

s. 22(1)(a)(ii)

From: DTS
Sent: Wednesday, 13 January 2016 12:41 PM
To: s. 22(1)(a)(ii)
Cc: DTS; s. 22(1)(a)(ii)
Subject: FW: Media enquiry: Truvada shipment, GST issue and discrimination claim [DLM=For-Official-Use-Only]

s. 22(1)(a)(ii)

Here is some advice from TGA regarding multiple packed personally prescribed imports – which tends to support the status quo that these are considered to be in compliance with their legislation.

They have also provided a contact for any further enquires with their Compliance area if you want to refer any matters to them for consideration.

Regards,

s. 22(1)(a)(ii)

| Assistant Director Drugs and Therapeutic Substances | Restricted Goods Policy Section
 Trade and Customs Branch | Traveller, Customs and Industry Division
 Department of Immigration and Border Protection
 P: s. 22(1)(a)(ii) | E: dts@border.gov.au

From: s. 47F(1) [mailto:s. 47(1)(a)@tga.gov.au] **On Behalf Of** DCS
Sent: Wednesday, 13 January 2016 12:13 PM
To: DTS
Subject: RE: Media enquiry: Truvada shipment, GST issue and discrimination claim [DLM=For-Official-Use-Only]

Hi s. 22(1)(a)(ii)

This is about as much as I can for you today:

"It appears from the information to hand that each product is individually labelled or identified for use by persons resident of Australia which may well be within the personal import scheme at item 1 of Schedule 5 to the *Therapeutic Goods Regulations 1990*. Provided the other requirements of the personal import scheme are met, the scheme creates an exemption for medicines to be included in the Australian Register of Therapeutic Goods (ARTG) prior to importation and is an exemption from the criminal offence and civil penalty provisions in that Part 3-2 of the *Therapeutic Goods Act 1989*."

If the issue hangs around, then you may wish to email the Reg Compliance guys here at the TGA:
RLO@tga.gov.au

Regards

s. 47F(1)

Drug Control Section
 Phone: s. 47F(1)
 Email: DCS@health.gov.au

From: DTS [mailto:dts@border.gov.au]
Sent: Wednesday, 13 January 2016 9:18 AM

To: DCS

Cc: DTS

Subject: FW: Media enquiry: Truvada shipment, GST issue and discrimination claim [DLM=For-Official-Use-Only]

Importance: High

Hi s. 47F(1)

As discussed here is the media enquiry which we seek your advice on.

I think the issue boils down to whether multiple imports on behalf of individual importers together is in the spirit of the TGA legislation and/or whether they are using an approved process as per the registered prescriber route you mentioned.

Any assistance much appreciated.

Regards,

s. 22(1)(a)(ii) | Assistant Director Drugs and Therapeutic Substances | Restricted Goods Policy Section
Trade and Customs Branch | Traveller, Customs and Industry Division
Department of Immigration and Border Protection
P: s. 22(1)(a)(ii) | E: dts@border.gov.au

s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Monday, 18 January 2016 8:59 AM
To: Andrew CHANDLER; s. 22(1)(a)(ii) DTS; s. 22(1)(a)(ii)
Subject: RE: Media enquiry: Truvada shipment, GST issue and discrimination claim [SEC=UNCLASSIFIED]

Hi

It was in the press on the weekend (but not in our press clips)

<http://www.news.com.au/lifestyle/health/health-problems/contradictory-rulings-by-australian-border-force-staff-leaves-lifesaving-drugs-in-limbo/news-story/bbb6b093a55f9741ebad9ce0c37aebdb>

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Director Import/Export Policy
 Trade and Customs Branch | Traveller, Customs & Industry Policy Division
 Policy Group
 Department of Immigration and Border Protection
 P: s. 22(1)(a)(ii) | M: s. 22(1)(a)(ii)
 E: s. 22(1)(a)(ii) @border.gov.au

From: CHANDLER Andrew
Sent: Wednesday, 13 January 2016 5:22 PM
To: s. 22(1)(a)(ii)
Subject: FW: Media enquiry: Truvada shipment, GST issue and discrimination claim [SEC=UNCLASSIFIED]

FYI

Regards,
 Andrew

Andrew Chandler
 Assistant Secretary Trade and Customs
 Department of Immigration and Border Protection
 T: s. 22(1)(a)(ii) | M: s. 22(1)(a)(ii)
 E: s. 22(1)(a)(ii) @border.gov.au

Executive Assistant: s. 22(1)(a)(ii)
 T: s. 22(1)(a)(ii) E: s. 22(1)(a)(ii) @border.gov.au

From: MCDONALD Mark
Sent: Wednesday, 13 January 2016 4:30 PM
To: CHANDLER Andrew
Subject: RE: Media enquiry: Truvada shipment, GST issue and discrimination claim [SEC=UNCLASSIFIED]

Hi Andrew,

I do for the moment, your staff have been most helpful. We will need to work with TGA to ensure clarity and consistency in terms of what constitutes a "personal import" and with the ATO around the interpretation of "supply is to an individual for private or domestic use or consumption" within section 38.50 (7b) of the GST legislation as this underpins the gst exemption.

