[redacted]

From: KELLY, Larry [redacted]
Sent: Wednesday, 20 January 2016 7:01 PM
Subject: RE: Follow up questions - MMDR regulatory costings relevant to your branch [DLM=Sensitive]

[redacted]

Please see my emails on the registry costings. If you still believe there are serious flaws then please go ahead and correct, but remember we are satisfied with ball park figures that are defensible not necessarily ones accurate to the second decimal place.
Larry

Sent with Good (www.good.com)
Larry Kelly
First Assistant Secretary
Monitoring and Compliance Division
Therapeutic Goods Administration
Department of Health
[redacted]

From: [redacted]
Sent: Wednesday, 20 January 2016 6:20:47 PM
To: SKERRITT, John; KELLY, Larry
Cc: [redacted]
Subject: RE: Follow up questions - MMDR regulatory costings relevant to your branch [DLM=Sensitive]

John, Larry

[redacted] is working hard to consolidate our comments/amendments directly on the spreadsheet - should have this to you by tomorrow am...

She also explained to me that the Registry Associated Cost that this spreadsheet is concerned with is not the same as the cost of running a registry... I would still increase the per registry cost estimate to business.

John, some of your questions to [redacted] are quite hard to answer because theyl vary from device to device and requires estimates of numbers that we don't currently have (numbers used per annum, etc). Most such devices are implanted in private hospitals and clinics and there is also need for compliance at the outcome end ie when an implant is revised or the patient needs some sort of intervention- that requires reporting to the registry – usually from a private clinic or private hospital.

[redacted] and I are meeting later tonight. I will ask her about the list of implants that fit the definition of "high risk implantable devices" that may need a registry.

Regards

[redacted]

From: SKERRITT, John
Sent: Wednesday, 20 January 2016 5:58 PM
To: KELLY, Larry; [redacted]

Cc: [redacted]
Subject: RE: Follow up questions - MMDR regulatory costings relevant to your branch [DLM=Sensitive]

Larry

Thanks

I think that the DOH spreadsheet of high risk implantable devices is just the prostheses list – aren't there a range of high risk devices that are not on the list ? If so, what are the broad categories.

I thought we had a list of 12 or so groups of registries that would be needed, and that prostheses list entries only accounted for 7-8 of them ?

John

Adjunct Prof John Skerritt FTSE FIPAA (Vic)

Deputy Secretary for Regulatory Services
Department of Health

PO Box 100 Woden ACT 2606 Australia
Phone: [redacted] Fax: (02) 6203 1265
Email [redacted]

From: KELLY, Larry
Sent: Wednesday, 20 January 2016 5:20 PM
To: SKERRITT, John; [redacted]
Cc: [redacted]
Subject: RE: Follow up questions - MMDR regulatory costings relevant to your branch [DLM=Sensitive]

See my comments in red:

- Costs to public hospitals cant be included as we are told that costs to governments/ government employees cant be included THEY HAVEN'T BEEN INCLUDED
- If the Cost of establishing registries is paid for by either the taxpayer or through increased annual charges it also cant be included as a regulatory burden. ALSO NOT INCLUDED
- If there was an initial cost in training and in "set up" within the private hospitals this could be counted as a one off costs of some millions – we should probably add this THIS IS INCLUDED
- We also need to consider whether private specialists working in rooms but outside the private system would implant any of the high risk devices – [redacted] – grateful for your advice as I think you did the list of devices for possible registries for the MMDR ? [redacted] LATER EMAIL COVERS THIS.

The critical source of information is from DoH which is the number of procedures per year, but I don't know exactly what procedures are being referred to. It says 'procedures involving high risk medical devices' and refers to DoH excel spreadsheet. Even though there is still to be an agreed definition of 'high risk implantable devices' we will have to assume this DoH file is a reasonable estimate.

So, I think we must accept the registries' costings.

Larry

Dr Larry Kelly
First Assistant Secretary,

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From: SKERRITT, John
Sent: Wednesday, 20 January 2016 4:14 PM
To: KELLY, Larry; [redacted]
Cc: [redacted] SKERRITT, John
Subject: RE: Follow up questions - MMDR regulatory costings relevant to your branch [DLM=Sensitive]

Yes, there are a lot of things that common sense would tell you should be included but they cant under the "Regulatory Burden Costing model"

When it comes to registries

- Costs to public hospitals cant be included as we are told that costs to governments/ government employees cant be included
- If the Cost of establishing registries is paid for by either the taxpayer or through increased annual charges it also cant be included as a regulatory burden.
- If there was an initial cost in training and in "set up" within the private hospitals this could be counted as a one off costs of some millions – we should probably add this
- We also need to consider whether private specialists working in rooms but outside the private system would implant any of the high risk devices – [redacted] – grateful for your advice as I think you did the list of devices for possible registries for the MMDR ?

John

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From: KELLY, Larry
Sent: Wednesday, 20 January 2016 4:02 PM
To: SKERRITT, John; [redacted]
Cc: [redacted]
Subject: RE: Follow up questions - MMDR regulatory costings relevant to your branch [DLM=Sensitive]

John
The issue of registries, particularly just one when the review calls for multiple, hit me. But as I looked into their costings it seems they are costing the burden on the hospitals (and only the private ones) for collecting the information. While we know the establishment and maintenance of individual registries is in the $millions this cost is not factored into the EY costings. I don't know why, but it may be because it would be a compliance cost, either annual charges or a levy as per NJRR which I don't believe are counted in. If industry was being asked to build and pay for registers then that would be costed. I wasn't at the meetings where this was discussed but others would have been.

Larry

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From: SKERRITT, John
Sent: Wednesday, 20 January 2016 2:13 PM
To: [redacted]
Cc: [redacted] KELLY, Larry
Subject: Follow up questions - MMDR regulatory costings relevant to your branch [DLM=Sensitive]
Importance: High

[redacted]

Further to the message I sent this morning on the regulatory costings, I'd be grateful for some specific advice on the following issues raised in the regulatory burden costings, that are specific to your branch/es

Devices

- There's a lot of data on numbers of application for inclusion per year in different categories; I assume that they have come from us, but grateful if DAB could review the spreadsheets. Please check

- I think the additional administrative burden for operation of registers for all high risk devices, calculated at $ 1.2 m pa is probably an under-estimate. While we are proposing to government that this be deferred at this stage I would still be keen for the estimate to be as realistic as possible, please.

- The cost needs to be per register – what was the number of different device registries proposed (including breast and cardiac) ?

Please get back to me as soon as you can, as we want to be able to discuss accurate figures with the Ministers offices on Friday. I will be talking to the E&Y folks early tomorrow.

John

Adjunct Prof John Skerritt FTSE FIPAA (Vic)

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