# Medsafe consultation submission

## Medsafe Signals Proposed Changes to Evaluation Administrative Processes

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| **Name and designation** | Stefan Tulloch, Therapeutic Lead |
| **Company/organisation name and address** | **GSK Pharma**<br>Level 4, 436 Johnston Street, Abbotsford, VIC 3067<br>PO Box 18095, Melbourne, Victoria, 8003<br>(GlaxoSmithKline Australia Pty Ltd ACN.100162481) |
| **Contact phone number and email address** | **Email** stefan.t.tulloch@gsk.com<br>**Tel** +613 9413 7373 \| **Fax** +613 8761 2410 |

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| 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)*

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| ☐ 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:**

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| Proposed changes to format of correspondence<br><br>GSK have no objection to receiving correspondence in electronic format only and are supportive of an initiative that will deliver correspondence in a more timely manner.<br><br>GSK agree with the recommendation for use of a generic email address. |
| Proposed changes to requirements for electronic submissions<br><br>*"Applicants would continue to be required to submit applications and responses to RFIs in hard copy. Medsafe does not have the facility to receive applications and responses to RFIs via email."*<br><br>GSK is very supportive of Medsafe's current policy allowing submission of m4 and m5 data in electronic format only (i.e. CD and DVD) where there are a large number of volumes.<br><br>GSK recommend that Medsafe update the policy to also accept m2 and m3 in electronic format only for major submissions such as NMAs and CMNs referred under 24(5). This would enable the sponsor to provide a complete hyperlinked dossier with all components in electronic format. |
| Additional Comments |

**Please include additional pages if necessary.**