Australian Government
Department of Home Affairs

OFFICIAL: Sensitive

Management of Therapeutic Goods Controlled under the Therapeutic Goods Act 1989

Procedural Instruction

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1. Purpose

The purpose of this Procedural Instruction is to provide guidance on the treatment of substances and goods that are regulated under the provisions of the *Therapeutic Goods Act 1989* (TG Act), and to provide guidance on their administration by the ABF in the import environment. It should be noted that the TG Act has built parallel provisions to cover export of therapeutic goods: however, these provisions are not generally applied at the border.

The information in this instruction specifically describes the powers of the ABF that underpin the end-to-end activities relating to the management of therapeutic substances and goods, and provides guidance on recommended procedures around the referral of these goods.

It is important to note that Australia has a complex drugs control framework in place. The Department of Home Affairs (the Department) and the Australian Border Force (the ABF) contribute to the framework through:

- administering the import and export restrictions for drugs specified in the *Customs (Prohibited Imports) Regulations 1956* (the PI Regulations) and the *Customs (Prohibited Exports) Regulations 1958* (the PE Regulations) as per technical advice from the Office of Drug Control
- identifying border controlled drugs and plants specified in the *Criminal Code Act 1995* (the Criminal Code) on behalf of Australian Federal Police (the AFP)
- administering and investigating the import and export of border controlled precursors also specified in Criminal Code
- identifying and seizing of therapeutic goods specified in the TG Act under direction of Therapeutic Goods Administration (TGA).

It is the ABF border responsibilities in relation to goods in the last category and their clearance that are the subject of this instruction.

2. Scope

2.1. In Scope

This Procedural Instruction applies to all ABF officers who process goods at the border that are presented or labelled as likely to have therapeutic use, and covered by the provisions of TG Act. The form of such goods could include tablets, capsules, ointments, oils, lotions, crystals, and powders. Furthermore, these procedures apply to medical devices and biologicals that are intended to, or claim to, cure, improve, mitigate, treat or prevent disease, and are therefore taken to make a therapeutic claim.

Officers detecting these substances and goods will be required to determine the appropriate course of action for the substance or good based on the nationally consistent policy defined in this instruction.

The responsibilities of the ABF encompassed by this PI include:

- the identification of substances suspected to be therapeutic goods
- the correct application of legislated controls that apply to therapeutic goods
- the directed seizure process.

This Procedural Instruction focuses on border regulation of therapeutic goods on import as this route presents a higher threat to the safety of the Australian community through potentially exposing the Australian consumer to sub-standard therapeutic goods or goods that ordinarily require prescription. Parallel provisions covering exports exist in the TG Act, however they are not generally used.

2.2. Out of Scope

This Procedural Instruction **does not** provide instruction on the management of substances that are border controlled and listed in Schedule 2 to the *Criminal Code Regulations 2019* (the CCR) and/or prohibited under Schedules 4, 7A or 8 to the PI Regulations. Detailed instruction on this subject is under development.

This instruction does not detail the safe handling procedures for dangerous substances, but officers must be aware that substances detected, especially in mislabelled liquid or powder forms, may present a serious safety risk, and as such, this document must be read in conjunction with the relevant Work, Health and Safety Procedural Instructions:

- *Management of Hazardous Chemicals and Other Hazardous Substances Procedural Instruction (HR-2135)*
- *Managing Unidentified Substances Procedural Instruction (TT-6312).*

3. Procedural Instruction

3.1. Detection of Drugs and Therapeutic Substances – Role of the ABF

ABF officers have responsibilities within every tier of Australia's complex framework for managing (as much as possible) the border movement of serious drugs, their analogues and precursors, prohibited imports, therapeutic goods, new psychoactive substances (NPS) as well as serious drug alternatives (SDA). When performing this role, ABF officers may encounter goods of interest to the TGA, which operates within the Australian Government Department of Health and Aged Care, and provides for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods.

In practice, the TGA is generally made aware of an intended importation of prescription medicine, a medical device, or medication that does not meet the required standard. This is generally through a referral from the ABF when officers working in a Customs Place detect relevant goods as part of fulfilment of their general search duties.

More information relating to the standard requirements for a referral of goods to TGA is provided in Section 3.3.6.1 of this instruction.

Note: Trade and Goods Operation Policy (TGOP) Section is the ABF operational policy liaison point with AFP and various sections of the Department of Health and Aged Care on matters relating to the classification and border management of these substances and goods. All general questions to assist with classification of drugs and therapeutic substances must be raised through the TGOP Mailbox in the first instance, via s. 47E(d) @abf.gov.au.

3.2. Import and export controls – drugs framework

All drugs and therapeutic substances, identified as part of border processing procedures, fall into one of the four general categories, which determine the processing methodology, applicable legislation, define the roles of relevant partner agencies and are importantly associated with different responsibilities of ABF officers.

Furthermore, there are multiple pieces of legislation controlling the importation and exportation of drugs (including analogues), plants, precursors and therapeutic goods and substances at the border and the TG Act is only one of these.

The four categories of drugs and therapeutic substances under Australian Legal Framework are:

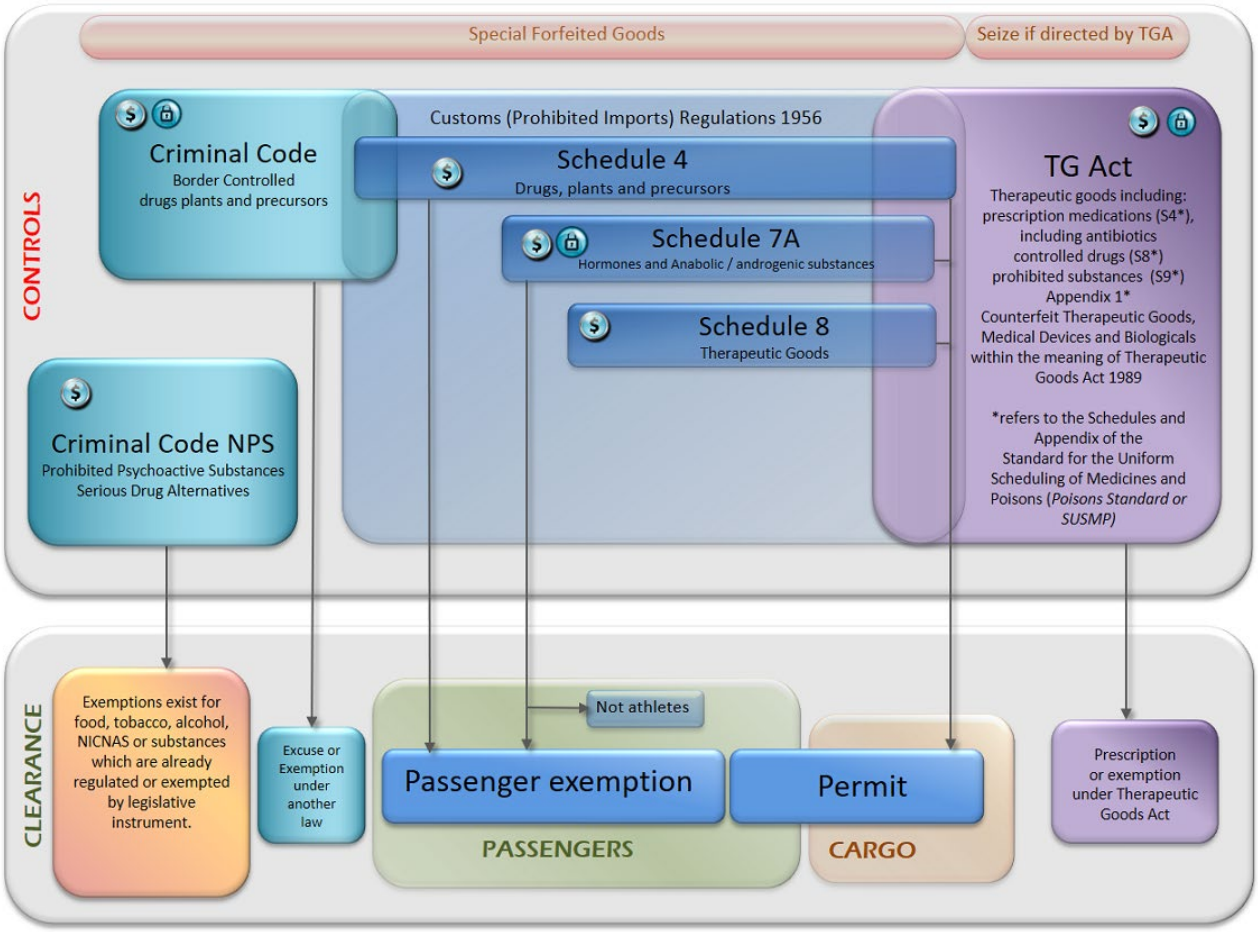
- Border Controlled Drugs (including analogues), Border Controlled Plants and Border Controlled Precursors captured by provisions of the Criminal Code and specifically by reg 14 (Schedule 2), reg 15 and reg 16 of the CCR imported without permission
- Prohibited Drugs covered by reg 5 (Schedule 4), reg 5H (Schedule 7A) and 5G (Schedule 8) of the PI Regulations
- Substances, suspected to represent a NPS or SDA, as defined in the Criminal Code, which are not otherwise regulated or exempt
- Therapeutic Goods: Medicines (other than prohibited or border controlled drugs), medical devices and biologicals that are regulated under the provisions of the TG Act.

A drug, plant, precursor or substance may be controlled under more than one piece of legislation.

