Australian Government
Department of Health and Ageing

Minute

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Assistant Secretary
Private Health Insurance Branch

HUMAN TISSUE APPLICATIONS FOR THE AUGUST 2013 PROSTHESES LIST

Purpose

The purpose of this Minute is to:

- advise you of the applications received for Part B of the August 2013 Prostheses List; and
- seek your approval on the suggested approach to these applications.

Background

The Prostheses List Part B Human Tissue is not subject to the reforms that were announced in April 2003 and introduced in October 2005 and April 2007. Human tissue prostheses on the Prostheses List are not subject to clinical assessment, centralised benefits negotiations, gap permitted products or mandatory cost recovery.

The Department processes all applications for human tissue and makes recommendations to the Minister (or delegate) on the listing of new human tissue and amendments (generally benefit increase proposals).

The guidelines that suppliers of human tissue must comply with to be listed on the Prostheses List are:

- the supplier must have a TGA licence to collect, process and store the tissue (for currently listed products);
- for applications to list new products on the Prostheses List, the supplier must have a relevant ARTG;
- the tissue must be surgically implanted;
- there must be a Medicare benefit payable for the professional service associated with the provision of the prosthesis (human tissue);
- the tissue must 'permanently' replace, totally or partially, a bodily function and remain with the patient on discharge; and
- the patient must be under hospital care.

There are currently four categories in Part B Human Tissue - cardio-thoracic, ophthalmic, orthopaedic and dermatologic.

FOI request number 042-1314

Part 6 of this FOI request sought the number of applications for a product to be listed on Part B of the Prostheses List that are being considered by the Minister for Health & Ageing (or his or her authorised delegate), including when those applications were received by the Department, broken down as follows:

(a) As at 26 July 2013, the number of applications for a product to be listed on Part B of the Prostheses List that were being considered at that date and which were supported by, or include a reference to, the number allocated to a product (ARTG Number) on the Australian Register of Therapeutic Goods, as kept by the Therapeutic Goods Administration;

(b) As at 16 August 2013, the number of applications for a product to be listed on Part B of the Prostheses List that were being considered at that date and which were supported by, or include a reference to, an ARTG Number; and

(c) As at the date of this FOI application, the number of applications for a product to be listed on Part B of the Prostheses List that were being considered at that date and which were supported by, or include a reference to, an ARTG Number.

Date Received	No. of Applications	No. of applications supported by or including a reference to an ARTG number, as kept by the Therapeutic Goods Administration, as at: 26 July 2013	No. of applications supported by or including a reference to an ARTG number, as kept by the Therapeutic Goods Administration, as at: 16 August 2013	No. of applications supported by or including a reference to an ARTG number, as kept by the Therapeutic Goods Administration, as at: Date of this FOI Application
16 April 2012	2	2	2	2
8 May 2013	5	5	5	5