EXPLANATORY STATEMENT

<u>Issued by the Authority of the Minister for Health and Ageing</u>

A New Tax System (Goods and Services Tax) Act 1999

GST-free Supply (Health Goods) Determination 2011

Purpose

The purpose of this determination is to broaden the range of nicotine replacement therapy products that are granted GST-free status under a determination. Specifically, all nicotine replacement therapies for transdermal and oromucosal use used as an aid in withdrawal from tobacco smoking will receive GST free status under this determination.

A new determination is being issued to maintain the existing GST-free treatment of certain nicotine replacement therapies where these products would have otherwise become taxable from 1 January 2012 through being removed from the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

This Determination revokes the determination titled *GST-free Supply (Health Goods) Determination 2005* (previous Determination) from 31 December 2011.

Paragraph 177-10(4)(b) of the *A New Tax System (Goods and Services Tax) Act 1999* (the GST Act) provides that the Health Minister may make a determination in respect to subsection 38-47(1) of the GST Act. This sub-section of the GST Act provides that a supply is GST-free if it is a supply of goods of a kind that the Health Minister, by determination in writing, declares to be goods the supply of which is GST-free.

This Determination

This determination expands the entry for nicotine from that covered by the previous determination. The new entry for nicotine covers all forms of nicotine replacement therapy where the product is for use as an aid in withdrawal from tobacco smoking and the nicotine is administered through a preparation for transdermal or oromucosal use. In addition, for the purpose of sub-section 38-47(1) of the GST Act, for the goods in Schedule 1 of the determination to be GST-free, they must under the *Therapeutic Goods Act 1989* be required to be included in the Australian Register of Therapeutic Goods, or be goods in a class of goods required to be in the Australian Register of Therapeutic Goods.

In September 2011, a delegate to the Secretary of the Department of Health and Ageing announced a final decision to exempt from listing in the SUSMP from 1 January 2012, nicotine in preparations for human therapeutic use for use as an aid in withdrawal from tobacco smoking, in preparations for oromucosal or transdermal use. To effect this decision, the delegate decided to delete the Schedule 2 entry for nicotine and amend Schedule 4 by exempting nicotine in preparations for human therapeutic use except for use as an aid in withdrawal from tobacco smoking in preparations for oromucosal or transdermal use. As a result of this decision, certain forms of nicotine replacement therapies would be permitted to be sold in non-pharmacy settings (such as supermarkets) from 1 January 2012. The

consequence of this decision is that these products will lose GST-free status if a determination is not made.

Consultation

Consultation was not conducted, in accordance with Section 18 of the *Legislative Instruments Act 2003*, on the grounds that the instrument is minor and does not substantially change the law.

The changes made by this determination are minor and machinery in nature.

Supply of the items being added to this determination are currently GST-free or have not been available for sale in Australia and the purpose of this determination is to maintain the GST-free status of items already GST-free and extend the GST-free status to items that are not currently sold in Australia where it is anticipated that they will be available in the future. Therefore the issue of this determination will retain the status quo and will not impact on business or restrict competition.

General

This legislative instrument commences on 31 December 2011.

This Instrument is a legislative instrument for the purposes of the *Legislative Instruments Act* 2003.

A provision by provision description of this Instrument is contained in the Attachment.

PROVISION BY PROVISION DESCRIPTION OF THE GST-FREE SUPPLY (HEALTH GOODS) DETERMINATION 2011

Section 1 Name of Determination

This section provides that the name of the determination is the GST-free Supply (Health Goods) Determination 2011.

Section 2 Commencement

This section provides that this Determination commences on 31 December 2011.

Section 3 Definition

This section provides definitions of terms used in this Determination.

Section 4 GST-free supplies

This section provides that the supply of goods included in Schedule 1 are GST free only if under the *Therapeutic Goods Act 1989*, the goods are required to be included in the Australian Register of Therapeutic Goods or are goods in a class of goods required to be included in the Australian Register of Therapeutic. 'Australian Register of Therapeutic Goods' is defined in section 3.

Section 5 Revocation of GST-free Supply (Health Goods) Determination 2005

This section provides that this Determination revokes the *GST-free Supply (Health Goods) Determination 2005* from 31 December 2011.

Schedule 1 Health goods the supply of which may be GST-free

This Schedule lists the health goods the supply of which may be GST-free under this Determination.