A diagram summary of the complete Australian Drugs and Therapeutic Substances framework, including existing controls and clearance processes, is summarised in **Figure 1**. The key legal difference between the four categories of drug and therapeutic substances in relation to application of Customs Powers is that:

- Border Controlled Drugs (including analogues), plants and precursors, prohibited imports and NPS/SDA goods fall under the definition of special forfeited goods under subsection 229(1) of the *Customs Act 1901* (the Customs Act). When these goods are identified in a Customs Place as part of s186 customs examination activities, these goods may be seized without warrant in line with the standard provisions of s203B of the Customs Act
- Medicines, medical devices and biological goods as defined in the TG Act are only able to be seized by the ABF as prohibited imports or exports under the Direction of a Delegate of the Secretary of the Department of Health and Aged Care.

Figure 1. Australia's Legislative Drugs and Therapeutic Substance Framework



Notes on **Figure 1**:

1] While **Figure 1** refers to Permits that are available under the provisions of the PI Regulations, this reference is included for general overview of the Drugs and Therapeutic Substances Framework. Permits for border controlled and prohibited drugs will be further discussed in other instruction, which are under development.

2] New Psychoactive Substances (NPS) Exemptions prevent for goods that are generally taken to be food, alcohol, tobacco and industrial goods may from being considered under the NPS provisions. An example of this is caffeinated drinks, which are taken to be a food/drink despite the fact that caffeine has a potent effect on the nervous system.

3.3. Import and Export Controls – Therapeutic Goods Act

This section is designed to help ABF officers understand the legislative controls, which apply to therapeutic goods at the border via the TG Act.

3.3.1 Controls on medicines and substandard medicines under the Therapeutic Goods Act

A definition for 'therapeutic goods' is included in the Glossary section of this Procedural Instruction.

A number of provisions exist under the TG Act that refer to the management of the import and export of different types of therapeutic goods (medicine, medical devices and biologicals). The most commonly used provision in relation to regulation of medicines at the border is s19B.

Subsections19B(1), (4), (4A) of the TG Act specify that a person commits an offence if they import, export, manufacture or supply therapeutic goods that are prescription pharmaceuticals for use in humans, and none of the following conditions apply in relation to the goods:

(i) The goods are registered goods or listed goods in relation to the person

(ii) The goods are exempt goods

(iii) The goods are exempt under s18A

(iv) The goods are the subject of an approval or authority under s19

(v) The goods are the subject of an approval under s19A.

The above provisions usually apply in cases where importers are accessing prescription only medicine from other countries without authority.

Parallel controls relating to border management of medicines that do not meet the Australian standards set by the TGA are in s14 of the TG Act. Further details of existing TG Act controls to cover all types of therapeutic goods and medical equipment imports and exports are in Section 3.3.2.

3.3.2 Controls on medical devices and biologicals under the TG Act

Two further types of therapeutic goods identified in and controlled by the TG Act are medical devices and biologicals. The TGA makes the determination when the definition of a medical device or biological for the purposes of the TG Act is appropriate for an imported therapeutic good on referral. Full definitions for both therapeutic product types are included in the Glossary section of this Procedural Instruction.

In brief, medical devices are instruments, apparatus, appliances or other articles that do not achieve their principle intended action in or on the body by pharmaceutical, chemical, immunological or metabolic means.

Importation and exportation of a medical device related offences are described under subsections 41MA(1), (4), (4A), (9), (12), subsections 41MAA(1), (3), subsections 41MB(1), (4), (5) and s41MIB.

Biological therapeutic goods controlled by the TG Act are products made from or containing human cells or human tissues (or otherwise specified), including human tissues therapy products (skin, bone, collagen, heart valves, cornea, cell-based tumour vaccine).

Importation and exportation of biological therapeutic goods related offences are described under subsection 32BA(1), (4), (4A) or subsections 32BB(1), (4), (4A) of TG Act.

3.3.3 Controls counterfeit therapeutic goods under the Therapeutic Goods Act

Section 42E of the TG Act specifies that a person is guilty of an offence if they intentionally manufacture, supply, import or export counterfeit therapeutic goods and they are either:

- aware the goods are counterfeit, or
- reckless as to whether the goods are counterfeit.

The definition for counterfeit therapeutic goods for the purpose of this offence is included in the Glossary section of this Procedural Instruction.

In limited circumstances counterfeit medication may also breach Intellectual Property Rights (IPR) under the provisions of the *Trade Marks Act 1995* (the TM Act) and *Copyright Act 1968* (the CR Act). However, counterfeit Therapeutic Goods will always be dealt with under the TG Act, as there is less chance of the goods entering the community.

3.3.4 Directed Application of the Customs Act

Each of the controls described above have associated provisions within the TG Act that enable the application of the Customs Act by authorised officers in relation to the goods upon direction from the TGA. These are summarised in **Table 1. TG Act Provisions relating to the Directed Application of the *Customs Act 1901* to Imported and Exported Therapeutic Goods.**

The authorised officers in the circumstances are ABF (Customs) officers exercising powers in a Customs Place (within the meaning of s183UA of the Customs Act). TGA directed application of the Customs Act provisions has the effect that therapeutic goods intercepted at the border are forfeited to the Crown under s229 because they are:

- prohibited imports within the meaning of the Customs Act, or
- prohibited exports within the meaning of the Customs Act.

The administrative steps that must occur to enable the directed application of s229 of the Customs Act provisions to therapeutic goods by authorised officers are as follows:

- The importation or exportation of the particular type of therapeutic goods is an offence as per relevant sections of the TG Act (**Table 1**), as established by TGA on referral from the ABF and
- The Secretary of the Department of Health and Aged Care notifies the Comptroller-General of Customs in writing that the Secretary of the Department of Health and Aged Care directs the Customs Act to apply to that importation or exportation as per the requirement of s56A of TG Act.

Table 1. TG Act Provisions relating to the Directed Application of the Customs Act to Imported and Exported Therapeutic Goods

Type of Therapeutic Good	Provisions Offences relating to Import and Export in the TG Act	Relevant TG Act Provision for application of s229 of Customs Act
Prescription Medication (obtained without authority - prescription)	subsection 19B (1, 4 or 4A)	subsection 19B(7)
Medication that does not meet Standards	subsection 14(1, 4, 4A, 10, 13 or 13AA) or 14(1 or 3)	subsection 14B
Biologicals within the meaning of the TG Act	subsection 32BA(1, 4 or 4A) or 32BB(1, 4 or 4A)	subsection 32BBA or subsection 32BF(7)
Medical Device	subsection 41MA(1, 4, 4A, 9.12 or 13) or 41MAA(1 or 3)	subsection 41MD
Unregistered Medical Device	subsection 41MI (1, 4, 5) or 41MIB	subsection 41MJ
Counterfeit Therapeutic Goods	subsection 42E or s42EA	subsection 42F

The Secretary of the Department of Health and Aged Care generally delegates the power to issue a Notification to the Comptroller General regarding the application of the Customs Act *1901* to officers of the TGA under s57of the TG Act. Examples of all types of such Notifications are available at **Attachment D**.

A **Legislation Summary** describing the **Interaction between the TG Act and the Customs Act** in relation to border management of therapeutic Goods is available at **Attachment E**.

3.3.5 Permissions and Exemptions

There are two Personal Importation exemption schemes which may apply to therapeutic goods. If the goods are prohibited imports and imported by passengers, then the exemptions available under the Customs Act should be considered first.

Where these exemptions do not apply, the goods are prohibited imports and should be seized. That is, the goods either meet the concession or not. The ABF should not be splitting consignments to provide an importer with an amount meeting the concession and seizing the excess[1].

[1] *CEO of Customs v Brad DAVIDSON*

If therapeutic goods are controlled under multiple pieces of legislation (e.g. the Customs Act, the Criminal Code and the TG Act):

- When imported through International Mail or Cargo streams, containing border controlled or prohibited ingredients that are also regulated under the TG Act (e.g. fentanyl patches or Adderall) then a valid permit will always have to be presented.
- When imported through the passenger stream, the passenger concessions should be applied.

3.3.5.1 Exemptions for Travellers under the Customs Act

A Traveller Exemption is applicable to certain prohibited imports and exports under the Customs Act, with the requirement that:

- goods are imported in the accompanying luggage
- are declared
- the traveller has a letter or prescription from their foreign or Australian doctor
- importation amounts do not exceed 3 months' supply.

The only exception to the traveller exemption are certain classes of PIs (Schedule 8 Therapeutic Substances). Furthermore, athletes may not be able to import certain PIs (Schedule 7A) under traveller exemptions if the imported goods in question are considered to enhance performance. This exemption does not apply to goods which are imported via the international mail or cargo streams.

It is important to note that this is separate and different from the TG Act personal import scheme described at 3.3.5.2.

3.3.5.2 Exemptions for the importation of therapeutic goods under the TGA Personal Importation Scheme

The TG Act and TG Regulations make provision for a Personal Importation Scheme (PIS), whereby a person may legally import a quantity of up to 3 months' supply of most therapeutic goods (at the manufacturer's maximum recommended dosage), provided they are for personal use only.

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.

The TGA can assist in determining whether imported goods meet the requirements of this scheme and further information is available on their public website, accessible using the following link: https://www.tga.gov.au/personal-importation-scheme.

ABF officers should note the passenger exemptions outlined in the PI and PE Regulations do not apply to goods imported through international mail and air cargo, but the TGA's PIS may.

Therefore, there are many circumstances when therapeutic goods controlled under the TG Act will meet the requirements of this exemption. The determination on the exemption can be made by the TGA, and will largely be based on confirmation that:

- the therapeutic/pharmaceutical goods do not contain goods controlled or prohibited by the Criminal Code, Customs Act and PI and PE Regulations
- the importer has provided a copy of the prescription and all other import requirements have been met.

3.3.6 Standard for the Uniform Scheduling of Medicines and Poisons and ABF authority to refer therapeutic goods detections to the TGA

3.3.6.1 Scheduling Principles and Relevance to TGA

Scheduling is a national classification system that controls how medicines and/or poisons are made available to the public. The Australian Health Ministers' Advisory Council Scheduling (Scheduling Committee), a committee established by s52B of the TG Act, drives the scheduling of medicines and poisons. The final scheduling decisions captured in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), also known as Poisons Standard.

