[redacted]

From: [redacted]
Sent: Thursday, 21 January 2016 8:37 AM
Subject: RE: Follow up questions - MMDR regulatory costings relevant to your branch [DLM=Sensitive]
Attachments: 07012016152816-0001.pdf

John,

Please see the email below that I sent [redacted], who is on the DoH task group working on the figures you sent around. This email lists the device registries that would cover the majority of high risk implantable medical devices. I have used groupings rather that individual device names in most cases. The attached document is an old document that was used as basis to begin the list below. There are a couple of devices mentioned in the attachment that are not on the list below. These were removed because there isn't any indication that there are issues with them now or even at the time of placement on the list, such as the TMJ prosthesis.

Regards
[redacted]

Hi [redacted]

As discussed today via telephone please find attached a few papers from a paper drafted for "The Commission" about registers for recalling of high risk medical devices. This is a different purpose to the registers proposed under the review.

The paper has five criteria/categories (page 7) for selecting devices that were recommended for following through a register. The next two pages describe specific devices that were considered to be priority candidates for inclusion into a registry. There is also a table with estimates of numbers of devices supplied for 2009. I think it is safe to say that the number could be multiplied by about 1.5 to 2 to get an estimate of the number supplied in 2015.

As you will note in the list of specific devices there are some that have or should be combined. For example the cardiac devices register will cover four of the devices listed on page 8.

I suggest the following devices or device group registers (red indicates already operating or in development):

- Orthopaedic joint replacement
- Cardiac devices - current inclusion on the register is:
  - Heart valves - both mechanical and tissue
  - Pacemakers
  - Defibrillators
  - Leads for pacemakers and defibrillators
  - Occlusion and structural devices
  - Stents - bare metal, drug eluting and resorbable
- Breast implant devices - silicone, saline, tissue expanders
- Urogynaecological medical devices (mesh or other material/biological used to treat incontinence and prolapse)
- Heart assist devices – could at some point be incorporated into the cardiac devices register
- Implantable infusion pumps
- Diaphragmatic/phrenic nerve stimulators
- Deep brain (neurological) stimulators
- Hydrocephalic valves/shunts
- Gastric and bariatric devices (Lap-band, endobarrier, staplers used in bowel shortening or diversion procedures)
- Stents used in the gastrointestinal system (biliary, oesophageal, pancreatic duct)
- Vascular devices (Abdominal and thoracic aneurysm stents, peripheral stents, Inferior Vena Cava filters)

- Intra-ocular lenses
- Aural devices (Cochlear, Baha)

I hope this information is of assistance.

Kind regards
[redacted]

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Ph: +[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)

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Department of Health

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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
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From: SKERRITT, John
Sent: Wednesday, 20 January 2016 4:14 PM
To: KELLY, Larry; GARCIA, Jorge
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

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