Review of arrangements for scheduling substances under Part 6-3 of the Therapeutic Goods Act 1989 - summary of issues raised in written submissions, public forums and meetings and how the panel dealt with these issues

System of access controls

Section 52E Secretary to take certain matters into account

Issue raised	Source	Response	Report reference
Public health focus should be strongly supported	Forums and meetings	Panel agreed.	Chapter 4 - System of access controls - Recommendation 3
Practice issues should be taken into account	Submissions: PSA, PGA	Panel agreed this is within scope of the arrangements; greater clarity and transparency of issues considered by the Secretary or delegate needed.	Chapter 4 - System of access controls/Regulatory impact and practical issues in the decision-making process
Implementation matters should be taken into account	Submissions: PSA, PGA, ASMI Forums and meetings	Panel agreed this is within scope of the arrangements; greater clarity and transparency of issues considered by the Secretary or delegate needed.	Chapter 4 - System of access controls/Regulatory impact and practical issues in the decision-making process
Cost-benefit and/or regulatory impact assessment should be taken into account	Submissions: Accord, ASMI, PSA Forums and meetings	Panel noted OBPR and regulatory impact assessments are within scope of the arrangements.	Chapter 4 - System of access controls/Regulatory impact and practical issues in the decision-making process

Issue raised	Source	Response	Report reference
Information considered by the advisory committees and delegate should be public	Submissions: ADA, PSA, PGA Forums and meetings	Panel agreed that transparency is important but needs to be balanced against protecting personal, professional and commercial business information.	Chapter 4 - Clarity and transparency of process to amend the Poisons Standard
Circumstances when Secretary amends Poisons Standard on own initiative should be clear	Submissions: PSA, Accord, CHF Forums and meetings	Panel agreed that more information could be made available.	Chapter 4 - System of access controls/Clarity and transparency of process to amend the Poisons Standard
How the delegate exercises his/her power How risk/benefit and risk management decisions are made How the advisory committees and delegate applied the SPF	Submissions: PGA, Accord, ASMI Forums and meetings	Panel noted that secretariat and delegates are considering the level of detail to be included in a notice of decision. Panel recommended that level of detail, clarity and transparency contained in public notices is improved (Recommendation 1).	Chapter 4 - System of access controls/Clarity and transparency of process to amend the Poisons Standard
Policy oversight, development and maintenance of the Scheduling Policy Framework (SPF) and other guidelines relevant under s52E	Submissions: PSA, PGA, ASMI Forums and meetings	Panel recommended establishment of a mechanisms for policy oversight (Recommendation 2).	Chapter 4 - System of access controls/Scheduling Policy Framework for Medicines and Chemicals/ Policy oversight review and development

Issue raised	Source	Response	Report reference
Implications arising out of the proposed establishment of a trans-Tasman joint medicines agency	Submissions: Accord, ASMI Forums and meetings	Panel understands that implications for scheduling arrangements will be addressed.	Chapter 8 - Other matters/ Transition to the Australia New Zealand Therapeutic Products Agency
Need for more guidance on the: -matters the Secretary or delegate considers necessary to protect public health -approach for risk-benefit assessment -principles for decision-making criteria for excluding substances -approach to combination products -data and information requirements	Submissions: PSA, PGA, ASMI, APVMA Forums and meetings	Panel recommended that certain policy issues be considered (Recommendation 3).	Chapter 4 - System of access controls/Scheduling Policy Framework for Medicines and Chemicals/ More guidance on scheduling issues
Streamlining processes to enable: -greater flexibility for delegate-only decisions -regulatory agency decides whether scheduling consideration is warranted and/or make recommendation directly - ability to reject of defer applications	Submissions: Accord, ASMI, APVMA Forums and meetings	Panel recommended that certain process policy settings be considered (Recommendation 3).	Chapter 4 - System of access controls/Scheduling Policy Framework for Medicines and Chemicals/ Streamlining the scheduling processes

Issue raised	Source	Response	Report reference
Better alignment with regulatory registration/approval process	Submissions: PSA, ASMI, APVMA Forums and meetings	Panel noted effect on industry. The panel found that scheduling and regulatory processes should be aligned to the extent possible and encouraged further work to achieve this.	Chapter 6 - Effects of 2009 amendments on industry/process issues Chapter 8 - Other matters /Role, profile and integration of scheduling with other parts of regulation, policy and processes

