GIR/pharmaceutical-health-forum-ch1 -

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GST Pharmaceutical Health Forum – issues register

This issues register, originally published on our main website, provides guidance on issues identified during past consultation with industry participants.

Issues in this register that are a public ruling can now be found in the *Public Rulings* section of this Legal Database.

Issues in this register that have not been labelled as public rulings, constitute written guidance. We are committed to providing you with accurate, consistent and clear information to help you understand your rights and entitlements and meet your obligations.

If you follow our information on these issues and it turns out to be incorrect, or it is misleading and you make a mistake as a result, we must still apply the law correctly. If that means you owe us money, we must ask you to pay it but we will not charge you a penalty. Also, if you acted reasonably and in good faith we will not charge you interest. If correcting the mistake means we owe you money, we will pay it to you. We will also pay you any interest you are entitled to.

If you feel that the guidance in this issues register does not fully cover your circumstances, or you are unsure how it applies to you, you can seek further assistance from us.

For goods and services tax (GST), luxury car tax (LCT) and wine equalisation tax (WET) purposes, from 1 July 2015, when the term 'Australia' is used, it is referring to the 'indirect tax zone' as defined in subsection 195-1 of the *A New Tax System (Goods and Services Tax) Act 1999* (GST Act).

Find out about:

- How to use the register
- Issue 1. Section 38-45 Medical aids and appliances
- Issue 2. Section 38-47 Other GST-free health goods
- Issue 3. Section 38-50 Drugs and medicinal preparations
- Issue 4. General questions

How to use the register

This register is a list of product classification issues which have been identified as a result of consultations with the Pharmaceutical Health sector. The document was then refined using input from the GST Pharmaceutical Health Committee. These discussions and consultations have been instrumental in the ATO undertaking a technical clearance process bearing in mind the intention of the policy for each major issue and outlining the ATO's position for each subsidiary question.

The issues raised cover a number of the sections in Subdivision 38-B-Health of the GST Act. These sections include: 38-45 Medical Aids and Appliances, 38-47 Other GST-free Health Goods and 38-50 Drugs and Medicinal Preparations. Other issues discuss GST general concepts and related questions.

This document does not cover section 38-38 which is about disability supports provided to National Disability Insurance Scheme (NDIS) participants. For information on this section see the fact sheet, GST and the National Disability Insurance Scheme.

The format of the register contains an explanation of the relevant section followed by specific questions and answers. It should be noted that whilst health specific sections are addressed, the general provisions of the GST Act also need to be considered.

The ATO's position that is outlined in each subsidiary question is specific to that question. Each response should be considered as pertaining to the particular circumstances described in the question and should not be viewed as a generic position held by the ATO. Where organisations find that the question does not fit the unique circumstances as outlined then it is important that further clarification is sought from the ATO. This would best be done by writing to us at:

Australian Taxation Office PO Box 3524 Albury NSW 2640

All references to sections herein are references to sections of the GST Act.

Issue 1. Section 38-45 Medical aids and appliances

Non-interpretative – straight application of the law.

Explanation

Section 38-45 provides that where the elements of that section are satisfied, a medical aid or appliance listed in Schedule 3 or specified in the regulations is GST-free.

The elements of subsection 38-45(1) require that the medical aid or appliance be:

- covered by Schedule 3 or a subsequent regulation, and
- specifically designed for people with an illness or disability, and
- not widely used by people without an illness or disability.

Once an item meets all of the above elements then its supply will be GST-free all the way down the supply chain and not only when supplied to a person who has an illness or disability. One exception to this applies and that is when the supplier and the recipient agree to treat the supply as if it were taxable pursuant to subsection 38-45(3).

Further, subsection 38-45(2) provides that a spare part that is specifically designed as a spare part for a GST-free medical aid or appliance will be GST-free.

The following questions explore what is within the concept of 'medical aid and appliance' for the purposes of section 38-45. None of the questions and answers should be read in isolation but rather as part of the whole of the information contained in this document.