Cheers,

Mark

Mark McDonald

A/g Commander Customs Compliance

Border Management Division

Australian Border Force

s. 22(1)(a)(ii) @border.gov.au | s. 22(1)(a)(ii) | s. 22(1)(a)(ii)

From: CHANDLER Andrew

Sent: Wednesday, 13 January 2016 4:14 PM

To: MCDONALD Mark

Subject: RE: Media enquiry: Truvada shipment, GST issue and discrimination claim [SEC=UNCLASSIFIED]

Mark,

Do you now have what you need from us on this?

Regards,

Andrew

Andrew Chandler

Assistant Secretary Trade and Customs

Department of Immigration and Border Protection

T: s. 22(1)(a)(ii) | M: s. 22(1)(a)(ii)

E: s. 22(1)(a)(ii) @border.gov.au

Executive Assistant: s. 22(1)(a)(ii)

T: s. 22(1)(a)(ii) E: s. 22(1)(a)(ii) @border.gov.au

From: MCDONALD Mark

Sent: Wednesday, 13 January 2016 1:07 AM

To: CHANDLER Andrew

Subject: FW: Media enquiry: Truvada shipment, GST issue and discrimination claim [SEC=UNCLASSIFIED]

Importance: High

Hi Andrew,

As per the attached link, are you able to confirm that for the imports relating to this enquiry the consignee (s. 47F(1)) is considered the "importer".

If that is the case, it would appear his acting as an intermediary is in contravention of the TGA guidelines below

<http://www.tga.gov.au/personal-importation-scheme>

Advice appreciated,

Thanks,

M

Mark McDonald

A/g Commander

Customs Compliance s. 22(1)(a)(ii) @border.gov.au s. 22(1)(a)(ii) s. 22(1)(a)(ii)

From: Portfolio Media

Sent: 12/01/2016 6:30 PM

To: CHANDLER Andrew; Portfolio Media

Cc: s. 22(1)(a)(ii)

Subject: RE: Media enquiry: Truvada shipment, GST issue and discrimination claim [SEC=UNCLASSIFIED]

Thanks Andrew.

s. 22(1)(a)(ii) – FYI, we have now received a second enquiry on this matter:

From: s. 47F(1)

Sent: Tuesday, 12 January 2016 4:10 PM

To: Portfolio Media

Subject: s. 47F(1) - media enquiry - Customs

Good afternoon,

I have a query about shipments of medicines from s. 47F(1) to Australia for the use as a pre-exposure prophylaxis, or PrEP, for people at high risk of HIV infection who are trying to avoid the virus.

These types of medicine are approved by the TGA for use as a medication for people with HIV but it is still going through TGA approval for use by people without it. Until that happens, people can only access it on medical trials or by importing it.

One way people are importing it is purchasing the meds from overseas pharmacies. Including one in s. 47F(1) called s. 47F(1) which packages up the various orders and sends them to an Australian organisation called s. 47F(1) which acts as a conduit between the pharmacy and the people in Aus.

s. 47F(1) say they have been very careful to ensure the orders are done not through them but through the pharmacy so it can't be suggested this is a bulk or commercial order is in, indeed, for personal use. They provide the individual prescriptions, order documentation and payment details to show this. However, a number of the orders have got held up in Customs for a number of reasons all relating to the suggestion they are indeed one bulk order.

However, even this is inconsistent with some orders waved through in hours and others stuck until ministerial intervention or stuck in limbo until GST payments are made - GST payments s. 47F(1) say are not needed.

Of 19 packages that have gone through since October, 13 have had no issues, 4 (before Christmas) were stuck until the minister got involved while 1 s. 47F(1) is in limbo now awaiting spurious GST payments. All the holdups appear to relate to one custom officer's interpretation of what constitutes a personal supply or a bulk supply. Another order s. 47F(1) has just arrived.

Can I ask:

- Why has there been such inconsistency with how these essentially identical packages have been dealt with?
- Do the ABF believe these orders are PrEP are liable for GST, because they are a bulk order, or exempt because each individual order is below \$1000 and for personal use only?
- Given the ABF has documentation showing the most recent package contains orders from individual people, all paid for individually to the s. 47F(1) pharmacy, why is a Customs officer attempting to charge for the release of the packages in question? What is this charge for?