Section 52EAA Application for amendment of the Poisons Standard

Issue raised	Source	Response	Report reference
Application template: -clarity and consistency when mandated -clearer and better structured format needed	Submissions: Accord, ASMI Forums and meetings	Panel recommended application requirements be clarified and made more flexible (Recommendation 4).	Chapter 4 - System of access controls/Application for amendment of the Poisons Standard
Facilitate electronic and hard copy	Submissions: CPA, Accord, ASMI, APVMA	Panel noted stakeholder preference that both electronic and hard copy formats are permitted.	Chapter 4 - System of access controls/Application for amendment of the Poisons Standard

Outcomes of administration

Section 52 A Definitions

Issue raised	Source	Response	Report reference
Clarity and guidance for definition of 'substance' Clarity on 'substance' being considered	Submissions: PSA, Accord, APVMA Forums and meetings	Panel agreed that development of guidance document could be beneficial.	Chapter 5- Outcomes of administration/Definitions
Specificity and clarity of schedule entries	Submissions: PSA, Accord	Panel noted that Secretary or delegate may ask advice on schedule entries.	Chapter 5 - Outcomes of administration/Definitions

Sections 52B, Section 52C and Section 52CA Function of the ACMS and ACCS and associated Regulations

Issue raised	Source	Response	Report reference
Membership of committees: -extend range of specialist expertise - include ACCC as observer -clarify observer role - applicant present to committees	Submissions: CPA, PGA. APVMA, ASMI, CMIC State and territory survey Forums and meetings	Panel found membership categories remain appropriate. Panel encouraged Secretary or delegate to seek specialist advice when needed. Panel encouraged ACCC to be observer. Panel encouraged chairs to clarify roles of observers. Panel notes that advisory committees can call on applicant if needed.	Chapter 5- Outcomes of administration/Functions of the ACMS and ACCS and associated Regulations/Membership of the committees

Issue raised	Source	Response	Report reference
Greater flexibility in how and when committees meet Reduce joint committee meetings Implement 24 month forward meeting timetable	Submissions: Member of ACCS, APVMA, Accord Forums and meetings	Panel noted that ad hoc approach to meetings may be impractical. Panel encouraged Secretary or delegate to refine circumstances when join meetings are required. Panel encouraged secretariat to develop a 24 month meeting timetable.	Chapter 5 - Outcomes of administration/Functions of the ACMS and ACCS and associated Regulations/Administrative arrangements of the committees
Trans-Tasman harmonisation supported	Submissions: PGA, ASMI Forums and meetings	Panel understands that arrangements for exchange of scheduling information exists.	Chapter 5 - Outcomes of administration/Functions of the ACMS and ACCS and associated Regulations/Committee - timelines and consultation processes

Issue raised	Source	Response	Report reference
Clarify roles and responsibilities of the secretariat, Secretary or delegate and the advisory committees	Submissions: PGA, Accord, APVMA Forums and meetings	Panel recommended development of a document to describe roles, responsibilities and relationships (Recommendation 6).	Chapter 5 - Outcomes of administration/Functions of the ACMS and ACCS and associated Regulations/Roles and responsibilities
Administration of advisory committees; secretariat sufficiently resourced	Submissions: ASMI Forums and meetings	Panel recommended prioritisation of business functions and resources (Recommendation 5). Panel recommended cost recovery project proceed (Recommendation 7).	Chapter 5 - Outcomes of administration/Functions of the ACMS and ACCS and associated Regulations/Roles and responsibilities

Section 52 D Amendments to the Poisons Standard and associated Regulations

Issue raised	Source	Response	Report reference
Timelines for processes Timeliness of public information Timeframe for implementation of decisions	Submissions: PSA, PGA, Accord, ASMI, APVMA State and territory survey Forums and meetings	Panel found clarity and transparency regarding timelines could be improved.	Chapter 5 - Outcomes of administration/Functions of the ACMS and ACCS and associated Regulations/Committee timelines and consultation processes
Adequacy of information about proposals and decisions	Submissions: PSA, PGA, Accord Forums and meetings	Panel noted that secretariat and delegates are considering the level of detail to be included in a notice of decision. Panel recommended that level of detail, clarity and transparency contained in public notices is improved (Recommendation 1).	Chapter 4 - System of access controls/Clarity and transparency of process to amend the Poisons Standard
Increase communication of decisions to public	Submissions: PSA, PGA, Accord, ASMI Forums and meetings	Panel noted that TGA communication and education reforms provide opportunities for increased communication.	Chapter 8 - Other matters/Role, profile and integration of scheduling with other parts of regulation, policy and processes

