat to screen and manage chemicals applications.
Improving the clarity of the SPF	6	Incorporate a number of changes to the SPF identified during collaboration with jurisdictions to improve the clarity and usability of the SPF.

Ongoing improvements and development of guidance materials		
Decision-making principles	1	Undertake a trial to assess the value of applicants presenting to the advisory committees
Risk:benefit value tree	2	Prepare worked examples of the risk:benefit tree for recent scheduling considerations and determine if there is utility for using as part of scheduling applications.
Proactive consideration of candidate substances for rescheduling	3	Implement a system for proactively identifying substances for rescheduling.

Ongoing improvements and development of guidance materials		
Parallel processes	4A	Develop a possible mechanism for aligning prescription to OTC medicine rescheduling applications with applications to TGA for market authorisation Of products containing the potentially rescheduled substances at OTC medicines.
	4B	Consider options for market incentives for down-scheduling.

Advertising of pharmacist only (Schedule 3) medicines		
Advertising Schedule 3 medicines	1	Develop and consult on options for reforming pharmacist-only medicines (Schedule 3 substance) advertising requirements.

Introduction

In October 2014 the Government announced the Expert Panel Review of Medicines and Medical Devices Regulation (MMDR). In 2015 the Panel delivered two reports and made 58 recommendations for reform.[1] Recommendations 11 and 12 of the Review, which were accepted by Government, as announced on 15 September 2016 were as follows:

Recommendation 11:

The Panel recommends that the Scheduling Policy Framework be reviewed, in consultation with the State and Territory Governments, to provide for:

1. The development and adoption of a formal risk-benefit methodology to assess scheduling applications; and
2. Opportunities to enhance input from interested parties into the scheduling process.

The Scheduling Policy Framework (SPF), document that is managed by the Commonwealth and all States and Territories via the Australian Health Ministers Advisory Council (AHMAC).

Recommendation 12:

The Panel recommends that the Schedule 3 Advertising Guidelines be reviewed, in consultation with the State and Territory Governments, and in concert with the review of the SPF, to:

1. Provide for the development and adoption of a formal risk-benefit methodology for the assessment of Schedule 3 substance for inclusion on Appendix H of the Poisons Standard; and
2. Identify synergies between application requirements for re-scheduling and for inclusion of a Schedule 3 substance on Appendix H, so as to streamline these processes and reduce duplication.[2]

[1] For the MMDR and the Government's response, see <https://www.tga.gov.au/mmdr>
[2] Direct-to-consumer advertising of Schedule 3 (Pharmacist Only) medicines is not permitted in Australia, unless the active substance in that medicine is also listed in Appendix H of the SUSMP

A further recommendation (No 53) was made in relation to the continued prohibition of the advertising to the public of prescription medicines (Schedules 4 and 8) and advertising of pharmacist-only medicines (Schedule 3) except those listed in Appendix H of the Poisons Standard. The Government also accepted this recommendation noting the issue of advertising Schedule 3 medicines to the public would be considered as part of the review of the Scheduling Policy Framework (Recommendations 11 and 12).

In addition to medicines scheduling, the Government agreed that this review should also consider ways to improve scheduling processes and encompass issues affecting chemical scheduling, which is also regulated under the *Therapeutic Goods Act 1989* (the Act) and managed through the Scheduling Policy Framework (SPF).

This review work was also noted at the 2 December 2016 meeting of the AHMAC, given that any revised version of the SPF will need its endorsement.

Background

What is scheduling?

Whether a medicine is available on prescription only, may be purchased over-the-counter in pharmacies or is available on general sale in supermarkets is determined by the scheduling of its active ingredient(s) (referred to as the "substance") in the *Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP), more commonly known as the *Poisons Standard*.

The scheduling of a medicine involves consideration of a number of factors, such as the toxicity of the substance, potential for abuse, safety in use and the need for access to the substance. The scheduling of a substance further underpins the need for particular healthcare professionals to be involved in the supply of certain medicinal substances in order to promote safe and quality use. The scheduling of medicines is intended to promote the quality use of medicines, and balance consumer access with the need to manage risks associated with a medicine.

The scheduling of chemicals in schedules 5, 6 or 7 of the Poisons Standard involves consideration of a number of factors including the toxicity of the substance, purpose of use, potential for abuse, safety in use, the need for specialist training or personal protective equipment for safe or effective use, and the need for access to the substance. Similarly to medicines, the scheduling also supports safer use of agricultural, veterinary and domestic chemical products through labelling with specific "alert" phrases keyed to the major threat level or phrases emphasising the need for intervention by particular professionals (where warranted). Where necessary the scheduling of certain veterinary chemicals reinforces the need for intervention by a veterinary practitioner to promote safe use.

Scheduling decisions in relation to access restrictions are given effect through State and Territory drugs and poisons legislation, with national uniformity in scheduling promoted through the *Scheduling Policy Framework* (SPF). Developed by the former National Coordinating Committee on Therapeutic Goods (NCCTG, which was an AHMAC subcommittee until its abolition in 2012), the SPF sets out the national system for 'applying access restrictions on all poisons', including medicines for human use. AHMAC continues to provide the governance mechanism for maintaining and updating the SPF. Under the SPF, the active ingredient (substance) of the medicine or chemical product is classified into one or more of the schedules, which affect the way in which products containing the relevant substance are to be sold, as a result of the level of control on access to the product required to manage risk.

