Australian Government

Department of Health and Aged Care

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).

You will be asked to provide the following information

Sponsor Name	
TGA eBS Client ID	
Your Name	
Your Position	
Your E-mail	
Your Phone	
Australian Contact Person for Pharmacovigilance is completing the survey	o Yes o No

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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 **types** of medicines you have on the ARTG (select all that apply).

☐ Over the counter medicines

☐ Prescription medicines

☐ Vaccines

☐ Generic medicines

☐ Listed medicines

Q2. 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 Q2 is '0' then **skip** to Q6 otherwise proceed to Q3.*

**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.*

Q3. Please select the **proportion** of your **supplied** 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%

Q4. Please select the **proportion** of your **supplied** medicines (medicine ARTG entries) which are **in-licensed** from another sponsor or company

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

☐ 1-50%

☐ 51-100%

☐ Don't know

Q5. Please select the **proportion** of your **supplied** medicines (medicine ARTG entries) which are **out-licensed** to another sponsor or company in Australia.

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

☐ 1-50%

☐ 51-100%

☐ Don't know

Q6. In the last **2 years**, have you **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

Q7. Do you have any medicine in the ARTG which has been included in the TGA's Black Triangle Scheme?

☐ No

☐ Yes

☐ Don't know

Q8. 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

Q9. 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

Q10. In the last **2 years**, did you have any medicine in the ARTG recalled, voluntarily withdrawn, suspended or cancelled by the TGA, due to a potential impact to safety?

☐ No

☐ Yes

☐ Don't know

Q11. In the last **2 years**, did you have any medicine in the ARTG recalled, voluntarily withdrawn, suspended or cancelled by any foreign regulatory agency due to a potential impact to safety?

☐ No

☐ Yes

☐ Don't know

Please answer the following questions about your *pharmacovigilance system*

Q12. 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: Please select all activities and functions that apply:

☐ adverse event case collection, processing or conducting follow-up

☐ submission of serious adverse 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) and/or local label and packaging

☐ production or submission of aggregate safety reports (e.g. PSURs)

☐ production or submission of RMP-ASA and/or fulfilment of associated additional pharmacovigilance risk minimisation measures

☐ pharmacovigilance training

☐ management or retention of pharmacovigilance records

☐ pharmacovigilance audits

☐ Australian pharmacovigilance contact person or qualified person for pharmacovigilance in Australia (QPPVA)

- Management of risk minimisation activities such as patient support programs
- No
- Don't know

*If your response to Q12 is either 'No' or 'Don't know' then **skip** to Q13, otherwise proceed to Q12.1*

Q12.1 If you did engage a third party to conduct any of these pharmacovigilance activities or functions on your behalf, have they ever been **inspected** as part of a TGA pharmacovigilance inspection, either through you or through another sponsor.

☐ No

☐ Yes

☐ Don't know

Q13 In the last **2 years**, have you experienced any changes to your drug safety database or your pharmacovigilance processes?

☐ A new safety database

☐ Significant data migration

☐ Introduction of Machine Learning or Artificial Intelligence into your pharmacovigilance processes

☐ Transfer of services to a third party

☐ Change to the site where an activity is conducted

☐ Other (please explain):

☐ No

☐ Don't know

Q13.1 In the next 2 years are you planning to implement any changes to your drug safety database or your pharmacovigilance processes?

☐ A new safety database

☐ Significant data migration

☐ Introduction of Machine Learning or Artificial Intelligence into your pharmacovigilance processes

☐ Transfer of services to a third party

☐ Change to the site where an activity is conducted

☐ Other (please explain):

☐ No

☐ Don't know

Q14. Where are activities related to ongoing safety evaluation (e.g. signal detection and assessment, ongoing monitoring of benefit-risk, screening global medical literature etc.) **predominantly** conducted?

☐ Global headquarters (including headquarters located in Australia)

☐ Global pharmacovigilance service provider

☐ Local (Australian) sponsor office

☐ Local pharmacovigilance service provider

☐ Parent company (in-licensed) medicines

☐ Don’t know

14.1 Where are activities related to significant safety issue assessment and decisions regarding notification to the TGA **predominantly** conducted?

