



### **Important Notice: Pharmacovigilance Guideline-Delay of Implementation Date**

Members should note that post the PV seminar the TGA has advised the release of the *draft Australian guideline for pharmacovigilance responsibilities of sponsors of medicines* has been delayed and it will **not be coming into effect on 1 October 2011**. The TGA is considering further minor amendments to the revised guideline to clarify certain recommendations. The date that the new guideline will come into effect is yet to be confirmed. Until the revised guideline has been finalised, the current pharmacovigilance guideline remains in effect.

### **ASMI-CHC Pharmacovigilance Seminar Summary**

ASMI and CHC hosted a half-day seminar on the recently updated Pharmacovigilance Guideline in Canberra on the 6<sup>th</sup> of September 2011. As noted above, the TGA are making further minor amendments to the guideline following this event.

Dr. Jane Cook, Head of the TGA's Office of Product Review (OPR), gave a presentation on sponsor's Pharmacovigilance responsibilities. Jane's presentation also covered how the TGA processes adverse event reports received, and how signal detection is carried out. Her presentation also answered a number of the questions forwarded by ASMI and CHC before the seminar.

Three speakers from our member companies: Fiona Dunagan of GSK; Pamela Wood of Johnson & Johnson; and David Tsui of Blackmores also gave presentations. These focussed on PV generally, on the monitoring systems used by the companies, and on the practicalities of collecting and submitting reports. The presentations were followed by a question-and-answer session, which delegates found very informative and useful.

Delegates were impressed with Jane Cook's open, direct manner and appreciated her willingness to address all the questions put to her. They also appreciated the opportunity to meet Dr. Cook and to ask her questions directly.

Dr. Cook's presentation and industry presentations will be published on the CHC and ASMI websites, along with a summary of the Q & A session. The seminar handouts included an information sheet prepared by the associations with links to several consultants and information sources that may assist sponsors. This will also be published on the association websites.

After the presentations, Dr. Cook expressed her willingness to engage in regular contact with industry and mentioned the possibility of further PV information sessions in the state capitals.

**Members should note**, the TGA requires all sponsors to notify the TGA of their current Qualified Person responsible for Pharmacovigilance (QP or QPPV). At present this needs to be done in writing, in a letter addressed to the OPR. In the future the TGA is expected to set up an electronic portal for sponsors to submit and update this information.