[redacted]

From: KELLY, Larry [redacted]
Sent: Wednesday, 20 January 2016 5:07 PM
Subject: RE: URGENT Draft calculations - change in regulatory burden from implementatioon of MMDR recommendations [DLM=Sensitive]

BSI has this on their web site:

Please Note: Our programmes do not guarantee a CE marking certificate will be issued within a certain amount of working days, but are based on completing the review process with either a positive or negative recommendation. FastTrack is not available for devices utilising animal tissue, blood derivatives or medicinal substances.

I recall now that MDSAP did not want AOs touting for business based on delivering within guaranteed times.

The BSI site nevertheless also has a Fast track that aims to have a CE mark within 45, but no guarantees. This is not available for the types of products we do CA on (containing animal tissue, blood derivatives or medicinal substances).

Larry

Dr Larry Kelly
First Assistant Secretary,
Medical Devices & Product Quality Division
Phone: [redacted]
Mobile: [redacted]
Email [redacted]

Therapeutic Goods Administration
Department of Health
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From: SKERRITT, John
Sent: Wednesday, 20 January 2016 4:30 PM
To: KELLY, Larry; [redacted]; MCRAE, Cheryl
Subject: RE: URGENT Draft calculations - change in regulatory burden from implementatioon of MMDR recommendations [DLM=Sensitive]

OK – what figure could we use instead of 90 days – 120 days ? and is there a web link reference for this (EY will need it)

Adjunct Prof John Skerritt FTSE FIPAA (Vic)

Deputy Secretary for Regulatory Services
Department of Health

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Email [redacted]

From: KELLY, Larry
Sent: Wednesday, 20 January 2016 4:26 PM
To: SKERRITT, John; [redacted]; MCRAE, Cheryl
Subject: RE: URGENT Draft calculations - change in regulatory burden from implementatioon of MMDR recommendations [DLM=Sensitive]

The position paper from Team NB issued October 29 2015 states that:
"The quotation process is now longer than before (2 -3 month instead of 1week to 1 month; and
The time from contract signature, either for a new client or a scope extension with an existing client, to audit planning is now around 6 months although it was usually around 3 months in the past; the same delay might occur for the start of dossier reviews."

So, even in the present climate, it could take anything from 14 -15 months from contract signing (our equivalent of application lodgement) to finalised dossier review.

Team NB is an authoritative source for this kind of information.

Larry

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From: SKERRITT, John
Sent: Wednesday, 20 January 2016 4:06 PM
To: [redacted]; MCRAE, Cheryl
Cc: KELLY, Larry; SKERRITT, John
Subject: RE: URGENT Draft calculations - change in regulatory burden from implementatioon of MMDR recommendations [DLM=Sensitive]

Thanks, [redacted]

Coincidentally [redacted] phoned me this morning and made a similar point – although he felt at present EU NBs were a bit faster than us. We can't take into account further behaviour changes in Europe that may or may not take place and its hard to get current data on their CE certificate times.

A problem we have is that discussions with the devices industry and the Panel – and the submissions of groups such as MTAA to the MMDR all talked about a standard 90 period (and a 45 day expedited period) for CA timeframes from NBs.

Even if we think that the 90 day period now is more likely to be 120 days etc unless if there was an authoritative published reference to this we would have to stick with the 90 day figure. The only alternative is to contact someone like [redacted] from MHRA and see if he has statistics that he can share with us and is satisfied that they were provided to E &Y.

Larry – your thoughts ?

John

Adjunct Prof John Skerritt FTSE FIPAA (Vic)

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From: [redacted]
Sent: Wednesday, 20 January 2016 3:17 PM
To: [redacted] MCRAE, Cheryl
Cc: SKERRITT, John
Subject: RE: URGENT Draft calculations - change in regulatory burden from implementatioon of MMDR recommendations [DLM=Sensitive]

Hi [redacted],
I have reviewed the draft calculations spreadsheet and found an issue on the assumptions tab under Medical Devices – conformity assessment timeframes for Pathway 1B applications.
The assumption for new devices:

New devices

Reduced time taken for conformity assessment	Median Working days	Median Calendar days	
Base case (current timeframes)	151	212	*TGA Half-Yearly Performance Report Jan-June 2015, Table 26, p26*
Scenario 1 (Pathway 1B implemented)	90	126	*TGA subject matter experts*
Net saving	61	86	

This shows that a notified body designated by the TGA (pathway 1B) would process CA applications in 90 working days vs 151 for TGA. This assumption is incorrect in the current climate. A recent article by A. Brandwood (http://brandwoodbiomedical.com/tga-2015-report-card-on-target/) shows that NBs are not faster than TGA:

> not include "stop clocks" when TGA is waiting for manufacturer responses to review questions. Nonetheless TG **actual** processing times are broadly equivalent to those of European Notified Bodies – which tend to complete Conformity Assessment in around 6 calendar months (although anecdotal reports suggest that some European Bodies are themselves struggling with backlogs at the moment). In comparison, the US FDA sets a target time c days for a 510(k) and 180 days for the PMA process for the highest risk devices. FDA meets its target for over 9[redacted] 510k submissions and PMA supplements (No summary data are published for full PMAs).

