

Medsafe consultation submission

Medsafe Signals Proposed Changes to Evaluation Administrative Processes			
Name and designation			
Company/organisation name and address	Bristol-Myers Squibb (NZ) Limited C/O Simpson Grierson, 88 Shortland Street, Auckland 1141, New Zealand		
Contact phone number and email address			
I would like the comments I have provided to be kept confidential: (Please give reasons and identify specific sections of response if applicable)			lentify ☐ Yes ☒ No
I would like my name to be removed from all documents prior to publication and for my name not to be included within the list of submissions on the Medsafe website.			not to
It would help in the analysis of stakeholder comments if you provide the information requested below.			
I am, or I represent, a: (tick all that apply)			
☐ Importer	☐ Manufacturer	Supplier	⊠ Sponsor
Government	Researcher	☐ Professional body	☐ Industry organisation
☐ Consumer organisation	☐ Member of the public	☐ Institution (e.g. university, hospital)	
☐ Regulatory affairs consultant	☐ Laboratory professional		
☐ Health professional – please indicate type of practice:			
☐ Other - please specify:			

Please return this form to: Alyssa Currie

Email: alyssa_currie@moh.govt.nz

OR

Medsafe

PO Box 5013

Wellington 6011

Medsafe is seeking comments on:

Proposed changes to format of correspondence			
The respondent is supportive of the proposal to send correspondence in electronic format. However, there are potential security implications if confidential information is routinely sent unsecured via email. Would Medsafe consider using a secure email, or perhaps establish a secure portal that sponsors and Medsafe could each log into?			
If email remains the preferred mechanism, it would be advantageous if multiple sponsor recipient email addresses could be specified.			
Proposed changes to requirements for electronic submissions			
Not applicable.			
Additional Comments			
Whilst recongizing that it is out of scope for this consultation, the respondent would be supportive of the use of electronic format being expanded in the future (for example, covering submissions and responses to RFI), whether that be via a secure portal, secure email or posting of a CD.			

Please include additional pages if necessary.