Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Budget Estimates 2011-2012, 31 May 2011

Question: E11-453

OUTCOME: 1 Population Health

TOPIC: WITHDRAWAL OF THE DE PUY ASR HIP DEVICE

Hansard Page: CA 36

Senator Fierravanti-Wells asked:

Can you explain the risk process for devices and the classification criteria?

Answer:

The regulatory framework has a risk-based classification system for medical devices, which is based on the recommendations of the Global Harmonization Task Force (GHTF). The classification rules are located in Schedule 2 of the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations), and the implementation of the rules is covered by Regulation 3.3. The different classification levels for medical devices are:

Classification	**Relative level of risk**
Class I	lowest risk
Class IIa	low–medium risk
Class IIb	medium–high risk
Class III	highest risk
Class AIMD (Active implantable medical device)	