Medsafe consultation submission

Medsafe Signals Proposed Changes to Evaluation Administrative Processes	
Name and designation	Ellen Chan / Senior Regulatory Affairs Associate
Company/organisation name and address	Bayer Australia Ltd / 875 Pacific Highway Pymble NSW 2073
Contact phone number and email address	61 2 9391 6171 / ellen.chan@bayer.com

I would like the comments I have provided to be kept confidential: *(Please give reasons and identify specific sections of response if applicable)*	☐ 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.	☐ Yes ☒ No

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
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☐ Regulatory affairs consultant	☐ Laboratory professional		
☐ Health professional – *please indicate type of practice*:			
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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 Bayer welcomes the proposed changes to format of correspondence especially to receive decision letters electronically which would be more convenient for the sponsors. It is understood that responses to RFIs are required to be submitted in hard copy due to the limitation in size of attachments can be sent via email. However for applications whereby short response period is given (i.e. 28 days for applications with priority status), Bayer wishes that Medsafe consider exercising flexibility to accept the responses without the attachments via email or fax to meet the short timeframe.
Proposed changes to requirements for electronic submissions
Additional Comments With respect to applications for prescription medicine, the current guideline requires that all data must be submitted in hard copy, prior discussion with the Evaluation Team Leader is required should the applicants intend to submit data in electronic form. With an increase in electronic dossier being widely adopted globally, Bayer proposes that Medsafe consider accepting electronic dossier without a hardcopy as a standard business rule for major applications (i.e. NMA, CMN 24(5)). In Bayer's experience, we have always been granted permission to submit Modules 4 and 5, sometimes Modules 2 - 5 electronically. With over 3 years of electronic only for the majority of the data package, it would be good to formalise this as a default position in a communication without the need for application specific requests to submit electronically only. This would be similar to communication regarding the decision to discontinue hard copy rendition of evaluation reports to sponsors however with an option for hard copy to be provided if required. This format would be in sync with global practice, and for ease of evaluation and more streamlined dossier preparation and handling/transport/storage. We look forward to Medsafe formalising this as the standard option.

Please include additional pages if necessary.