Within the SUSMP, medicines and poisons are organised into Schedules according to the expected level of regulatory control over the availability of the medicine or poison required to protect public health and safety. Schedules are updated regularly to maintain the currency of the content. **Attachment F** provides further details on the purpose of each Poison Schedule and includes the formal definition of a poison.

Poisons in Schedule 4 to the SUSMP are Prescription Only Medicines, which also include certain types of prohibited imports, notably hormones, androgenic substances and the border controlled substance cannabidiol. Imports of Schedule 4 poisons, except for therapeutic substances that are border controlled or prohibited at the border, are managed in accordance with policy and Direction from TGA via an initial referral from the ABF.

The majority of substances in the SUSMP Schedules 8, 9 and 10 are controlled or prohibited and are managed at the border by the ABF in accordance with the CCR and PI Regulations. However, due to the chronology of poisons scheduling, a small number of poisons included in these higher risk scheduled may not be border controlled or prohibited until the annual or even bi-annual amendments of relevant legislation. Until their incorporation into the CCR and or PI Regulations, the ABF can refer such newly scheduled Schedule 8-10 Poisons to the TGA.

There are two ways for ABF officers to establish if a referral of a therapeutic good (pharmaceutical/medicine) to TGA is warranted:

- Officers can consult the **ABF Drugs and Therapeutic Substances Sharepoint Database** at s. 47E(d) , which lists all:
  - Border Controlled Drugs, Plants Precursors and Some Analogues
  - PI and PE Schedules 4, 7A and 8
  - Substances and SUSMP 4 and
  - Newly listed SUSMP 8-10 with their relevant classification.
- Officers can refer to **Goods Management System** (GMS), as part of processing a consignment, which will prompt them to action each identified substance in accordance with the correct classification

If ABF Officers are uncertain of how an identified substance should be managed, a referral of the case for classification advice should be made to the TGOP Mailbox at s. 47E(d) @abf.gov.au. Outcomes of all classification decisions managed by TGOP will be captured in the Sharepoint Database and GMS to maintain currency of ABF information and subject matter policy.

3.3.6.2 Referral of Unscheduled Substances

There are currently no formal arrangements in place between the ABF and TGA in relation to managing substances that make a therapeutic claim but are unscheduled in the SUSMP or excluded from the definition of Therapeutic Goods under the TGA Act. Since a number of Commands are able to share intelligence relating to importation of unscheduled medicines, dietary supplements and vitamins on the basis of active Standing Authorisation to Disclose Immigration and Border Protection Information (**Attachment G**), ABF officers can always refer information relating to consignments that may be of interest to TGA for their post-border investigation. In these cases, low risk goods may not need to be held. The option to refer consignments to TGA always remains open; however, referring officers should make a note as per record keeping practices in the relevant work area, recording the reasons why a case was escalated to a referral.

If officers are concerned about a consignment and remain uncertain of therapeutic substance scheduling or authorisation related to holding relevant goods or potential of community risk, they can consult TGOP via s. 47E(d) @abf.gov.au Mailbox before making a decision to refer to the TGA.

3.3.7 TGA Referral vs New Psychoactive Substance Seizure Options

Unscheduled psychoactive substances intercepted at the border, that are not border controlled, prohibited or otherwise exempt, can be considered under the New Psychoactive Substance (NPS) Scheme.

Psychoactive substances are defined in the s320.1 of the Criminal Code as those that have the capacity to induce psychoactive effect when consumed. Psychoactive effect is further defined, in relation to a person, as:

- stimulation or depression of the person's central nervous system, resulting in hallucinations or in a significant disturbance in, or significant change to, motor function, thinking, behaviour, perception, awareness or mood, or
- causing a state of dependence, including physical or psychological addiction.

The following pharmacological action descriptors are common examples of evidence that a substance may be psychoactive: Anxiolytics, anorexiants, sleeping pills, sedatives and tranquilizers. For the NPS Scheme to apply, goods with these properties must not already be controlled or regulated at the border, including under the provisions of the TG Act.

Occasionaly, It can be difficult to make a distinction between therapeutic goods and NPS, particularly because importers can sometimes state that the good is intended to improve health (e.g. a supplement). It is appropriate to consider a claimed "therapeutic good" under the provisions of the NPS Scheme if that good is not commercially packaged (not in blister packs in dose amounts, no labelling or dosage information, description or warnings are not on the package) and difficult to identify (as it is presented as unlabelled and unidentifiable powder). However, officers are reminded that they must NOT attempt to identify unknown powders without following the instruction in the *Managing Unidentified Substances PI (TT-6312)*.

Please note that detailed instruction on NPS is under development.

3.3.8 TGA Referral vs Serious Drug Alternative Seizure Options

Under some circumstances, a substance that does not readily present itself as a therapeutic substance may represent a Serious Drug Alternative (SDA). SDAs are generally psychoactive substances that are not related biochemically or otherwise easily associated with known goods with mind-altering properties, which are well described in open source literature.

In the absence of technology and detection equipment standards, suspicion that a substance represents an SDA may be built on the labelling of a substance. Relevant labels generally include words and/or illustrations that suggest drug use or are known names of goods associated with SDA imports. Examples of substances that are captured by SDA provisions include:

- make up or lollies, where packaging is covered with pictures of Cannabis leaves
- tea in packages with illustrations suggesting drug use

- powder bombs with label "Bath Salts"
- substances labelled as "Moonshine", "Ecstasy" or similar names
- cannabis or marijuana incense (as a powder can be collected from incense sticks)
- "Legal High".

Provisions relating to the importing of SDA are found in s320.3 of the Criminal Code and are parallel to NPS. As with NPS, the ABF must have a suspicion that a substance is intended to be used as a drug alternative on presentation and labelling of the good and the importer must provide evidence to the contrary via the ABF Claims process.

As SDA offence is concerned with the presentation of the substance, not with whether the substance is actually capable of inducing a "psychoactive effect", it is unlikely that officers would have difficulties distinguishing between an SDA and a therapeutic good. Hygiene products, such as soaps and unidentifiable powders (which do not make therapeutic claims), bearing labels of concern may be the only examples where classification would dictate a SDA assignment.

Additional information on detention, seizure and claims processes for SDA is available in the *Detention and Seizure of Prohibited and Restricted Goods PI (TT-2403)*. Further detailed instruction on SDA is under development.

3.4. ABF processes in relation to Referral and Management of Therapeutic Goods

The step by step ABF process relating to the management of therapeutic goods during the referral to TGA is provided in **Table 2** and laid out in a process map in **Attachment H: ABF Management of Therapeutic Goods**.

Table 2. ABF process for Management of Therapeutic Goods held pending TGA Direction

Step	Action
Considerations before ABF referral to TGA	
1	On balance with high-risk substances, such as border controlled narcotics and prohibited drugs/therapeutics, mainstream therapeutic goods represent lower risk to the community. Any ABF initiated targeted intervention activities involving medicines, medical devices and biologicals, must be considered from the point of view of: • Legislative basis under provision of the TG Act • authority related to Poisons Scheduling of the good and • existing arrangements between TGA and the ABF in relation to limited number of therapeutic goods that may be considered for temporary targeting by the ABF on the basis of risk management priorities developed by TGA.
2	Any unidentified substances without labels (including substances in tablet forms) must be handled with utmost caution, in line with *Managing Unidentified Substances Procedural Instruction (TT-6312)*.
3	ABF Technology and Detection Equipment may be deployed to identify some unlabelled medicines, although it is important to note that instrumental identification capacity may be limited since the actual amount of active ingredient in most compounded medicines is under 10% by weight, which is an amount that is below the measurement threshold of ABF detection instruments.

	It is not recommended that ABF Technology and Detection Equipment be deployed to confirm the ingredients of any labelled medication.
4	When ABF officers identify medication as part of performing their general examination duties under the provision of s186 of the Customs Act, officers **must first consider whether the active ingredients are reasonably suspected to be border controlled under the Criminal Code and regulation and/or prohibited under the PI/PE Regulations** before TGA referrals are considered. This can be done by referring to Drugs and Therapeutic Substances (DTS) Sharepoint Database at s. 47E(d) or requesting classification advice from TGOP team through s. 47E(d) at s. 47E(d) @abf.gov.au. There are common groups of medicines, which can sometimes be difficult to classify and differentiate from general therapeutic goods because understanding of their activity and relevant application of drug and therapeutic substance related controls shifts based on emerging scientific evidence, which warrants their technical inclusion as PI/PEs or NPS over a period of time. Examples of these substance include Schedule 7A substance Items (particularly Selective Androgen Receptor Modulators (SARMs) and synthetic hormone analogues), Schedule 8 Item 1 Abortifacients and New and Emerging Psychoactive Substances. ABF Officers who encounter medicines with recorded androgenic, hormone-like and mind altering (effects on the nervous system) properties, and which are not specifically border controlled or prohibited, are encouraged to seek classification advice from TGOP. ABF Officers who encounter substances and goods that meet the definition of SDA vs making a therapeutic claim should also seek classification confirmation from TGOP.
5	Information sharing with TGA is allowed under the existing Authorisations (**Attachment G**), which is in place for a number of Portfolio Divisions and Commands, specifically Port Operations Command; Border Patrol and Coordination Command; and Enforcement Command. The TGA must follow up on the details of the importation/exportation of therapeutic goods with the importer/exporter, and direct the ABF to either release the goods or treat them as prohibited imports/exports under the provisions of the Customs Act. ABF officers should not follow up on details with the importer on behalf of TGA.
6	All misdirected mail containing general therapeutic goods (medicines, medical devices and biologicals) that is not intended for consumption in Australia, can be returned to the mail stream, without making a referral to TGA. This is because actions performed by TGA, in relation to determining whether the relevant goods will be permitted into Australia, are centred on contacting the Australian importer. This requirement cannot be fulfilled unless the consignment has Australian address and/or client contact details. **Note:** Border controlled and prohibited goods that are misdirected **must not** be returned to the mail stream.
Making a Referral to TGA	
7	Where goods are not controlled under the PI or PE Regulations or the Criminal Code, but an officer suspects they may be controlled under TG legislation, initially the goods are held, not seized, and the details of the consignment must be referred to the TGA Regulatory Compliance via e-mail to the s. 47E(d) mailbox. A referral to TGA can be made in GMS by generating a TGA referral template/referral email. Relevant information (labelling, goods description, consignee details) relating to therapeutic goods consignments may be provided to TGA as part of the referral. Photographs of the goods, packaging and any other relevant details relating to the consignment can also be