Table 1: Issue 1. Section 38-45 medical aids and appliances

Date	Issue
26/02/01	1.a. What descriptions of goods has the ATO determined for the medical aids and appliances listed in the third column of Schedule 3 of the GST Act?
26/02/01	1.b. What goods have been added by regulation for the purposes of subsection 38-45(1)?
26/02/01	1.c. What factors should be taken into account in determining whether a medical aid or appliance is specifically designed for people with an illness or disability?
26/02/01	1.d. What factors should be taken into account in determining whether a medical aid or appliance is widely used by people without an illness or disability?
26/02/01	1.e. Subsection 38-45(1) provides that for a medical aid and appliance listed in Schedule 3 to be GST-free, it must be specifically designed for and not widely used by people without an illness or disability. Are aged persons included in ' people with an illness or disability' for the purposes of section 38-45?
26/02/01	1.f. Are supplies of medical aids and appliances only GST-free when supplied to the person with an illness or disability?
26/02/01	1.g. What is a spare part for the purposes of subsection 38-45(2)? Are supplies of spare parts for GST-free medical aids and appliances only GST-free when supplied to the person with an illness or disability?
26/02/01	1.h. Are leads and attachments supplied with an item covered by Schedule 3 (such as electrodes supplied with a Transcutaneous Electrical Nerve Stimulator (TENS) machine) GST-free?
26/02/01	1.i. Is the hire of goods GST-free where those same goods would be GST-free under section 38-45 if purchased?

Date	Issue
26/02/01	1.j. Where a person hires or purchases goods through a hospital which are not listed in Schedule 3 or specified in the regulations, will the goods be GST-free?
26/02/01	1.k. Are there items of suppositories which: (i) will not qualify for GST-free (supply chain) status under Schedule 3; but (ii) will qualify for GST-free (non-supply chain) status under any of sub-sections 38-50(1), (2), (4) or (5)?
26/02/01	1.I. Is each supplier in the supply chain responsible for determining the GST treatment of a supply or does that responsibility rest with say the manufacturer?
26/02/01	1.m. What meaning does the category heading in the second column in Schedule 3 of the GST Act have?
24/05/01 (a)	1.n. Are walking sticks GST-free?
24/05/01 (w)	What are the arrangements for subsequent reviews of Schedule 3?

(a) added, (u) updated, (w) withdrawn

1.a. What descriptions of goods has the ATO determined for the medical aids and appliances listed in the third column of Schedule 3 of the GST Act?

Non-interpretative – straight application of the law.

Certain items in the third column of Schedule 3 of the GST Act have been addressed in ATO Interpretative Decisions (ATO IDs). The ATO IDs are on the <u>ATO Legal database</u> and can be found be searching for '38-45'.

Supplies of these goods will be GST-free where all the requirements of subsection 38-45(1) are satisfied.

1.b. What goods have been added by regulation for the purposes of subsection 38-45(1)?

Non-interpretative – straight application of the law.

Section 38-45.01 of the GST regulations has been made which specifies the following medical aids and appliances for the purposes of subsection 38-45(1), in addition to those covered in Schedule 3 of the GST Act.

Table 1.b: Goods which have been added by regulation for the purposes of subsection 38-45(1)

Item	Category	Medical aids or appliances
1	Advanced wound care	(a) alginate(b) hydro colloids(c) hydro gel(d) polyurethane film(e) polyurethane foam
2	Communication aids for people with disabilities	(a) tracheostomy appliances and accessories (b) laryngotomy appliances and accessories
3	Continence	skin bond

Item	Category	Medical aids or appliances
4	Daily living for people with disabilities	(a) artificial ears (b) nose prostheses
5	Hearing/speech	hearing loops
6	Infusion systems for the delivery of a measured dose of a medication	(a) infusion sets (b) infusion pumps
7	Mobility of people with disabilities - physical: orthoses	compression garments
8	Mobility of people with disabilities - physical: prostheses	supplements and aids associated with mammary prostheses
9	Mobility of people with disabilities - physical: seating aids	postural support seating
10	Mobility of people with disabilities - physical: walking aids	accessories associated with walking frames or specialised ambulatory orthoses
11	Personal hygiene for people with disabilities	customised modifications and accessories for the aids or appliances mentioned in items 111 to 121 of Schedule 3 to the Act
12	Respiratory appliances	tilt tables
13	Stoma	stoma products including all bags and related equipment for patients with urostomies

1.c. What factors should be taken into account in determining whether a medical aid or appliance is specifically designed for people with an illness or disability?

The content for this issue is a public ruling for the purposes of the *Taxation Administration Act 1953* and can be found <u>here</u>.

1.d. What factors should be taken into account in determining whether a medical aid or appliance is widely used by people without an illness or disability?

The content for this issue is a public ruling for the purposes of the *Taxation Administration Act 1953* and can be found <u>here</u>.

