



21 October 2011

Dr Bu Wilson  
Principal Research Officer  
Standing Committees on Finance and Public Administration  
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Dear Dr Wilson

**RESPONSES TO ADDITIONAL QUESTIONS – COMMUNITY REFERENCES  
COMMITTEE – Regulatory standards for the approval of medical devices**

Thank you for your recent email requesting further information to the Senate References Committee – Regulatory standards for the approval of medical devices.

The Australian Orthopaedic Association (AOA) provides the following responses to the additional questions:

**Question 1**

Can the AOA provide further information on what codes of practice cover the declaration of financial inducements offered to surgeons?

Response:

AOA has had a professional code of conduct for members which was reviewed and strengthened following the USA FDA investigation of device companies during 2004/05.

In 2009 AOA developed a Position Statement on Interaction with Medical Industry. (See copy attached).

**Question 2**

During the hearing Mr Cosenza stated that the AOA's code of ethics applied only to AOA members. Is this code legally binding?

Response:

No it is not legally binding; the code is not a legal document.

**Question 3**

What penalties are in place if the code is found to have been breached?

Response:

A member may be counselled, censured, suspended or expelled from the Association depending on the outcome of assessment and review of the complaint.

**Question 4**

Does AOA investigate possible breaches? How does this process work?

Response:

Firstly the complaint has to be a written complaint directly to AOA to initiate the complaint handling process. The complaint would be referred to the AOA Professional Conduct Committee for assessment and review.

The assessment and review process would be in line with the relevant clause contained within the AOA's Constitution.

**Question 4**

How many breaches have been investigated in the last five years? How many have been found to have actually occurred?

Response:

There has been one written complaint received by AOA and that was in 2010 but it was not progressed internally as it was regarded as raising issues outside AOA's remit. The complainant was advised to report the matter to AHPRA.

**Question 5**

Does the AOA report these breaches to any other organisation?

Response:

AOA would report breaches to relevant other organisations dependent on the assessment and review of the individual complaint.

**Question 6**

How does the AOA's code compare with other codes, such as that of the Royal Australasian College of Surgeons?

Response:

The AOA code was developed with regard to other available codes including the one developed by the Royal Australasian College of Surgeons. It is similar to the RACS code.

**Question 6**

What is AOA's position on a single, legally enforced code applying to all medical practitioners licenced in Australia?

Response:

AOA would prefer to continue the use of self-regulation rather than a legally enforceable code.

If you require further information please contact Ms Kathy Hill

Yours sincerely,



Adrian Cosenza  
**Chief Executive Officer**