	forwarded to TGA to assist in their decision-making in establishing whether exemption or authority to import is in place. GMS batch numbers are also accepted by TGA when a photo cannot be provided. Any documents and photos included in TGA referral must also be uploaded into GMS.
8	The TGA will determine whether the goods are therapeutic goods or counterfeit goods under the TG Act. The TGA will also determine whether the goods or the importer are registered, exempt or subject of an approval or authority. As part of managing the referrals of therapeutic goods from the ABF, the TGA will consider whether any personal importation scheme exemptions outlines in section 3.3.5 apply to the goods. The TGA may attempt to contact the importer to establish whether an appropriate authority or prescription has been obtained in relation to the goods. ABF officers should not follow up on details with the importer on behalf of TGA.
9	In limited circumstances, ABF officers may be able to assess a small quantity of prescription medication, consider any included evidence within a parcel or consignment of an existing Australian prescription and release the consignment without TGA referral. These types of decisions in relation to therapeutic goods must only be made in relation to medication for a period of days to a couple of weeks. This approach would prevent a delay in client accessing a small amount of their prescription medication required immediately. In case of larger consignments, officers must not attempt to determine if the limits permitted under PIS are exceeded as part of their assessment (3 months at a time and/or total quantity of the goods imported within a 12 month period does not exceed 15 months' supply). They should complete a referral to TGA providing the details of quantities detected. **Note:** TGA has recently advised ABF that based on their experience consignments of larger than 3 months amounts of therapeutic goods, often represent counterfeit and sub-standard products
10	During the referral period, therapeutic goods must be held in a secure location as per the *Detained Goods Management PI (TT-4786)* and as per the additional requirement described in the *Evidence Handling PI (BE-2882)*. As with all other goods, taken into ABF custody, the location and ongoing management of held therapeutic goods must be tracked in GMS. For further information on using GMS, please consult the *Managing Goods in Goods Management System Supporting Material (TT-6393)*.
11	If no exemption or authority exists in relation to the goods, the TGA will notify the Comptroller-General of Customs in writing that the Secretary of the Department of Health and Aged Care directs that provisions of the Customs Act apply to the consignment. The Notification will be sent to the referring ABF Officer and/or their team and reference the relevant provisions of the TG Act that refer to the importation (suspected medicine, including counterfeit preparation, medical device or biological good) as well as those that trigger the Direction to apply s229 Customs Act powers by ABF. Each Notification will include a TGA reference number (RIES Number). Please refer to **Table 1** for more information on the TG Act Reference and **Appendix D** for examples on different types of Notification to the Comptroller General regarding the application of the *Customs Act 1901*.
12	If a response to a referral is not received within 90 days and TGA does not make contact with ABF to formally confirm any further extension arrangements for a consignment, photographs of the goods should be taken, if they have not been taken at the point of the referral, and the consignment should be released.

	This policy position is based on administrative arrangements in s48H and s48J of the TG Act, which allows a therapeutic good to be retained for a period of 90 days and stipulate that a Magistrate's permission is obtained before the end of 90 day period to retain the relevant consignment further.
13	All therapeutic goods that are cleared for release by the TGA can simply be returned to the relevant clearance stream and/or directly to the importer. Further information on the steps involved in releasing goods is referenced in **Section 3.5** of this instruction.
Post TGA Notification Actions	
14	Where the ABF receives the TGA Direction in the form of Notification to the Comptroller General regarding the application of the *Customs Act 1901*, the relevant therapeutic good must be treated as a prohibited import or export. The ABF will then have the power to seize the goods under s203 or s203B as either forfeited with warrant or special forfeited without warrant depending on whether they are at a Customs Place or not. Further detailed information regarding the seizure and claims process is provided in **Section 3.5** of this instruction.
15	Providing the goods are not prohibited exports, the ABF may allow re-export. It is at the discretion of ABF that therapeutic goods will be returned to sender and the offer of re-export must not be made by TGA to the importer without discussing this with ABF referring officers. National Claims Processing Section (NCPS) is able to assist ABF with the assessment of re-export request and make case-by-case recommendations. Further information regarding re-export can be found in the *Detained Goods Management PI (TT-4786)* and *Managing Goods in Goods Management System Supporting Material (TT-6393).*
16	TGA will occasionally request that a physical sample of certain therapeutic goods be transferred to them, for laboratory testing. Such direct testing of relevant therapeutic goods is a step, required to confirm the presence or absence of certain active pharmaceutical ingredients (API) that may not appear on the packaging of the goods. Testing at the TGA laboratories is intended to support or allay any concerns that TGA may have that a therapeutic good is counterfeit in accordance with the definition of counterfeit therapeutic goods in s42E(2) and (3) of the TG Act. TGA will send a written request to ABF requesting ABF to provide a sample of the held goods for testing. ABF will provide a sample of the held goods to the TGA by safe hand to support their decision-making and formulation of the relevant TGA Direction as required. Following testing and analysis, the TGA will determine whether the goods are therapeutic or counterfeit goods under the TG Act, and whether any exemptions apply, and will advise ABF as soon as practicable once testing is complete. ABF and TGA have agreed on a process for sampling of suspected counterfeit therapeutic goods and transferring them to the TGA. The relevant process is that ABF removes the smallest sealed box, bottle or portion of the therapeutic goods (e.g. a packaged box containing multiple blister sheets, or sealed container such as a vial or bottle containing tablets) where the outer packaging should have all relevant product and company information. Arrangements can then be made for the Safe Hand delivery of these goods to TGA. **Note:** Loose powder of claimed therapeutic substances are detected in large quantities by ABF, a request by TGA to sample the product may be declined in line with the consideration of ABF officer's health and safety. The full agreed process for therapeutic substance sampling is described in detail in the Letter of Exchange for Sampling of Therapeutic Goods by Australian Border Force for the purposes

	of enforcement of provisions of the *Therapeutic Goods Act 1989* (LoE – Sampling of Therapeutic Goods) describes the relevant process in detail. This document can be found in TRIM Record ADD2021/4044511.
17	TGA may express an interest in receiving therapeutic goods by way of donation, for the purposes of general compliance of registered sponsors and/or enforcement of TGA's therapeutic standard under other provisions of TG Act. This request may occur with or after a TGA Direction has been given to the ABF in relation to a particular consignment. It is essential that such requests are addressed after Customs Act process and post claims period expiry. When goods are donated to TGA in this manner, the GMS record must reflect the method of destruction appropriately. The normal disposal procedure through a Disposal Delegate must still be followed as per the processes described in the *Detained Goods Management PI (TT-4786)*.
18	In cases where the TGA is pursuing a prosecution, and requires therapeutic goods to be transferred post seizure, the TGA is required to advise the ABF in writing if they wish to apply s203 or s203B to support the transfer of relevant therapeutic goods before goods are released for evidentiary purposes. Further information relating to Claims can be found in the *Claims for the Return of Seized Goods PI* (TT-6223).

3.5. Seizure

3.5.1 Seizure under Direction of the Therapeutic Goods Administration

As described in section 3.3.4 of this Procedural Instruction, the Secretary of the Department of Health and Aged Care may notify the Comptroller-General of Customs in writing that the Secretary directs that the Customs Act apply to a therapeutic good consignment.

In practical terms, the Regulatory Compliance and Support Section of the TGA will issue a written direction to the Comptroller General, but it will be sent to the referring ABF officer instead of the Commissioner.

The direction to treat the goods as prohibited imports will lay out the circumstances of the importation, the facts established by the TGA and a direction to treat the goods as prohibited.

The goods should then be managed accordingly, which means that a B511 Seizure notice must be issued and information that the claims for return process under s205B of the Customs Act is available to importers.

Note: The written direction sets out the grounds for seizure and should be retained by the ABF. This document should not be provided to the importer.

The grounds for seizure of therapeutic goods (SUSMP Schedule 4 Medicine obtained without prescription) under s203B of the Customs Act can be written as:

The goods have been seized as prohibited imports under Section 203B of the Customs Act 1901 on the grounds that an authorised delegate of the Secretary to the Department of Health and Aged Care, acting in accordance with s 19B(7) of the Therapeutic Goods Act 1989 has notified the Comptroller General of Customs that:*

- *the importation of the goods described in this Seizure Notice (the goods) contravenes s19B(4)* of the Therapeutic Goods Act; and*
- *the delegate wishes the Customs Act to apply to the importation of the goods described as forfeited to the Crown under s229 of that Act because they were prohibited imports within the meaning of that Act.*

*** Note:** s19B provisions refer to prescribed medication only. As described in Section 3.3.4, other TGA offences and provisions of the TG Act exist that are related to directed seizure under provisions of the Customs Act. TG Act references relevant to all types of therapeutic goods are listed in **Table 1**.

3.5.2 Claims for Return of Seized Goods

If goods are seized, the importer can make a claim for the return of the goods seized within 30 days of the seizure notice being served on the owner. The claim must be made in the approved *Form B144 – Claim for Return of Goods Seized*, the form prescribed under s205B(2) of the Customs Act. If no claim is made within the allowed timeframe, the goods then become forfeited to the Crown and they can be disposed of.

All claims are processed by the NCPS of the Department.