Under the Act, a "person" (which can in effect be an individual, company, clinical professional society or academic group) may apply to amend the *Poisons Standard*. Such amendments relate

to the addition of a new substance, which occurs at the point of registration of a new prescription medicine (new chemical entity) by TGA, or it can be an application for rescheduling of an existing substance. Scheduling decisions in respect of medicines and chemicals are made by a delegate of the Secretary of the Department of Health, who may receive advice from the Advisory Committee on Medicines Scheduling (ACMS) and/or the Advisory Committee on Chemicals Scheduling (ACCS).

Scheduling factors

When the delegate makes a scheduling decision, (s)he is obliged under the Act to take into consideration:

- the risks and benefits of the use of the substance;
- the purposes for which the substance is to be used and the extent of use of the substance;
- the toxicity of the substance;
- the dosage, formulation, labelling, packaging and presentation of the substance;
- the potential for abuse of the substance; and
- any other matters the delegate considers necessary to protect public health.

The delegate is also obliged to take into account recommendations from the ACMS (or ACCS) and comply with the SPF. The SPF sets out a number of scheduling factors which inform the way the ACMS (and ACCS) makes recommendations and the delegate makes decisions. The application of these factors embodies a 'cascading principle', in which a substance intended for therapeutic use in humans is first assessed against the factors for Schedule 9 prohibited substances, then Schedule 8 controlled drugs, then Schedule 4 prescription only medicines, and if these are not applicable the Schedule 3 factors, and so on and so forth.

For chemicals, the substance is first assessed against the factors for Schedule 7, then Schedule 6 and then Schedule 5.

The legislation

Part 6-3 of the *Therapeutic Goods Act 1989* provides the legal basis for scheduling decision-making and can be accessed at the Federal Register of Legislation website.

Past reviews[3]

The current arrangements for scheduling arose from the *Final Report of the National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation* (the 'Galbally Report') in 2001. Amongst other things, the Galbally report recommended that there be separate committees for medicines and chemicals, constituted from jurisdictional representatives, independent experts and others from government and community sectors, and also recommended that the Act be amended to confer decision making powers on medicines scheduling to the Secretary of the (then) Department of Health and Ageing.

The Galbally Report was followed by the *Chemicals and Plastics Regulation Productivity Commission Research Report July 2008* which recommended that the Secretary of the

[3] For a comprehensive background to scheduling please see http://www.health.gov.au/internet/main/publishing.nsf/Content/2AF4A71E2F5A1AB5CA257BF0001ACD84/$File/Part-B-Background.pdf

Department of Health and Ageing should also make decisions on matters of chemicals scheduling. This report also recommended that State and Territory governments should adopt poisons scheduling decisions made by the Department of Health and Ageing directly by reference, as published in the SUSMP.

Following these recommendations the SPF and revised scheduling arrangements came into force in 2010. As part of these new arrangements, the SPF was further reviewed in 2013 as required by the Act. Details of this review can be accessed at the Department of Health website.

From the Executive Summary of the report of the 2013 review:

The review found that the new arrangements introduced by the 2009 amendments, provide for an effective and flexible process for the scheduling of substances. However, the review also found ***there is scope to make the operation of the scheduling arrangements more efficient and effective.***

Greater transparency and timely access to information *would enhance the confidence of stakeholders in the arrangements. It would also facilitate the implementation of scheduling decisions by states and territories, and industry.*

Stakeholders are ***uncertain about who is responsible for on-going policy oversight of the scheduling framework****. This is an issue that needs to be addressed. While the panel made no recommendations for further changes to the scheduling regime, the panel made eight recommendations that it believes would support and improve the effectiveness and efficiency of the operation of Part 6-3 of the TG Act.*

The recommendations from this review were not acted on due to government entering a Caretaker period and the subsequent announcement of the MMDR. There is a strong correlation between some of the issues identified in the 2013 review and this current work.

Advertising of pharmacist-only (Schedule 3) medicines

Direct-to-consumer advertising of pharmacist only medicines (Schedule 3) is not permitted in Australia unless all Schedule 3 ingredients are substances listed in Appendix H of the *Poisons Standard.* As of December 2016, there were sixteen such substances in Appendix H, which means a significant number of schedule 3 substances are not permitted to be advertised.

Australia's approach to scheduling including the advertising of medicines containing Schedule 3 substances is not comparable to many other countries. The broad view in these countries is that if a medicine has been deemed appropriate for sale to the public without a prescription then it should be able to be advertised to the public. There are usually either voluntary or mandatory prohibitions on advertising of certain OTC products such as those containing pseudoephedrine or codeine (where these are available OTC). Further, there may be fewer medicines available for general sale in those countries where there are not separate pharmacy and pharmacist only categories such as in the USA.

Appendix H decisions are made by a delegate of the Secretary of the Department of Health who must take into account matters set out in the Schedule 3 advertising guidelines developed in 2000 by NCCTG. These guidelines require that the decision maker consider a number of matters, including:

- The potential public health benefit, for example more appropriate use of scarce health resources or a better informed community.
- The likelihood of advertising of the substance leading to inappropriate patterns of medication use.

