[redacted]

From: [redacted]
Sent: Wednesday, 23 December 2015 1:25 PM
To: [redacted]
Cc: [redacted]
Subject: FW: RIS costings Devices - R15-21 [SEC=UNCLASSIFIED]
Attachments: R15-21 Devices - agreed outcomes and data request.pptx

Importance: High

Follow Up Flag: Follow up
Flag Status: Flagged

Dear All

Please see the request below for data. The taskforce would like as much information as possible to assist in a meeting on 8 January.

[redacted]

From: [redacted]
Sent: Wednesday, 23 December 2015 12:53 PM
To: [redacted]
Cc: MMD Review Taskforce; [redacted]
Subject: RIS costings Devices - R15-21 [SEC=UNCLASSIFIED]
Importance: High

Hi [redacted],

Please find attached the write up of the RIS costings workshop on variations (R13). Could you please forward on to the TGA attendees for comment and follow up on actions items?

As discussed in the previous email EY will be meeting with Dep Sec Skerritt on 8 January to discuss the RIS costings so it would be great if could get as many as possible of the items below actioned in time for that meeting.

Action Items

- TGA to provide number of sponsors (devices) over last 5 years in order to determine if the number of sponsors is increasing/decreasing.
- TGA to provide 5+ years historical data on:
    - Number of pathway one applications
    - Number of successful pathway one applications
    - Number of pathway two applications
    - Number of successful pathway two applications
- TGA to confirm that there is no comparable overseas regulator that we can benchmark against for our estimated uptake of the expedited approval pathway (i.e. 5%)
- TGA to provide 5 year history on number of applications for Class II b implantables and Class III devices.
- TGA to 5+ years historical data in relation to Class IIb implantables, Class III devices and IVD (class IV and point of care (POC)) for:
    - Number of applications
    - Number of successful applications
    - Number of applications subject to audit
    - Number of level 1 audits

    - Number of level 2 audits
    - % subject to application audit if Review recommendations are implemented – i.e. a proportion of the 10 big notified bodies.
- TGA to provide an estimate of time taken by sponsor to respond to TGA during an application audit.
- TGA to provide 5+ years historical data on the time taken to conduct:
    - Level 1 application audits.
    - Level 2 application audits.
- TGA to provide detail on potential reductions in timeframes that could be achieved through using notified bodies in Australia (proposed pathway 1B) based on previous work done by Deloitte looking at time taken to undertake conformity assessment.
- TGA to provide an estimate of the reduction in assessment time that could be achieved under pathway 3 (expedited approval).
- TGA to provide an estimate of the likely decrease or increase in time spent by the sponsor doing an application under pathway 3.

Workshop attendees

[redacted]
RPS
Taskforce
[redacted]