1.e. Subsection 38-45(1) provides that for a medical aid and appliance listed in Schedule 3 to be GST-free, it must be specifically designed for and not widely used by people without an illness or disability. Are aged persons included in 'people with an illness or disability' for the purposes of section 38-45?

Non-interpretative – straight application of the law.

It is considered that medical aids or appliances listed in Schedule 3 which are capable of being used by aged persons, satisfy the requirements that the medical aid or appliance be 'specifically designed for people with an illness or disability and not widely used by people without an illness or disability'.

For example, 'medical alert devices' are included at item 33 of Schedule 3. Medical alert devices are devices which have been designed for the purpose of alerting medical/caring personnel or an ambulance service that a person is in need of emergency medical assistance.

It is considered that medical alert devices which may be acquired by aged persons for use in the event that an illness or disability befell them, will satisfy the requirements set out in subsection 38-45(1) and be GST-free.

1.f. Are supplies of medical aids and appliances only GST-free when supplied to the person with an illness or disability?

Non-interpretative – straight application of the law.

Medical aids and appliances which satisfy all of the elements of section 38-45 are GST-free at all stages of the supply chain. There is no subjective purpose test to be applied.

1.g. What is a spare part for the purposes of subsection 38-45(2)? Are supplies of spare parts for GST-free medical aids and appliances only GST-free when supplied to the person with an illness or disability?

The content for this issue is a public ruling for the purposes of the *Taxation Administration Act 1953* and can be found here.

1.h. Are leads and attachments supplied with an item covered by Schedule 3 (such as electrodes supplied with a Transcutaneous Electrical Nerve Stimulator (TENS) machine) GST-free?

Non-interpretative – straight application of the law.

It is considered that the initial supply of electrodes for a TENS machine, form an integral part of the supply of the TENS machine, and are GST-free.

Supplies of replacement electrodes for a TENS machine are considered to be spare parts for a TENS machine which will be GST-free under subsection 38-45(2), provided that the electrodes are specifically designed as spare parts for a GST-free TENS machine.

1.i. Is the hire of goods GST-free where those same goods would be GST-free under section 38-45 if purchased?

Non-interpretative – straight application of the law.

Subsection 38-45(1) states that the supply is GST-free. The section does not require that the medical aid or appliance be purchased to be GST-free. Where the purchase of a medical aid or appliance is GST-free, it is accepted that the hire of the same medical aid or appliance will also be GST-free.

1.j. Where a person hires or purchases goods through a hospital which are not listed in Schedule 3 or specified in the regulations, will the goods be GST-free?

The content for this issue is a public ruling for the purposes of the *Taxation Administration Act 1953* and can be found here.

1.k. Are there items of suppositories which:

(i) will not qualify for GST-free (supply chain) status under Schedule 3; but

(ii) will qualify for GST-free (non supply chain) status under any of subsections 38-50(1), (2), (4),(4A) or (5)?

Non-interpretative – straight application of the law.

'Enemas, suppositories and applicators' are included at item 25 of Schedule 3. It is considered that only suppositories used for the relief of constipation come within this item.

In deciding on this interpretation, it was determined that there is some ambiguity created by the context within which the word 'suppositories' appears in Schedule 3. Section 182-15 provides that because interpretation of the word 'suppositories' in the context of its surrounding words is ambiguous, reference should be made to the heading in the second column in Schedule 3. In this case, the heading is 'Continence'. Accordingly, it was concluded that 'suppositories' as it appears in Schedule 3 is limited to those which are intended to relieve constipation.

Accordingly, suppositories used for the relief of constipation will be GST-free at all points in the supply chain pursuant to subsection 38-45(1). Suppositories used for a purpose other than the relief of constipation will not be GST-free at all points in the supply chain but may be GST-free where supplied to an individual for private or domestic use or consumption under section 38-50. (Refer to the explanatory section at the commencement of issue 3 which discusses the elements of section 38-50).

Suppositories used for a purpose other than for relief of constipation and which do not meet the requirements so that they are GST-free under section 38-50, will not be GST-free.

1.I. Is each supplier in the supply chain responsible for determining the GST treatment of a supply or does that responsibility rest with say the manufacturer?

Non-interpretative – straight application of the law.

For GST purposes, the responsibility to remit GST rests with the supplier. Consequently, it is not the manufacturer who decides the GST-status of the product at all points in the supply chain. Rather, each supplier in the chain must determine what the GST status of a particular product is.

