



26 April 2005

1st + 2nd QM 04/05
Submission No:501.....



Mr Bob Baldwin MP
Chairman
Joint Committee of Public Accounts and Audit
Parliament House
CANBERRA ACT 2600

JOINT COMMITTEE OF
10 MAY 2005
PUBLIC ACCOUNTS & AUDIT

Dear Mr Baldwin

JCPAA REVIEW OF AUDIT REPORT NO. 18 2004-05: REGULATION OF NON-PRESCRIPTION MEDICINAL PRODUCTS.

You may recall that, at the Committee's review of the above report, the Committee asked whether it is unusual for a regulatory authority not to follow ISO or some similar international quality standards.

I undertook to get back to the committee as to whether ANAO had knowledge on this area. The Australian National Audit Office is currently auditing two such regulators in the Health and Ageing Portfolio: the Private Health Insurance Administrative Council (PHIAC) and the Office of the Gene Technology Regulator (OGTR). Our audits are not yet complete, but our work indicates that they both have regard to such standards.

The PHIAC has compared its risk management standards against the *Australian Standard for Risk Management, AS/NZS 4360:1999*. It concluded that its standards were consistent with these standards. The Australian Standard is, in turn, consistent with the relevant ISO standard.

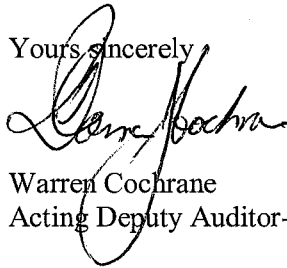
We also note that the PHIAC utilises standards for its certification processes. Directors of registered health benefits organisations are required to certify annually that their organisation has referred to the above Australian Standard as an accepted measure of appropriate risk management processes.

The OGTR has advised that it has received ISO Quality Management accreditation for its compliance and investigation activities. It has also adopted ISO standards for its monitoring activities, although it has not yet received certification for these systems.

For you information, we anticipate tabling the report on the PHIAC in the second half of this year. The audit of the OGTR has just commenced, and will be tabled early 2006.

You may also like to note that the Australian Pesticides and Veterinary Medicines Authority uses the ISO 9000 series of standards as the framework of its quality system. Its annual report notes that, through this, it places an emphasis on responsiveness to customers and stakeholders, in addition to consistency of output, efficient resource management and continuous improvement.

I hope that these observations are helpful. Please let me know if you would like any further information.

Yours sincerely

Warren Cochrane
Acting Deputy Auditor-General