Technical Alert

Revised Pharmacovigilance Guidelines and Pharmacovigilance Inspection Program Inspection Guidelines Released

The Pharmacovigilance and Special Access Branch (PSAB) of the TGA has released the revised Pharmacovigilance Guidelines, and published information and guidance about its new Pharmacovigilance Inspection Program (PVIP).

The revised Pharmacovigilance Guidelines, including data retention requirements, will be enforceable and compliance with these requirements will be audited through TGA's Pharmacovigilance Inspection Program. Inspections will commence after the PVIP information sessions have been completed. Sponsors will be given six to eight weeks notice prior to an inspection taking place.

Revised Pharmacovigilance Guidelines

The '*Pharmacovigilance responsibilities of medicine sponsors - Australian recommendations and requirements*', also known as the (revised) Pharmacovigilance Guidelines, has been published today on the TGA website and is available as a PDF. It outlines the responsibilities of sponsors of listed and registered medicines on the ARTG, including mandatory reporting requirements. The document also offers recommendations on pharmacovigilance best practice.

Pharmacovigilance Inspection Program and PVIP Inspection Guidelines

All Australian sponsors of medicines included on the ARTG are subject to the pharmacovigilance inspection program. The document '*Pharmacovigilance inspection program - Guidance for medicine sponsors*', also called the PVIP Inspection Guidelines, has now been published on the TGA website and in a PDF version. Guidance on how the TGA will prepare for, conduct, report on and follow up on inspections and sponsors' inspection-related responsibilities is outlined in this guidance.

The TGA has also published an overview of the Pharmacovigilance Inspection Program, including frequently asked questions and information about the Pharmacovigilance Inspection Program Information Sessions. Registration is closing next Wednesday **6 September** for the Sydney information session, and on the **15 and 22 of September** for the Melbourne and Brisbane sessions respectively. Attendance at one of these free sessions is recommended for all sponsors of ARTG listed or registered medicines. Registration for the information sessions is available here.

ENDS

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