By way of example, where a manufacturer supplies products to a wholesaler, the manufacturer must determine the GST status of the products being supplied to the wholesaler. Whilst the GST status of the supply from the manufacturer to the wholesaler is an indication of the GST status of the product, the wholesaler should make an independent appraisal of the GST status of the product before supplying it on to a retailer.

1.m. What meaning does the category heading in the second column in Schedule 3 of the GST Act have?

Non-interpretative – straight application of the law.

Section 182-15 of the GST Act states that the second column of the table in Schedule 3 of the GST Act is not operative. In interpreting an item in the table this column may only be considered for a purpose for which an explanatory section may be considered under subsection 182-10(2).

That is, the category heading in the second column of Schedule 3 may only be considered in interpreting an operative provision:

- in determining the purpose or object underlying the provision, or
- to confirm that the provision's meaning is the ordinary meaning conveyed by its text, taking into account its context in this Act and the purpose or object underlying the provision, or
- in determining the provision's meaning if the provision is ambiguous or obscure, or
- in determining the provision's meaning if the ordinary meaning conveyed by its text, taking into account its context in this Act and the purpose or object underlying the provision, leads to a result that is manifestly absurd or is unreasonable.

For example, for the purposes of item 37 of the table in Schedule 3, it is considered that the meaning of the term 'needles and syringes' is sufficiently clear such that it is not necessary to consider the category heading in column two, 'Diabetes'. That is, the interpretation of the term 'needles and syringes' is not restricted by the 'Diabetes' category heading. Therefore, it is not only needles and syringes for use by diabetics which fall within item 37. However, it is considered that the individual items 'needles' and 'syringes' must be interpreted by reference to the fact that they are listed together. On this basis, it is considered that a needle that is not designed for use with a syringe, or a syringe that is not designed for use with a needle, will not be covered by item 37 in Schedule 3. Thus, an item such as a needle for inserting sutures is not covered by Schedule 3.

1.n. Are walking sticks GST-free?

Non-interpretative – straight application of the law.

A medical aid or appliance is GST-free where it is:

- covered by Schedule 3 or subsequent regulation, and
- specifically designed for people with an illness or disability, and
- not widely used by people without an illness or disability.

Once an item meets all of the above elements then its supply will be GST-free all the way down the supply chain and not only when supplied to a person who has an illness or disability.

Item 97 of Schedule 3 refers to 'walking sticks - specialised'. The word 'specialised' was used to exclude non-functional and purely ornamental walking sticks and to only include those walking sticks that were intended for use by ill or disabled people. This reflects the inherent nature of the items included in Schedule 3.

Accordingly, walking sticks are GST-free when they:

- aren't non-functional and purely ornamental walking sticks
- are handheld devices, the principal function of which is to assist a person to walk by taking some of the weight of that person when that person is unable to walk unaided
- have been specifically designed for people with an illness or disability and are not widely used by people without an illness or disability.

This interpretation of item 97 was made on 24 May 2001 and replaces all alternative interpretations made prior to this date.

Issue 2. Section 38-47 Other GST-free health goods

Non-interpretative – straight application of the law.

Explanation

Section 38-47 states 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 for which the supply is GST-free. Once an item meets all of the requirements set out in the Ministerial Determination, then its supply is GST-free all the way down the supply chain. One exception to this is when the supplier and the recipient agree to treat the supply as if it were taxable pursuant to subsection 38-47(2).

Related questions - The following questions explore what is within the concept of 'Other GST-free Health Goods' for the purposes of section 38-47. None of the questions and answers should be read in isolation but rather as part of the whole of the information contained in this document.

Table 2: Issue 2. Section 38-47 other GST-free health goods

Date	Issue
26/02/01 05/06/2013 (u)	2.a. What other health goods has the Health Minister, by determination in writing, declared to be GST-free?
26/02/01	2.b. Are supplies of the goods listed above only GST-free where supplied to an individual for private or domestic use or consumption?
26/02/01	2.c. How can additional health goods become GST-free?
26/02/01	2.d. What are 'sunscreen preparations for dermal application'?
26/02/01	2.e. What factors should be taken into account in determining whether a sunscreen preparation is marketed principally as a sunscreen? Are supplies of sunscreen preparations dermal application with a SPF rating factor of 15 or more, an ARTG number and which satisfied the 'marketed principally for use as a sunscreen preparation for humans' test used in item 91 of Schedule 1 to the Sales Tax Act, GST-free?
26/02/01	2.f. Do folate supplements for the purposes of the Health Ministers Determination include any product with folate included in the formulation? For example: multivitamins.
04/12/18 (a)	2.g. Is the supply of menstrual products GST-free?

