Section	Version 2.2 *Current*	Version 3.0 *Proposed update*	Major changes
Introduction	Subsections: • Scope • Responsibilities • Adverse events and adverse reactions • Significant safety issues	Subsections: • Scope • Responsibilities	*Adverse events and adverse reactions* and *Significant safety issues* subsections amended with relevant content changes and moved from *Introduction* section (V2.2) into *Your regulatory requirements: What, when and how to report* section (V3.0)
Your regulatory reporting requirements	Subsections: • What you must report • When to report • How to report serious adverse reactions • How to report significant safety issues • Reporting requirements for special situations	Subsections: • What, when and how to report • Reporting requirements for special situations	Content from *Introduction* section, *When to report, How to report serious adverse reactions* and *How to report significant safety issues* subsections consolidated into *What, when and how to report* subsection
Your regulatory reporting requirements Summary table	Page 11	Page 7	Addition of *Other safety issues* report type and reporting timeframe
Your regulatory reporting requirements Significant safety issues / Safety issues	Pages 9-10, 13-14, 15 and 22	Pages 16-18	Content consolidated into one section for improved flow and readability SSI definition amended for clarity and closely aligned with the European Medicines

			Agency's definition of emerging safety issue Two-tiered reporting system introduced: Significant safety issues (≤72 hours) and Other safety issues (≤30 calendar days) with clearer guidance on what constitutes each type of issue Inclusion of a safety issue reporting form (link to be made available on TGA website) to facilitate complete, correct safety issue reporting Timeframe defined for expedited communication of SSIs from global personnel to Australian personnel (3 calendar days)
Your record keeping requirements	-	-	Nil major changes
Your pharmacovigilance system	-	-	Nil major changes
Pharmacovigilance and the law	-	-	Nil major changes

Other pharmacovigilance requirements	Subsections: • Pharmacovigilance Inspection Program • Periodic Safety Update Reports • Reporting requirements for medicines supplied through an exemption scheme • Reporting requirements between application submission and prior to inclusion in the ARTG	Subsections: • Pharmacovigilance Inspection Program • Periodic Safety Update Reports • **Risk Management Plans** • **Black Triangle Scheme** • Reporting requirements for medicines supplied through an exemption scheme • Reporting requirements between application submission and prior to inclusion in the ARTG	Addition of sponsors' pharmacovigilance requirements relating to risk management plans and the Black Triangle Scheme These are not new requirements but were previously unreferenced in the PV Guidelines
Appendix A	-	Page 40	Addition of *Safety issue reporting decision tre*e to aid decision making on when to report safety issues to the TGA