Chapter 1

Introduction

Terms of reference

1.1 On 16 June 2011 the Senate referred the following matter to the Senate Community Affairs References Committee for inquiry and report by 12 October 2011:

> The regulatory standards for the approval of medical devices in Australia, with particular attention to devices with high revision rates, and in undertaking the inquiry the committee consider:
>
> (a) the role of the Therapeutic Goods Administration in regulating the quality of devices available in Australia;
>
> (b) the cost effectiveness of subsidised devices;
>
> (c) the effectiveness and accuracy of the billing code and prostheses list;
>
> (d) the processes in place to ensure that approved products continue to meet Australian standards;
>
> (e) the safety standards and approval processes for devices that are remanufactured for multiple use;
>
> (f) the processes in place to notify the relevant authorities and the general public of high revision rates or possible faulty devices;
>
> (g) the effectiveness of the current regimes in place to ensure prostheses with high revision rates are identified and the action taken once these devices are identified;
>
> (h) the effectiveness of the implemented recommendations of the Health Technology Assessment; and
>
> (i) any other related matter.

1.2 The reporting date was extended to 8 November 2011 and subsequently to 22 November 2011.

Conduct of the inquiry

1.3 The inquiry was advertised in *The Australian*, and through the internet. The committee invited submissions from the Commonwealth Government and interested organisations.

1.4 The committee received 34 public submissions. The list of individuals and organisations which made public submissions to the inquiry, together with other information authorised for publication by the committee, is at appendix 1. The committee held a public hearing in Canberra on 27 September 2011. The list of witnesses who gave evidence at the public hearing is available at appendix 2. In addition, the committee received responses in relation to potential adverse reflections. Following the public hearing on 27 September 2011, the committee received

correspondence from St Jude Medical raising concerns about evidence provided at the hearing by Ms Karen Carey.

1.5 Submissions, additional information, the Hansard transcript of evidence and responses to potential adverse reflection (contained in submissions or expressed at the public hearing) may be accessed through the committee's website at http://www.aph.gov.au/senate/committee/clac_ctte/index.htm

Acknowledgement

1.6 The committee thanks those organisations and individuals who made submissions and gave evidence at the public hearings.

Note on references

1.7 References in this report are to individual submissions as received by the committee, not to a bound volume. References to the committee Hansard are to the proof Hansard. Page numbers may vary between the proof and the official Hansard transcript.

Structure of the report

1.8 The report is structured as follows:

- Chapter 2 discusses issues related to the regulation of medical devices in Australia;
- Chapter 3 provides a background to the DePuy ASR hip system. It goes on to focus on the experience of consumers with DePuy ASR hip prostheses, and their associated revision surgery. It also examines the effectiveness of the current regime in place to ensure prostheses with high revision rates are identified; and the action taken once these devices are identified;
- Chapter 4 covers the cost effectiveness of subsidised devices and the effectiveness and accuracy of the billing code and Prostheses List; and
- Chapter 5 presents a summary of the committee's conclusions.