- Whether the application may result in the advertising of goods for an indication other than those approved by TGA during the registration process.
- The desire of consumers to manage their own medication and the level of patient education necessary to ensure correct use.

As part of this review, we have undertaken initial discussions with stakeholders to determine a range of potential reform options for advertising of Schedule 3 substances.

International comparisons

Throughout this paper, reference is made to regulations in counterpart jurisdictions, in particular the UK. Alignment with other regulators is a key objective for regulatory reform by the Government, together with learning and adapting from practices of other regulators. For scheduling and advertising of schedule 3 medicines, this is complicated by fundamental differences in the frameworks in place. For example, in the UK access to medicines via scheduling is based on products, rather than substances, as is the case in Australia. As a result, it is unlikely that a framework administered by counterpart regulators could be adopted in totality, although adaption to the Australian context could well be feasible.

The consultation process

During the review, the panel consulted with a wide range of stakeholders on scheduling policy and medicines advertising issues. However, the panel did not make specific recommendations and proposed that further consultation and deliberation take place on options for change prior to any Government decision.

Since the release of the MMDR reports, a number of workshops and stakeholder meetings were held. Feedback from these meetings identified the following key issues with the current process:

- More overt analysis of the risk-benefit balance in assessing appropriate substances
- Greater decision-making transparency
- Review of decision-making principles
- Review of information availability around scheduling applications and input to decision-making
- Governance of the Scheduling Policy Framework
- Business processes relating to management of rescheduling proposals and committee and delegate deliberations
- Incentives for submission of rescheduling applications.

These issues were further discussed in several meetings and forums with invited stakeholders. These stakeholder groups included:

- Representatives from State and Territory governments who met to discuss the key issues, and also reviewed the SPF in detail
- Members of the Advisory Committee for Medicines Scheduling and the Advisory Committee for Chemicals Scheduling

- Stakeholders involved in medicines scheduling, with representatives for industry, healthcare professionals (medical practitioners and pharmacists) and consumers
- Stakeholders involved in chemicals scheduling, with representatives from the chemicals industry, including the agricultural chemicals and veterinary medicine industry, and various government departments.

The content of this consultation paper has been developed from discussions at these meetings and forums.

This consultation paper

How to use this paper

Throughout this paper, where a "?" icon appears next to a boxed recommendation, stakeholders are asked to provide feedback on the proposal.

Alternative views or options would also be welcomed.

Issues for stakeholder comment

Governance

The general model of scheduling decisions being made by a delegate of the Secretary for Health (typically a senior medical officer and senior toxicology scientist for medicines and chemicals respectively) on the advice of ACMS and ACCS was consistently supported by both the expert panel review and in subsequent consultations in late 2015 and 2016. Since the NCCTG was disbanded as a subcommittee of AHMAC in 2013, the SPF has been under the direct purview of AHMAC. A wide range of stakeholders raised concerns that because of the wide range of issues that AHMAC must consider, and the crowded agendas of AHMAC meetings, a policy void now exists in the absence of the NCCTG, making amendments to the SPF difficult to achieve.

We do not propose changes to the overall policy approach towards scheduling and the associated substance classification scheme, but it can argued that much of the SPF addresses business and consultation processes rather than a true "policy framework". To address the need to be able to effectively evolve to reflect changing practices and requirements, we propose to split the current SPF document into two documents; the first outlining the policy and remaining the responsibility of AHMAC, the second being a handbook outlining the process underpinning the policy, guidance notes for applicants and administrative details.

The handbook would be maintained by the Scheduling Committee Secretariat within the Department of Health, with advice on updates from meetings of the combined ACMS and ACCS, and other stakeholder groups. An informal Working Group would also meet as required to provide advice on possible amendments to the SUSMP to ensure that it also remains relevant and up to date.

We envisage that chapters 1-3 of the SPF would form the basis of the policy document. Chapters 4-6 would form the basis of the Scheduling Handbook, with additional guidance material developed to assist stakeholders.

Policy Recommendation 1 - Split the SPF into a policy document and a guidance handbook.

These documents would also incorporate changes to the current SPF that are agreed following the current consultation.

Policy Recommendation 2 - Establish an informal working group to provide advice on possible amendments to the SUSMP

Establish an informal Working Group comprising state and territory representatives, industry, healthcare professionals and consumers to provide advice on possible amendments to the SUSMP to ensure it remains up to date.

Decision-making principles

The cascading principle is central to the current scheduling classification process, and continuation of this approach was supported during consultations. Under this process, substances are first assessed against the criteria for the highest applicable schedule, and if that is not applicable the next schedule down is considered, and so on until the appropriate schedule is reached. Consultations so far, have determined that stakeholders are comfortable with this approach, and the current decision-making process is generally regarded as robust.

However, some areas for improvement have been identified as follows:

- A clearer explanation of the cascading principle and how it is applied would be beneficial.
- Decision-making and advice from the advisory committees would be enhanced if the reasons for particular recommendations were more closely described in terms of the scheduling factors.
- Include more detail of the committee's discussion in the minutes of meetings, and minutes (or a summary of the discussion) could be made available on the TGA website. Alternatively, a structured "records of reasons" could be used for capturing scheduling considerations. Public communications would need to be further considered with respect to the timing of the announcement of delegates' decisions, and recognition that the role of the committees is advisory.