(a) added, (u) updated, (w) withdrawn

2.a. What other health goods has the Health Minister, by determination in writing, declared to be GST-free?

Non-interpretative – straight application of the law.

The <u>GST-free Supply (Health Goods) Determination 2011</u> for the purposes of section 38-47 provides that the following categories of goods will be GST-free where 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 Goods:

- condoms
- barrier dams, femidoms and harness devices

- personal and surgical lubricants that are water-soluble and suitable for use with condoms
- preparations for use by humans that contain folic acid as a single active ingredient and have a recommended daily dose of 400 to 500 micrograms
- sunscreen preparations for dermal application that are marketed principally for use as sunscreen and have a sun protection factor rating of 15 or more
- nicotine for use as an aid in withdrawal from tobacco smoking where the nicotine is administered in preparations for transdermal or oromucosal use.

The A New Tax System (Goods and Services Tax) (GST–free Health Goods)

<u>Determination 2018</u> provides that the following products are GST-free when supplied on or after 1 January 2019:

- maternity pads
- menstrual cups
- menstrual pads and liners
- menstrual underwear
- tampons
- other similar products specifically designed to absorb or collect lochia, menses or vaginal discharge.

Additional goods can only be added by way of a further written determination by the Health Minister.

2.b. Are supplies of the goods listed above only GST-free where supplied to an individual for private or domestic use or consumption?

Non-interpretative – straight application of the law.

No. Goods which satisfy all of the elements of the Health Ministers Determination are GST-free at all stages of the supply chain.

2.c. How can additional health goods become GST-free?

Non-interpretative – straight application of the law.

Additional goods can only be added by way of a further written determination by the Health Minister.

2.d. What are 'sunscreen preparations for dermal application'?

The content for this issue is a public ruling for the purposes of the *Taxation Administration Act 1953* and can be found **here**.

2.e. What factors should be taken into account in determining whether a sunscreen preparation is marketed principally as a sunscreen? Are supplies of sunscreen preparations dermal application with a SPF rating factor of 15 or more, an ARTG number and which satisfied the 'marketed principally for use as a sunscreen preparation for humans' test used in item 91 of Schedule 1 to the Sales Tax Act, GST-free?

The content for this issue is a public ruling for the purposes of the *Taxation Administration Act 1953* and can be found here.

2.f. Do folate supplements for the purposes of the Health Ministers Determination include any product with folate included in the formulation? For example, multivitamins.

Non-interpretative – straight application of the law.

No. The product must have folic acid as a single active ingredient and have a recommended daily dose of 400-500 micrograms.

2.g. Is the supply of menstrual products GST-free?

Non-interpretative – straight application of the law.

Yes. The A New Tax System (Goods and Services Tax) (GST–free Health Goods)

<u>Determination 2018</u> provides that the following products are GST-free when supplied on or after 1 January 2019:

- maternity pads
- menstrual cups
- menstrual pads and liners
- menstrual underwear
- tampons
- other similar products specifically designed to absorb or collect lochia, menses or vaginal discharge.

The Determination does not cover:

- feminine washes marketed for feminine hygiene and/or vaginal washing and cleaning
- feminine deodorants such as talc, powder and spray products marketed for feminine hygiene and/or to deodorise the vaginal area
- intimate wipes marketed for feminine hygiene
- supplements and vitamins marketed for use during menstruation and/or pregnancy
- nursing pads
- pads specifically designed for incontinence.

Issue 3. Section 38-50 Drugs and medicinal preparations

Some of the content for this issue is a public ruling for the purposes of the *Taxation Administration Act 1953* and can be found here.

The following questions explore what is within the concept of 'drugs and medicinal preparations' for the purposes of section 38-50. None of the questions and answers should be read in isolation but rather as part of the whole of the information contained in this document.

