Senate Community Affairs Committee

ANSWERS TO ESTIMATES QUESTIONS ON NOTICE

HEALTH AND AGEING PORTFOLIO

Supplementary Budget Estimates 2010-11, 20 October 2010

Question: E10-121

OUTCOME 1: Population Health

Topic: DENTAL DEVICES

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Senator Xenophon asked:

a) Is it correct that dentists are able to bring unregistered dental products into the country for personal use?
b) How are personal use exemptions defined and how are they monitored?
c) Do we know how many unregistered dental products come into Australia?

Answer:

a) Yes. Any person may import therapeutic goods into Australia for the treatment of the importer, or a member of the importer's immediate family (often referred to as 'personal use') if the requirements set out in the legislation are complied with. The relevant rules are set out in the document *Access to Unapproved Therapeutic Goods – Personal Importation*, October 2004 that is available at www.tga.gov.au/docs/pdf/unapproved/personalimp.pdf.

b) Therapeutic goods including medical devices that are imported into Australia for personal use are exempt from the requirement to be included in the Australian Register of Therapeutic Goods (ARTG). The 'personal use' exemption does not apply to a health professional using the medical device in their practice to treat members of the public.

A medical device will be exempt from inclusion on the ARTG if it is mentioned in Part 1.1 of Schedule 4, of the *Therapeutic Goods (Medical Devices) Regulations 2002* which refers to a:

> Medical device that is imported into Australia for use in the treatment of the importer, or a member of the importer's immediate family, or for use in the in vitro examination of a specimen obtained from the importer or a member of the importer's immediate family, if:
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> (a) the device does not contain a substance the importation of which is prohibited under the *Customs Act 1901*; and
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> (b) in the case of:
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> (i) a device, other than an IVD medical device, that is manufactured using tissues, tissue derivatives, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of bacterial or recombinant origin; or

(ii) a device, other than an IVD medical device, that incorporates, or is intended to incorporate, as an integral part, a stable derivative of human blood or blood plasma — the device is the subject of an approval under section 41HB of the Act; and

(c) in the case of a Class 4 IVD medical device, Class AIMD medical device, Class III medical device, Class 3 IVD medical device, Class IIb medical device, Class 2 IVD medical device or Class IIa medical device:

(i) the quantity imported in one importation is not more than the amount required to give 3 months treatment using the device according to the treating medical practitioner's directions; and

(ii) the total quantity imported in a 12 month period is not more than the amount required to give 15 months treatment using the device according to the treating medical practitioner's directions; and

(d) in the case of a device that is subject to Schedule 4 or Schedule 8 to the current Poisons Standard, or a device that incorporates, or is intended to incorporate, as an integral part, a substance that is subject to either of those Schedules — the device, or substance, is acknowledged in writing by a medical practitioner registered under a law of a State or Territory to be appropriate treatment for the importer or family member (unless the device is carried by the importer as a passenger on a ship or an aeroplane).

Importation for personal use is not monitored by the TGA as it occurs under an exemption of the *Therapeutic Goods Act 1989*.

c) It is an offence under the *Therapeutic Goods Act 1989* to import medical devices that are not included in the ARTG where an exemption from such inclusion (such as the exemption for personal use) does not apply or where the importation is not otherwise authorised. Alternatively, civil penalties may be payable.

The TGA does not know how many unregistered dental medical devices come into Australia nor how many are imported for personal use in accordance with the relevant requirements. However, if someone is aware of instances where medical devices have been illegally imported and/or supplied in Australia, they are encouraged to report those details to the TGA for further investigation.