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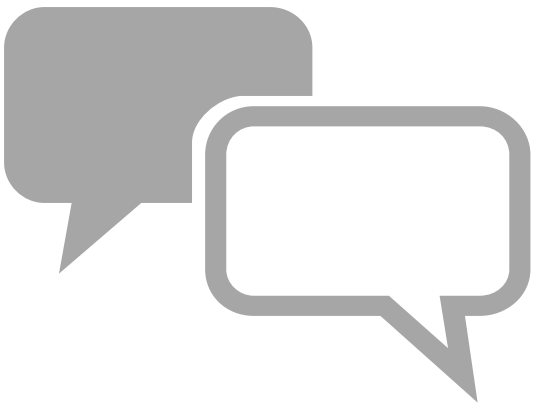

Department of Health
Review of Medicines and Medical Devices Regulation – First Report

Stakeholder Forums

Summary of feedback

Devices Forum

6 August 2015
Recommendation 19

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 Review 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 decision making structure of the regulator, that will bring greater transparency to the current decision making process and opportunities for greater engagement by sponsors and consumers.

Devices Forum

6 August 2015

Recommendation 19

Main points discussed by the stakeholders about recommendations in focus:

Benefits

- Pathway 3 (expedited assessment of innovative devices in certain circumstances) could foster innovation (first mover advance).
- Potentially earlier access to market and earlier access by patients to treatments / diagnosis not previously available.
- Potentially achieve better outcomes for patients / consumers.

Risks

- The uptake of Pathway 3 will largely be dependent on criteria for "novel". Ensuring a clear definition, that has been fully-canvassed with stakeholders and articulated comprehensively in guidance materials will be important for the success of the recommendation.
- Lowering of evaluation / assessment standards if approval of a device is given with less evidence.
- Novel technology brings with it less quantifiable, and greater risk. There is potential for increased risks, due to increased speed to market and reduction of information, which has potential to cause harm to consumers.
- Use of Pathway 3 for commercial advantage (note: balanced by group with encouragement of innovation).
- Unintended commercial advantages for sponsors using Pathway 3 if later applicants for the same kind of device have to provide more information because no longer "novel".
- Inefficient use of regulator resources / committee resources in determining whether device is "novel". Re-direction of resources could mean slower approvals for non-novel devices.
- Query whether "novel" is different from "unmet need" concept and which should be used.

Devices Forum

6 August 2015

Recommendation 19

Main points discussed by the stakeholders about recommendations in focus:

Considerations

- The details of design need to be considered in collaboration with stakeholders. For example:
  - Clear definition of a “novel” device.
  - Is fast track (with less evidence) appropriate for implantable devices which pose a higher risk?
  - Appropriate conditions should be imposed to ensure effective post-market monitoring (e.g. clinical data to be provided).
  - If the device is to be identified as coming through this pathway on the basis of less data (including particular conditions), what is the process for removal of conditions?
    - Should not be costly for the sponsor.
    - Conditions imposed will need to be predictable.
  - Criteria – Need different criteria for different types of devices?
  - Need for a stronger feedback loop (monitor data collection, link to pre-market etc.).
  - What will be the process for follow up once device in the market?
  - Should the definition focus on public health/unmet need rather than whether “novel” (which may be susceptible to gaming).

Devices Forum

6 August 2015

Recommendation 19

Main points discussed by the stakeholders about recommendations in focus:

Other

- The adequate resourcing of the regulator will need to be considered when adopting an accelerated Pathway, to ensure that the operation of other pathways are not compromised.
- Regulator timeframes need to be realistic and commensurate to the level of data available.
- Commercial viability of designated bodies setting up shop in Australia is low. Ease of obtaining European Certification (CE mark) is a major barrier to this.

Main points raised about other Recommendations:

Recommendation 29

- Comment was made that recent TGA business process improvements have resulted in better engagement between the TGA and sponsors (particularly SMEs). In making changes to the decision-making structure, it will be important to ensure that recent positive improvements are not unravelled.

- In addition, there was concern that changing the decision–making structure could slow the current process down – noting that the evaluation component of the process would take the same amount of time and the evaluation would go to the new Committee for either Medicines or Devices for decision, not the submission itself.

Recommendation in focus

Recommendation 19

Context of Recommendation nineteen

Recommendation nineteen sits within a suite of recommendations aimed at improving the regulatory framework for medical devices. These issues can be broadly categorised as:

1. Reducing duplication in the pre-market assessment of medical devices.
2. Enhanced harmonisation of regulatory requirements with the EU.
3. Enhanced transparency of processes and timeframes to manage the complex and poorly understood framework and to assist those who have to interact with it.
4. Enhanced post-market monitoring.
5. Threshold issues for 'devices'.

Recommendation 15 suggests that in order to provide timely access to devices that are safe, high quality and fit for purpose, there be multiple pathways to seek approval for the inclusion of medical device in the ARTG.

Of these multiple pathways, the Panel recommends that there be a pathway which provides for expedited assessment of innovative devices in specific circumstances (Recommendation 15, Pathway 3).

While this pathway may not be utilised very often, such a provision will enhance flexibility.

As such, Recommendation 19 suggests that the Australian NRA should develop criteria, in consultation with health care consumers, health practitioners and industry, under which application may be made for accelerated assessment of novel medical devices for inclusion in the ARTG using this pathway.

Recommendation nineteen

The Panel recommends that

1. The Australian Government develop transparent criteria under which application may be made for accelerated assessment of novel medical devices for inclusion in the ARTG.

2. In circumstances where accelerated assessment is granted, the Australian NRA have capacity to place conditions on the inclusion of the medical device in the ARTG.

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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