Issue raised	Source	Response	Report reference
Accuracy and administrative burden of redacting	Submissions: PSA, ASMI	Panel recommended prioritisation of business functions and resources (Recommendation 5).	Chapter 5 - Outcomes of administration/Functions of the ACMS and ACCS and associated Regulations/Roles and responsibilities
User-friendliness of website	Submissions: PGS, Accord Forums and meetings	Panel noted that TGA communication and education reforms provide opportunities for increased communication.	Chapter 8 - Other matters/Role, profile and integration of scheduling with other parts of regulation, policy and processes

Avenues for review

Issue raised	Source	Response	Report reference
Applicants should have access to full range of review processes	Submissions: PGA, Accord, ASMI, CSL Behring Forums and meetings	Panel found no indication that a review mechanism is required (Recommendation 8).	Chapter 7 - Avenues for review

Issue raised	Source	Response	Report reference
Uncertain how review mechanism would operate Efficiency of scheduling process should not be reduced Publication of interim decision provides an avenue to review the proposed decision	Submissions: Accord, PGA Forums and meetings	Panel found no indication that a review mechanism is required (Recommendation 8).	Chapter 7 - Avenues for review
As no avenues for review, greater transparency needed	Submissions: ADA, Accord, ASMI Forums and meetings	Panel noted that secretariat and delegates are considering the level of detail to be included in a notice of decision. Panel recommended that level of detail, clarity and transparency contained in public notices is improved (Recommendation 1).	Chapter 4 - System of access controls/Clarity and transparency of process to amend the Poisons Standard

Other matters

Issue raised	Source	Response	Report reference
Scope of review should encompass all aspects of scheduling	Submissions: ASMI Forums and meetings	For matters that were broader than the current operation of Part 6-3 the panel made a number of observations throughout the report and in Chapter 8.	Chapter 8 - Other matters

Issue raised	Source	Response	Report reference
Better integration with other parts of regulation, policy and processes	Submissions: CMIC, CHC, Accord, ASMI, APVMA, CHF Forums and meetings	Panel noted effect on industry. The panel found that scheduling and other relevant policies and processes should be aligned to the extent possible and encouraged further work to achieve this.	Chapter 6 - Effects of 2009 amendments on industry/Process issues Chapter 8 - Other matters /Role, profile and integration of scheduling with other parts of regulation policy and processes
Lack of profile of chemicals scheduling	Forums and meetings	Panel noted that TGA communication and education reforms provide opportunities for increased communication.	Chapter 8 - Other matters/Role, profile and integration of scheduling with other parts of regulation, policy and processes

Issue raised	Source	Response	Report reference
Exclusivity provisions for rescheduling applications	Submissions: ASMI	The panel did not review this matter. Exclusivity considerations are relevant and regulated for the purpose of access to market through registration/approvals.	
Pharmacovigilance of rescheduled substances	Submissions: PSA Forums and meetings	The panel did not review this matter. Mandatory adverse experience reporting mechanisms are already in place for therapeutic products, agricultural and veterinary chemical products and consumer goods.	
Poor alignment in access controls	Forums and meetings	Panel noted complexities arising from inconsistencies in state and territory approaches to impose regulatory controls on substances.	Chapter 8 - Other matters/Importance of consistency in state and territory medicine and chemicals access controls
Certainty regarding future work and ongoing use of Schedule 2 and 3	Submissions: PGA, ASMI	The panel did not review this matter. The operation of Schedule 2 and 3 is separate AHMC project and Galbally review recommendation.	

Issue raised	Source	Response	Report reference
Enhance consumer understanding of the basis and implications of scheduling decisions	Submissions: CHF Forums and meetings	Panel noted that TGA communication and education reforms provide opportunities for increased communication.	Chapter 8 - Other matters/Role, profile and integration of scheduling with other parts of regulation, policy and processes
Approaches to reclassification of medicines in different countries	Panel contact by overseas researcher	The panel considered this to be outside its terms of reference and did not review this matter.	

Key performance indicators

Issue raised	Source	Response	Report reference
Various suggestions for key performance indicators provided	Submissions: Accord, APVMA State and territory survey Forums and meetings	Panel encouraged the collection of data to facilitate any future review of the scheduling arrangements.	Chapter 8 - Other matters

Acronyms

ACCS – Advisory Committee on Chemicals Scheduling

ACMS – Advisory Committee on Medicines Scheduling

ADA – Australian Dental Association

AHMC – Australian Health Ministers' Conference

APVMA – Australian Pesticides and Veterinary Medicines Authority

ASMI – Australian Self Medication Industry

OBPR – Office of Best Practice Regulation

PGA – Pharmacy Guild of Australia

PSA – Pharmaceutical Society of Australia

RIS – Regulation Impact Statement

SPF – Scheduling Policy Framework for Medicines and Chemicals

TGA – Therapeutic Goods Administration