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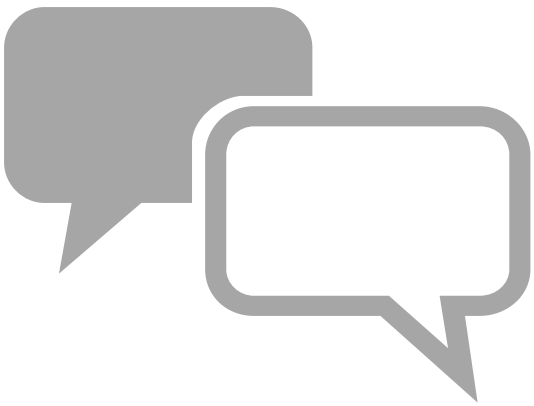

Department of Health
Review of Medicines and Medical Devices Regulation – First Report

Stakeholder Forums

Summary of feedback

Unapproved Products Forum

6 August 2015

Recommendations 24-26

In collaboration with:

Industry associations

Consumer groups

Clinical and professional groups

Government agencies

In consultation with:

THINKPLACE
Bridging vision and reality

Key themes emerging from the forums – Stakeholder comments

Efficiency without lowering the standard of regulation

Stakeholders want more streamlined processes and reduced duplication, but do not want to see a reduction in the current high standard of regulation in Australia.

The devil is in the detail

Ongoing engagement with stakeholders throughout the design process will be critical in ensuring the long-term success, viability and uptake of the Reviews recommendations and that expectations are met.

Enhanced post market monitoring

Stakeholders consider it essential that any changes in pre-market assessments needs to be balanced by more robust post-market monitoring and appropriate enforcement.

Ensure sufficient resourcing for the Therapeutic Goods Administration

Stakeholders acknowledge that implementation and ongoing management of the changes suggested by the recommendations would require reallocation of resources within Therapeutic Goods Administration (TGA). Stakeholders identified sufficient resourcing for the TGA as essential for the successful implementation of the recommendations discussed.

Decision-Making Structure

Further work will need to be undertaken in considering how Recommendation 29 would work in practice and possible alternatives to the proposed structure of the regulator, that will bring greater transparency to the current decision making process and opportunities for greater engagement by sponsors and consumers.

Unapproved Products Forum

6 August 2015

Recommendations 24, 25, 26

Main points discussed by the stakeholders about recommendations in focus:

Benefits

- An online system for managing the Special Access Scheme (SAS) and the Authorised Prescriber Scheme has potential to provide:
  - Increased transparency and oversight of the processes.
  - Greater capacity to capture important data regarding safety, adverse events, supply patterns, efficacy, off-label use and other observations.
  - Better management of 6-monthly reports from suppliers.
- The changed processes have potential to create efficiencies including:
  - Less administrative / regulatory burden for prescribers.
  - Shifting resources to analyse what is being used and by whom, and adverse events.

Risks

- Misuse or 'gaming' of the system, such as:
  - Process used as an alternative to registration (creation of a de facto market).
  - Process used as an alternative for a section 19A application (e.g. where the sponsor seeks regulator approval in the event of medicine shortages), which may pose greater risk due to different formulations and language.

Unapproved Products Forum

6 August 2015

Recommendations 24, 25, 26

Main points discussed by the stakeholders about recommendations in focus:

Considerations

- Any changes to existing processes must result in a reduction of paperwork/time for prescribers.
- Protection of privacy must be considered in the development of an online system.
- What will be the process for inclusion of products on the list of pre-authorised medicines or medical devices for Category B?:
  - How will this happen?
  - Can other stakeholders (such as peak bodies or registries) apply to have products added?
  - What would be the application process?
  - How long would any such process take?
- The criteria for identifying Category B SAS list of medicines/medical devices subject to automatic approval is to be developed by the regulator in conjunction with relevant stakeholders.
- Direct links to health care professional (HCP) prescribing software would be beneficial.
- Further work needs to be undertaken in reviewing authorised prescriber (AP) arrangements, in particular who can be endorsed as an authorised prescriber.
  - Colleges: There are often multiple specialties represented by a single college. It is important that AP status can be given based on endorsement by one of the specialty societies where the College does not have the relevant expertise.
  - Ethics committees: Must have the appropriate expertise to endorse / authorise a prescriber. Look at alternatives such as hospital DTCs?
- What will be the process for handling re-supply of products?
- Resourcing capacity will need to be considered in the creation of new IT systems which need to be fast and secure.
- Any changes to Category B process will need to be accompanied by comprehensive guidance, possible training and online educational activities for prescribers/users .
- Category A for emergency and life-threatening treatments: Category A usage not being notified and is open for opportunists. Investigate ways of pre-qualifying suppliers to ensure that hospitals (and patients) get a quality product.
- The development of an online system presents an opportunity for better data on Category A products and usage.

Recommendations in focus

Recommendations 24, 25, 26

Recommendation twenty four

The Panel recommends that:

1. The current criteria and processes for Category A SAS remain unchanged
2. The Australian NRA develop and apply transparent criteria for identifying Category B applications that could be subject to automatic approval. Such criteria might include applications for products that:
    A. Were previously registered in the ARTG for the proposed indication and were not cancelled or withdrawn for safety reasons;
    B. Have been approved for the proposed indication by a comparable overseas NRA;
    C. Have been deemed by the Australian NRA as suitable for automatic approval for treatment of a particular indication; and
    D. Have been approved by the Australian NRA under Category B in response to a medicine shortage, in circumstances where there is no need to triage the use of the unapproved product.
3. The Australian NRA continue to require individual assessment and approval for certain Category B products, including products that:
    A. Do not have a history of safe use for the proposed indication through either the SAS scheme or in comparable overseas markets;
    B. Have not been approved for the proposed indication by a comparable overseas NRA;
    C. Were cancelled or withdrawn from the ARTG for safety reasons, or had an application for registration rejected by the Australian NRA for safety reasons;
    D. Were previously approved overseas but were withdrawn or removed from the market for safety reasons; and
    E. Have been approved by one comparable overseas NRA for an indication but were rejected by another comparable overseas NRA for that indication.

Recommendation twenty five

The Panel recommends that the NRA establish an integrated, online system to manage SAS notifications, approvals and reporting requirements. Such a system should have capacity to:

A. Establish a Schedule of Category B Products that are eligible for automatic approval;
B. Allow clinicians to enter a restriction code to auto-populate information relating to SAS notifications, automatic approvals and applications;
C. Utilise smart-forms to reduce unnecessary administrative burden on clinicians and sponsors; and
D. Provide data for real-time monitoring of the SAS by the Australian NRA, to identify potential trends and abuses.

Recommendation twenty six

The Panel recommends that the role of the NRA under the Authorised Prescriber Scheme should be to authorise a prescriber, and the supply of an unapproved medicine or device to that prescriber, in circumstances where it is satisfied that:

1. Approval for the prescriber to use the unapproved medicine or device in the proposed patient cohort has been provided by a properly constituted ethics committee; and
2. There is no medicine or device available in the ARTG that would be suitable in the proposed circumstances; and
3. There are no emerging safety concerns in respect of the medicine or device that may alter the consideration of risk and benefit.

Australian Government

Department of Health

Further Information

If you would like more information on the Review of Medicines and Medical Devices Regulation, please contact the Department of Health.

Email: MMDReviewTaskforce@health.gov.au

Phone: (02) 6289 1404 (MMD Review Taskforce Hotline)

Website: http://www.health.gov.au/internet/main/publishing.nsf/Content/Expert-Review-of-Medicines-and-Medical-Devices-Regulation

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