- Will the ABF release the most recent packages of PrEP? Or will the ABF stand by the decision of the Customs officer that a charge needs to be paid on each package?
- Is the final decision on whether these important medicines are released in the hands of one Customs officer or will someone higher in the ABF make a decision on the issue?
- Why were the 4 packages before Christmas held up and why were they subsequently released?
- Is it true that there was intervention by minister Peter Dutton's office to expedite the passage of the 4 packages containing PrEP medicines through Customs before Christmas?
- Do the ABF have concerns these drugs will be resold once in Australia?
- s. 47F(1) [redacted] says if people are forced to import each order individually, rather than in one package, it will significantly increase the cost of the medicines and could put this game changing medicine out of reaching at many people at risk of HIV. IS it the ABF's advice to people to order these drugs individually to avoid delays at Customs?

My deadline is 12noon on Wednesday 13 January.

s. 47F(1) [redacted]

News Reporter

s. 47F(1) [redacted]

s. 47F(1) [redacted]

s. 22(1)(a)(ii) [redacted]

Queensland Public Affairs Officer

Communication and Media Branch | Executive Division

Department of Immigration and Border Protection

T: s. 22(1)(a)(ii) [redacted] | M: s. 22(1)(a)(ii) [redacted]

24-hour media line: 02 6264 2244

E: s. 22(1)(a)(ii) [redacted] @border.gov.au

From: CHANDLER Andrew

Sent: Tuesday, 12 January 2016 4:49 PM

To: Portfolio Media

Cc: s. 22(1)(a)(ii) [redacted]

Subject: RE: Media enquiry: Truvada shipment, GST issue and discrimination claim [SEC=UNCLASSIFIED]

s. 22(1)(a)(ii) [redacted]

Apologies for the delayed response, but I've been in meetings all afternoon. I understand that this issue has now evolved somewhat and that Compliance is taking the lead. Thanks.

Regards,
Andrew

Andrew Chandler

Assistant Secretary Trade and Customs

Department of Immigration and Border Protection

T: s. 22(1)(a)(ii) [redacted] | M: s. 22(1)(a)(ii) [redacted]

E: s. 22(1)(a)(ii) [redacted] @border.gov.au

Executive Assistant: s. 22(1)(a)(ii) [redacted]

From: Portfolio Media
Sent: Tuesday, 12 January 2016 3:59 PM
To: Portfolio Media; CHANDLER Andrew
Cc: s. 22(1)(a)(ii)
Subject: RE: Media enquiry: Truvada shipment, GST issue and discrimination claim [SEC=UNCLASSIFIED]
Importance: High

Good afternoon,

Just chasing up this one – we are getting very close to deadline. Is it possible to get a response ASAP?

Kind regards,

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Queensland Public Affairs Officer

Communication and Media Branch | Executive Division

Department of Immigration and Border Protection

T: s. 22(1)(a)(ii) | M: s. 22(1)(a)(ii)

24-hour media line: 02 6264 2244

E: s. 22(1)(a)(ii) @border.gov.au

From: Portfolio Media
Sent: Tuesday, 12 January 2016 12:17 PM
To: CHANDLER Andrew
Cc: s. 22(1)(a)(ii)
Subject: Media enquiry: Truvada shipment, GST issue and discrimination claim [SEC=UNCLASSIFIED]

Good afternoon Andrew,

As discussed with s. 22(1)(a)(ii) please see attached enquiry from the s. 47F(1)

s. 47F(1)

The enquiry has come to us from the Minister's Office and we need to get back to the journalist by COB today.

I have not copied in the officer mentioned by name by the journalist, but someone on s. 22(1)(a)(ii) / s. 22(1)(a)(ii) side of things might want to inform him of this enquiry once the response is formalised. When I speak to the journalist I will of course request very strongly that they do not name him, but ultimately I cannot force the issue. I would suggest we need a line in the TPs countering the claim of the existence of discrimination if that is indeed the case.

Please see attached.

Kind regards,

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Queensland Public Affairs Officer

Communication and Media Branch | Executive Division

Department of Immigration and Border Protection

T: s. 22(1)(a)(ii) | M: s. 22(1)(a)(ii)

24-hour media line: 02 6264 2244

UNCLASSIFIED

Morning team – could you look into the matters below.

From: s. 47F(1)
Sent: Tuesday, 12 January 2016 11:27 AM
To: Minister's Mailbox; s. 22(1)(a)(ii)
Subject: Media Request: s. 47F(1)

Hi s. 22(1)(a)(ii)

I hope your week is going well.

I have some questions about shipments of Truvada into Sydney in the past week. I've put the background into the story first and my questions for the Minister are below.

Two shipments of Truvada were delivered by FedEx from s. 47F(1) s. 47F(1) to Sydney on Thursday 7 January s. 47F(1) and Monday 12 January s. 47F(1).

The shipment contains 24 individual orders, prescriptions and payment details for Truvada (PrEP) and are not a bulk order of the drug.

The orders were organised by s. 47F(1) on behalf of his organisation s. 47F(1) for the 24 people.