I had a brief chat with [redacted] about this and she indicated the NB timeframes in the assumption may have come from industry a few years ago when the RIS for Australian manufacturers (using EU NBs) was in development. NBs may have been faster then, but that was before the implementation of the EU Regulation 920/2013 which has resulted in a higher degree of rigour (and resulting longer timeframes) from the NBs.

This assumption also carries through to the calculations.

[redacted] also indicated she is planning to review and edit the spreadsheet this afternoon for a collated response.

Kind regards,
[redacted]

[redacted]
Conformity Assessment
Medical Devices Branch

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From: [redacted]
Sent: Wednesday, 20 January 2016 9:23 AM
To: [redacted] MCRAE, Cheryl; [redacted]
Cc: SKERRITT, John
Subject: RE: URGENT Draft calculations - change in regulatory burden from implementatioon of MMDR recommendations [DLM=Sensitive]

Colleagues

I was not involved in these discussions and therefore not across them. Note the deadline.

Can you cast your eyes over the assumptions and flag any issues to me by COB today? I can pass on to John...

Regards

[redacted]
A/g Assistant Secretary
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From: SKERRITT, John
Sent: Wednesday, 20 January 2016 9:15 AM
To: [redacted] KELLY, Larry; HORNER PSM , Philippa; [redacted]
Cc: [redacted] CRAE, Cheryl; [redacted]
Subject: URGENT Draft calculations - change in regulatory burden from implementatioon of MMDR recommendations [DLM=Sensitive]
Importance: High

Colleagues

Thanks to those of you who were able to attend the workshop on Friday 8 January with E&Y on calculating increases and decreases in regulatory burden associated with potential implementation of different recommendations of the MMDR. To recap, this is a critical part of the information that Ministers need in considering the potential merits and impact of individual recommendations and together with colleagues from Woden I will be meeting with both Ministers and their staff on this coming Friday as well as next Wednesday.

So while its recognised that the numbers put forward involve a long list of assumptions, it's important for them to be as realistic as possible. Please find below an email from EY attaching the draft model on the estimated change in regulatory

burden for medicines and medical devices. I'm told by the MMDR team at Woden EY received the outstanding information from TGA yesterday afternoon and is yet to receive the data from PBS to further inform certain calculations.

As the source of expertise that would enable the figures to be as realistic as possible, it's important that we at TGA review these numbers. We need to review them ASAP – and provide feedback by 10 am tomorrow given that the meeting with the MO is Friday. Can I ask the key Branch and Division heads to collate feedback to me on this. I'm aware that the following folks are away at present: [redacted], Cheryl McRae

The data is not in the most user-friendly form – some spreadsheets are massive and have embedded figures. While I will ask E&Y to fix this up in the final report we don't have time to ask them to fix it now and send the excel file back to us.

I will spend a couple of hours on the data this morning checking the calculations and assumptions behind the headline figures, but some initial feelings from me / and specific questions for the relevant branches are:

- The Prescription medicines numbers (regulatory saves) now seem too high – they are based on cancer meds profitability and I don't think these are representative of the profitability of the mainstream innovator medicines for chronic diseases. The business model for the latter is different – moderate profits per annum, but recognising that unlike cancer medicines these are taken for many years. Can the people in the Prescription medicines branch please also check the figures around variations which also seem too high ?

- The generics numbers (regulatory saves) seem too low – perhaps the changes in business processes have not been captured ?

- I'm not surprised that there is a small increase in regulatory burden for the unapproved therapeutics area – do we need to think more about how we are proposing for the electronic system to be introduced/ implemented ? Should there be an initial increase in burden followed by a decrease over years 3-10 ? After all if it's going to increase burden for the users why would the MMDR be so hot on it and why would we push to implement it ?

- Not surprised that the comp meds work sees an increase in burden and that some of the recs that we have agreed to propose to government NOT be implemented would reduce the increase in burden, but keen to have these figures checked, please.

- Advertising burden changes seem small ?

