[redacted]

From: [redacted]
Sent: Wednesday, 20 January 2016 5:01 PM
Subject: RE: Follow up questions - MMDR regulatory costings relevant to your branch [DLM=Sensitive]

John,

I am aware that some private specialists have their own set-ups in their rooms or have dedicated clinics to implant some of these devices, particularly breast implants. However, the majority (approx. 95-98%) of the other implants would be inserted in public and private hospitals only, as there is a lot of support required post operatively for most patients, procedure and devices.

Regards

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Ph: +[redacted]

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

Adjunct Prof John Skerritt FTSE FIPAA (Vic)

Deputy Secretary for Regulatory Services
Department of Health

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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

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