Section 3: Delivering an option

How will the new arrangements be implemented?

162. Decisions on who would implement the new regulation will be subject to future government decisions. Implementation will include development of secondary legislation which will set out details of the system, particularly elements which are likely to need to change over time.
163. The market authorisation system will be operated and enforced by the Crown. The form of any regulator is discussed in a separate Cabinet Paper.
164. The regulation of medical devices will change significantly. This will require several years to enable a smooth transition period, in addition to the time needed to develop secondary legislation.
165. Education campaigns are likely to be needed for healthcare professionals, industry and the public, where there are significant changes from the status quo.
166. The Ministry of Health will retain a stewardship and oversight role.
167. As with all new systems, there is significant risk of time and cost over-runs. There are lessons New Zealand can learn from its existing regime for medical devices. In addition, comparable jurisdictions, such as Australia, have already undergone similar regulatory reform, and we can learn from their experiences. Costs can be contained in the design of the different pathways for market authorisation, in particular those involving reliance and notification.

Transition

168. There will need to be sufficient transition periods for regulatory requirements to come into force for medical devices.
169. Requirements will likely need to be implemented in phases, where requirements are gradually increased over time.
170. Lessons can be learned from the implementation of the Medical Device Regulation and In-Vitro Diagnostic regulations in the European Union and other jurisdictions, where the introduction of new requirements led to many medical devices being unable to be supplied because of administrative backlogs.
171. Stakeholder feedback on the TPA implementation was that the transition periods (six months, three years and five years) were insufficient, and the regulator would not have the capacity to assess the many thousands of in-market medical devices over the transition period.

How will the new arrangements be monitored, evaluated, and reviewed?

172. The regulator will have reporting requirements, to be determined as part of policy work on the form and responsibilities of the regulator. The metrics are likely to include:
    - time taken to approve medical devices via the various pathways
    - time taken to process registration for controlled activities
    - compliance and enforcement action taken.
173. Potentially there will be a review of the new system within five years of it taking effect.
174. The medical devices industry and the healthcare sector have productive relationships with the Ministry and Ministers of Health. We expect them to be proactive in raising any problems or concerns with the new system.
175. Work will be needed on how to ensure that patient/consumer problems with the new system are heard and responded to.