If a claim for return of goods is made by an importer, the Department then has 120 days to commence legal proceedings for the condemnation of the goods, unless a period of retention has been granted by the Court (s 205E). In this period, the importer may decide to withdraw their claim to avoid legal proceedings. When a claim is withdrawn, the goods are automatically forfeited to the Crown and can be disposed of.

If a claim is made and the Department fails to commence action within the time frame, the goods must be released to the importer.

There may be some situations where goods directed to be seized by TGA may be released to the importer through the claims process. This in particular refers to situations were ownership of prescribed medication is unclear at the point of TGA interaction with the importer, prompting the issue of a Notification under s19B(7) of the TG Act. Further documents relating to the circumstances of the import can be considered at the point of Claim processing. An example of such a situation includes a case of a release of prescribed medication that was order to be seized by TGA as it was addressed to the importers' General Practitioner. Further evidence provided in this case was sufficient to prove that the importer was a consignee on the parcel and the goods could be released.

3.6. Release, Re-Export and Disposal of Therapeutic Substances

The process for release, re-export or disposal of therapeutic goods is detailed in the Detained Goods Management Procedural Instruction (*Detained Goods Management PI TT-4786*).

3.7. Powers and responsibilities

3.7.1 Powers of the TGA

On receipt of a referral from the ABF, the TGA will either issue a written Direction for the ABF to treat the goods as prohibited imports within the meaning of the Customs Act or advise that the goods may be released.

The powers of the TGA are limited to directing the ABF to treat goods controlled under the TG Act as Prohibited Imports/Exports or not.

TGA does not have the power or an ability to direct or target ABF resources beyond providing Direction in relation to therapeutic goods. This means that if TGA is unable to order the seizure of the therapeutic goods, the ABF has no grounds to continue holding them. TGA is also unable to order ABF to re-export the goods or sample therapeutic goods prior to a Direction in relation to therapeutic goods being given.

3.7.2 Powers of the ABF

The ABF has the power to:

- determine whether the goods are controlled under the Customs Act, Criminal Code or is NPS/SDA with the assistance of TGOP

- refer details of consignments to the TGA for determination
- treat goods as Prohibited Imports or Exports, undertake seizure action under s203 or s203B and issue B511 Seizure notice; or allow re-export if applicable, on receipt of a written instruction from TGA
- manage the claims process with guidance from NCPS Team in the Department
- dispose of the goods, when the claims process expires, or when no claim is made.

The ABF is not able to dispose of goods including transferring goods to the TGA unless the goods are first seized and the claims process has concluded or no claim is made. The procedures in the *Detained Goods Management PI (TT-4786)* must be followed during the entire disposal process.

There is no statutory basis for the ABF to detain and refer consignments to a State Health Authority for the purpose of seizure, where the goods are not controlled on importation.

ABF officers are reminded that the technical policy responsibility for **all** border controlled substances under the Criminal Code and subordinate regulations rests with the AFP and technical policy responsibility for **all** Schedule 4, 7A and 8 to the PI Regulations and parallel PE Regulations rests with the Office of Drug Control (ODC) of the Department of Health and Aged Care. TGOP is the ABF operational policy liaison point for both AFP and ODC: All general questions related to classification and border processing of drugs and therapeutic substances must be raised through TGOP Mailbox in the first instance, via s. 47E(d) @abf.gov.au.

3.7.3 Activities in relation to therapeutic goods that are not authorised or supported by policy

A number of activities previously performed in relation to therapeutic goods importation are not supported by TGOP as the authority for these activities does not exist or is uncertain.

For example:

- The ABF cannot be directed to split therapeutic goods consignments to help meet the concession requirements: TGA must determine if the goods meet the concession or not and advise accordingly.
- The ABF cannot be directed by TGA to conduct any presumptive testing on therapeutic goods that are easily identifiable by packaging and labelling.
- The ABF cannot be directed to re-export all or part of a consignment: As per earlier advice further policy regarding re-export i available in *Detained Goods Management PI (TT-4786).*
- The ABF must not action any classification advice in relation to prohibited goods on the advice of TGA: Where TGA advises that a good referred to them is prohibited under reg 5, 5G and 5H of the PI Regulations, this information must be verified through TGOP with ODC.
- The ABF cannot be directed to make referrals to State and Territory Health Department for the purposes of enforcement of seizure under State/ Territory legislation.

4. Accountabilities and Responsibilities

Role	Description
ABF Officers	Responsible for conducting clearance of passenger, international mail and/or cargo in line with relevant procedures. Therapeutic goods are an example of a good type that can be encountered as part of the clearance activities. Officers conducting assessments and managing therapeutic goods at the border must be familiar with the PI. Furthermore, it is essential that

Role	Description
	questions relating to the management of therapeutic goods by ABF (including questions related to classification) are only raised with TGOP and not the TGA.
National Claims Processing Section (NCPS)	The area within the Legal Division responsible for the national management of claims received for the return of seized goods.
Trade and Goods Operational Policy	Trade and Goods Operational Policy (TGOP) has responsibility for developing and maintaining trade and goods operational policy and procedures on behalf of the ABF. This responsibility includes developing operational policy in line with the Policy and Procedure Control Framework (PPCF). Specifically TGOP is responsible for developing all the internal policy in relation to management of drugs and therapeutic goods by the ABF at the border, which includes ownership of relevant procedural instructions, maintenance of up-to-date classification of Drugs and Therapeutic Substance in Sharepoint site, as well as GMS.
TGA Regulatory Compliance	The TGA Regulatory Compliance (TGA RC) team is part of the TGA and is responsible for enforcing the provisions of the TG Act. The RCU collects intelligence in relation to the manufacture of therapeutic goods. Delegated Officers of the TGA RC are responsible for receiving referrals from ABF and issuing lawful direction to ABF in relation to therapeutic goods detected at the border.

5. Version Control

Version number	Date of issue	Author(s)	Brief description of change
0.1	02/2020	Trade and Goods Operational Policy	Original Draft of the Instruction based on existing Legal Advice and Management of case management of complicated TGA goods processing situations by the ABF with advice from TGOP.
0.2	04/2020	Trade and Goods Operational Policy	Final version for approval and publication.
0.3	07/2021	Trade and Goods Operational Policy	Changed made to the reflect the endorsement of Letter of Exchange – Sampling of Therapeutic Goods and the formal establishment of procedures for sampling therapeutic goods for the purposes of enforcement of the TG Act.
0.4	08/2022	Trade and Goods Operational Policy	Minor updates to reflect renamed departments due to the new Administrative Arrangements Order commencing 1 July 2022.

Attachment A – Definitions

Term	Acronym (if applicable)	Definition
Active pharmaceutical ingredient	API	Active pharmaceutical ingredient is the term used to refer to any biologically active component of a therapeutic product (e.g. tablet, capsule).
Antibiotics		Antibiotics are selective antimicrobial agents other than disinfectants, antiseptics and substances used solely as antineoplastics that, on application to living tissue or by systematic administration, kill or prevent the growth of susceptible micro-organisms
Australian Border Force	ABF	As defined in section 4 of the *Australian Border Force Act 2015*. The Australian Border Force means that part of the Department known as the Australian Border Force. The Australian Border Force, as operationally independent body within the Department of Home Affairs, is Australia's frontline border law enforcement agency and Australia's customs service. The Australian Border Force delivers critical border protection and national security outcomes while facilitating the movement of people and goods across the border.
Australian Federal Police	AFP	The statutory authority established under the *Australian Federal Police Act 1979* whose role is to enforce Commonwealth criminal law, contribute to combating complex, transnational, serious and organised crime affecting Australia's national security and to protect Commonwealth interests from criminal activity in Australia and overseas.
Australian Register of Therapeutic Goods	AGTR	A register maintained by the TGA for the purpose of compiling information in relation to, and providing evaluation of, therapeutic goods for use in humans. AGTR can be found and searched online and contains both summary and detailed documentation to all registered therapeutic goods (including those that are prohibited and border controlled). Furthermore, a description of registered therapeutic substance (appearance of packaging, labelling and tablets) is provided for reference.
Biologicals for the purposes of *Therapeutic Goods Act 1989*	Biologicals	As defined in section 32A of *Therapeutic Goods Act 1989*. (1) Subject to subsection (3), a biological is a thing that: (a) either: (i) comprises, contains or is derived from human cells or human tissues; or (ii) is specified under subsection(2); and

Term	Acronym (if applicable)	Definition
		(b) is represented in any way to be, or is, whether because of the way in which it is presented or for any other reason, likely to be taken to be: (i) for use in the treatment or prevention of a disease, ailment, defect or injury affecting persons; or (ii) for use in making a medical diagnosis of the condition of a person; or (iii) for use in influencing, inhibiting or modifying a physiological process in persons; or (iv) for use in testing the susceptibility of persons to a disease or ailment; or (v) for use in the replacement or modification of parts of the anatomy in persons. (2) The Secretary may, by legislative instrument, specify things for the purposes of subparagraph (1)(a)(ii). (3) The Secretary may, by legislative instrument, determine that a specified thing is not a biological for the purposes of this Act. An example of a biological is stem cell treatment.
Border Controlled Drugs, Plants, and Precursors		As defined in subsection 4(1) of the *Customs Act 1901*, border controlled drugs, plants and precursors have the same meaning as in Part 9.1 of the *Criminal Code Act 1995* (Serious drug offences). Specifically, section 300.2 of the *Criminal Code Act 1995* (Definitions) provides: • 'border controlled drug' has the meaning given by Section 301.4 of the *Criminal Code Act 1995* • 'border controlled plant' has the meaning given by Section 301.5 of the *Criminal Code Act 1995* • 'border controlled precursor' has the meaning given by Section 301.6 of the *Criminal Code 1995*.
Claim		Means a claim for the return of seized goods made in writing on an approved form, being the B144 form, pursuant to Section 205B of the *Customs Act 1901*
Comptroller-General of Customs		Means the person who is the Comptroller General of Customs in accordance with subsection 11(3) or subsection 14(2) of the *Australian Border Force Act 2015*.
Criminal Code Act 1995	Criminal Code	The *Criminal Code Act 1995* contains the general principles of criminal responsibility in Commonwealth law. These