Senior ABF Officer, Compliance Operations (Sydney) s. 22(1)(a)(ii) has decided the above two shipments are subject to GST because their total value exceed \$1000.

However, they are individual orders and not considered a bulk order, therefore not subject to GST charges.

The TGA advised s. 22(1)(a)(ii) this was the case, but he has indicated that decision is at his discretion.

It is understood the Minister's office has also cleared previous shipments of Truvada.

Previous shipments of Truvada from s. 47F(1) (e.g. s. 47F(1)) were cleared without paying GST.

The GST Act states: Section 38.50 of the *A New Tax System (Goods and Services Tax) Act 1999* (Cth) states the supply of a drug is GST free if it is "restricted, but may be supplied on prescription." According to the ATO ruling on drugs and medicinal preparations, this covers medications listed under Schedule 4 of the *TGA Standard for the Uniform Scheduling of Medicines and Poisons* (SUSMP). Both tenofovir and emtricitabine - the constituent medications of Truvada and its generics - are listed under schedule 4 of the SUSMP.

Could I please get a response to the below questions:

- Is the decision to charge GST at the discretion of individual ABF officers?
- What will the Minister do to clear this urgent medication?
- How can this confusion be avoided in the future?
- How does this Minister respond to suggestions the delay is due to personal discrimination by s. 22(1)(a)(ii) ?
- Anything else you'd like to add.

My deadline is later this afternoon/evening. If I could have something back by 6pm that would be great.

Please give me a call on my mobile if you have any questions.

Thanks,

--
s. 47F(1)

Journalist

s. 47F(1)

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Freedom of Information Act 1982

s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Monday, 8 February 2016 4:57 PM
To: DTS
Subject: FW: Media Enquiry - Truvada.docx [SEC=UNCLASSIFIED]
Attachments: Media Enquiry - Truvada (2).docx

Importance: High

Follow Up Flag: Follow up
Flag Status: Flagged

FYI – re Truvada

s. 22(1)(a)(ii) | Assistant Director Drugs and Therapeutic Substances | Restricted Goods Policy Section
 Trade and Customs Branch | Traveller, Customs and Industry Division
 Department of Immigration and Border Protection
 P: s. 22(1)(a)(ii) | E: dts@border.gov.au

From: Import/Export Policy
Sent: Wednesday, 13 January 2016 10:52 AM
To: s. 22(1)(a)(ii)
Cc: Import/Export Policy
Subject: FW: Media Enquiry - Truvada.docx [SEC=UNCLASSIFIED]
Importance: High

Hi,

As discussed

Kind regards,

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Assistant Director Import /Export Policy
 Trade and Customs Branch | Traveller, Customs and Industry Policy Division
 Policy Group
 Department of Immigration and Border Protection

s. 22(1)(a)(ii)

s. 22(1)(a)(ii) @border.gov.au

From: s. 22(1)(a)(ii)
Sent: Wednesday, 13 January 2016 10:05 AM
To: MCDONALD Mark; CHANDLER Andrew
Cc: Import/Export Policy; Portfolio Media; s. 22(1)(a)(ii)
Subject: RE: Media Enquiry - Truvada.docx [SEC=UNCLASSIFIED]
Importance: High

Hi

This is ok – I've made a couple of minor suggestions for clarity.

s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

Director Import/Export Policy
 Trade and Customs Branch | Traveller, Customs & Industry Policy Division

Policy Group
Department of Immigration and Border Protection
P: s. 22(1)(a)(ii) M: s. 22(1)(a)(ii)
E: s. 22(1)(a)(ii) [@border.gov.au](mailto:info@border.gov.au)

From: MCDONALD Mark
Sent: Wednesday, 13 January 2016 9:53 AM
To: CHANDLER Andrew; s. 22(1)(a)(ii)
Cc: Import/Export Policy; Portfolio Media; s. 22(1)(a)(ii)
Subject: Media Enquiry - Truvada.docx [SEC=UNCLASSIFIED]
Importance: High

Good morning Andrew and s. 22(1)(a)(ii)

Attached is the detail in relation to a media enquiry received yesterday. Can you please have a look at the response and advise if there are any issues from an import policy perspective as soon as possible.

Thanks very much,

Mark

Mark McDonald

A/g Commander Customs Compliance
Border Management Division
Australian Border Force

 s. 22(1)(a)(ii) [@border.gov.au](mailto:info@border.gov.au) |  s. 22(1)(a)(ii) |  s. 22(1)(a)(ii)

s. 22(1)(a)(ii)

From: DTS
Sent: Tuesday, 9 February 2016 9:27 AM
To: s. 22(1)(a)(ii)
Cc: DTS
Subject: Truvada Shipments [SEC=UNCLASSIFIED]
Attachments: FW: s. 47F(1) Trade and Regulated Goods: Prohibited Drug List - PREP/Truvada (C/DUTTON/PG-TCIP) [DLM=For-Official-Use-Only]

Importance: High

Follow Up Flag: Follow up
Flag Status: Flagged

Morning s. 22(1)(a)(ii)

As discussed I know we were assisting your area with responding to media enquiries regarding Truvada shipments.