Table 3: Issue 3. Section 38-50 drugs and medicinal preparations

Date	Issue
26/02/01 06/06/2013 (u)	3.a. What analgesics with a single active ingredient has the Health Minister, by determination in writing, declared to be GST-free?
26/02/01	3.b. Will the supply of 'over the counter' drugs and medicines by a pharmacist be subject to GST?
26/02/01	3.c. Will all drugs and medicines be GST-free if there is a prescription?
26/02/01	3.d. Where the GST Act requires that for a supply to be GST-free it must be made on prescription, does the Pharmacist need to actually dispense the drug or medicine or can they simply sight a prescription and supply the drug or medicine as an over the counter sale?
26/02/01	3.e. Are supplies of drugs by manufacturers and wholesalers GST-free?
26/02/01	3.f. What responsibility does a Pharmacist have in regard to subsection 38-50(7)?
26/02/01 06/06/2013 (u)	3.g. Some State legislation provides for certain products to be Schedule 2 SUSMP, and others not to be Scheduled at all. As a wholesaler we provide an indication of the tax treatment the pharmacist will apply to the product. Where the product is GST-free to consumers in five States but not in one, we could consider that product to be GST-free. What is the risk to us of doing that?
26/02/01 06/06/2013 (u)	3.h. It is understood that it is proposed to add drugs and medicines sold by Chinese Herbalists to Schedule 1 of the Standard for the Uniform Scheduling of Drugs and Poisons. If this proposal is undertaken, will supplies of such products be GST-free?
26/02/01 06/06/2013 (u)	3.i. Drugs and Medicines which are not on the Australian Register of Therapeutic Goods cannot be supplied in or exported from Australia. However, individuals can legally import most therapeutic goods for personal use under the Personal Import Scheme. This scheme allows for treatments to be imported for personal use in quantities that are no greater than three month's supply. Are these taxable importations?

(a) added, (u) updated, (w) withdrawn

3.a. What analgesics with a single active ingredient has the Health Minister, by determination in writing, declared to be GST-free?

Non-interpretative – straight application of the law.

The Ministerial Determination <u>GST-free Supply (Drugs and Medicinal Preparations)</u>
<u>Determination 2015</u> provides that an analgesic with a single active ingredient is GST-free if it:

- is required, under the Therapeutic Goods Act 1989, to be registered or listed, or is included in a class of goods required to be registered or listed, and
- contains aspirin, paracetamol or ibuprofen, and
- is intended to be taken by mouth.

3.b. Will the supply of 'over the counter' drugs and medicines by a pharmacist be subject to GST?

Non-interpretative – straight application of the law.

A supply of an 'over the counter' drug or medicinal preparation which does not fall within one of the GST-free drugs and medicines mentioned above will not be GST-free. A pharmacist who is registered or required to be registered for GST will charge GST on these supplies.

3.c. Will all drugs and medicines be GST-free if there is a prescription?

Non-interpretative – straight application of the law.

Not all scripted drugs and medicinal preparations will be GST-free. Only drugs and medicines which meet the requirements so that they are GST-free under section 38-50 (refer to the explanatory section at the commencement of issue 3) and sold on the required form of script (that is, a NHS or a private script) will be GST-free.

3.d. Where the GST Act requires that for a supply to be GST-free it must be made on prescription, does the Pharmacist need to actually dispense the drug or medicine or can they simply sight a prescription and supply the drug or medicine as an over the counter sale?

Non-interpretative – straight application of the law.

It is considered that for an item to be supplied on prescription, the Pharmacist must actually dispense the drug or medicine. Where the Pharmacist chooses not to dispense the drug or medicine and supply the item as an 'over the counter' sale, the patient is entitled to retain possession of their original prescription.

Accordingly, 'over the counter' sales of drugs and medicines covered by the Pharmaceutical Benefits Schedule will not be GST-free.

3.e. Are supplies of drugs by manufacturers and wholesalers GST-free?

Non-interpretative – straight application of the law.

One of the elements required by section 38-50 for a supply of a drug or medicinal preparation to be GST-free is that the supply must be to an individual for private or domestic use or consumption.

Therefore, under section 38-50 supplies from a manufacturer to a wholesaler will be subject to GST, as will a supply from a wholesaler to a pharmacist.

In accordance with section 11-25, where the retailer or the wholesaler is registered, they will be entitled to an input tax credit for any creditable acquisition that they make, to the extent the creditable acquisition is used for a business purpose.

Section 11-5 states that you make a creditable acquisition when:

- you acquire anything solely or partly for a creditable purpose, and
- the supply of the thing to you is a taxable supply, and
- you provide, or are liable to provide, consideration for the supply, and
- you are registered, or required to be registered.

