Tariff Classification Guide on Placebos

1. Guidance on Use

This publication is intended to provide guidance and information to the trade community. It reflects the position on, or interpretation of, the applicable laws or regulations by the Department of Home Affairs as of the date of publication. It does not in any way replace or supersede relevant laws or regulations. Only the latest official version of the relevant laws or regulations is authoritative.

1.1. What this Guide does

This Guide is intended to assist importers and brokers to assess the particular goods they are bringing into Australia.

This Guide does not replace the *Customs Tariff Act 1995* (the Act).

The classification of placebos can be complex. This Guide does not cover all possible permutations of placebos. While care has been taken to ensure that the classifications given are correct at the time of publication, only the latest official version of the Act is authoritative and you should still consult the Act to confirm classifications.

If you are importing commercially and are in doubt about the treatment of your goods, it may be advisable to seek professional advice or approach the Department for assistance. It is recommended that commercial importers or brokers use the Tariff Advice Service where they believe that classification is uncertain. Relevant information and contact details can be found on the Department's website https://www.homeaffairs.gov.au/busi/cargo-support-trade-and-goods/importing-goods/tariff-classification-of-goods/tariff-advice-system.

1.2. Previous Treatments

Where there has been, or appears to have been, different treatment of placebos in one or more areas by the Department (including by the former Department of Immigration and Border Protection or Australian Customs and Border Protection Service) in the past, or differing interpretations in previous publications or notices, this Guide will be taken as giving the current accepted practice.

2. Classification of Placebos

2.1 Importation from 1 July 2018 of placebos and combinations of drugs and placebos for clinical trials

Alterations to the *Customs Tariff Act 1995* with date of effect of 1 July 2018

Department of Home Affairs Notice 2018/21 refers.

The Australian Government has committed to reducing the regulatory burden on companies conducting clinical trials in Australia and to provide a 'Free' rate of customs duty for clinical trial kits and placebos used in clinical trials.

These commitments will be implemented through a new item, in Schedule 4 of the *Customs Tariff Act 1995* which provides for concessional rates of customs duty for eligible goods.

The new concessional item, Item 56, will provide a 'Free' rate of customs duty for goods that are either:

- kits containing either or both medicaments and placebos, that do not indicate whether their contents are medicaments or placebos, that are imported for use in a clinical trial in Australia and which satisfy the requirements prescribed by by-law; or
- placebos imported for use in a clinical trial in Australia;

Importations of medicaments and/or placebos for 'blinded' trials under Item 56 (a)(i) will have classification 9999.40.56. Importations of known placebos must be classified as per this Guide with Treatment Code 756 for a 'Free' rate. The rate of 'Free' applies from 1 July 2018.

2.2 What are placebos?

Placebos are usually relatively inert or innocuous substances, designed to look like a medicament, for use primarily in controlled experiments testing the efficacy of another substance.

'Active placebos' contain substances designed to create an adverse effect, for example a headache or indigestion.

As placebos mimic the medicament, they come in a variety of forms including, but not limited to, tablets, liquids, injections and patches.

2.3 Goods not covered under the "classification of placebos" section of this Guide

Comparator medicaments

This Guide does not cover "comparator medicaments" as they are not placebos.

Comparator medicaments are medicaments classified under the Harmonized System headings 3003 or 3004 that are intended to be used in clinical trials comparing new medicaments with existing medicaments to determine any differences in effectiveness or side effects.

In clinical trials that use a comparator medicament, both the group of subjects on the comparator medicament and the group on the new medicament are being treated. The comparator medicament retains its classification as a medicament of headings 3003 or 3004.

Nutritional or hydrating preparations administered by injection or by a drip method, i.e. "intravenous administration only"

Nutrition or hydration preparations that are injected directly into the blood stream are considered to be preparations for therapeutic or prophylactic purposes. Medicaments administered by an injection, or by a drip inserted into a vein, are frequently mixed or carried on a nutritive or hydrating solution. In such mixes, both the intravenous nutritive or hydrating solution *and* the substance being carried are considered to be medicaments of headings 3003 or 3004. These are not placebos.

If nutritional or hydrating preparations presented as injections or as 'intravenous administration only' preparations are to be used as a 'placebo', they, like comparator medicaments, retain their classification in headings 3003 or 3004 as applicable.

If a placebo is added to such a good to give the preparation the colour, texture or other characteristics of the medicament being trialled, the nutritional or hydrating therapeutic or prophylactic purpose of the preparation is not changed and the mix retains classification in 3003 or 3004 as applicable.

Injectable placebos, other than nutritional or hydrating preparations, presented as a set with the injecting apparatus

If a placebo is presented as part of a set with syringes, needles, catheters, cannulae and other goods classified under subheading 9018.3, only the placebo will be classified as per the treatment below for placebos. The rest of the set will be classifiable under the normal procedures for set classification.

