MMDR Regulatory Burden Costing - Medical Devices Feedback

Changes marked in red text in spreadsheet: Calculation of regulatory burden measurement by E and Y for MMDR 19 1 16 - MDB feedback (TRIM Ref: R16/39259).

<table>
<tr><th>Tab</th><th>Cell Ref</th><th>Issue / Suggested Change</th><th>Notes</th></tr>
<tr><td colspan="4">Device Change Requests (DCR)
Line area suggested these also included DCR given they reflect a significant workload. These are a parallel workflow for variations.</td></tr>
<tr><td>Assumptions calcs</td><td>D581 plus K:581:M581</td><td>Assume 50% of these relate to high risk devices (approx. based on advice from line area).</td><td>DCR for high risk devices are equivalent workload as for device variations (very similar process).</td></tr>
<tr><td>Assumptions</td><td>D547</td><td>DCR included in ‘Successful variations’ numbers (included as Class III)</td><td></td></tr>
<tr><td colspan="4">NOTE: Amendments do flow through to the calculations (eg Summary tab, rows 105-118) – needs to be verified (minor changes)</td></tr>
<tr><td colspan="4">Selected for Audit
Had previously supplied ‘completed - audit’ figures (to align with other completed application figures) – line area suggests that ‘selected – audit’ would be a more appropriate reflection of workload. A significant number of audit applications will not be completed eg those withdrawn by applicants advised the application likely to be rejected, those unable to provide additional data requested. While the application is not completed, the workload of audit assessment has largely been completed. Using only the completed applications misses this workload.</td></tr>
<tr><td>Assumptions calcs</td><td>Row 612</td><td>Added as ‘Selected and audited, but application not completed’
Actual ‘selected’ figures:<table><tr><td>2011</td><td>2012</td><td>2013</td><td>2014</td><td>2015</td></tr><tr><td>365</td><td>335</td><td>426</td><td>367</td><td>367</td></tr></table></td><td>Figures included are the net difference from ‘Completed’ figures (in rows 607 – 611)</td></tr>
<tr><td></td><td>Row 614</td><td>Formula amended to include row 612</td><td></td></tr>
<tr><td colspan="4">Conformity assessment Timeframes – Assumption for Notified Bodies
We had advices use of a 90 (calendar day) timeframe for the delay of undertaking conformity assessment with a notified body. This was the figure previously advised by industry and used in the Australian manufacturers RIS.
Further advice indicates this is too short, given changes in the past couple of years in Europe in tightening requirements for notified body assessments: eg:
Position paper from Team NB issued October 29 2015 states that:
“The quotation process is now longer than before (2 -3 month instead of 1 week to 1 month; and The time from contract signature, either for a new client or a scope extension with an existing client, to audit planning is now around 6 months although it was usually around 3 months in the past; the same delay might occur for the start of dossier reviews.” (emphasis added)
Use of 6 months (180 calendar days) as opposed to 3 months (90 calendar days) could be supported on this basis. However this would make the CA timeframe for notified bodies longer than the current TGA average.</td></tr>
<tr><td>Assumptions</td><td>Row 606</td><td>Change to reflect 6 month (180 calendar day) timeframe
Median working days – 129
Median calendar days - 180</td><td>Note the 90 days timeframe was a calendar day figure – working and calendar day calculations adjusted accordingly.</td></tr>
<tr><td></td><td>Row 614</td><td>Adjusted – TGA takes less time for variations cf conformity assessment (40% - 60 working days for variation compared to 151 for CA) – have</td><td></td></tr>
</table>

		amended estimated NB timeframe to reflect a similar proportion (previously use CA timeframe of 90 days for both). Median working days – 51 Median calendar days – 72	
NOTE: This 6 month estimate may conflict with the perception of industry stakeholders, who will be basing their experience of notified body timeframes on a longer time period. Certificates typically are valid for 5 years – this means around 60% of certificates would not have been renewed since the tightening of European oversight of notified body operations, so up to 60% of applicants may have no direct experience of the changed European arrangements. If this is a concern suggest that 120 calendar days (reflecting 4 months) or 150 calendar days (5 months) could be used to reflect the likely balance of industry perception.			