☐ Global headquarters (including headquarters located in Australia)

☐ Global pharmacovigilance service provider

☐ Local (Australian) sponsor office

☐ Local pharmacovigilance service provider

☐ Parent company (in-licensed) medicines

☐ Don’t know

Q15. How do you currently **retain**[1] pharmacovigilance records?

☐ Electronic and hard copy

☐ Electronic only

☐ Hard copy only

☐ No system for keeping records

[1] Records regarding information relating to pharmacovigilance activities and the safety of the medicine include, but is not limited to, all adverse reaction reports (serious and non-serious), information surrounding significant safety issues, special situation reports, ongoing monitoring activities, PSURs, literature reviews, contracts with pharmacovigilance providers, documentation regarding changes to reference safety information, reference safety documents and non-valid reports containing drug-event pairs. Please refer to the Pharmacovigilance responsibilities of medicine sponsors for a full definition.

Q16. Is the name and contact information of your **current** nominated Australian Pharmacovigilance Contact Person lodged and up to date in your TGA Business Services Portal?

☐ No

☐ Yes

☐ Don't know

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

Q17. In the last **2 years**, have you conducted (i.e. initiated, funded or managed) any post-registration study or post-marketing initiatives in Australia? Please select all that apply:

☐ Compassionate supply programs

☐ Early access programs

☐ Observational studies

☐ Market research

☐ Patient support programs

☐ Post-authorisation safety studies

☐ Product familiarisation programs

☐ Registries

☐ Other (please specify):

☐ No (none of the above)

☐ Don't know

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

Q18. In the last **2 years**, have you submitted any **serious**[2] adverse reaction report to the TGA?

☐ No

☐ Yes

☐ Don't know

[2] 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 Q18 is either 'No' or 'Don't know' then **skip** to Q20, otherwise proceed to Q19*

Q19. Regarding the serious adverse 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%

Q20. In the last **2 years**, have you submitted any **significant safety issue**[3] to the TGA?

☐ No

☐ Yes

☐ Don't know

[3] 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 Q20 is either 'No' or 'Don't know' then **skip** to Q21, otherwise proceed to Q20.1*

Q20.1 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*

Q21. In the last **2 years**, have you submitted to the TGA, any **safety-related variation**[4] 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 for any medicine in the ARTG)

☐ Don't know

[4]A safety-related variation is any update to the Australian PI that involves the modification to the Therapeutic Indications section which will lead to a reduction in the population that can receive the medicine, the addition or modification to the 'Contraindications', 'Special Warnings and Precaution For Use', 'Interactions With Other Medicines and Other Forms of Interactions', "Effects on Ability to Drive and Use Machine", 'Adverse effects (Undesirable effects)' section, or an important safety-related addition or modification to the 'Fertility, pregnancy and lactation', 'Dose and Method of administration' or 'Overdose' sections, including those variations that fall outside of safety-related request and are submitted as a Category 1 application.

*If your response to Q21 is either 'No' 'Don't know' or 'Not Applicable' then **skip** to Q22*

If you are a product innovator, proceed to Q21.1 and skip 21.2.

If you are a generics sponsor skip 21.1 and proceed to 21.2.

If you are a sponsor of both innovator and generic products, you will be prompted to answer both Q21.1 and Q21.2.

Q21.1 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 was required?

☐ 0%

☐ 1-49%

☐ 50% or more

Q21.2 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 1 month** from the date the safety related changes were made by the innovator?

☐ 0%

☐ 1-49%

☐ 50% or more

Q22. In the last **2 years**, have you made any **safety related updates** to your products (including updates to labels, packaging etc)

☐ No

☐ Yes

☐ Don't know

Please answer the following questions about *pharmacovigilance inspections*

Q23. In the last **5 years**, has your company, including your global headquarters, any international affiliate or subsidiary, or any parent companies (for in-licenced products), 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

Q24. Has your company ever been the subject of a **TGA Pharmacovigilance Inspection** (this excludes the TGA pilot pharmacovigilance inspection program?

☐ Yes

☐ No

End of Survey