We have received the attached Ministerial regarding ABF treatment of these shipments.

We would appreciate your advice on the matter, whether it would be best to transfer to your area or we can respond with your input.

Many thanks,

s. 22(1)(a)(ii) Assistant Director Drugs and Therapeutic Substances | Restricted Goods Policy Section
 Trade and Customs Branch I Traveller, Customs and Industry Division
 Department of Immigration and Border Protection
 P: s. 22(1)(a)(ii) E: dts@border.gov.au

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Australian Government
Department of Immigration
and Border Protection



Australian
BORDER FORCE

MEDIA ENQUIRY

Subject: Truvada shipment		
Deadline: 6pm, 12 January 2016		
Journalist: s. 47F(1)	Outlet: s. 47F(1)	
Phone: s. 47F(1)	Mobile: s. 47F(1)	Email: s. 47F(1)
Enquiry Received (Time & Date): 11:30am, Tuesday 12 January 2016		
Media Officer: s. 22(1)(a)(ii)	Media Ph: s. 22(1)(a)(ii)	

QUESTION / ISSUE

Journalist's email:

I have some questions about shipments of Truvada into Sydney in the past week. I've put the background into the story first and my questions for the Minister are below. Two shipments of Truvada were delivered by FedEx from s. 47F(1) to Sydney on Thursday 7 January s. 47F(1) and Monday 12 January s. 47F(1)

The shipment contains 24 individual orders, prescriptions and payment details for Truvada (PrEP) and are not a bulk order of the drug. The orders were organised by s. 47F(1) on behalf of his organisation s. 47F(1) for the 24 people. Senior ABF Officer, Compliance Operations (Sydney) s. 22(1)(a)(ii) has decided the above two shipments are subject to GST because their total value exceed \$1000. However, they are individual orders and not considered a bulk order, therefore not subject to GST charges. The TGA advised Mr Vuga this was the case, but he has indicated that decision is at his discretion. It is understood the Minister's office has also cleared previous shipments of Truvada. Previous shipments of Truvada from s. 47F(1) (e.g. s. 47F(1)) were cleared without paying GST.

The GST Act states: Section 38.50 of the A New Tax System (Goods and Services Tax) Act 1999 (Cth) states the supply of a drug is GST free if it is "restricted, but may be supplied on prescription." According to the ATO ruling on drugs and medicinal preparations, this covers medications listed under Schedule 4 of the TGA Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). Both tenofovir and emtricitabine - the constituent medications of Truvada and its generics - are listed under schedule 4 of the SUSMP.

Is the decision to charge GST at the discretion of individual ABF officers? What will the Minister do to clear this urgent medication? How can this confusion be avoided in the future? How does this Minister respond to suggestions the delay is due to personal discrimination by s. 22(1)(a)(ii)

TALKING POINTS

- While the Therapeutic Goods Administration's (TGA) Personal Importation Scheme allows for the personal importation of Truvada, it also requires that the medication is imported by an individual for their personal use, or use by a member of their immediate family. The medication is not to be supplied to any other person.

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 and Border Protection**



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The consignments in question were addressed to s. 47F(1), who it appears is neither the end user or prescription holder for this medication.

- It is important to note that if the consignments had been separated by the supplier and consigned to the individual prescription holders, the GST exemption would apply.
- The consignments in question however were shipped to s. 47F(1) as the declared consignee and, as per *A New Tax System (Goods and Services Tax) Act* (the GST Act), consignments such as this which are valued at over \$1000 would attract GST.
- The GST Act provides an exemption in relation to the importation of medication in certain circumstances, including if the supply is to an individual for private or domestic use or consumption. It is expected that these importations will be accompanied by prescriptions for specific patients.
- The ABF encourages s. 47F(1) to seek advice from the ATO on exemptions and refunds of GST that may apply to importations he arranges on behalf of other parties.

IF ASKED

Allegations the ABF officer involved was being discriminatory

- The ABF would strongly rebuff any claims of personal discrimination in this matter as simply untrue and unfair. We are working closely with ATO and other agencies to ensure appropriate revenue is collected on all imported goods, while ensuring important medical imports are able to enter the country on a lawful basis.

Additional question from s. 47F(1) s. 47F(1)

*Why were the four packages before Christmas held up and why were they subsequently released?
 Is it true that there was intervention by Minister Peter Dutton's office to expedite the passage of the four packages containing PrEP medicines through Customs before Christmas?*

- On 23 December 2015, the Ministers office referred to ABF for its consideration an enquiry from s. 47F(1) in relation to a shipment consigned to him. The goods, which were below the \$1000 GST exemption threshold, had been referred to the ABF from a non-government agency seeking advice as to whether the goods required permission to be imported. Once the appropriate documentation (including prescriptions) was provided to the ABF, the shipments were cleared.

