Australian Government
Department of Health
Therapeutic Goods Administration

TGA Pharmacovigilance Inspection Program Risk Assessment Survey

To help you prepare responses to the Pharmacovigilance Inspection Program Risk Assessment Survey, a copy of the questions have been provided below. Please note that the survey questions relate only to your **medicines** (not medical devices or biologicals) in the ARTG. This includes all listed, registered and provisionally registered medicines.

Please note: Your final responses MUST be submitted online. DO NOT submit your responses using this form (you will be requested to re-submit your responses online).

Please provide the following information

Company Name	
TGA eBS Client ID	
Your Name	
Your Position	
E-mail	
Phone	

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au https://www.tga.gov.au
Reference/Publication #

TGA Health Safety Regulation

Please answer the following questions about your *medicine portfolio*

**Important: Please note that in this survey, the 'no. of medicines' refers to the no. of distinct medicine ARTG entries, including different strengths / formulations/ brands of the same active ingredient.*

Q1. Please select the total **number** of medicines (medicine ARTG entries) that you currently supply to the Australian market.

☐ 0 (i.e. no medicine is currently supplied to the Australian market)

☐ 1-20

☐ 21-50

☐ 51-200

☐ 201-300

☐ More than 300

*If your response to Q1 is '0' then **skip** to Q5, otherwise proceed to Q2.*

Q2. Please select the **proportion** of your marketed medicines (medicine ARTG entries) that are included in **Schedule 4** or **Schedule 8** of the current Poison Standard.

☐ 0% (i.e. no medicine is included in schedule 4 or schedule 8 of the current Poison Standard)

☐ 1-49%

☐ 50-80%

☐ 81-100%

Q3. Please select the **proportion** of your marketed medicines (medicine ARTG entries) which are **in-licensed** from another sponsor or marketing authorisation holder (MAH).

☐ 0% (i.e. no medicine is in-licensed from another sponsor or MAH)

☐ 1-50%

☐ 51-100%

☐ Don't know

Q4. Please select the **proportion** of your marketed medicines (medicine ARTG entries) which are which are **out-licensed** to another sponsor or marketing authorisation holder (MAH) in Australia.

☐ 0% (i.e. no medicine is out-licensed to another sponsor or MAH in Australia)

☐ 1-50%

☐ 51-100%

☐ Don't know

Q5. In the last **2 years**, have you **newly acquired** any medicine included in the ARTG, of which you are now the sponsor?

For example, through the sale of products or mergers/acquisitions.

☐ No

☐ Yes

☐ Don't know

Q6. Do you have any medicine in the ARTG which has been included in the TGA's Black Triangle Scheme?

- ☐ No
- ☐ Yes
- ☐ Don't know

Q7. In the last **2 years**, did you have any medicine in the ARTG that required an **additional pharmacovigilance** activity, as part of a Risk Management Plan, either in Australia or worldwide?

- ☐ No
- ☐ Yes
- ☐ Don't know

Q8. In the last **2 years**, did you have any medicine in the ARTG that required an **additional Australian risk minimisation** activity, as part of a Risk Management Plan?

- ☐ No
- ☐ Yes
- ☐ Don't know

Q9. In the last **2 years**, did you have any medicine in the ARTG withdrawn, suspended or cancelled by any foreign regulatory agency, for safety reasons?

- ☐ No
- ☐ Yes
- ☐ Don't know

Please answer the following questions about your *pharmacovigilance system*

Q10. In the last **2 years**, did you engage a **third party** (either in Australia or internationally) to conduct any of the following pharmacovigilance activities or functions:

- *case collection, processing or conducting follow-up*
- *submission of serious adverse drug reaction reports to the TGA*
- *screening local or international medical literature/safety-related publications*
- *ongoing safety evaluation (e.g. signal detection/ ongoing monitoring of benefit-risk, notification of significant safety issues)*
- *maintaining reference safety information (e.g. Australian Product Information)*
- *production or submission of aggregate safety reports (e.g. PSURs)*
- *pharmacovigilance training*
- *management or retention of pharmacovigilance records*
- *pharmacovigilance audits*
- *Australian pharmacovigilance contact person or qualified person for pharmacovigilance in Australia (QPPVA)*

☐ No

☐ Yes

☐ Don't know

*If your response to Q10 is either 'No' or 'Don't know' then **skip** to Q11, otherwise proceed to Q10.1*

Q10.1 If you did engage a third party to collate, process and submit cases to the TGA on your behalf, have they ever been **audited** as part of a TGA pharmacovigilance inspection, either through you or through another sponsor.

☐ No

☐ Yes

☐ Don't know

☐ Not Applicable

Q11. In the last **2 years**, have you experienced any of the following changes to your pharmacovigilance system?