Accordingly, where the retailer or the wholesaler is registered for GST, they are entitled to claim as an input tax credit the GST paid on stocks of drugs and medicines they buy, to the extent those stocks of drugs and medicines are used for a business purpose.

In limited circumstances, a supply of a drug or medicinal preparation may be GST-free under sections 38-45 and/or 38-47, as well as section 38-50. Reference should be made to the answer at issue 4.b. for guidance where more than one GST-free provision of the GST Act is applicable.

3.f. What responsibility does a Pharmacist have in regard to subsection 38-50(7)?

The content for this issue is a public ruling for the purposes of the *Taxation Administration Act 1953* and can be found here.

3.g. Some state legislation provides for certain products to be Schedule 2 on the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), and others not to be Scheduled at all. As a wholesaler we provide an indication of the tax treatment the pharmacist will apply to the product. Where the product is GST-free to consumers in five States but not in one, we could consider that product to be GST-free. What is the risk to us of doing that?

Non-interpretative – straight application of the law.

The main principal of the GST Act is that responsibility to remit GST is with the supplier. As the supplier is liable for GST, the supplier must determine what the GST status of a product is. Where certain products are GST-free in most but not all States, the wholesaler should take the location of sale into account if they take it upon themselves to advise the GST status of products.

3.h. If drugs and medicines sold by Chinese herbalists are added to Schedule 1 of the Standard for the Uniform Scheduling of Medicines and Poisons, will supplies of such products be GST-free?

Non-interpretative – straight application of the law.

Subsection 38-50(2) provides that supplies of drugs and medicines are GST-free if, under the State or Territory law applicable to where the supply is made, the supply of that drug or medicine to an individual for private or domestic use or consumption is restricted but may be made by a medical practitioner, dental practitioner, pharmacist or any other person permitted by or under that law to do so.

The primary mechanism for restricting access of drugs and medicinal preparations is through 'scheduling'. Scheduling is the grouping of products containing specified substances into schedules representing levels of restriction on distribution. Scheduling decisions are made by the Secretary to the Department of Health and Ageing in consultation with the Advisory Committee on Chemicals Scheduling (ACCS) and published as the Standard for

the Uniform Scheduling of Medicines and Poisons (SUSMP), which is generally adopted by the States and Territories.

Supplies of such products will be GST-free, provided the provisions of the SUSMP dealing with Schedule 1 substances are amended and adopted under the relevant State or Territory law where the supply is made, or, the State or Territory law applicable to where the supply is made has separate legislation restricting supplies of drugs or medicines of that kind.

3.i. Drugs and medicines which are not on the Australian Register of Therapeutic Goods cannot be supplied in or exported from Australia. However, individuals can legally import most therapeutic goods for personal use under the Personal Import Scheme. This scheme allows for treatments to be imported for personal use in quantities that are no greater than three month's supply. Are these taxable importations?

For source of ATO view, refer to <u>GSTR 2003/15</u> – *Goods and services: importation of goods into Australia*

Section 13-10 provides that an importation is not a taxable importation if it would have been a GST-free supply, if it had been a supply.

A supply made for consideration, in the course or furtherance of an enterprise carried on by the supplier, connected with Australia, by a supplier that is registered for GST, will be GST-free where one of the GST-free provisions of the GST Act is satisfied.

Accordingly, where the supply of an imported drug or medicine by a registered entity for consideration in the course of or furtherance of an enterprise and connected with Australia would be GST-free, the importation of that drug or medicine by an individual will be a non-taxable importation.

Further, section 42-5 provides that an importation of goods is a non-taxable importation if the goods are covered by item 26 in Schedule 4 to the *Customs Tariff Act 1995*. Item 26 in Schedule 4 to the *Customs Tariff Act 1995* covers imports of goods sent by the postal system, with a value not exceeding \$1,000 and goods sent by air and sea cargo, with a value not exceeding \$1000, respectively.

Accordingly, goods sent by the postal system, and goods sent by air and sea cargo, with a value not exceeding \$1000, are non-taxable importations.