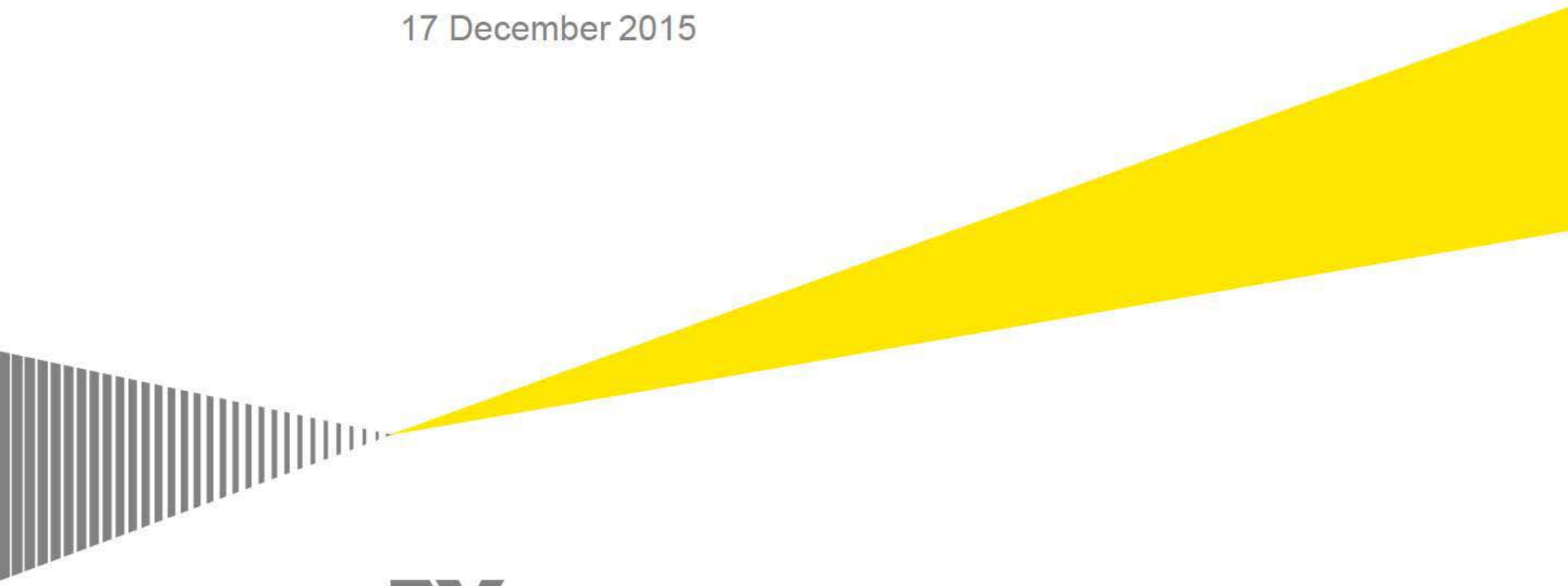
Regards

[redacted] | Medicines and Medical Devices Review Task Force | Best Practice Regulation Branch | Health Systems Policy Division | Australian Government Department of Health | [redacted] | GPO Box 9848 | Woden ACT 2601 | [redacted]

Medicines Regulatory Reform: Regulation Impact Statement

Regulatory Burden Measurement

17 December 2015



EY
Building a better working world

Understanding the new regulatory framework

Calculation:

Time take to assess new regulatory framework (hours per application) x cost per hour of employee assessing framework

Component	Metric
Time taken to understand new regulatory framework* - understand changes to Pathways - changes in TGA approach to application audits - approach to variations - changes to post-market monitoring	1 day of training per sponsor TGA to provide information on the number of sponsors (ideally around 5 years of history to allow me to determine if the number of sponsors is increasing/decreasing and, if so, determine a trend growth rate).
Cost per hour of employee	Professional wage rate

* One year impact only

QUESTION: Clarify relationship between a sponsor and manufacturer

Split of applications between Pathways

	Number of applications	Current number of successful applications
Pathway 1	TGA to provide (ideally 5+ years of history)	TGA to provide (ideally 5+ years of history)
Pathway 2	TGA to provide (ideally 5+ years of history)	TGA to provide (ideally 5+ years of history)
Pathway 3	N/A – doesn't currently exist	N/A – doesn't currently exist

Information requirement from TGA

At least 5 years (7-10 if possible) of historical data showing the number of applications and the number of successful applications

Total applications (2014)	*3,046 applications (excluding IVD)*	
Class I (measuring and sterile)	196 applications	low-medium risk
Class II a	1,355 applications	low-medium risk
Class II b	707 applications	medium –high risk
Class III	788 applications	high risk
IVD (all classes)	462 applications	classified in classes

	Current (% of applications)	Future – immediate (% of applications)	Future – long run (% of applications)
Pathway 1	Estimate using data provided above		
Pathway 2	Estimate using data provided above		
Pathway 3	0%	5% of Class II b implantable and Class III (phased in over three years)	

Compulsory application audits – reduced delay costs

Calculation
Delay costs
Time taken to undertake application audit x number of submissions subject to audit x profit per day
Administration costs
Time taken for sponsor to engage with TGA during application audit x number of submissions subject to audit x cost of employee time

Narrative: Over time, TGA will build confidence in a subset of Designated Authorities (Pathway 2A) and non-EU conformity assessment processes (Pathway 2B) based on criteria developed with consumers, health professionals, industry. This will allow for the inclusion of devices on the ARTG without an application audit.

