Review of medicines and poisons scheduling arrangements

May 2013

Agenda

- Introductions
- Terms of reference for the review
- Summary of issues raised in submissions
- Outline of areas the panel specifically wishes to discuss
- General discussion
- Detailed discussion on key issues raised during forum

What this review is about

- Independent review of the operation of Part 6-3 of the *Therapeutic Goods Act 1989*
- Particular reference to the amendments of 2009

Background and context

- National Competition Policy Review of Drugs, Poisons and Controlled Substances Legislation (Galbally review) 2001
- Chemicals and Plastics Regulation Productivity Commission Research Report 2008
- Report of the Senate Standing Committee on Community Affairs inquiry 2009

Other sourced documents

- Explanatory Memorandum to amendment bill
- Hansard record 9 September 2009
- Submissions to Senate Standing Committee inquiry

Objective of the amendments to 6-3

- Replacement of the National Drugs and Poisons Scheduling Committee
- Secretary responsible for scheduling decisions
- Two expert advisory committees to provide advice
- Changes to definitions
- Updated instruments to apply as they are revised

Requirements for this review

The review must report on:

- the system of access controls
- the outcomes of the administration
- the effect of the amendments on industry
- avenues for review of decisions
- make recommendations for further changes to the regime

Requirements for this review

The review must:

- start by 1 July 2013
- be completed within 6 months
- invite and consider public submissions

How we are consulting

- Inviting public submissions
- Department of Health and Ageing website
- Links from other Australian Government websites
- Direct contact with key stakeholders
- Newspaper advertisements
- Teleconferences with ACMS and ACCS
- Survey of state and territory officials
- Forums and meetings with selected key stakeholders

Summary of submissions

Objectives of the amendments

- broad support for the new arrangements, including separation of chemicals and medicines
- scope to make arrangements more efficient and effective
- work is needed on the *Scheduling Policy Framework* (SPF)

Summary of submissions

System of access controls

- increased transparency needed
- policy and process work is required is several areas
- ongoing responsibility for the SPF and other NCCTG guidelines needs to be identified
- roles of various players need to be clarified
- harmonization with NZ is needed
- specific expert advice should be sought on plant based substances

Summary of submissions

Outcomes of administrations: definitions

- definitions generally acceptable
- definitions are quite broad
- SPF should be used to clarify ‘groups’ of similar substances
- further guidance of how to interpret could be provided in SPF

Summary of submissions

Outcomes of administrations: functions of the advisory committees

- Include ‘registered health practitioner’ and/or ‘practicing pharmacist’
- Observer status of APVMA and NICNAS could be formalised
- Applicants / sponsors could be observers
- Examine timelines for various processes
- How and when committees meet could be more flexible
- Implement concurrent consultative processes of scheduling and regulators

Summary of submissions

Outcomes of administrations: amendments to the Poisons Standard

- Process generally seen as clear
- SPF should reflect current practices
- Interim decisions contrary to ACCS/ACMS advice should be referred back to the relevant committee(s)
- Clarification on process of rescheduling is needed

Summary of submissions

Outcomes of administrations: regulations relating to proposed amendments

- Most found no difficulties
- Issues were raised around the:
  - timeliness of public information
  - timeframes for implementation of decisions
  - adequacy of information about proposals
  - accuracy and administrative burden of redacting
  - user-friendliness of the TGA website

Summary of submissions

Avenues for review

- Should be generally required as a matter of principle
- Regulators have avenues for review
- Unsure how it would work in practice
- Do not want efficiency of scheduling process reduced

Summary of submissions

Other matters

- Interface with other associated regulatory controls
- Pharmacovigilance of rescheduled substances was proposed
- Certainty is needed regarding S2 & S3
- Risk management of OTC medicines
- Better integration of regulators and scheduling
- Consequences for recommendations and decisions for widely used substances

Timetable for the review

- March - review commenced
- April - public call for submissions
- May - identification of further information needs
  - forums and meetings with key stakeholders
- June - draft report and recommendations written
- July - final report and recommendations written
- August - preparation of report for presentation to Parliament
- September - report delivered to Minister for tabling

Today's discussion

- What works (and why)
- What does not work (and why)
- What needs to be changed (and how)
- Information/evidence needed to support arguments for/against change