Issue 4. General questions

Table 4: Issue 4. general questions

Date	Issue
26/02/01	4.a. Are goods supplied free to retailers as incentive stock, subject to GST? For example, if a Pharmaceutical Distributor runs a promotional campaign in which 20 'bonus' products are given to Pharmacists who achieve their monthly sales targets
26/02/01	4.b. Under the rules of statutory interpretation, where two specific sections made a supply GST-free, which section applies?
26/02/01 06/06/2013(u)	4.c. The Therapeutic Goods Regulations 1990 require that packs which contain a 'Pharmacy only' scheduled medicine and an unscheduled medicine be packaged and labelled as a 'Pharmacy only' medicine. Will supplies of the pack be GST-free?
29/07/05 06/06/2013(u)	4.d. Are payments under the Medicines Information to Consumers program, Home Medicines Review program, Quality Care Pharmacy Program, and payments of Rural Pharmacy Maintenance Allowance consideration for a taxable supply?

⁽a) added, (u) updated, (w) withdrawn

4.a. Are goods supplied free to retailers as incentive stock, subject to GST? For example, if a pharmaceutical distributor runs a promotional campaign in which 20 'bonus' products are given to Pharmacists who achieve their monthly sales targets.

Non-interpretative – straight application of the law.

Subsection 9-10(2) provides that a supply includes an entry into, or release from, an obligation to:

- do anything, or
- refrain from an act, or
- tolerate an act or situation.

It is considered that where a Pharmaceutical Distributor runs a promotional campaign in which 20 'bonus' products are given to a Pharmacist for achieving their monthly sales targets, the 20 products represent consideration for a supply made by the Pharmacist to the Pharmaceutical Distributor for entering into an obligation to promptly turnover stock.

That is, the 20 'bonus' products are supplied on condition and in consideration for the Pharmacist entering into an obligation to promptly turnover stock and will be subject to GST.

It is important to note that in determining whether GST applies to goods supplied as incentive stock, each case is determined on its merits.

4.b. Under the rules of statutory interpretation, where two specific sections made a supply GST-free, which section applies?

Non-interpretative – straight application of the law.

The rules of statutory interpretation provide that where two sections of an Act have the propensity to apply to a factual situation, the section which is more specific in its terms to the particular circumstance, will be the applicable section.

For example within the GST Act, both subsection 38-45(1) and subsection 38-50(2) could be applicable to the supply of suppositories. Scheduled suppositories (refer to the

discussion in question 3.g. on 'scheduled' medicines) could be GST-free where the requirements of subsection 38-50(2) are met. However, 'enemas, suppositories and applicators' are specifically itemised at item 25 of Schedule 3 to subsection 38-45(1). Therefore under the rules of statutory interpretation, suppositories will be GST-free under subsection 38-45(1) where the other requirements of that section are met, rather than subsection 38-50(2) and the practical outcome is that that class of suppositories will be GST-free at all points in the supply chain.

4.c. State and Territory legislation may require that packs which contain a 'Pharmacy only' scheduled medicine and an unscheduled medicine be packaged and labelled as a 'Pharmacy only' medicine. Will supplies of the pack be GST-free?

Non-interpretative – straight application of the law.

Subsection 38-50(2) provides that supplies of drugs and medicinal preparations are GST-free if, under the State or Territory law applicable to where the supply is made, the supply of that drug or medicinal preparation to an individual for private or domestic use or consumption is restricted. (Refer to issue 3.g. for a discussion on restricted medicines)

Where it is a requirement of State or Territory legislation that packs, containing one or more scheduled medicines and one or more unscheduled medicines, be classified and sold as a single medicine in the same schedule as the highest scheduled medicine in the pack, the supply of the entire pack will be GST-free.

4.d. Are payments under the Medicines Information to Consumers program, Home Medicines Review program, Quality Care Pharmacy Program and payments of Rural Pharmacy Maintenance Allowance consideration for a taxable supply?

For source of ATO view, refer to <u>GSTR 2012/2</u> - *Goods and services tax: financial assistance payments.*

No, pursuant to GSTR 2012/2, payments under the Medicines Information to Consumers program, Home Medicines Review program, Quality Care Pharmacy Program and payments of Rural Pharmacy Maintenance Allowance are not consideration for supplies, and therefore cannot be consideration for taxable supplies.

Payments under these programs are made by the Health Insurance Commission (Medicare Australia from 1 October 2005).

Applicants for these payments do not enter into binding obligations with the payer to do anything for which the payment is consideration.

Applicants for these payments lodge an application for payment of an entitlement. While the information contained in the application for payment may meet the statutory definition of a 'supply', the information contained in the application is not the purpose for which the payment is paid. For GST purposes the payment is therefore not consideration for the information contained on the application.

Submitting the application, together with the information required to consider it, is merely a mechanism to establish whether a payment will be made.

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