Term	Acronym (if applicable)	Definition
		principles extend to all Commonwealth offences, whether or not they are included in the *Criminal Code Act 1995*.
Criminal Code Regulations 2019	CCR	The *Criminal Code Regulations 2019* is an instrument made under the *Criminal Code Act 1995* that prescribes substances and plants for the purposes of Part 9.1 of the *Criminal Code Act 1995* (Serious drug offences). Schedule 2 to the *Criminal Code Regulations 2019* specifically refers to border controlled drugs.
Copyright Act 1968	CR Act	An Act relating to copyright protection
Counterfeit Therapeutic Good		As defined in subsections 42E(3) and (4) of the *Therapeutic Goods Act 1989* (2) Goods are ***counterfeit*** if any of the following contain a false representation of a matter listed in s(3): (a) the label or presentation of the goods; (b) any document or record relating to the goods or their manufacture; (c) any advertisement for the goods. (3) The matters are as follows: (a) the identity or name of the goods; (b) the formulation, composition or design specification of the goods or of any ingredient or component of them; (c) the presence or absence of any ingredient or component of the goods; (d) the strength or size of the goods (other than the size of any pack in which the goods are contained); (e) the strength or size of any ingredient or component of the goods; (f) the sponsor of therapeutic goods, source, manufacturer or place of manufacture of the goods. Note: the sponsor is a representative, who registers and is subsequently approved by TGA and to formal import, package and/or manufacture/compound and supply therapeutic goods in Australia
Customs Place		As defined in subsection 183UA(1) of the *Customs Act 1901* as: (aa) a place owned or occupied by the Commonwealth for use for the purposes of the *Customs Act 1901*; or (a) a port, airport or wharf that is appointed, and the limits of which are fixed, under s15; or

Term	Acronym (if applicable)	Definition
		(aaa) a place to which a ship or aircraft has been brought because of stress of weather or other reasonable cause as mentioned in s58(1), while that ship or aircraft remains at that place; or (b) a place that is the subject of a permission under s58(2); or (c) a boarding station that is appointed under s15; or (d) a place described in a depot licence that is granted under s77G; or (e) a place described in a licence for warehousing goods that is granted under s79(1); or (f) a place approved in an instrument under s(2) as a place for the examination of international mail; or (g) a place from which a ship or aircraft that is the subject of a permission under s175 is required to depart, between the grant of that permission and the departure of the ship or aircraft; or (h) a place to which a ship or aircraft that is the subject of a permission under s175 is required to return, while that ship or aircraft remains at that place; or (i) a s234AA place that is not a place, or a part of a place, referred to in paragraph (aa), (a), (aaa), (b), (c), (d), (g) or (h).
Customs Act 1901	Customs Act	Means the *Customs Act 1901*. The Customs Act concerns customs related functions and is the legislative authority that sets out the customs requirements for the importation, and exportation, of goods to and from Australia.
Customs General Powers of Examination of Goods subject to Customs Control		General Powers of Examination that ABF officers have in relation to goods that are loaded onto or unloaded from international vessels and aircraft, prescribed in section 186 of the *Customs Act 1901*.
Customs (Prohibited Exports) Regulations 1958	PE Regulations	The PE Regulations detail goods subject to export prohibition or restriction at the border as prohibited exports defined by section 112 of the *Customs Act 1901*.
Customs (Prohibited Imports) Regulations 1956	PI Regulations	The PI Regulations detail goods subject to import prohibition or restriction at the border as prohibited imports defined by sections 50 and 51 of the *Customs Act 1901*.
Drugs		Generally medicines or elicit substances which have a physiological effect when ingested or otherwise introduced into the body.

Term	Acronym (if applicable)	Definition
Forfeited Goods		Has the same meaning as in Section 183UA of the *Customs Act 1901*, which relevantly defines 'forfeited goods' as goods described as forfeited to the Crown under: (a) s228, s228A, s228B, s229A, s229 or s230 of this Act; or Section 7, 10, 11, or 13 of the *Commerce (Trade Descriptions) Act 1905*.
Goods		Subsection 4(1) of the *Customs Act 1901* defines 'goods' as movable personal property of any kind and, without limiting the generality of the expression, includes documents, vessels and aircraft.
Goods Management System	GMS	The Department's system for recording detained and seized goods
Hormones		A hormone is any member of a class of signaling molecules produced by glands in multicellular organisms that are transported by the circulatory system to target distant organs to regulate physiology and behavior. Hormones have diverse chemical structures, mainly of 3 classes: eicosanoids, steroids, and amino acid derivatives.
Medical Device		Is defined in detail in section 41BD of the *Therapeutic Goods Act 1989* as any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following: (i) diagnosis, prevention, monitoring, treatment or alleviation of disease; (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability; (iii) investigation, replacement or modification of the anatomy or of a physiological process; (iv) control of conception; *It is important to note that the TGA makes the determination as to whether a device meets the definition of a medical device.*
Medicine		Medicines for the purpose of this Procedural Instruction are therapeutic products that act by pharmaceutical, chemical, immunological or metabolic means. Examples of medicines are antibiotics, insulin, common vaccines containing microorganisms and antibodies (antesera).

Term	Acronym (if applicable)	Definition
National Claims Processing Section	NCPS	The area within the Legal Group responsible for the national management of claims received for the return of seized goods.
New Psychoactive Substance	NPS	As defined in section 183UA of the *Customs Act 1901*, 'prohibited psychoactive substance' means a psychoactive substance (within the meaning of Part 9.2 of the *Criminal Code Act 1995*) that: • is not a substance to which Section 320.2(2) of the *Criminal Code Act 1995* applies; and • has been imported into Australia.
Officer of Customs (or Customs Officer in *Therapeutic Goods Act 1989*)		As defined in subsection 4(1) of the *Customs Act 1901*, 'officer of Customs' means: (a) the Secretary of the Department of Home Affairs; or (b) the Australian Border Force Commissioner (including in his or her capacity as the Comptroller-General of Customs); or (c) an APS employee in the Department of Home Affairs; or (d) a person authorised under subsection (1B) to exercise all the powers and perform all the functions of an officer of Customs; or (e) a person who from time to time holds, occupies, or performs the duties of an office or position (whether or not in or for the Commonwealth) specified under subsection (1C), even if the office or position does not come into existence until after it is so specified; or (f) in relation to a provision of a *Customs Act 1901*: i. a person authorised under Subsection (1D) to exercise the powers or perform the functions of an officer of Customs for the purposes of that provision; or ii. a person who from time to time holds, occupies, or performs the duties of an office or position (whether or not in or for the Commonwealth) specified under Subsection (1E) in relation to that provision, even if the office or position does not come into existence until after it is so specified. Note: An ABF officer in this instruction would be an 'officer of Customs' for the purposes of the *Customs Act 1901*, as they are APS employees in the Department of Home Affairs.
Office of Drug Control	ODC	The Drug Control Section of the Department of Health and Aged Care (ODC), which is part of the Health Products Regulation Group of the Department of Health and Aged Care, regulates and provides advice on the import, export and

Term	Acronym (if applicable)	Definition
		manufacture of controlled drugs, as well as the cultivation of cannabis for medicinal purposes to support Australia's obligations under International Drug Conventions.
Personal Protective Equipment	PPE	Protective clothing and safety equipment, including boots, respirators, face masks, gloves, helmets, goggles, or other garments or equipment designed to protect the wearer's body from injury or illness.
Personal Importation Scheme	PIS	A Scheme that permits an individual to import a 3 months' supply at the one time (at the maximum dose recommended by the manufacturer) of unapproved therapeutic goods into Australia without any approval required by the TGA provided that: • the goods are for importer's own treatment or the treatment of your immediate family member and • importer does not supply (sell or give) the medicine to any other person and • where possible, importer keeps the medicines or medical devices in their original packaging with any dispensing labels intact and • the goods are not restricted under provisions of Biosecurity rules and the goods do not contain a controlled or prohibited substance and • the goods are not injections that contain material of human or animal origin (except insulin) and • the total quantity of the goods imported within a 12 month period does not exceed 15 months' supply of the goods (for medicines, at the maximum dose recommended by the manufacturer) and • if the goods are medicines in Schedule 4 or 8 of the SUSMP a prescription from an Australian-registered medical practitioner is held for the medicines.
Poison		As defined in subsection 3(1) of the *Therapeutic Goods Act 1989*, poison means an ingredient, compound, material or preparation which, or the use of which, may cause death, illness or injury and includes any ingredient, compound, material or preparation referred to in a schedule to the current SUSMP.
Prohibited Goods (Imports and Exports)		As defined in subsection 4(1) of the *Customs Act 1901*, prohibited goods means: • goods for which importation or exportation is prohibited by the *Customs Act 1901* or any other law of the Commonwealth, or