Applicants want confidence that all of the information they have provided (that is relevant to the considerations under the Act and Scheduling Policy Framework) has been considered in making scheduling decisions and would like an opportunity to defend or clarify any issues during the consideration process. More broadly, applicants and other stakeholders want greater confidence and understanding of factors influencing decisions.

The ability for applicants to make a brief presentation directly to the advisory committee has been successfully implemented with some other expert advisory committees, such as the Pharmaceutical Benefits Advisory Committee). This has the potential to improve clarity and transparency during scheduling considerations. However, this may generate additional burden on stakeholders, impact on duration of committee meetings, and result in new material being presented that had not been adequately reviewed prior to the committee meeting. There may be merit in trialling an approach whereby applicants could ask to present briefly to the committee.

Ongoing Improvements 1 - Applicants presenting to the advisory committees

A pilot exercise to assess the value of applicants presenting directly to the advisory committees should be undertaken.

Business Improvement Measures 1 - Structure and content of the committee's advice

a. A clearer explanation of the cascading principle and how it is applied should be included in the SPF.

b. The structure and the content of the Committee's advice, and the delegate's reasons should be revised to ensure they are meeting the needs of stakeholders. Particular consideration should be given to explaining how the advice and reasons relate to the scheduling factors, and how the information that applicants have submitted has been reflected in the decision-making process.

Transparency

The scheduling process is commonly criticised as a being seen as a "black box", with limited information on the background to the application, and few updates of the status of an application being made available to the applicant and general public.

Major issues for consideration include:

- The extent of information available on the application is generally regarded as inadequate for stakeholders to make meaningful input.
- Concerns were raised by both medicines and chemicals stakeholders regarding the timing of consultations and ensuring that key stakeholders who would be affected by a scheduling decision were made aware of the proposal and could make a submission. Currently, stakeholders who have registered to receive updates when changes are made to the Scheduling website can receive an alert email, but this is not generally regarded as a sufficient engagement mechanism.

Business Improvement Measures 2 – Public summary of the scheduling submission and other communication processes

a. A summary for public dissemination should be provided by scheduling applicants, and this would be published as part of the public consultation process. This could be included in the application template. If an appropriate summary is not provided by the applicant, the default option could be that the entire (de-identified) application would be published for public consultation.

b. A mechanism should be developed to alert stakeholders of items

being considered for scheduling. For example, the delegate could identify a small number of affected stakeholders for comment, and the Secretariat could contact them directly.

c. Develop communication milestones and application tracking to improve communication between the Secretariat and applicants.

Risk-benefit value tree

The MMDR report strongly advocated the development and adoption of a formal risk-benefit methodology for assessing scheduling applications, such as that described by Brass et al.[4] Although there is an argument for the framework to include a greater and broader emphasis on potential benefits from rescheduling, most stakeholders consulted to date did not support the use of a **formal** value tree approach for assessing scheduling applications and framing decisions.

The major concerns included:

- The variation in the types of applications for scheduling would make it impossible to create a schema that could be used in all situations, especially as the model proposed is very prescriptive.
- Not all scheduling considerations require equal consideration of both risk and benefit.
- Concern that this could create additional burden for applicants in addition to the current data requirements.
- Scheduling applications are considered on the grounds of public health, and there was limited support by those consulted for a significant change to scheduling policy to enable formal consideration of economic benefit. Rather, specific benefits to patients or chemical users of wider public access could be considered.

There may be merit in developing a risk : benefit value tree to assist applicants when preparing their submissions, but this should be an optional tool and thus only included in guidance. Additional worked examples would also be useful to assess any tool(s) for overall utility.

It appears that many of the concerns that gave rise to the suggestion of using a value tree would be addressed by improvements to transparency and the scheduling process itself.

Business Improvement Measures 3: Greater emphasis on benefits as well as risks

When updating the SPF guidance for submissions, consider how greater emphasis can be placed on potential benefits as well as risks of proposed rescheduling of substances.

[4] Brass E.P., Lofstedt R., & Renn O. (2011), 'Improving the Decisions-Making Process for Nonprescription Drugs: A framework for Benefit-Risk Assessment', *Clinical Pharmacology and Therapeutics*, 90: 791-803

Ongoing Improvements 2: Improved guidance on risk and benefit

Prepare worked examples of the risk: benefit tree for recent scheduling considerations and assess the utility of this approach for scheduling applications.

Interim decisions

For a scheduling consideration that has been referred to either or both of the advisory committees, publication of an interim decision is required by the Act and under the SPF. This interim decision outlines the delegate's views following his/her consultation with the advisory committee(s). It is published on the TGA website and further public comment is invited.

During the course of this review, a number of concerns were identified with the current interim decision process.

There is a view that rather than only permitting those who made initial submissions to provide further submissions on the interim decision, the interim decision should be open to full public consultation and comment.

Stakeholders also contended that it would be beneficial for the interim decision to be published in "plain English", to better explain the intent of the scheduling proposal. Finally, it was considered that the current specification of maximum times available for submissions on interim decision was inflexible – more time may be required to comment on complex or contentious interim scheduling decisions but less time for others.

