^ent by: I he	To: cc: bcc:	"medsafeadrquery@moh.govt.nz" <medsafeadrquery@moh.govt.nz>,
15/05/2015 02:15 p.m.	Subject:	GSK response to PV guideline consultation

Dear Sir/Madam,

GSK welcomes the opportunity to comment on Medsafe's consultation document titled *'Guideline on the Regulation of Therapeutic Products in New Zealand. Part 8: Pharmacovigilance. Edition 2.0'*. In principle GSK supports the updates to this guideline. GSK would like to provide the following in response to the Medsafe consultation document.

Draft Guideline Wording	Compared to EU	GSK Response
Major concern		
3.5.13 Media reports Reports of suspected adverse reactions originating from a non-medical source, such as the lay media, should be considered to be a spontaneous report. 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. When sponsors become aware of unsolicited cases of suspected adverse reactions from the internet or digital media, these should be considered to be spontaneous reports and reported to CARM, subject to the criteria for a valid report (see Section 3.3.2).	GSK noted that: For section 3.5.13 Media Reports. The wording around sponsors regularly monitoring lay internet sites is similar to the draft wording that was in the EU GVP Module VI. Based on input from industry the final version of the module only obligated sponsors to monitor internet sites they owned or controlled. The final wording from the relevant section is copied below. ***VI.B.1.1.4. Information on suspected adverse reactions from the internet or digital media*** Marketing authorisation holders should regularly screen internet or digital media6 under their management or responsibility, for potential reports of 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 marketing authorisation holder7. The frequency of the screening should allow for potential valid ICSRs to be reported to the competent authorities within the appropriate reporting timeframe based on the date the information was posted on the internet site/digital medium. Marketing authorisation holders may also consider utilising their websites to facilitate the collection of reports of suspected adverse reactions (See VI.C.2.2.1). If a marketing authorisation holder becomes aware of a report of suspected adverse reaction described in any non-company sponsored digital medium, the report should be assessed to determine whether it qualifies for reporting. Unsolicited cases of suspected adverse reactions from the internet or digital media should be handled as spontaneous reports. The same reporting time frames as for spontaneous reports should be applied (see VI.B.7).	GSK welcomes the addition of this section and the generally helpful guidance it provides. In particular the fact that it aims to address the fact that technology has advanced exponentially. In this respect, we broadly agree with the requirements for company sponsored sites, recognising that these may evolve over time. GSK however has significant concerns regarding the proposal to routinely monitor digital media sources which are not company sponsored. The current proposals would constitute a significant bureaucratic burden which is unlikely to be value added, do not appear consistent with risk proportionality principles and importantly, are unlikely to result in improved public health protection. We do not think non-company sponsored sites should be monitored using conventional adverse event collection. The Council for International Organizations of Medical Sciences CIOMS V states there is no obligation to report adverse events from secondary care databases as the information does not originate from defined projects and can be generated by multiple individuals for various reasons and uses. This rationale applies to non-company sponsored sites in todays digital era. Furthermore, in monitoring non-company sponsored sites, there are risks of duplicate reporting and concerns around feasibility and appropriateness of follow-up.

	In relation to cases from the internet or digital media, the identifiability of the reporter refers to the existence of a real person, that is, it is possible to verify the contact details of the reporter (e.g., an email address under a valid format has been provided). If the country of the primary source is missing, the country where the information was received, or where the review took place, should be used as the primary source country.	GSK therefore proposes similar wording to the EU (changes highlighted): **3.5.13 Media reports** Reports of suspected adverse reactions originating from a non-medical source, such as the lay media, should be considered to be a spontaneous report. If a Sponsor becomes aware of a report of suspected adverse reaction described in any non-company sponsored digital medium, the report should be assessed to determine whether it qualifies for reporting. Sponsors should ~~also~~ regularly monitor and review digital media sites for which they are responsible. When sponsors become aware of unsolicited cases of suspected adverse reactions from the internet or digital media, these should be considered to be spontaneous reports and reported to CARM, subject to the criteria for a valid report (see Section 3.3.2).
Minor changes proposed		
Sections 3.2 and 3.4 use 'serious expected and/or serious unexpected adverse reactions'.	NA	GSK does not believe there needs to be a separation for the type of adverse reactions as they should both be treated in the same manner. Therefore, change 'serious expected and/or serious unexpected adverse reactions' to 'serious adverse reactions' throughout both sections.
Clarity requested		
3.5.4 Lack of efficacy All cases of a lack of therapeutic efficacy for any medicine should be reported to CARM, as the consequences may be potentially very serious for: vaccines	NA	GSK believes this section requires further elaboration; can you advise if the interpretation of vaccine lack of efficacy is consistent with the EU interpretation (EMA/488220/2012).

contraceptives medicines used in critical conditions or life-threatening situations. For example, a lack of efficacy for antibiotics or vaccines may indicate newly developing resistance or waning immunity, both making further study necessary.		
3.5.9 Medication errors ..... Reports of medication error, whether associated with a suspected adverse reaction or not, are also encouraged to be reported to the Medication Error Reporting Programme (MERP).	NA	GSK would like to confirm that as it states that reporting of medication errors is encouraged, that it is not mandatory. Currently medication errors not associated with a serious ADR are collected and classified as non-serious cases. Requiring Sponsors to report this information is inconsistent with the general principles outlined in Section 3.2.
7.2 Dear Healthcare Professional letter ..... Drafts of DHCP letters should be provided to Medsafe for review and the final wording agreed prior to distribution, to ensure that the safety issue has been appropriately covered and managed.		GSK would like to confirm that as it states that DHCP letters should be provided for review, that it is not mandatory.

GSK looks forward to reviewing the outcomes of this consultation.

If you require any additional information or clarification on any of the points above please feel free to contact me, my details are below.

Regards

GSK
Level 4, 436 Johnston Street, Abbotsford, Victoria, 3067.
PO Box 18095. Melbourne, Victoria, 8003.
Email
Tel
Fax
(GlaxoSmithKline Australia Pty Ltd ACN.100162481)

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	GlaxoSmithKline Australia Pty Ltd	
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)* (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?

See table in body of the email

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?

See table in body of the email

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.

See table in body of the email

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?

See table in body of the email

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?

See table in body of the email

Section 6: Submission of Safety Monitoring Documents eg,

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

See table in body of the email

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?

See table in body of the email

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?

See table in body of the email

Please include additional pages if necessary.