

E-mail Message

From: [REDACTED]
Sent: 13/11/2012 at 4:11 PM
Received: 13/11/2012 at 4:11 PM
Subject: OTC business process consultation document

Dear [REDACTED],

Firstly, our sincere apologies for the delay in responding.

Further to the telecon with Kate Lynch (CEO of GMiA), the generic industry body offers in principle support of the proposed reforms to the business processes for the evaluation of over-the-counter (OTC) medicines.

GMiA is particularly supportive of the concept of developing monographs for some OTC medicines and the proposed initial list is a positive beginning. Although the initial number of monographs was reduced for the launch of the new process, GMiA looks forward to a commitment to develop new OTC medicine monographs for other molecules as the process evolves.

The concept of risk based categories is also welcomed and the proposed categories appear acceptable at this stage.

The premise of the streamlined submission process is predictability of timeframes. It is noted that the target times included in Figures 5 and 6 of the consultation documents are aspirational timelines. GMiA reiterates (as it has done in the prescription medicine process) that the TGA make a genuine commitment to deliver on the aspirational timelines and to remove the notion of aspirational timelines as the process evolves to ensure predictability.

Finally, GMiA also welcomes the support from representatives of Medsafe and their presence in the discussions has been beneficial.

GMiA looks forward to continue working with the TGA on the development of an effective business process that is beneficial for both the TGA and industry.

Should you require any additional information please feel free to contact me.

Kind regards

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