Better information also needs to be developed to explain how scheduling decisions are given effect, why they are not disallowable under the *Legislative Instruments Act 2003* (this is because scheduling decisions are an integral part of a joint Commonwealth – State/Territory framework for the scheduling of medicines and chemicals and are implemented through State and Territory rather than Commonwealth law) and why scheduling decisions cannot be appealed under section 60 or the Act (as they are legislative in character, apply to all products containing the scheduled substance and thus effect all suppliers of such products, not just the applicant).

The broader improvements to transparency and the scheduling process discussed in this paper may also address many of the concerns associated with the lack of an appeals mechanism.

Policy Recommendation 3: Public consultation on interim decisions

Amend the Therapeutic Goods Regulations to allow general public consultation and receipt of submissions from any interested parties on the interim decision and remove the prescriptive requirements on time available for submissions.

Business Improvement Measure 4: Guidance on legal nature of scheduling and scheduling decisions

Include an explanation of the legislative nature of scheduling decisions and

why they are not appealable in the SPF.

Timing of scheduling decisions

When considering options for reform to the timing for implementation of a scheduling decision (as opposed to the timing of the decision), a range of stakeholder needs must be considered.

Industry needs certainty of timeframes to enable products to be ready for the market and changes to be made to existing products on the market; jurisdictions need time to amend legislation and regulation; and in some cases, professional groups require time to educate their members when scheduling decisions are associated with significant changes to the access to a medicine or chemical, for example a switch from Schedule 4 (Prescription Only) to Schedule 3 (Pharmacist Only) for a medicine, or vice-versa.

Conversely, chemicals stakeholders have raised concerns that delays in finalising decisions impact on the regulator's statutory timeframes for product assessment. Further, depending on the timing of the relevant advisory committee meetings, scheduling consideration may result in agrochemical products being delayed to market. This could result in products missing a critical period in a growing season. To better manage the timing of decisions for chemicals and coordination with other regulatory decisions made around agricultural and veterinary chemicals, industry stakeholders could potentially grant permission to share the marketing authorisation data provided to the APVMA as part of the pre-submissions process with the scheduling secretariat and delegate for initial consideration.

To further streamline the scheduling process for chemicals, a scheduling delegate could be established within the APVMA. The advantages of this approach include that the delegate would be more closely associated with the marketing authorisation evaluation process for pesticides and veterinary chemicals and could better prioritise decision making activities associated with scheduling decisions, to reduce delays in time to market for these products. However, given that this would create two chemicals scheduling delegates in different government portfolios, and some substances are used in more than one category (as agricultural/veterinary and/or domestic and/or industrial chemicals), the roles and responsibilities of each delegate would need to be clearly defined and responsibilities for particular decisions managed.

It is expected that more delegate-only decisions for Schedule 5 and Schedule 6 substances (refer to Business Improvement Measure 6) should result in shorter times to market for some agricultural chemicals. It is also anticipated that improved communication between the Secretariat and the applicant will enhance understanding of the process and allay concerns that the scheduling process is a "black box". However, business improvement measures proposed can be undertaken to further improve the scheduling process.

Policy Recommendation 4 – consider a chemicals scheduling delegate within APVMA

In consultation with the Agriculture and Water Resources portfolio, explore options to establish a delegate in the APVMA to streamline scheduling applications for relevant (agricultural and veterinary) chemicals, with due consideration to the management of the process and ensuring that the specific

roles and responsibilities of each delegate are clearly defined.

Business Improvement Measures 5- Decision transparency and information sharing.

Include an explanation in the SPF of jurisdictional requirements for decisions to enhance stakeholder understanding.

Identify an early alert mechanism to ensure the initial applicant, the jurisdictions, and stakeholder groups have the maximum time available for activities associated with a decision.

Develop a mechanism to allow early information sharing between the APVMA and the Secretariat to better screen and manage agricultural and veterinary chemicals applications.

Proactive consideration of candidate substances for rescheduling

In a number of international jurisdictions, the regulator/s, in conjunction with a group of stakeholders undertake a proactive review of substances to identify potential candidates for potential rescheduling (termed "reclassification" in most countries). For example, in the UK, Ireland, Singapore and Denmark, an informal committee of medical practitioners, pharmacists, consumer representatives and the regulator meet every one to three years to identify whether particular medicines may be suitable candidates for reclassification from prescription only to general sale (or vice versa). The recommendations of the committees are not binding on the regulator and a formal submission for reclassification is still required to be drafted, submitted and considered by the regulator. Nonetheless, this process provides a signal that particular cases for reclassifications could be pursued and would be considered carefully by the regulator.

Initial stakeholder consultations have identified general support for an approach of this type being carried out in Australia, and that after an initial, more thorough review of certain substances in particular schedules in the first year or two, reviews of this type would subsequently need to be undertaken only every few years. The review committee would not need to have official status and could be convened by the regulator/s as required, and may potentially be the same ad hoc committee that would review scheduling guidelines and policy issues from time to time (again recognising that AHMAC would have the final say on policy).

It should be emphasised that any outcome from such a process, for example a recommendation for a rescheduling consideration for a particular substance or group of substances, would still need to be reviewed by the delegate and decision made according to the Act.

Ongoing Improvements 3 – Proactive identification of substances for rescheduling

Implement a system for proactively identifying substances for rescheduling, similar to schemes in place in some comparable international jurisdictions.

