

SUBMISSION NO. 35
TT on 28 February 2012

ANSWERS TO QUESTIONS ON NOTICE

Joint Standing Committee on Treaties (JSCOT)

HEALTH AND AGEING PORTFOLIO

JSCOT Public Hearing held Monday 7 May 2012

OUTCOME: 1: Population Health

Treaty: AGREEMENT BETWEEN AUSTRALIA AND THE EUROPEAN UNION AMENDING THE AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS BETWEEN AUSTRALIA AND THE EUROPEAN COMMUNITY.

Topic: TGA fees and charges structure for medical devices conformity assessment certification.

The Hon Dr Stone MP asked:

Can you give us an indication of the cost associated with, say, testing one of these new prostheses? Does it vary according to the complexity or is it a standard fee? Could you provide information about what fees are typically charged?

Answer:

TGA Conformity Assessment Fees

Depending on the classification of a device, there are a number of different conformity assessment procedures that a manufacturer may use. The cost to a manufacturer to obtain TGA conformity assessment certification is made up of two components: an application fee and an assessment fee. The latter fee varies according to the risk classification of the device and the assessment pathway selected by the manufacturer. Higher classification devices must undergo more stringent conformity assessment procedures than lower classification devices.

The conformity assessment fees for medical devices as at 1 July 2011 are shown below.

Fees for 2011-2012 for Conformity Assessment Certification Pathways for Medical Devices*

Conformity Assessment	Fee \$
Application for Conformity Assessment Certificate - All Procedures	820
Schedule 3, Part 1 - Full Quality Management System Audit	24,600
Schedule 3, clause 1.6 - Design Examination	48,500
Schedule 3, Part 2 - Type Examination (including management of testing, analysis, and reporting on examination of the type)	33,800
Schedule 3, Part 3 - Verification (including management of testing, analysis, and reporting on verification tests)	23,600
Schedule 3, Part 4 - Production Quality Management System Audit	21,500
Schedule 3, Part 5 - Product Quality Management System Audit	18,400

TGA Fee Structure for Mutual Recognition Agreement (MRA) Activities

Australian manufacturers who wish to access the European Union (EU) market - using certification issued by the TGA under the MRA - enter into a contract with the TGA for provision of the relevant conformity assessment services.

The TGA will only issue EU certification to Australian manufacturers who already hold Australian conformity assessment certification. Therefore, manufacturers obtain TGA-issued EU certification under the MRA - in addition to their Australian conformity assessment certification - by paying an additional fee set out in the MRA contractual agreement. For the majority of applicants, this fee is set at \$3330.

EU Conformity Assessment Fees

The TGA is unable to comment on the costs borne by the medical devices industry in obtaining conformity assessment services through an EU notified body.

* <http://www.tga.gov.au/about/fees-current.htm>

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Outcome: 1: Population Health

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Minister

The attached proposed answer is submitted for information.

National Manager

15/5/12.

Date

Director
Parliamentary

Date

Noted

Adviser / Minister

Date