# Medsafe consultation submission

## Guideline on the Regulation of Therapeutic Products in New Zealand - Part 8: Pharmacovigilance (Edition 2.0)

| | |
|---|---|
| **Name and designation** | |
| **Company/organisation name and address** | Gilead Sciences (NZ),<br>Level 6, 417 St Kilda Road East Melbourne VIC 3004 Australia |
| **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)*<br><br>(Reasons for requesting confidentiality must meet Official Information Act criteria) | ☒ Yes ☐ No |
| I would like my name to be removed from all documents prior to publication on the Medsafe website. | ☒ Yes ☐ No |
| I would like for my name not to be included within the list of submissions published 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, an organisation that is based in:**

☐ New Zealand ☒ Australia ☐ Other (*please specify*):

**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:**

**Email:** medsafeadrquery@moh.govt.nz including 'Pharmacovigilance guideline' in the subject line

**Or Post:** Clinical Risk Management
Medsafe
PO Box 5013
Wellington 6145

**Medsafe is seeking comments on:**

*Section 1: Legislation eg,*

- Are the guidance documents appropriate?
- Are there other guidance documents that would be relevant to the conduct of pharmacovigilance in New Zealand?

*Section 2: Roles and Responsibilities eg,*

- Does the information adequately describe the roles and responsibilities of the various parties?
- Was the information appropriately presented?
- Was the information easy to find?
- Are there any changes you would like to suggest?

Please include additional pages if necessary.

*Section 3: Reporting eg,*

- Do you have any suggestions regarding the definitions and interpretations used in this section?
- Do the subsection headings appropriately and adequately describe each reporting circumstance?
- Is each reporting circumstance and the process involved adequately described and explained?
- Would it be easy to find the information you need in each particular reporting circumstance?
- Are there circumstances that are not in this guideline but should be? If yes, please provide more details.

**Section 3.1 states that Sponsors must report all serious spontaneous reports of suspected adverse reactions even if they disagree with the reporter(s) assessment of causality**

Gilead wishes to clarify this section as the guidance is not clear, it initially states 'all spontaneous reports notified by healthcare professionals or consumers are considered to be suspected adverse reactions, unless the reporter specifically states that the events are unrelated or that a causal relationship can be excluded' however the guidance then states that all serious spontaneous reports should be reported even if sponsors disagree with reporters assessment of causality. Further clarification on this section is necessary.

**Section 3.5.4 Lack of Efficacy**

Gilead wishes to clarify if cases of lack of therapeutic efficacy are to be treated as a 15 day report?

***Section 3.5.6 states that valid ICSRs associated with off-label use should be forwarded to CARM (The Centre for Adverse Reactions Monitoring).***

Gilead wishes to clarify that the intent of the proposed guidance is that only off label use with an associated AE is reportable to CARM. EU guidance (European Medicines Agency Guideline on Good Pharmacovigilance Practices) states that reports of off-label use with no associated adverse reaction should not be reported. They should be considered in periodic safety update reports (PSURs) as applicable. When those reports constitute safety issues impacting on the risk –benefit balance of the medicinal product they should be notified to the regulatory authorities. As PSURs are not routinely submitted in New Zealand, this could be implemented should CARM wish to review all off-label use.

***Section 3.5.13 states that Sponsors should regularly monitor and review lay internet sites (such as chat rooms and discussion forums) for potential reports of suspected adverse reactions. Sponsors should also regularly monitor and review digital media sites for which they are responsible***

Gilead monitors all digital media sites for which we are responsible for to ensure Drug Safety information is captured. However, given the number of internet sites such as chat rooms and discussion forums that are associated with the therapeutic areas that Gilead is involved in, for example HIV, it is not possible to monitor all applicable lay internet sites and as such this guideline is too broad for sponsors.

EU guidance (European Medicines Agency Guideline on Good Pharmacovigilance Practices) advises that sponsors should regularly screen internet or digital media under their management or responsibility, for potential reports or suspected adverse reactions. In this aspect, digital media is considered to be company sponsored if it is owned, paid for and/or controlled by the sponsors.

Gilead therefore does not support section 3.5.13 of the guidelines and proposes that the Medsafe guidance surrounding internet sites be amended to align with European advice due to the vast number of internet sites that would be applicable for screening is too far reaching for sponsors to monitor adequately.

**Section 3.8 Suspected Medicine Adverse Reaction Search**

Gilead requests further clarity on the use of the SMARS database. Are sponsors expected to retrieve data from the website for the global safety database? The expectation for sponsors in relation to database needs further clarification and comment.

*Section 4: Signal Management Process eg,*

- Does the content of each subsection adequately explain what the steps in the process involve?
- Do the subsections on the Early Warning System and Medicines Monitoring adequately explain how these tools can be used?
- Do you understand what the role of the sponsor is in these situations?

Please include additional pages if necessary.

*Section 5: Significant Safety Issues eg,*

- Does the text in this section adequately explain what is required?
- Are there other pharmacovigilance-related safety issues or safety concerns about medicines that you consider should be included in this section?

**Section 5.3 Timeframe for reporting signification safety issues.**

Gilead wishes to clarify that the 72 hour awareness period is when the NZ sponsor is made aware of such issues?

Gilead also wishes to clarify what regions this is applicable to (i.e. is Medsafe concerned about changes to labelling in Botswana or only concerned about changes to labelling in major regions (i.e. EU, USA, Canada, Australia etc).

*Section 6: Submission of Safety Monitoring Documents eg,*

- Are there other suggestions or recommendations that could be included in this section?

Please include additional pages if necessary.

*Section 7: Safety Communications eg,*

- Are there other suggestions or recommendations that could be included in this section?
- Is it appropriate to use the European template for safety communications?

*Additional Comments*

- Is the order of the information presented in each section appropriate?
- Do you agree with the proposed structure of the guideline?
- Is the information easily understood?
- Is there any other information or subject that should be included in this guideline?

Please include additional pages if necessary.