BACKGROUND (*not* for public release)

Truvada is a pharmaceutical product. It has been approved by the Therapeutic Goods Administration for use in the treatment of HIV but has not been licenced for use as a preventative measure and not therefore available at a subsidised price through the Pharmaceutical Benefits



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Scheme (PBS). The medication can be prescribed by a General Practitioner for the latter purpose. Open source information suggests purchase through the local supplier would cost in the vicinity of \$13,500 per annum. Generic versions can be purchased overseas and imported at significantly reduced costs from suppliers including the ^{s. 47F(1)}. The cost of overseas purchase is in the vicinity of \$180 for a three-month supply.

Overseas purchase and importation is permitted under the TGA Personal Importation Scheme.

However, while the TGA has approved the personal importation of certain medications without prior permission it also requires that the medication is imported by an individual for their personal use, or use by a member of their immediate family. The medication is not to be supplied to any other person.

Section 38.50 (1) of the GST Act states that a supply of a drug or medicinal preparation is **GST-free** if the supply is on prescription and:

(a) under a * State law or a * Territory law in the State or Territory in which the supply takes place, supply of the drug or medicinal preparation is restricted, but may be supplied on prescription; or

(b) the drug or medicinal preparation is a pharmaceutical benefit (within the meaning of Part VII of the [National Health Act 1953](#)).

However, 38.50 (7) states that a supply of a drug or medicinal preparation covered by this section is GST-free if, and only if:

(a) the drug or medicinal preparation is for human use or consumption; and

(b) the supply is to an individual for private or domestic use or consumption.

^{s. 47F(1)} has demonstrated awareness of the threshold for GST liability and would appear to be coordinating import volumes accordingly. Since October 2015 there have been a number of importations consigned to ^{s. 47F(1)} of varying quantities. The three most recent consignments were reported within a seven day window and were all valued at between \$900 and \$950. Of note, Fedex subsequently amended the original value of the shipment referred to on ^{s. 47F(1)} to ^{s. 47F(1)} to \$4822.69. It is assumed this is based on commercial documents provided to them by ^{s. 47F(1)}.

The ABF is not actively targeting importations by ^{s. 47F(1)}, or his organisation. In fact, each shipment in question has been referred to us by Fedex for the purpose of seeking advice as to the control status of the medication.

The consignments in question were addressed to ^{s. 47F(1)}, who it appears is neither the end user or prescription holder for this medication. While the ABF officer's assessment that the GST exemption does not apply appears to be correct, we are seeking clarification from the Australian Tax Office.

If the consignments had been separated by the supplier and consigned to the individual prescription holders, the GST exemption would apply.



Australian Government
**Department of Immigration
 and Border Protection**



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On the 23rd of December an enquiry was received from the Minister's Office in relation to shipments of goods consigned to ^{s. 47F(1)} [REDACTED]. The goods had been referred to the ABF by Fedex seeking advice as to whether the goods (declared as 'ANTIRETROVIRAL TABLETS') required permission to be imported. Once the appropriate documentation (including prescriptions) was provided to the ABF the shipments were cleared.

CLEARANCE:

Drafted by	Title	Time/Date cleared
s. 22(1)(a) (ii) [REDACTED]	Superintendent, National Compliance Operations Coordination	16:18 16 January 2016

Cleared by	Title	Time/Date sent	Time/Date cleared
Mark McDonald	A/Commander Customs Compliance	16:18 16 January 2016	16:29 16 January 2016
[REDACTED]	Strategic Communication Advisor	17:35 16 January 2016	17:40 16 January 2016
David Seale	A/g AS, Communication and Media	16:40 16 January 2016	17:40 16 January 2016

MO cleared	Sent to MO	Cleared by MO

Released by DIBP under the
 Freedom of Information Act 1982

UNCLASSIFIED

s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Tuesday, 9 February 2016 9:13 AM
To: s. 22(1)(a)(ii)
Subject: FW: s. 47F(1) Trade and Regulated Goods: Prohibited Drug List - PREP/Truvada (C/DUTTON/PG-TCIP) [DLM=For-Official-Use-Only]

s. 22(1)(a)(ii)

Senior Policy Officer Restricted Goods Policy Section
 Trade and Customs Branch | Traveller, Customs and Industry Policy Division
 Policy Group
 Department of Immigration and Border Protection
 P s. 22(1)(a)(ii)
 E: s. 22(1)(a)(ii) @border.gov.au dts@border.gov.au

From: Dutton, Peter (MP) [mailto:Peter.Dutton.MP@aph.gov.au]
Sent: Monday, 18 January 2016 9:52 AM
To: Minister's Mailbox
Subject: s. 47F(1) Trade and Regulated Goods: Prohibited Drug List - PREP/Truvada (C/DUTTON/PG-TCIP)

From: noreply@peterdutton.com.au [mailto:noreply@peterdutton.com.au]
Sent: Sunday, 17 January 2016 8:49 AM
To: Dutton, Peter (MP)
Subject: Contact from www.peterdutton.com.au

A user has submitted the contact form on the website of Peter Dutton MP.