Tools for better 'management' of rescheduled medicinal substances

It emerged from the stakeholder workshops and further discussions with ACMS and ACCS members that there were concerns that under the current SPF it was difficult to adequately manage certain aspects of risk if a medicinal substance was down-scheduled. In wider stakeholder consultations, this was also seen by stakeholders as a potential barrier to supporting recommendations that certain substances be down-scheduled, in particular certain Schedule 4 prescription medicines to Schedule 3 pharmacist-only medicines.

For example, when a substance is rescheduled from Schedule 4 to Schedule 3 there frequently are concerns about the lack of capacity of the Poisons Standard to be able apply appropriate controls to supply at the pharmacy level. Currently, there is limited capacity to include, as part of rescheduling decisions, specific requirements on pharmacists when providing a product containing a newly down-scheduled substance. Examples of requirements that could potentially be imposed include requirement for specific training of pharmacists, provision of diagnostic questionnaires to patients (e.g. to confirm that they do not have comorbidities or are taking particular medicines such that medicines containing the down-scheduled substance in question would be contraindicated, requirements for referral to other healthcare professionals, etc). There was support from the states and territories and other medicines stakeholders to explore options further.

The SUSMP, particularly through its appendices, does have the scope to provide the ability for additional controls around practice to manage risk – and already does so around medical practitioners in relation to particular substances in prescription medicines. For example, Schedule D of the Poison Standard ("Additional controls on possession or supply of poisons included in Schedule 4 or 8") specifies that certain Schedule 4 medicines which carry additional specific risks, can only be prescribed by particular medical specialists or specific medical practitioners permitted by state or territory departments of health, , while obtaining of specific information from patients such as whether they are pregnant or likely to become pregnant can be mandated for medical practitioners before they are authorised to prescribe particular products under this schedule. . For Schedule 8 medicines some states and territories impose additional controls such as requiring the prescriber to hand write the prescription.

In a number of comparable countries, such as the UK and New Zealand, similar practice controls can be required of pharmacists prior to provision of recently-rescheduled medicines. For example, for medicines such as sumatriptan (for migraine), erectile dysfunction medicines, or trimethoprim (for urinary tract infections), when these substances were rescheduled to OTC certain controls were introduced as part of the rescheduling process. In these cases, there was the requirement for the pharmacist to undertake specific professional training in the use of the product, and/or to conduct and record a patient interview or for the patient to fill in a questionnaire before being supplied with the product.

In NZ, specific pharmacist training requirements are specified for certain down-scheduled products, along with other requirements such as a limitation on pack size. More generally for pharmacist only medicines in NZ, a register of the names and addresses of the purchaser and information on the quantities of medicines sold is required to be kept.

In the UK, when a new pharmacy medicine becomes available following reclassification (down-scheduling), the Medicines and Healthcare Products Regulatory Agency will have considered the necessary risk minimisation measures which may include pharmacy support and training materials. These will be included in the marketing authorisation as a requirement of the risk management plan, and MHRA will also routinely pre-vet the advertising materials for down-scheduled medicines.

When sumatriptan was first reclassified in the UK from prescription use to supply through pharmacies, as part of the authorisation MHRA agreed a questionnaire with the sponsor which was supplied to pharmacies for use prior to supplying the product to the patient. Separately the (UK) Royal Pharmaceutical Society produced professional guidance for pharmacists, technicians and counter staff which provided additional supporting information on the conditions for over-the-counter supply and made reference to the questionnaire. More recently MHRA have reviewed the usefulness of such questionnaires as part of the risk minimisation measures in the pharmacy, and a number of stakeholders indicated that the questionnaires were "off-putting" for both the pharmacists and the patient. Instead, in some more recent reclassifications, pharmacists instead have been required to use a more structured verbal set of questions to enable structured identification of patients who are unsuitable for the particular rescheduled medicines. In addition, there has been a move to "active packs" where the key points for discussion at the point of supply are on the back of the medicines pack. Finally when the UK NHS commissions services from pharmacies such as emergency contraception services, it will usually be a condition pharmacists undertake additional accredited professional training.

While requirements such as these are thus at the interface between professional practice and substance regulation, there is precedent (e.g. with Schedule 4 and Schedule 8 substances) and the ability for requirements of this type to be included in the SUSMP as part of conditions of rescheduling.

We propose that a new appendix to the SUSMP be developed to provide controls for particular Schedule 3 substances. While these would be "additional controls" it is likely that this would facilitate appropriate OTC access for certain products that are currently prescription-only in Australia but not in a number of comparable countries. As experience builds with the product provided in an OTC environment, the controls on particular products would also subsequently be able to be modified.

Policy Recommendation 5: New controls for certain medicines that have been down-scheduled to pharmacist only classification (S 3)

Create a new Appendix in the Poisons Standard (SUSMP) to enable additional controls or requirements for certain Schedule 3 substances to be specified, in particular for substances that have been down-scheduled from Schedule 4 (prescription only). This new appendix will function in a similar manner to Appendix D, which specifies additional controls for particular Schedule 4 or 8 substances.

