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 using the online survey. DO NOT submit your responses using this form (you will be requested to re-submit your responses online).

Please provide the following information

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<th>Company Name</th>
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<td>TGA eBS Client ID</td>
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Please answer the following questions about your medicine portfolio.

Q1. Please select the number of medicines in the ARTG that you currently supply to the Australian market.

- [x] 0
- [ ] 1-50
- [ ] 51-100
- [ ] 101-200
- [ ] 201-400
- [ ] More than 400

If your response to Q1 is ‘0’ then skip to Q2, otherwise proceed to Q1.1

Q1.1 Please select the proportion of your marketed medicines which are prescription only medicines.

- [ ] 0-49%
- [ ] 50-59%

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Phone: 1800 020 653  Fax: 02 6203 1605  Email: info@tga.gov.au  https://www.tga.gov.au
Q1.2 Do you have any medicines in the ARTG approved and marketed for use in children less than 18 years of age in Australia?

☐ No
☐ Yes
☐ Don't know

Q2. Do you have any medicines in the ARTG that require additional pharmacovigilance or risk minimisation activities as part of a risk management plan (RMP)?

☐ No
☐ Yes
☐ Don't know

Q3. Do you have any medicines in the ARTG which have been provisionally registered?

☐ No
☐ Yes
☐ Don't know

Q4. Do you have any medicine in the ARTG which is a new chemical entity and has less than five years post-marketing experience worldwide?

☐ No
☐ Yes
☐ Don't know

Q5. Please select the proportion of your medicines in the ARTG with shared licensing/marketing arrangements.

☐ 0% - not applicable
☐ 1-50%
☐ 51-100%
☐ Don't know

Q6. In the last 12 months, has your company newly obtained any medicine that was already 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

Please answer the following questions about your pharmacovigilance processes.
Q7. Do you **outsource** any of the following pharmacovigilance activities?

- collection, processing or follow-up of spontaneous Adverse Drug Reaction (ADR) reports
- submitting serious ADR reports to the TGA
- signal detection
- development of period safety update reports (PSUR's)
- conducting Australian post-marketing studies (e.g. post-authorisation safety studies, drug utilisation studies, patient registries, healthcare professional surveys)

☐ No  
☐ Yes  
☐ Don't know

*If your response to Q7 is either ‘No’ or ‘Don’t know’ then skip to Q8, otherwise proceed to Q7.1*

Q7.1 Do you have **procedures** in place to effectively monitor the activities of your pharmacovigilance providers?

*For example, regular auditing, standard operating procedures etc.*

☐ No  
☐ Yes  
☐ Don't know

Q8. Do you provide **training** on the identification and collection of adverse drug reaction reports for all company personnel that may receive such reports?

☐ No  
☐ Yes  
☐ Don't know

Q9. Do you currently have any **post-marketing study** in Australia that is initiated, funded or controlled by you?

☐ No  
☐ Yes  
☐ Don't know

Q10. In the last **12 months**, have you had any **significant** changes to your pharmacovigilance system?

*These may include significant changes to your drug safety database or pharmacovigilance processes, or a change to your Australian pharmacovigilance contact person or qualified person responsible for pharmacovigilance in Australia (QPPVA).*

☐ No  
☐ Yes  
☐ Don't know
Q11. In the last 12 months, have you submitted any serious adverse drug reaction reports to the TGA?
☐ No
☐ Yes
☐ Don't know

*If your response to Q11 is either 'No' or 'Don't know' then skip to Q12, otherwise proceed to Q11.1*

Q11.1 Thinking about the serious adverse drug reaction reports submitted to the TGA in the last 12 months, approximately what proportion of these were submitted within 15 calendar days of first receipt?
☐ 100% - All reports were submitted in 15 calendar days or less of first receipt
☐ 80-99%
☐ 60-79%
☐ 40-59%
☐ 20-39%
☐ 1-19%
☐ 0% - All reports were submitted more than 15 calendar days after first receipt

Q12. In the last 12 months, have you failed to report any serious adverse drug reactions to the TGA?
☐ No
☐ Yes
☐ Don't know

Q13. In the last 12 months, did you fail to notify the TGA of any significant safety issue relating to your medicine within the specified timeframe of 72 hours?
☐ No
☐ Yes
☐ Don't know

Q14. In the last 12 months, have you been required to submit Periodic Safety Update Reports (PSUR's) for any of your medicines?
☐ No
☐ Yes
☐ Don't know

Please answer the following questions about regulatory action.

Q15. In the last 12 months, have you had any medicine withdrawn, suspended or cancelled by any regulatory agency due to safety concerns, where this medicine was also included in the ARTG?
☐ No
☐ Yes
☐ Don't know
Q16. In the last 12 months, have you recalled any medicine from the Australian market (either voluntarily or at the TGA’s request) because of issues or deficiencies relating to product quality or presentation?

☐ No
☐ Yes
☐ Don’t know

Please answer the following questions about regulatory inspections.

Q17. When was your most recent pharmacovigilance inspection by the TGA (this includes the TGA’s Pharmacovigilance Inspection Pilot Program)?

☐ Less than 3 years ago
☐ 3-5 years ago
☐ More than 5 years ago
☐ Never - the TGA has not conducted a pharmacovigilance inspection

*If your response to Q17 is ‘Never - the TGA has not conducted a pharmacovigilance inspection then skip to Q18, otherwise proceed to Q17.1*

Q17.1 Were any critical deficiencies (or equivalent) identified?

☐ No
☐ Yes

Q17.2 How many major deficiencies (or equivalent) were identified?

☐ None
☐ 1
☐ 2
☐ 3
☐ 4 or more

Q17.3 Have all Corrective and Preventative Actions (CAPA) resulting from the inspection been implemented?

☐ No
☐ Yes

Q18. In the last five years, has your global company been the subject of a pharmacovigilance inspection that was conducted by a foreign regulatory agency (other than the TGA)?

☐ No
☐ Yes
☐ Don’t know

*If your response to Q18 is ‘No’ or ‘Don’t know’ then skip to Q19 otherwise proceed to Q18.1*

Q18.1 Were there any critical deficiencies (or equivalent) identified from this inspection?

☐ No
☐ Yes
☐ Don’t know
Q19. In the last 2 years has your company been found to have any critical deficiencies (or equivalent) related to safety issues identified from Australian or International Good Clinical Practice (GCP)/Good Manufacturing Practice (GMP) inspections?

☐ No
☐ Yes
☐ Don't know

End of Survey