Reference	Questions	Apotex Response	Apotex Comments	Apotex NZ comments
General	Comments on timeline, business reform principle		Apotex is pleased to see that the OTC branch will maintain the ability for companies to directly contact the branch and discuss issues or "grey areas" associated with submissions	
Page 15	Do you support the concept of risk-based categories for OTC medicines?	Yes		Agree
	Do you agree with the proposed risk categories for new medicines?	Yes	High risk products cannot be ascertained from the chart, and is assumed that these automatically fall under full submission and prior approcal. Will this be explicitly indicated in the BPR process and/or ARGOM?	Agree
	Do you agree with the proposed risk categories for changed medicines?	Yes, however refer to comment	TGA should consider aligning the categories with EU IA, IB and II.	Agree
Page 13	Other comments		The New Medicines and Changed Medicines hcarts are not related. Clearer headings need to be used to show that they are indeed different and relate to different aspects for the product life cycle. Definition for "umbrella category" needs to be clearer, perhaps with examples provided. It was difficult to assess where a "generic product" fits into the N categories. Could this made clearer or defined.	Bottom paragraph page 13 Change use of 'Category 1 applications (N1 or C1…' The use of the wording 'category 1' could be confused with 'category 1' applications to TGA for prescription medicines Suggestions 'risk groups' or 'risk classifications'
Page 19	Do you support the proposed five-phase process?	Yes		Agree
	Do you agree with the principles that were applied when developing the proposed process?	Yes		Agree
	Other comments			

	Question		Apotex Comments	Apotex NZ Comments
Page 21	Do you support the concept of developing monographs for some OTC medicines?	Yes in principle	TGA should consider changing the term "monograph" in order to differentiate from pharmacopoeial or other standards.	Agree
	Do you agree with the proposed list of medicines that should be given priority for monograph development?	Yes	Industry to have input into the preparation and agreement of monographs.	Why is this list based on AU applications only? Are there different products that would be more relevant to the applications being made to Medsafe
	Other comments			What would be the proposed time period for reviewing OTC medicine monographs i.e. x yearly basis or ad hoc?
Appendices	Appendix 1: Risk categorisation framework for new medicines		If company requires "a" flagging for an OTC which category does this fall into? Clarify down scheduling, e.g. from S4 to S3 in instances where it is a new registration and a product is already registered and is no longer in S4?	
	Appendix 2: Risk categorisation framework for changed medicines			No comment
	Appendix 3: Change tables TGA		it is not clear at a glance which table covers the different categories, this should be made bold and clearer. TGA should consider grouping the change codes as this would simplify identification of changes applying to different categories, e.g. GPN falls udner C2 and C3.	
	Appendix 3: Change tables Medsafe			No comment (CMN form in a different format)

	Question		Apotex Comments	Apotex NZ Comments
Target timelines			Need to add in sponsor extension request. Level C1 timeline is very tight, especially if request for information is over weekend or public holidays.	Submitting to TGA from NZ (and vice versa) and having a 7 or 14 day turn around on an RFI. Having to coordinate this with HO or ARPL and then postal times or courier times would make this nigh on impossible meet. Additionally if a RFI is sent from TGA to NZ office Friday afternoon 5pm then this is 7pm NZ = no action until Monday! Even NZ to Medsafe or AU to TGA submission time frame for C1 to tight. Why would N2 RFI timeframe be shorter than that of a C2 change?
Fees				There has been no mention of changes to the fee structure. Will Medsafe and TGA maintain there current independent fee structures without any increases?