Parallel processes and other incentives (medicines)

A common concern is that the effective date of a rescheduling decision for a medicinal substance often does not align with a feasible date for market availability of the new products that contain the down-scheduled substance. This is due to the additional timeframes for subsequent regulatory approval of the products containing the substances. Perhaps the most common example is where an applicant submits a request for a substance in a medicine to be rescheduled from Schedule 4 to Schedule 3. Currently applicants are not permitted to submit the associated marketing authorisation application to the TGA until the scheduling decision has been made, and the outcome is a new Schedule 3 substance. A number of stakeholders supported relaxation or removal of this requirement, although there is the potential for increased workloads for applicants to prepare market authorisation applications (and TGA evaluators to review these applications), if the related rescheduling application for the substance in the products is subsequently unsuccessful.

Possible incentives for the submission of rescheduling applications were also discussed with stakeholders. In particular, whether or not a mechanism should (and could) be developed that might create a potential market advantage for applicants to be the first to initiate a rescheduling application. Similar models exist in other jurisdictions, such as the UK, and could include for example a period of market exclusivity for the applicant that initiated the rescheduling decision, if the same entity was also the sponsor of a product that is approved for supply in Australia. However it should be noted that the medicines classification framework in the UK, unlike Australia, can specifically refer to a product rather than a substance.

The jurisdictions were of the view that scheduling is about protecting public safety and commercial interests should not be a factor. Conversely, access to medicines as part of broader public health policy also needs to be considered. A key consideration would be whether or not a market exclusivity model would, in fact, result in a net public health benefit. For example, a period of market exclusivity for one brand of a Schedule 3 medicine might not confer overall greater access to that brand if pharmacists were able to legally dispense "Schedule 3 versions" of any remaining Schedule 4 brands under State and Territory laws.

Ongoing improvements 4 – Down-scheduling - alignment with OTC product submission and incentives?

a. Develop a mechanism to better align applications to reschedule an active substance from Schedule 4 to Schedule 3 with the marketing authorisation applications for newly rescheduled Schedule 3 medicines.

b. Consider options for market incentives for down-scheduling, for example similar to the UK system, and whether development of a similar mechanism for the Australian context would be in the interests of public health.

Improving the clarity of the SPF

A number of the changes proposed in the current review of the Scheduling Policy Framework aim to improve the clarity and usability of the SPF so as to assist stakeholders to use the related documents, as well as to improve the efficiency of the process. Some specific proposed changes to the SPF that should improve its clarity are summarised below.

Business Improvement Measures 6 - Improving the clarity of the SPF

1. Amend section 3.2 to provide the delegate with greater discretion when deciding to refer (or to not refer) particular substances to the relevant advisory committee(s) for advice, particularly for

    a. rescheduling considerations of "second in class" medicinal substances (where the committee has already considered and the delegate already determined that a substance in the same pharmacological / medicinal class be rescheduled, based on similar considerations);

    b. a number of Schedule 5 and Schedule 6 chemicals scheduling applications;

    c. straightforward considerations of scheduling of a particular

substance used in an agrochemical or veterinary medicine that has been subject to a recent evaluation by the Australian Pesticides and Veterinary Medicines Authority (APVMA);

d. and consideration of Appendix E, F and K entries of the SUSMP.

2. Clarification that Appendix E and F requirements do not apply to workplace chemicals where they are subject to the requirements of the Globally Harmonised System for the classification and labelling of chemicals (GHS, discussed further below).[5]

3. Decisions to include a substance in Appendix K can be a delegate-only decision and not require referral to the Advisory Committee for Medicines Scheduling.

4. Amendment to the description of the Cascading Principle and the details for inclusion in Appendix B.

Globally harmonised system and scheduling

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS) addresses classification of chemicals by types of hazard and proposes harmonised hazard communication elements, including labels and safety data sheets. It aims at ensuring that information on physical hazards and toxicity from chemicals is available in order to enhance the protection of human health and the environment during the handling, transport and use of these chemicals.

The hazard classification and hazard communication elements of the GHS have been implemented in Australia through the model Work Health and Safety (WHS) laws developed by Safe Work Australia and adopted in the Commonwealth, and most states and territories since 2011. The WHS laws included a 5 year transition period that expired on 31 December 2016. Since then, the hazard classification and hazard communication duties relating to workplace chemicals came into effect in all jurisdictions that have adopted the WHS laws. While the GHS is a hazard-based classification system and scheduling is risk based, there are a number of similarities between the two schemes, in particular the types of tests and end points for classification.

The most notable difference is that the GHS is intended to apply to workplace chemicals whereas scheduling applies to domestic and industrial chemicals, and medicines, irrespective of whether they are used in workplace or in wider situations. However, there is overlap between workplace and domestic use of particular chemicals. Situations have arisen, for example, in which the same product is required to have two different labels depending on where and by whom it is used.

The potential for aligning scheduling and GHS endpoints and classifications was discussed at stakeholder meetings but has been considered to be outside the scope of this review. Some issues include:

- A major benefit of aligning the two schemes would be consistency between the toxicological endpoints and decision on which tests are considered acceptable GHS is test method independent with guidance for usability of data, unlike the test guidelines and endpoints currently accepted for scheduling Medicines and cosmetics are exempt from GHS, thus it is

[5] For more information on the GHS, see http://www.safeworkaustralia.gov.au/sites/swa/whs-information/hazardous-chemicals/faqs/pages/faqs

only relevant to industrial chemicals and agrochemicals that are used in the workplace. Many paints, for example, need to have two different labels depending on whether they are sold as trade products or in a consumer setting. Similar complications exist for pool and spa chemicals.

