



17 October 2011

Dr Bu Wilson  
Principal Research Officer  
Standing Committees on Finance and Public Administration  
Suite SG 60  
PO Box 6100  
Parliament house  
Canberra ACT 2600

Dear Dr Wilson

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

Thank you for the opportunity to provide additional information to the Senate References Committee – Regulatory standards for the approval of medical devices.

The Australian Orthopaedic Association (AOA) responses to the Questions on Notice are as follows:

**QON 1**

How long has the professional code of conduct been in operation?

Response:

AOA has had a professional code of conduct for members for a number of years. However, following the USA FDA investigation of device companies during 2004/05, the AOA Code of Conduct was reviewed and strengthened.

The code of conduct since at least 2006 has outlined the requirement for members to disclose any financial interest in the sale of drugs, prostheses, or appliances that he/she may have when recommending that particular item to a patient.

AOA believes the previous code of conduct also outlined the same requirement but due to a change of website that occurred in that year the file format used previously is unreadable.

The code of conduct has been reviewed in 2006, 2008 and 2010.

**QON 2**

If an orthopaedic surgeon does not advise the patient of a commercial link with a device, for instance, what sanctions are there for that breach?

Response:

Firstly the complaint has to be a written complaint directly to AOA to initiate the process. The complaint would be referred to the AOA Professional Conduct Committee for assessment and review. Sanctions include counselling of the member through to removal of the member from the Association.

If the complaint involved anything of a criminal nature it would be referred to the relevant authority (ie police, AHPRA)

**QON 3**

Have there been any complaints in relation to that sort of conduct where a surgeon did not disclose their commercial interest in a device and what the outcomes of those were?

Response:

There have been no complaints to AOA that were progressed through to invoking sanctions. AOA received one written complaint in 2010 but it was not progressed internally as it was regarded as raising issues outside AOA charter. The complainant was advised to report the matter to AHPRA.

If you require further information please contact Ms Kathy Hill

Yours sincerely,



Adrian Cosenza  
**Chief Executive Officer**