Term	Acronym (if applicable)	Definition
		• goods for which importation or exportation is subject to restrictions or conditions under the *Customs Act 1901* or any other law of the Commonwealth, or • restricted goods that have been brought into Australia other than in accordance with a permission under Subsection 233BABAE(2), or • certain goods subject to customs control.
Receipt for Goods (Form B390)	Form B390	A written notice provided to the owner of goods when the goods are held in the physical custody of the ABF or Home Affairs.
Scheduling		Scheduling (for the purposes of Poisons Standard) is a national classification system that controls how medicines and poisons are made available to the public. Medicines and poisons are classified into Schedules according to the level of regulatory control over the availability of the medicine or poison required to protect public health and safety.
Seized Goods		Seized goods include goods subject to seizure as forfeited or special forfeited goods under s203 or s203B of the *Customs Act 1901*. It also includes goods subject to seizure at the border under another Act such as *the Criminal Code Act 1995*, *Therapeutic Goods Act 1989*, *Trade Marks Act 1995*, *Copyright Act 1968*, the *Commerce (Trade Descriptions) Act 1905*, *Major Sporting Events (Insignia and Images) Protection Act 2014* or the *Environment Protection and Biodiversity Conservation Act 1991*.
Serious Drug Alternative	SDA	As defined in Section 183UA of the *Customs Act 1901*, 'prohibited serious drug alternative' means a substance: • the presentation of which includes an express or implied representation that the substance is a serious drug alternative (within the meaning of Part 9.2 of the *Criminal Code Act 1995*) and • that is not a substance to which Subsection 320.3(3) of the *Criminal Code Act 1995* applies and • that has been imported into Australia.
Special Access Scheme	SAS	Arrangements, which provide for the importation and/or supply of an unapproved therapeutic good (i.e. those not included on the Australian Register of Therapeutic Goods (ARTG)) for a single patient, on a case-by-case basis. It is the responsibility of TGA to check that these approvals are in place.
Sponsor in relation to therapeutic goods	Sponsor	(a) a person who exports, or arranges the exportation of, the goods from Australia; or

Term	Acronym (if applicable)	Definition
		(b) a person who imports, or arranges the importation of, the goods into Australia; or (c) a person who, in Australia, manufactures the goods, or arranges for another person to manufacture the goods, for supply (whether in Australia or elsewhere); but does not include a person who: (d) exports, imports or manufactures the goods; or (e) arranges the exportation, importation or manufacture of the goods; on behalf of another person who, at the time of the exportation, importation, manufacture or arrangements, is a resident of, or is carrying on business in, Australia.
Standard, in relation to therapeutic goods	Standard	Refers to the quality of therapeutic goods in line with TGA operational procedures and agreements with sponsors of therapeutic goods in Australia
Standard for the Uniform Scheduling of Drugs and Poisons (aka Poisons Standard)	SUSMP	Document published by the Australian Health Ministers' Advisory Council, which is a Committee established by Section 52B of the *Therapeutic Goods Act 1989*. The Committee, which consists of nominated Commonwealth and State and Territory Members, makes recommendations to the Secretary in relation to the classification and scheduling of substances that make a therapeutic claim.
Substance scheduled in SUSMP	Substance	In accordance with the definition in Section 52A of the *Therapeutic Goods Act 1989*, a substance is: (1)(a) an ingredient, compound, material or preparation which, or the use of which, may cause death, illness or injury to persons or animals; or (b) an ingredient, compound, material or preparation specified under s(2); and includes any ingredient, compound, material or preparation referred to in a schedule to the current Poisons Standard (as in force immediately before 1 July 2010). (2) ingredient, compound, material or preparation for the purposes of paragraph (b), specified as a substance by the Secretary of the Department of Health and Aged Care by legislative instrument
Therapeutic Goods Administration	TGA	The Therapeutic Goods Administration is the regulatory body for therapeutic goods in Australia. It is a Division of the Australian Department of Health and Aged Care established under the *Therapeutic Goods Act 1989*.
Therapeutic Good	TG	Has the same meaning as in section 3 of the *Therapeutic Goods Act 1989*.

Term	Acronym (if applicable)	Definition
		Briefly, good that is represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be for therapeutic use; for use as an ingredient or component in the manufacture of therapeutic goods. A number of exemptions and exclusions apply within the *Therapeutic Goods Act 1989*. *It is important to note that the TGA makes the determination as to whether a good meets the definition of a therapeutic good.*
Therapeutic Goods Act 1989	TG Act	The object of the *Therapeutic Goods Act 1989* is to establish and maintain a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods used in Australia or exported from Australia.
Therapeutic use		As defined in subsection 3(1) of the *Therapeutic Goods Act 1989*, therapeutic use of a substance (medicine, therapeutic good or medical device) means use in or in connection with: (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or (b) influencing, inhibiting or modifying a physiological process in persons; or (c) testing the susceptibility of persons to a disease or ailment; or (d) influencing, controlling or preventing conception in persons; or (e) testing for pregnancy in persons; or (f) the replacement or modification of parts of the anatomy in persons.
Trade Marks Act 1995	TM Act	An Act relating to trade marks.

Attachment B – Assurance and Control Matrix

1.1. Powers and Obligations

Please Note: Staff exercising any powers, delegations or authorisations outlined in this Procedural Instruction (listed here) must check the latest delegation advice on the Intranet or the relevant instrument in LEGEND to ensure they currently hold the applicable power, delegation or authorisation.

Legislative Provision			Is this a delegable power?	If delegable, list the relevant instruments of delegation
Legislation	Reference (e.g. section)	Provision		
Customs Act 1901	50	Prohibition of the importation of goods	No	
Customs Act 1901	186	General powers of examination of goods loaded onto or unloaded from ships or aircraft	No	Power is exercisable by officers of Customs in their own right
Customs Act 1901	190	Securing goods	No	
Customs Act 1901	202A	Copies of seized things to be provided	No	
Customs Act 1901	203	When seizure warrants for forfeited goods can be issued	No	
Customs Act 1901	203A	The things that are authorised by seizure warrants for forfeited goods	No	
Customs Act 1901	203B	Seizure without warrant of special forfeited goods, or of evidential material relating to special forfeited goods, at a Customs Place	No	
Customs Act 1901	203K	Specific powers available to executing officers	No	
Customs Act 1901	203R	Retention of things seized as evidential material	No	
Customs Act 1901	203S	Magistrate may permit a thing seized as evidential material to be retained	No	
Customs Act 1901	204	Seized goods to be secured	No	
Customs Act 1901	205	Requirement to serve seizure notices	No	
Customs Act 1901	205A	Matters to be dealt with in seizure notices	No	

Legislative Provision			Is this a delegable power?	If delegable, list the relevant instruments of delegation
Legislation	Reference (e.g. section)	Provision		
Customs Act 1901	205B	Claim for return of goods seized	Yes	ABF (CG) No.1 of 2018
Customs Act 1901	205C	Treatment of goods seized if no claim for return is made	No	
Customs Act 1901	205D	Treatment of goods seized if a claim for return is made - general	No	
Customs Act 1901	205E	Magistrate may permit goods seized to be retained	No	
Customs Act 1901	208D	Disposal of forfeited goods	Yes	ABF (CG) No.1 of 2018
Customs Act 1901	227E	Approved storage for prohibited items	No	
Customs Act 1901	227F	Officer may take custody of items	Yes	ABF (CG) No.1 of 2018
Customs Regulation 2015	124	Disposal of certain abandoned goods - prescribed period	No	
Customs (Prohibited Imports) Regulations 1956	4(1AC)	Goods the importation of which is prohibited unless conditions or restrictions are complied with	Yes	ABF (M) No.1 of 2018
Work Health and Safety Act 2011	Section 5	Meaning of person conducting a business or undertaking (PCBU)	No	
Work Health and Safety Act 2011	Section 7	Meaning of worker	No	
Work Health and Safety Act 2011	Section 8	Meaning of workplace	No	
Work Health and Safety Act 2011	Section 17	Management of risks	No	
Work Health and Safety Act 2011	Section 18	What is reasonably practicable in ensuring health and safety	No	
Work Health and Safety Act 2011	Section 19	Primary duty of care	No	
Work Health and Safety Act 2011	Section 20	Duty of PCBU involving management or	No	

Legislative Provision			Is this a delegable power?	If delegable, list the relevant instruments of delegation
Legislation	Reference (e.g. section)	Provision		
		control of workplaces		
Work Health and Safety Act 2011	Section 27	Duty of officers	No	
Work Health and Safety Act 2011	Section 28	Duties of workers	No	
Work Health and Safety Act 2011	Section 29	Duties of other persons at the workplace	No	
Work Health and Safety Act 2011	Section 247	Officers	No	
Work Health and Safety Regulations 2011	Section 9	Provisions linked to health and safety duties in Act	No	
Work Health and Safety Regulations 2011	Part 6.3 Division 1	297 - Management of risks to health and safety 298 - Security of workplace	No	
Work Health and Safety Regulations 2011	Part 7.1 Division 5	Control of risk - Obligations of PCBUs	No	

1.2. Controls and Assurance

Related Policy	HR-1230 – Policy Statement - Work Health and Safety Governance Arrangements Policy Statement HR-3594 – Policy Statement - Management of Hazardous Chemicals and Other Hazardous Substances TT-4889 – Policy Statement - Prohibited Imports and Exports
Procedures / Supporting Materials	BC-699 – Procedural Instruction (Traveller) - Baggage Examination at the Border (s186 Customs Act) BC-689 – Procedural Instruction (Traveller) - Post Detection Procedures TT-2827 – Procedural Instruction - International Mail Management Procedural Instruction TT-1784 – Procedural Instruction - Conducting Cargo Examination TT-2403 – Procedural Instruction - Detection and Seizure of Prohibited and Restricted Goods TT-4786 – Procedural Instruction - Detained Goods Management TT-6391 – Supporting Material - Goods Management System (GMS) Governance TT-6393 – Supporting Material – Managing Goods in the Goods Management System TT-4937 – Procedural Instruction – Management of Intellectual Property Rights at the Border (counterfeit medication) TI-4857 – Procedural Instruction - Detection and Identification Technologies to assist with the Inspection of Passengers and Cargo Procedural Instruction TI-4858 – Procedural Instruction - Detection and Identification Technology Training Requirements and subordinate SOPs HR-2135 – Procedural Instruction - Management of Hazardous Chemicals and Other Hazardous Substances TT-6312 - Procedural Instruction - Managing Unidentified Substances HR-1643 - Procedural Instruction - Personal Protective Equipment BE-2978 – Procedural Instruction - Official Diaries and Notebooks TT-6223 – Procedural Instruction – Claims for the Return of Seized Goods
Training/Certification or Accreditation	Officers must at minimum have on the job training in relation to processing of goods of interest to TGA. Officers with duties relating to processing of drugs and therapeutic substances must have some level of Detection technology training. Detection identification technology training requirements are comprehensively detailed in the TI-4858 –Detection and Identification Technology Training Requirements Procedural Instruction.

