

From: SKERRITT, John [REDACTED]
Sent: Wednesday, 20 January 2016 6:01 PM
Subject: RE: URGENT Draft calculations - change in regulatory burden from implementation of MMDR recommendations [DLM=Sensitive]

And of course the challenge is that team NB are using the argument "there will be massive regulatory delays" to argue against some of the changes/ rapid changes to the EU devices regulatory system – so they have a vested interest in saying things are slowing down.

Adjunct Prof John Skerritt FTSE FIPAA (Vic)

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From: KELLY, Larry
Sent: Wednesday, 20 January 2016 4:56 PM
To: SKERRITT, John; [REDACTED]
 MCRAE, Cheryl
Subject: RE: URGENT Draft calculations - change in regulatory burden from implementation of MMDR recommendations [DLM=Sensitive]

The publication is at

<http://www.team-nb.org/wp-content/uploads/2015/11/Team-NB-Position-paper-Workload-NBs-20151029.pdf>

The current time is far more than 120 days. According to Team NB it is over a year from beginning to end. I wonder what is the impact of using 400 days in our calcs?

The problem we have is that unlike regulatory agencies where stats are published the commercial world of NBs provides no incentives for publication of time lines. BSI used to have info on its web site about expected times and expedited times but I haven't checked recently. [REDACTED] the author of the Team –NB paper attached was a senior operator with BSI (he left in Dec last year) so he is well placed to have reasonable data from both Team-NB's perspective as well as BSI's.. I will check the web site to see if they make any other claims about timelines.

Larry

Dr Larry Kelly
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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 implementation 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)

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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 implementation 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 implementation 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 MTA 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

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Email [REDACTED]

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 implementation 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

Base case (current timeframes)
Scenario 1 (Pathway 1B implemented)
Net saving

	Median Working days	Median Calendar days
Base case (current timeframes)	151	212
Scenario 1 (Pathway 1B implemented)	90	126
Net saving	61	86

TGA Half-Yearly Performance Report Jan-June 2015, Table 26, p26
TGA subject matter experts

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 of 180 days for a 510(k) and 180 days for the PMA process for the highest risk devices. FDA meets its target for over 98% of 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.

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

Kind regards,

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Medical Devices Branch

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From: ██████████
Sent: Wednesday, 20 January 2016 9:23 AM
To: ██████████ MCRAE, Cheryl; ██████████
Cc: SKERRITT, John
Subject: RE: URGENT Draft calculations - change in regulatory burden from implementation 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

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- 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

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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



██████████ Economics, Regulation and Policy Group

Ernst & Young