Registries

There was some discussion about the registries costing. It should be noted that costs incurred by Government (Commonwealth or state) are not included in deregulatory costings, and any fees and charges from Government (including where these are under cost recovery arrangements) are also excluded.

Also it should be noted that these are deregulatory costings, and do not include the Commonwealth implementation or ongoing costs. For example contracts with Universities etc to establish and operate registries etc, (estimated at around $1.2m (establishment) and $2.4m (ongoing) per registry – proposal for all high risk implantable to be covered would result in between 8 and 12 device group registries, depending on configuration).

(Assumptions for these costing are on the Assumptions tab, rows 646-673)

Specific concerns included:

- **Costs included only private sector costs**
  Costs to public hospitals cannot be included as we are told that costs to governments/ government employees can't be included. These costs have **not** been included.
- **Costs of establishing registries not included**
  Where the cost of establishing registries is paid for by either the taxpayer or via cost recovery (such as through increased annual charges or a cost recovery levy on affected ARTG entries) these cannot be included as a regulatory burden. These costs have **not** been included.
- **Initial training costs can possibly be included:**
  Initial cost in training and in "set up" within the private hospitals this could be counted as a one off costs of some millions. The assumption discussed with E&Y, with an assumed half day of training (3.5 hours) every two years for affected staff (theatre nurses or support staff typically tasked with completing registry data returns). These costs **are** included for private hospital procedures.
- **Private specialist working in rooms:**
  May consider whether private specialists working in rooms but outside the private hospital system would implant any of the high risk devices. There may be some procedures using these high risk implantable devices in the private rooms context. However there is no available data on the number of these procedures. Overall numbers are assessed as likely to be low, given the nature of the devices (typically requiring significant surgery). As such, these costs have **not** been included.

Net Change to Costing:

Current (inc TGA amendments)

Medical devices	Base Case Average per year	Scenario 1 Average per year	Average annual change in regulatory burden Negative = increase in regulatory burden Positive = reduction in regulatory burden
Administrative costs	**$665,527**	**$1,589,095**	**-$923,568**
Engagement with TGA during compulsory application audits	$665,527	$209,515	$456,012
Engagement with TGA during expedited approvals (Pathway 3)	$0	$162,726	-$162,726
Operation of register for high risk devices	$0	$1,216,854	-$1,216,854
Delay costs	**$24,238,723**	**$13,250,789**	**$18,765,115**
Value of delay getting to market due to compulsory application audits	$24,238,723	$7,630,617	$16,608,105
Value of additional days on market due to shorter conformity assessment timeframe under Pathway 1B	$0	$3,578,293	$3,578,293
Value of additional days on market due to accelerated approval under Pathway 3	$0	$310,297	$310,297
Variations - reduced delay costs due to shorter conformity assessment timeframes under Pathway 1B	$0	$1,731,581	-$1,731,581
TOTAL			**$17,841,547**

Previous (E&Y version)

Medical devices			
Administrative costs	**$521,544**	**$1,543,768**	**-$1,022,223**
Engagement with TGA during compulsory application audits	$521,544	$164,188	$357,356
Engagement with TGA during expedited approvals (Pathway 3)	$0	$162,726	-$162,726
Operation of register for high risk devices	$0	$1,216,854	-$1,216,854
Delay costs	**$24,238,723**	**$17,582,843**	**$26,560,331**
Value of delay getting to market due to compulsory application audits	$24,238,723	$7,630,617	$16,608,105
Value of additional days on market due to shorter conformity assessment timeframe under Pathway 1B	$0	$9,641,929	$9,641,929
Value of additional days on market due to accelerated approval under Pathway 3	$0	$310,297	$310,297
Variations - reduced delay costs due to shorter conformity assessment timeframes under Pathway 1B	$0	$0	$0
TOTAL			**$25,538,108**

TRIM Ref: R16/41506