

# Questions and Answers: Reporting Adverse Reactions Associated with Chinese Herbal Medicine

**Interview with Ian W Boyd\*** PhD  
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Dr Ian W Boyd from the Adverse Drug Reactions Unit at the Therapeutic Goods Administration earlier in 2006 kindly agreed to respond further in a question and answer format to provide an update on recent developments and to encourage reporting of adverse drug reactions (ADRs) among Chinese medicine practitioners.

**AJACM:** What are the Complementary Medicines Evaluation Committee's (CMEC) strategies for encouraging Chinese medicine practitioners or complementary medicine practitioners to report suspected adverse events?

**Boyd:** One of the measures recommended by CMEC is to make Chinese medicine practitioners or complementary medicine practitioners more aware of the reporting scheme. While there are no funds available for a publicity campaign, members of CMEC, ADRAC (Adverse Drug Reactions Advisory Committee) and their respective secretariats are attempting to find opportunities to increase awareness. The preceding article is one such opportunity.

**AJACM:** What is the current situation with regard to reporting suspected adverse reactions associated with Chinese medicine? How many such reactions have been reported and what types?

**Boyd:** This question is difficult to answer because the database does not have the appropriate grouping terms for such an analysis. We currently receive about 200 reports of complementary medicines ADRs each year. Most reports have been forwarded in the past five years.

A small proportion of these involve Chinese medicines. These are grouped according to the name of the product. In some cases we do not know the name so it is coded as 'Chinese medicine'. Cases in which the association between the adverse reaction and the medicine is considered 'unrelated', 'very unlikely' or 'un-assessable' on the basis of the information supplied are excluded from the database. Only those cases in which the association is considered 'certain', 'probable' or 'possible' are included.

Thirty identified and seven unidentified Chinese herbal medicines have been associated with 45 reports since 1972. Chinese herbal medicine products were the only suspected medicine in 24 of those 45 cases. In most cases more than one adverse reaction was reported and in total, 136 suspected adverse reactions have been reported in the 45 cases. For 92 of the 136 reactions, the Chinese medicine products were the only suspected medicine.

Like Western medications, the more commonly reported adverse reactions are relatively minor. A few life-threatening reactions have also been reported. Table 1 illustrates the number and nature of common reactions.

**AJACM:** Are there certain products associated with more adverse reactions than other products?

**Boyd:** The above-mentioned adverse reactions are associated with 30 identified Chinese medicine herbal products. Of those, each of the ten products had one report, whereas the remaining 20 products were related to two or more reports.

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TABLE 1 Number and nature of commonly reported adverse reactions associated with 30 identified Chinese medicine herbal products reported since 1972

System	Symptoms	No. of reports	Sole suspected
Eye disorders	Mydriasis	2	2
Gastrointestinal disorders	Nausea	6	5
	Vomiting	5	3
	Diarrhoea	3	1
	Abdominal pain	3	1
General disorders	Malaise	6	6
	Fatigue	2	1
Hepatobiliary disorders	Abnormal hepatic functions	3	2
	Jaundice	3	2
	Hepatic failure	2	2
Musculoskeletal and connective tissue disorders	Back pain	3	1
Nervous system disorders	Dizziness	3	0
	Abnormal co-ordination	2	0
	Convulsion	2	0
Psychiatric disorders	Hallucination	3	1
	Confused state	2	2
Renal and urinary disorders	Renal impairment	2	2
Skin disorders	Pruritus	7	5
	Rash	6	5
	Purpura	3	2

Usually one case was reported against each product and occasionally more than one case was reported. For instance, four cases were reported against *Long dan xie gan wan* (Gentiana combination).

**AJACM:** Can you clarify the origin of the source of reporting?

**Boyd:** Yes. For example, if we take unspecified Chinese medicines, we have four cases of adverse effects reported by hospitals, two by specialists and one from a community

pharmacist. In another example, six cases were reported by general practitioners, one by a hospital, two by a specialist and one by a consumer.

In general, it is unusual for companies that sponsor Chinese medicines or complementary medicines or Chinese medicine practitioners to report such events. We know that spontaneous reporting is subject to gross under-reporting, so the Chinese medicines reported to us are just a sample of what is occurring.