2.4 Why this Guide does not give hard classifications

The Harmonized System does not have a classification specifically for placebos. The classification of placebos depends upon the material that is used to manufacture the placebo.

As placebos are not standardised or regulated, individual pharmaceutical companies will make up formulations to suit their purposes. Placebos may be made from common foodstuffs, such as starches, sugars and oils, or from harmless non-nutritive chemicals. Many placebos are quite complex formulations of multiple substances. In the case of active placebos, they have pharmacologically active ingredients included.

2.5 Why placebos are NOT classified under headings 3003 or 3004

Placebos are used in medical trials but are not medicaments for therapeutic or prophylactic uses.

The *Therapeutic Goods Act 1989 (TGA Act)* includes a broad definition of a "therapeutic good" for the purposes of that Act only. Under the *Customs Tariff Act 1995,* a good must meet the terms of headings 3003 or 3004 to be classified as a medicament.

Heading 3003 covers:

> "Medicaments (excluding goods of headings 3002, 3005 or 3006) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale:"

Heading 3004 covers:

> "Medicaments (excluding goods of heading 3002, 3005 or 3006) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale."

Under general definition, a medicament is a curative or healing substance. Therapeutic use is use in the treatment of a disease or illness and prophylactic use is use in the prevention of a disease or illness.

Medicinal preparations of headings 3003 and 3004 are preparations based on one or more active substances that have been mixed or put up to have a therapeutic or prophylactic effect – that is, to cure, treat or prevent diseases or illnesses.

It is important for classification purposes to identify whether or not a product contains an active substance such as a drug, in order to decide if it is a medicament. Active substances are usually a chemically defined substance, or a chemically defined group of substances, such as alkaloids, polyphenols or anthocyanins, or a plant extract. The active substance must have medicinal properties intended to prevent or treat specific diseases and ailments, or their symptoms, for the product to be identified as a medicament.

Placebos are a substance or preparation that has no active ingredient that can cure or heal a disease or illness. Placebos are put up for the purpose of *not* acting as a medicament in trials designed to see if different outcomes occur in patients being treated by a medicament from those not being treated by a medicament (that is, they are being given a placebo).

This also applies to “active placebos”. Active placebos are placebos designed to create an adverse effect that will mimic already known side-effects of the medicament being tested. For example, if it is known that the medicament on trial causes headaches, a chemical may be added to the placebo to cause headaches of similar type and intensity. This prevents identification of whether a particular test subject is on the medicament or the placebo. Active placebos are not put up for therapeutic or prophylactic outcomes, instead they are intended to cause negative effects, and therefore do not meet the terms of heading 3003 or 3004.

2.6 Placebos of Section IV - placebos for oral consumption made wholly or principally of foodstuffs

If placebos are made of food substances such as sugars, starches, oils or fats, they may fall to the appropriate classification in Section IV. For example, sugar tablets or syrups of Chapter 17 remain in that Chapter even if used as placebos.

Placebos for oral consumption made wholly or principally of foodstuffs not specifically covered or included elsewhere go to heading 2106 - “food preparations not elsewhere specified or included”.

2.7 Placebos of Section VI - placebos made wholly or principally of chemicals of Section VI

If placebos are made wholly or principally from chemicals of Section VI, they are classified in Section VI.

Placebos of Section VI are normally covered under heading 3824. This heading covers “products of the chemical or allied industries (including those consisting of mixtures of natural products), not elsewhere specified or included”.

Where a more specific heading exists for the particular chemical composition that heading would take precedence.

2.8 Placebos in the form of patches

Placebos in the form of patches for transdermal application are not considered goods of Section IV regardless of whether the ingredients include foodstuffs. Transdermal patches are not orally consumed and are not considered to be foodstuffs or preparations of foodstuffs. A similar situation occurs between nicotine tablets or chewing gum (2106.90.20) and nicotine patches (3824.90.10).

As with other placebos, transdermal patch placebos are *not* classifiable to headings 3003 or 3004.

While heading 3005 covers adhesive articles impregnated with substances for medical, surgical, dental or veterinary *purposes*, the same considerations, i.e. that the purpose of the placebo is not to treat, excludes these patches from this heading as well.

Classification of transdermal patch placebos follows the general classification guidance for placebos of Section VI.

2.9 Placebos of other Sections

While Section IV or VI will normally cover most placebos, it may be possible that a particular placebo is classifiable in other Sections if made of materials outside of Section IV or VI.

Sections I – III and Section V generally have limitations on the levels of processing and the type of additives or other materials that can be included before the classification changes.

Change Record

July 2016	Draft publication
July 2018	Publication including legislative changes to Schedule 4