Technical Alert

Consultation: Revised Pharmacovigilance Guidelines

The Pharmacovigilance and Special Access Branch (PSAB) of the TGA has recently drafted a revision of the *Australian requirements and recommendations for pharmacovigilance responsibilities of sponsors of medicines*, also known as the Pharmacovigilance Guidelines.

CMA members are invited to participate in a targeted consultation for this revision (attached). Please provide your feedback via email to submissions@cmaustralia.org.au by close of business Friday 14 July 2017.

In considering your feedback, are there any aspects of the guidelines that might require further clarification? Following the targeted consultation process the revised version will be finalised and adopted by the TGA.

Given the passage of the Therapeutic Goods Amendment Bill 2016 through the Senate and amendments to the Therapeutic Goods Regulations 1990, the revised Pharmacovigilance Guidelines, including the data retention requirements, will be legally enforceable and compliance with these requirements will be audited through TGA's Pharmacovigilance Inspection Program.

Members should note that:

- The pharmacovigilance requirements and recommendations remain largely consistent with the current pharmacovigilance guidelines (Version 1.3, June 2014).
- There are several changes to the layout of the document which have been made necessary due to a transition to a web-based guidance format.
- This revision also aims to improve clarity in the guidelines based on enquiries and feedback received from sponsors.

Highlighted are the key changes for your consideration and to assist you in your review:

Change	Details	Section (Reference pages)
Title	*Pharmacovigilance responsibilities of medicine sponsors: Australian recommendations and requirements*	--
New information	Addition of information about reporting proposed actions or justifications for no action in response to a significant safety issue	*Significant safety issues* (p. 10)
	Addition of data requirement for Aboriginal and/or Torres Strait Islander origin	*Patient details* (p.20)

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	Addition of information about reports related to transmission of infectious agents, orphan drugs and suspended or discontinued products	*Reporting requirements for special situations* (p.27-33).
	Addition of information about safety contracts and agreements for third-party/external parties	*Safety contracts and agreements* (p.35)
	Addition of information about new searchable TGA literature database (under development)	*Reports from International literature* (p.40)
	Addition of information about the analysis of safety information	*Analysing information* (p.41)
	Addition of data retention requirements (Therapeutic Goods Amendment Bill 2016)	*Data quality control* (p.42)
Clarification	Clarification of what constitutes a significant safety issue	*Significant safety issues* (p.10-11)
	Clarification of the definition of Day 0 and sponsor personnel in the context of Day 0	*Day* 0 (p.15)
	Clarification that reports from post-marketing initiatives are considered solicited reports	*Reports from other post-marketing initiatives* (p.28)
	Clarification of the differences between PV Contact person and Qualified person responsible for pharmacovigilance	*Australian pharmacovigilance contact person* (p.13) and *Qualified person responsible for pharmacovigilance in Australia* (p. 34)
Updated	Updated procedure for nominating contact person for pharmacovigilance through TGA Business Services.	*Australian Pharmacovigilance contact person* (p.13)
	Updated TGA contact details for reporting	*Where to report* (p.25-26)

Any questions relating to this consultation should be directed to Emma Burchell on 02 6260 4022 or emma.burchell@cmaustralia.org.au

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