Name

First Name: s. 47F(1)

Last Name: s. 47F(1)

Contact Details

Email: s. 47F(1)

Phone: s. 47F(1)

Street Address: s. 47F(1)

Suburb: s. 47F(1)

State: s. 47F(1)

Postcode: s. 47F(1)

Preferred Contact: Email

Message

Message

Dear Mr Dutton, I write to you about the stopping of PREP/Truvada orders by customs officers. I am one the Australian citizens who is trying to actively manage my personal health and wellbeing by importing this life saving and changing drug for my personal use. This drug empowers me to life a healthy and happy life

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without the fear of contracting HIV. As you would be aware, living with HIV can be a very challenging thing and can be a drain on our already strained health care system. I understand how some of your officers may have initially been confused about the nature of the importing due to the shipping of separate as a single package in order to save on shipping (which would add over \$100 to each individual order). However, I do not understand why your officers would continue to detain these orders, after being presented with evidence of the separate individual personal orders. I ask that you please intervene and instruct your officers to permit these personal use orders through unimpeded to ensure a consistent regular supply for me and the other citizens actively involved in managing our health and wellbeing. Especially given that there is no cost to government in doing this and a very large amount of savings to be realised through avoided HIV care and treatment.

I do not wish to receive
community alerts and announcements Yes

Please enter the code

IP Address

s. 47F(1)

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s. 22(1)(a)(ii)

From: s. 22(1)(a)(ii)
Sent: Tuesday, 9 February 2016 12:02 PM
To: DTS
Cc: Mark MCDONALD; s. 22(1)(a)(ii)
Subject: RE: Truvada Shipments [DLM=For-Official-Use-Only]
Attachments: SB16-000242 Final.docx

Follow Up Flag: Follow up
Flag Status: Flagged

Hi s. 22(1)(a)(ii)

I just tried calling but you must be away from your desk.

Please find attached the back pocket brief to use in response to the Ministerial corro. We have dealt with the individual matter wrt a media enquiry, but think that the wider policy issue sits with your area. Happy to discuss further when you are available.

If you could provide a copy to run past our Exec before submitting, that would be great.

Regards,

s. 22(1)(a)(ii)

Customs Compliance Branch | Border Management Division
 Support Group
 Australian Border Force
 P: s. 22(1)(a)(ii) | M: s. 22(1)(a)(ii)
 E: s. 22(1)(a)(ii) @border.gov.au

From: DTS
Sent: Tuesday, 9 February 2016 9:27 AM
To: s. 22(1)(a)(ii)
Cc: DTS
Subject: Truvada Shipments [SEC=UNCLASSIFIED]
Importance: High

Morning s. 22(1)(a)(ii)

As discussed I know we were assisting your area with responding to media enquiries regarding Truvada shipments.

We have received the attached Ministerial regarding ABF treatment of these shipments.

We would appreciate your advice on the matter, whether it would be best to transfer to your area or we can respond with your input.

Many thanks,

s. 22(1)(a)(ii) Assistant Director Drugs and Therapeutic Substances | Restricted Goods Policy Section
 Trade and Customs Branch | Traveller, Customs and Industry Division
 Department of Immigration and Border Protection
 P: s. 22(1)(a)(ii) | E: dts@border.gov.au

**Department of Immigration and Border Protection
Supplementary Estimates – February 2016**

SB16 - 000242

Compliance Activity – Importations of Truvada

Key Talking Points

- The Australian Border Force (ABF) works collaboratively with key partner agencies, such as the Australian Tax Office (ATO), to ensure appropriate revenue is collected on imported goods.
- Through the application of a risk based approach to the assessment of imported goods, the ABF actively mitigates potential revenue evasion which may occur through undervaluation, misclassification and non-declaration of goods, incorrect claims for Goods and Services Tax (GST) exemptions, preferential treatment under free trade agreements, duty refunds and concessions.
- The ABF considers a consignments to be goods that are considered as those shipped to Australia from one consignor to one consignee. To facilitate transportation of a consignment, a shipping agent may separate a consignment into several parts and even though this may occur, the shipment continues to be considered as one consignment.
- Import duties and taxes payable are calculated by the Integrated Cargo System based on the declared commercial value of a consignment, the commodity type, origin and any applicable duty treatments or concessions. They are not determined by officer discretion.
- Consignments of goods with a commercial value in excess of \$1000 would ordinarily attract GST. The GST Act provides an exemption in relation to the importation of medication in certain circumstances, including if the supply is to an individual for private or domestic use or consumption.
- s. 47F(1) has imported fifteen consignments of goods described as medication since the beginning of 2015.
- s. 47F(1) is the declared consignee for each of the shipments.
- The ATO has advised the ABF that is s. 47F(1) has an agency relationship with the individual prescription holders, then the supply to those individuals would be GST-free.
- s. 47F(1) has advised the ABF that he has no connection to the importers, he is acting solely as a distributor to assist the overseas supplier.