Other required job role requirements	GMS Training available in TT-6393 – Supporting Material – Managing Goods in the Goods Management System
Other support mechanisms (e.g. who can provide further assistance in relation to any aspects of this instruction)	Trade and Goods Operational Policy Mailbox s. 47E(d) @abf.gov.au
Escalation arrangements	Whilst it is unlikely that therapeutic goods management will require escalation, it may be necessary if a substance believed to be a low risk therapeutic good, is at later point recognised as an unknown substance and containment is broken. In this instance, local HAZMAT emergency procedures should be followed. Unidentified substance may be found uncontained at the point of initial examination by the ABF or become loose as part of ABF activities, aimed to identify a substance through deployment of technology. If there are concerns with establishing the correct escalation procedures around management of identified and unidentified hazardous chemicals at an ABF work location, Trade and Goods Operational Policy is able to assist with the development of relevant local emergency procedures via s. 47E(d) @abf.gov.au.
Recordkeeping (e.g. system based facilities to record decisions)	TRIM is the approved Electronic Document and Records Management System (EDRMS) for all Departmental and ABF records. Other border specific systems include: • Goods Management System (GMS) – for recording detained and seized goods. • Official Notebooks – for making contemporaneous notes to record all daily duties and detailed information regarding operational activities and events. • Baggage Action General Statistics (BAGS) • Examination Data Management System (EXAMS)
Program or Framework (i.e. overarching Policy Framework or Business Program)	HR-3594 – Policy Statement - Management of Hazardous Chemicals and other Hazardous Substances details the overarching legislative framework for the management of chemicals and other hazardous substances within the Department of Home Affairs. TT-4889 – Policy Statement - Prohibited/Restricted Imports and Exports details the Portfolio responsibilities for the targeting, detection, seizure, storage, and related enforcement activities for prohibited and restricted goods that are being imported and exported, while facilitating the movement of legitimate trade and travel
Job Vocational Framework Role	30000497 – Border Enforcement Operations 30000504 – Trade Compliance 30001128 – Border Force Officer Recruit Trainee

Attachment C – Consultation

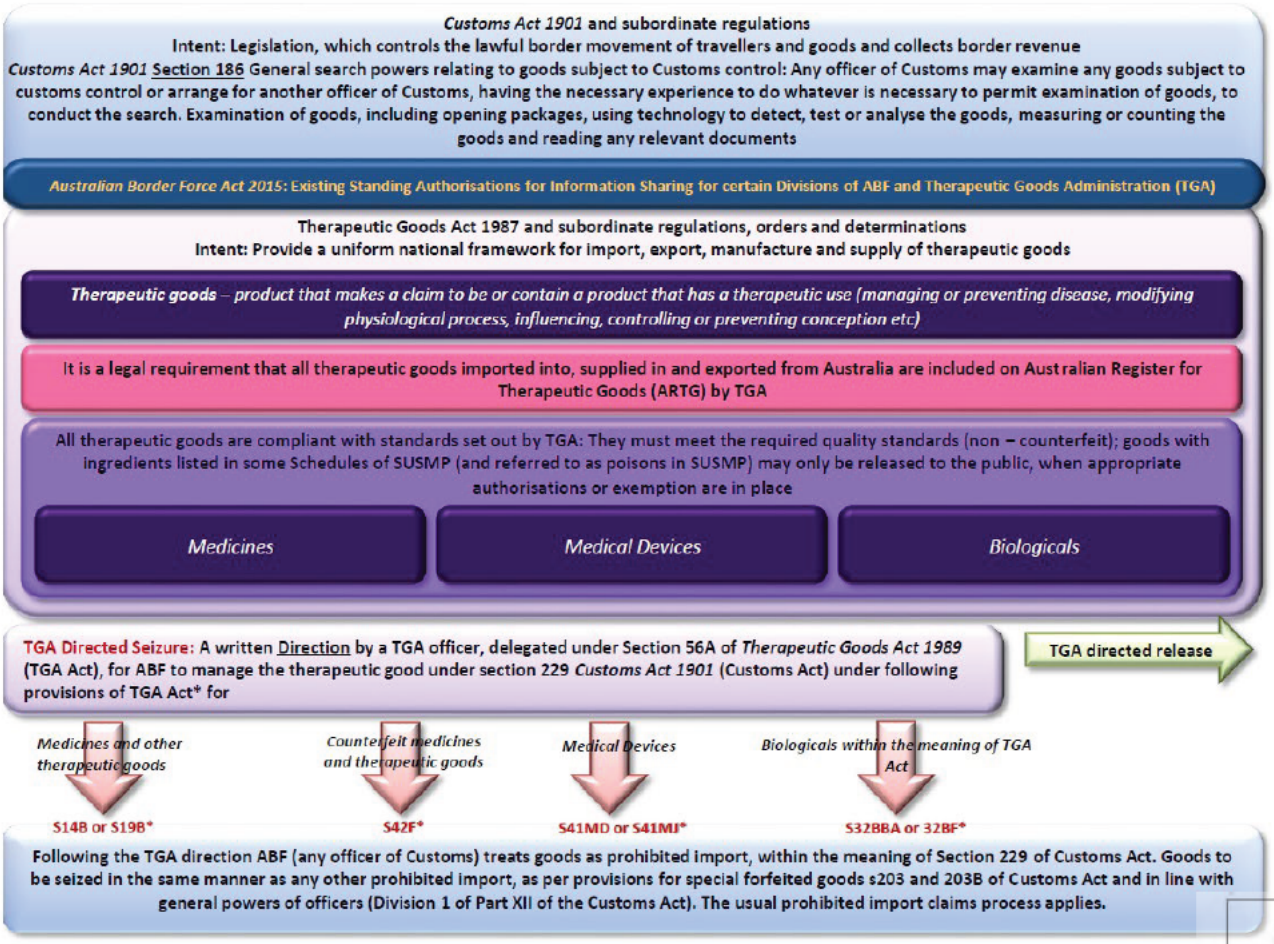
1.1. Internal Consultation

- Customs and Trade Policy Branch Customs Group
- Compliance Operations Trusted Trader and Trade Compliance Branch Customs Group
- National Goods Intervention Management Trusted Trader and Trade Compliance Branch Customs Group
- Pre-Clearance Intervention QLD Trusted Trader and Trade Compliance Branch Customs Group
- Pre-Clearance Intervention WA Trusted Trader and Trade Compliance Branch Customs Group
- Port Operations Command (Air Cargo VIC)
- Port Operations Command (Air Cargo NSW)
- Port Operations Command (WA Aviation Operations)
- Operational Practices Command, ABF College
- Legal Group

Attachment D Examples of TGA Notifications to the Comptroller-General of Customs regarding the application of the *Customs Act 1901*

Type of Therapeutic Good	Relevant TG Act Provision for application of s229 of the *Customs Act 1901*	TRIM Reference Example of TGA Notification Document
Prescription Medication (obtained without authority - prescription)	S19B(7)	ADD2020/711881
Medication that does not meet Standards	S14B	ADD2020/711939
Biologicals within the meaning of the TG Act	S32BBA and S32BF(7)	ADD2020/711951
Medical Device	S41MD	These are rare as application of the Direction would refer to a previously approved medical device that is then perceived to not meet the essential principle requirement – currently the ABF does not have a record of this Direction ever been used
Unregistered Medical Device	S41MJ	ADD2020/711983
Counterfeit Therapeutic Goods	S42F	ADD2020/711989

Attachment E: Legislation Summary – Interaction of the TG Act and Customs Act in Relation to Border Management of Therapeutic Goods



A high resolution version of this Diagram is available through the TRIM Reference ADD2020/848421

Attachment F: Poisons Scheduling under the Standard for the Uniform Scheduling of Drugs and Poisons (SUSMP)

Poison for the purpose of the TG Act is defined in *section 3 as an ingredient, compound, material or preparation which, or the use of which, may cause death, illness or injury and includes any ingredient, compound, material or preparation referred to in a schedule to the current SUSMP*. In accordance with its definition any therapeutic good, medicine, industrial substance or illicit substance can be determined to be a poison under SUSMP, provided that its toxic activity has been evaluated and recorded by the Scheduling Committee.

Schedule	*Purpose*
Schedule 1	Not currently in use
Schedule 2	Pharmacy Medicine - Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person
Schedule 3	Pharmacist Only Medicine - Substances, the safe use of which requires professional advice but which should be available to the public from a pharmacist without a prescription
Schedule 4	Prescription Only Medicine OR Prescription Animal Remedy - Substances, the use or supply of which should be by or on the order of persons permitted by State or Territory legislation to prescribe and should be available from a pharmacist on prescription
Schedule 5	Caution - Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label
Schedule 6	Poison - Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label
Schedule 7	Dangerous Poison - Substances with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply
Schedule 8	Controlled Drug - Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence
Schedule 9	Prohibited Substance - Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities
Schedule 10	**Substance of such danger to health as to warrant prohibition of sale, supply and use -** Substances of such danger to health as to warrant prohibition of sale, supply and use - Substances which are prohibited for the purpose or purposes listed for each poison.

Low risk medicines, available as pharmacy-only over the counter goods

Standard Prescription Medication that requires authorisation for access – include few PIs and controlled goods (hormones, anabolics and cannabidiols)

State and Territory Controlled Poisons, includes general hazardous goods as well

Majority are border controlled and prohibited goods, including narcotics and particularly toxic medicines

Attachment G: Summary Standing Authorisation to Disclose Immigration and Border Protection Information (Department of Health and Aged Care and TGA)

Available as an associated Document at TRIM Reference ADD2020/19097283

Attachment H: ABF Management of Therapeutic Goods

Available as an associated Document at TRIM Reference ADD2020/1798170