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

Importance: High

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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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