If asked

Did the ABF treat s. 47F(1) importations consistently?

- The ABF applies a risk based approach to the intervention of all imports. Goods such as those consigned to s. 47F(1) are subject to a range of legislation including the GST Act, the Customs Act and TGA requirements.
- The assessment of s. 47F(1)'s importations was based on information provided to the ABF by the cargo reporter and subsequently s. 47F(1). In some cases assessments identified inconsistencies in the import and commercial documentation, which resulted in some of his shipments being subject to additional scrutiny.

Background

Truvada is a pharmaceutical product. It has been approved by the Therapeutic Goods Administration (TGA) for use in the treatment of HIV but has not been licenced for use as a preventative measure and not therefore available at a subsidised price through the Pharmaceutical Benefits Scheme (PBS). The medication can be prescribed by a General Practitioner for the latter purpose.

Open source information suggests purchase through the local supplier would cost in the vicinity of \$13,500 per annum. Generic versions can be purchased overseas and imported at significantly reduced costs from suppliers: the cost of overseas purchase is in the vicinity of \$180 for a 3 month supply. The ^{s. 47F(1)} in ^{s. 47F(1)} is the declared consignor in each of the consignments shipped to ^{s. 47F(1)}.

Overseas purchase and importation of medication is permitted under the TGA's Personal Importation Scheme. On its public website, the TGA advises:

Personal importation occurs when:

- *An individual arranges from within Australia for a therapeutic good to be sent to them from an overseas supplier or family / friend; and*
- *The goods are to be used by that individual or a member of his / her immediate family and are not sold or supplied to any other person.*

This appears to be at odds with the advice the TGA has apparently previously provided to ^{s. 47F(1)} that the deliveries to ^{s. 47F(1)} "satisfied the requirements of the personal import scheme". We are seeking urgent clarification on this aspect from the TGA.

In relation to the applicability of GST, section 38.50 (1) of the GST Act states that a supply of a drug or medicinal preparation is **GST-free** if the supply is on prescription and:

*(a) under a * State law or a * Territory law in the State or Territory in which the supply takes place, supply of the drug or medicinal preparation is restricted, but may be supplied on prescription; or*

(b) the drug or medicinal preparation is a pharmaceutical benefit (within the meaning of Part VII of the National Health Act 1953).

However, section 38.50 (7) states that a supply of a drug or medicinal preparation covered by this section is GST-free if, and only if:

- (a) the drug or medicinal preparation is for human use or consumption; and*
- (b) the supply is to an individual for private or domestic use or consumption.*

The ATO has advised that importation by an agent may satisfy the requirements for a GST exemption, however if the existence of agency relationship cannot be established, the entity named as the owner in the import declaration will be considered to be making the taxable importation in their own right.

s. 47F(1)

has advised the ABF previously that he has no connection to either the importers or to the pharmacy that is distributing the medications from s. 47F(1). He has advised that upon receipt of the medications he forwards them to each individual prescription holder as a favour to one of the directors / owners of the s. 47F(1) who is also a family friend.

If the consignments had been separated by the supplier and consigned to the individual prescription holders, the GST exemption at 38.50(7) would apply.

In considering s. 47F(1)'s previous importations of medication, he has demonstrated a clear awareness of the threshold for GST liability and would appear to be coordinating import volumes accordingly. Since October there have been a number of importations consigned to s. 47F(1) of varying quantities. The three most recent consignments were reported within a seven day window and were all valued at between \$900 and \$950. Assessment of commercial documentation subsequently provided by s. 47F(1) indicates these shipments have a commercial value in excess of \$1000.

On the 23rd of December 2015 the ABF received an enquiry from the Minister's Office in relation to shipments of goods consigned to s. 47F(1). The goods had been referred to the ABF by Fedex seeking advice as to whether the goods required permission to be imported. Once the appropriate documentation (including prescriptions) was assessed by the ABF the shipments were cleared.

Consultation

Trade and Customs Branch

External agencies consulted: Australian Taxation Office

Responsible Officer

Erin Dale
Commander
Customs Compliance
Border Management Division

Ph: s. 22(1)(a)(ii)

Mob: s. 22(1)(a)(ii)

Contact Officer

s. 22(1)(a)(ii)
Superintendent
Customs Compliance
Border Management Division

Ph: s. 22(1)(a)(ii)

Mob: s. 22(1)(a)(ii)

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