- Not surprised at the significant increase in burden that a delay associated with possible CMO approvals would bring. I assume that this has been calculated across all products, which is fine for now as it provides metrics for the Minister. The take home message is that a delay of 3 months associated with CMO approvals would wipe out all of the calculated regulatory burden reductions arising from the MMDR. Simple message.

Anyhow, please do make it a priority today to spend some time looking at the assumptions that relate to your area in particular, and get back to me please through your branch/ division head .

thanks

John

Adjunct Prof John Skerritt FTSE FIPAA (Vic)

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Department of Health

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Email: [redacted]

From: [redacted]
Sent: Tuesday, 19 January 2016 5:23 PM
To: [redacted]
Cc: MMD Review Taskforce; [redacted]
Subject: Draft model - change in regulatory burden [SEC=No Protective Marking]

This email is to be read subject to the disclaimer below.

Hi [redacted]

Please find attached the draft model calculating the estimated change in the regulatory burden for medicines and medical devices, updated as per our discussion this afternoon. As discussed with you, the model is currently undergoing further internal QA review and so should be considered an initial draft only.

I am still **waiting for the data from the PBS area on new NCE and generic listings on the PBS to further inform the calculation of the profit per day metric for** NCEs (and the extension of indication variations) and generics. The previous discussion I have had with the PBS area is that they will provide 12 months of data (3 years was viewed as unmanageable in the timeframes) on all new NCE listings and generic listings including the ex-manufacturer sales revenue and number of listings. This will be used to inform the profit per day metric.

The current approach for NCEs is based on the estimated profitability of the top 100 cancer medicines. As you will see, the reduction in delay costs for NCEs and variations is responsible for around 85% of the reduction in the regulatory burden. As a result, the profit per day metric is highly integral to the overall result (as small changes will dramatically impact the overall result) and so it will be critical to agree the relevant assumptions with TGA and yourselves.

Using the assumption for NCE profitability described above, the initial estimate of the average annual reduction in the regulatory burden is $134.6m. The estimated change in the regulatory burden for each category is detailed in the table below.

The figures in the table below include the costs associated with the high risk devices register (Rec 22(1)) and the recommendations that will increase the burden on complementary medicine sponsors (publishing evidence on website (Rec 43), including prominent disclaimer on all promotional products(Rec 44)) that I understand do not have the support of the department.

Summary of deregulatory savings	**Average annual change in regulatory burden** Negative = increase in regulatory burden Positive = reduction in regulatory burden
NCEs	$41,951,684
Generics	$34,477
Variations	$70,362,425
Unapproved therapeutics	-$298,305
Complementary medicines	-$3,528,170
Medical devices	$25,538,108
Advertising and complaints resolution	$574,365
TOTAL	**$134,634,585**

These figures relating to Recs 22(1), 43 and 44 can be easily removed from the model - the estimated average annual reduction in the regulatory burden then increases to $137.1m (it increases because those recommendations are assumed to increase the regulatory burden).

Summary of deregulatory savings **EXCLUDING: regulatory costs arising from high risk device register, and publishing efficacy (comp meds) and changing labels (comp meds)**	**Average annual change in regulatory burden** Negative = increase in regulatory burden Positive = reduction in regulatory burden
NCEs	$41,951,684

Generics	$34,477
Variations	$70,362,425
Unapproved therapeutics	-$298,305
Complementary medicines	-$2,232,673
Medical devices	$26,754,962
Advertising and complaints resolution	$574,365
TOTAL	**$137,146,935**

The tables above do not include quantification of the increase in regulatory burden that is assumed to arise if Rec 29(1)(a) is implemented (the Chief Medical Officer becomes the delegate for decisions). In the workshop held on 8 January, John requested an two different scenarios be quantified: one where the implementation of Rec 29(a)(a) increases the average length of time it takes the TGA to assess an application (for NCEs, major variations, generics and high risk devices) by 3 months and a second where it increases the assessment timeframes by six months.

The average annual increase in the regulatory burden is detailed in the table below ($122m for 3 month increase and $244m for 6 month increase).

Indicative **increase** in average annual regulatory delay costs (for NCEs (including variations for new fixed dose and extension of indications), generics and high risk medical devices) from implementation of Recommendation 29(1)(a) - the CMO becomes the delegate for decisions	
Option 1 - 91 day (3 month) increase in TGA assessment timeframes	-$122,055,981
Option 2 - 182 day (6 month) increase in TGA assessment timeframes	-$244,111,961

As discussed with you, it would be good to seek a further round of feedback from relevant subject matter experts to confirm the assumptions are reasonable in light of the estimated outcomes.

Regards

[redacted] | Economics, Regulation and Policy Group

Ernst & Young

[redacted]