- GHS could be used as guidance for scheduling consideration, with hazard classification being used as a starting point for consideration, and risk mitigation a means of determining a final schedule.
- Consideration of possible greater GHS / scheduling alignment would need to be considered in a wider forum.

With the interface with workplace safety legislation it is considered that a project of this type would be major, and beyond the scope of the Government's response to the Expert Panel Review of Medicines and Medical Device Review regulation. Therefore it will not be pursued in the context of the current consultation.

Advertising of Schedule 3 (pharmacist only) medicines

The Government, in accepting Recommendation 12 of the MMDR has directed

"that the Schedule 3 Advertising Guidelines be reviewed, in consultation with a wider range of stakeholders including State and Territory Governments, and in concert with the review of the Scheduling Policy Framework, to:

1. *Provide for the development and adoption of a formal risk-benefit methodology for the assessment of Schedule 3 substances for inclusion on Appendix H of the Poisons Standard;*

and

2. *Identify synergies between application requirements for re-scheduling and for inclusion of a Schedule 3 substance in Appendix H, so as to streamline these processes and reduce duplication."*

   (Note that a broader review of the Scheduling Policy Framework also provides for a broader review of the role of the schedules of the SPF, so mechanisms for regulating direct-to-consumer advertising of pharmacist only medicines other than through modification of Appendix H requirements are also considered to be in scope. In other words, it would be possible to amend controls on the advertising of Schedule 3 substances by amendments to either or both the Scheduling Policy Framework and / or the Therapeutic Goods Act 1989 and Therapeutic Goods Regulations 1990).

Both the MMDR and stakeholder consultations conducted in late 2015 and 2016 have uncovered that there were a range of views on whether the restriction on direct-to-consumer advertising of Schedule 3 medicines (containing substances not included in Appendix H) should be lifted or altered. Some stakeholders argued that the ban on Schedule 3 advertising should be completely removed. A larger number of stakeholders were in favour of Appendix H instead becoming a list of Schedule 3 substances which cannot be advertised to the public, together with other controls in place on the nature of promotional and informational materials on OTC products that can be provided directly to patients by healthcare professionals. Finally, it was widely acknowledged that a ban on advertising of pharmacist-only medicines to the public was unique to Australia.

During the consultations, a range of options were proposed by stakeholders. These are shown in the highlighted box below.

Only some other countries have a legal differentiation between pharmacy-only and pharmacist-only products in their medicines regulatory frameworks. For example, in the UK, differences in the access of various OTC medicine types are written into pharmacy practice rules, not scheduling legislation. In the UK, advertising of all OTC medicines is permitted, although industry self-enforces a ban on some products, such as those containing codeine or pseudoephedrine in certain circumstances. When a product is down-scheduled from prescription to OTC in the UK, a communications and risk management plan is also required.

As with the proposal to adopt a risk-benefit methodology for scheduling consideration, we do not propose using a similar formal risk-benefit methodology for considering inclusions in Appendix H for advertising. However, stakeholder consultations to date identified support for removing Schedule 3 advertising from the SUSMP and incorporating the requirements into the TGA Advertising Framework. However, there are a range of views on what the requirements for advertising should be, with significant support to date for moving towards a "not permitted for advertising list" from a "permitted" (Appendix H) list. Another possibility is that the process for deciding whether a medicine containing a Schedule 3 substance can be advertised to the public could be undertaken by the TGA as part of the market authorisation of the product.

Advertising of Schedule 3 (Pharmacist only) medicines

We wish to obtain stakeholder feedback to support the development of options for government to consider around the reform of advertising requirements for pharmacist-only (Schedule 3) medicines. Some considerations include:

- Criteria for allowing advertising of medicines containing Schedule 3 substances under the TGA Advertising Framework.
- Possible retention of some form of "list" similar to Appendix H. We seek feedback on the alternatives of whether this would be a positive list (substances considered and permitted to be advertised, status quo) or a negative list (list of substances not permitted to be advertised to consumers, with anything off the list authorised to be advertised by default) from this public consultation.
- Any restrictions or requirements that should be applied to advertisements or other form of information provided for medicines containing these substances, e.g. mandatory and repeated mention that the product should be selected with the advice of a pharmacist, requirement to describe possible adverse events, requirement to emphasise that the particular OTC products containing the substance in question are only for short-term use.
- An exploration of what regulatory enforcement/compliance powers would be required in the event that restrictions for the advertising of S3 substances were changed, noting that the Government has agreed that advertising pre-approval processes should be removed once appropriate compliance and enforcement powers are in place (MMDR Recommendation 55).
- Relationship with possible additional requirements for pharmacist education and provision of information by patients (e.g. to declare that

they do not have certain pre-existing conditions for which the OTC medicine would be contra-indicated) at the point of sale, for particular medicines that have been down scheduled from S4 to S3.

- Consideration of a potential mechanism to allow sponsors to seek approval to advertise to the public products containing Schedule 3 substances as part of a market authorisation application for the medicine(s) in question.

Version history

Version	Description of change	Author	Effective date
V1.0	Template update	TGA Website & Regulatory Reforms Team	29/03/2017

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