- *significant changes to your drug safety database (e.g. a new database or significant data migration)*
- *significant changes to your pharmacovigilance processes (e.g. the transfer of services to a third party or a change to the site where an activity is conducted)*

☐ No

☐ Yes

☐ Don't know

Q12. Where are activities related to ongoing safety evaluation (e.g. signal detection/ ongoing monitoring of benefit-risk, screening global medical literature etc.) **predominantly** conducted?

☐ Global headquarters and/or global pharmacovigilance service provider

☐ Local (Australian) office and/or local pharmacovigilance service provider

☐ Don’t know

Q13. How do you currently **retain** pharmacovigilance records?

These include any record related to the safety of your medicine, e.g. call notes, medical enquiries, adverse drug reaction reports, reference safety information etc.

☐ Electronic and hard copy

☐ Electronic only

☐ Hard copy only

☐ No system for keeping records

Q14. Is the name and contact information of your **current** nominated Australian pharmacovigilance contact person lodged in your TGA Business Services Portal?

☐ No

☐ Yes

☐ Don't know

Please answer the following question about *post-registration* studies or *post-marketing* initiatives

Q15. In the last **2 years**, have you conducted (i.e. initiated, funded or managed) any post-registration study or post-marketing initiative in Australia?

These include, but are not limited to, post-authorisation safety studies, observational studies, registries, market research, patient support programs, product familiarisation programs, early access programs, compassionate supply programs etc.

☐ No

☐ Yes

☐ Don't know

Please answer the following questions about your *compliance* with pharmacovigilance reporting

Q16. In the last **2 years**, have you submitted any **serious**[1] adverse drug reaction report to the TGA?

☐ No

☐ Yes

☐ Don't know

[1] A serious adverse reaction is any medical occurrence that in relation to a medicine, at any dose, results in death, is life-threatening, results in inpatient hospitalisation or prolonged hospitalisation, results in persistent or significant disability or incapacity, is associated with a congenital anomaly or birth defect, is a medically important event or reaction.

*If your response to Q16 is either 'No' or 'Don't know' then **skip** to Q17, otherwise proceed to Q16.1*

Q16.1 Regarding the serious adverse drug reaction reports submitted to the TGA in the last 2 years, what **proportion** of these were submitted within **15 calendar days** of first receipt by any personnel of the company?

☐ 81-100%

☐ 50-80%

☐ Less than 50%

Q17. In the last **2 years**, have you submitted any **significant safety issue**[2] to the TGA?

☐ No

☐ Yes

☐ Don't know

[2] A significant safety issue is a new safety issue or validated signal considered by you in relation to your medicines that requires urgent attention of the TGA. Please refer to the Pharmacovigilance responsibilities of medicine sponsors for a full definition.

*If your response to Q17 is either 'No' or 'Don't know' then **skip** to Q18, otherwise proceed to Q17.1*

Q17.1 Regarding the significant safety issues submitted to the TGA in the last 2 years, what **proportion** of these were submitted within **72 hours** of first awareness by any personnel of the Australian sponsor?

☐ 100%

☐ 51-99%

☐ 50% or less

Please answer the following questions about the submission of *safety-related variations*

Q18. In the last **2 years**, have you submitted to the TGA, any **safety-related variation[3]** to update the Australian Product Information that was not directly requested by the TGA?

☐ No

☐ Yes

☐ Not Applicable (i.e. you are not required to maintain an Australian Product Information)

[3] A safety-related variation is any variation to the Australian PI that involves the addition or modification to the 'Contraindications', 'Warnings and Precautions', 'Interactions with other medicines' or 'Adverse effects' section, or an important safety-related addition or modification to the 'Fertility, pregnancy and lactation', 'Dose and method of administration' or 'Overdose' section, including those variations that fall outside of a section 9D(2) safety-related request to vary an ARTG entry.

*If your response to Q18 is either 'No' or 'Not Applicable' then **skip** to Q19, otherwise proceed to Q18.1*

Q18.1 Regarding the safety-related variations to update the Australian PI submitted to the TGA in the last 2 years, what **proportion** of these were submitted to the TGA **more than 6 months** from the date that it was first decided by any personnel of the company (local or international) that a variation is required?

☐ 0%

☐ 1-49%

☐ 50% or more

Please answer the following questions about *pharmacovigilance inspections*

Q19. In the last **5 years**, has your company, including your global headquarters or any international affiliate or subsidiary, been the subject of a pharmacovigilance inspection conducted by a comparable overseas regulator (i.e. UK MHRA, EMA, US FDA, Health Canada, PMDA Japan, Health Science Authority Singapore or SwissMedic)?

☐ Yes

☐ No

Q20. Has your company ever been the subject of a **TGA Pharmacovigilance Inspection** (this includes the TGA pilot pharmacovigilance inspection program conducted in 2015-16)?

☐ Yes, in 2015-16

☐ Yes, since 2017

☐ No, the TGA has never conducted a pharmacovigilance inspection

End of Survey