All Class III and IVD products and Class II b (implantable) are currently subject to a compulsory application audit. No compulsory audit for Class I and Class II a

Component	Class IIb (implantable)	Class III	IVD (class 4 and point of care (POC))
Number of applications	TGA to provide	TGA to provide	TGA to provide
Number of successful applications	TGA to provide	TGA to provide	TGA to provide
% currently subject to application audit	TGA to provide	100%	TGA to provide
Level 1 audits	11 (Jan-June 2015) – TGA to provide 5 years of historical data on number of Lvl 1 audits		
Level 2 audits	155 (Jan-June 2015) - TGA to provide 5 years of historical data on number of Lvl 1 audits		
% subject to application audit in future (some proportion of 10 big notified	TGA to provide	TGA to provide	TGA to provide

Component	Current	Comments
Time taken to respond to TGA during audit (ADMINSTRATION COST SAVINGS)	TGA to provide estimate of this	Professional wage rate
Lvl 1 audits – time taken	17 (sponsor), 5 (TGA) – Jan to Jun 2015	TGA to provide 5 years of history on average time taken by sponsors and TGA
Lvl 2 audits – time taken	42 (sponsor), 82 (TGA) – Jan to Jun 2015	TGA to provide 5 years of history on average time taken by sponsors and TGA

Conformity Assessment/Inclusion recommendation

Calculation

Delay costs
Time taken to receive conformity assessment x number of submissions x profit per day

Component	Current	Future	Timing considerations
Time taken to receive conformity assessment			
Pathway 1A (TGA)	255 legislated (averaging under 200 days)	Significant amount of work done in last two years to improve timeframes for Conformity assessment by TGA Having international benchmark is unlikely to be able to influence the time it takes TGA to assessment in the absence of other staffing changes	
Pathway 1B (designated entity)	Rec rejected	TGA to provide detail on potential reductions in timeframes that could be achieved based on previous work done by Deloitte looking at time taken to undertake conformity assessment	
Time taken to receive inclusion recommendation	20 days (time to decide to do application audit or not)		
Pathway 2			

Pathway 3

Calculation

Delay costs
Time taken to assess application x number of applications x profit per day

Substantive compliance costs
Time taken to comply with TGA requirements x number of applications x employee cost per hour

Component	Time taken
Time taken to assess application	Potential reduction in TGA assessment timeframes – TGA to provide (ie. 20 days during obtaining conformity certificate and 20 days during application assessment)

Component	Estimated time	Employee responding	Comments
Time taken to comply with TGA imposed requirements for expedited approval	TGA to provide estimate of whether it is a time increase or decrease and the likely quantum	Professional wage rate	Relative to the amount of information provided under existing regulatory arrangements, is there likely to be an increase?

Variations

Component	Number of variation applications	Number subject to de novo design examinations	Time taken to assess variation applications
Number of variations Low-medium risk devices Medium-high risk devices High risk devices	Subject Matter Expert advice is that the only way to reduce approval timeframes for variations is to automatically accept certification from Notified Bodies and forgo any TGA assessment. TGA already undertakes a risk based assessment – TGA to confirm language to be used		
Or better to look at in terms of Classes of devices?			

Post-market monitoring

Calculation:
Time taken to provide information (per device) x number of devices x employee hourly rate

Report recommends that 'all high risk (Class III and AIMD and some Class IIb) implementable devices be included on a registry ….' (p127)

Number of separations using high risk devices	≈ 350,000 DoH to confirm	Split between public and private hospitals DoH to confirm	
Substantive compliance burden (reporting for register)	15 minutes per separation using high risk device	Nurse wage rate	
Excluding impact of devices already captured on a register (ie. orthopaedic register)	Hopefully to be confirmed in breakdown of 350,000 separations		
Training	10 people per private hospital	3.5 hours per person every two years	
Phase in operation of the register	5 year period		

Creation of new Australian designated entities

Approach to be confirmed with OBPR in respect of regulatory costs.

Relative to the base case, there is likely to be an increase in regulatory costs through the imposition of standards/requirements on any new Australian designated entities (because these currently don't exist, if any are created then there is an increase in the regulatory burden).

If this is determined to be a regulatory burden, it cannot be quantified and may need to be discussed qualitatively as it is impossible to predict how many (if any) Australian designated entities may arise.

Information required

If may be useful to identify the likely regulatory burden imposed on EU Notified Body – if any information is available.

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  - Number of applications subject to audit
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  - Number of level 2 audits
  - % subject to application audit if Review recommendations are implemented – i.e. a proportion of the 10 big notified bodies.

Action Items Continued

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- TGA to provide an estimate of the reduction in assessment time that could be achieved under pathway 3 (expedited approval).
- TGA to provide an estimate of the likely decrease or increase in time spent by the sponsor doing an application under pathway 3.
- Taskforce to confirm number of separations using high risk devices (broken down by device group) and the % split between private and public hospitals.

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