Australian Government
Department of Health
Therapeutic Goods Administration

Code of practice for tamper-evident packaging of therapeutic goods

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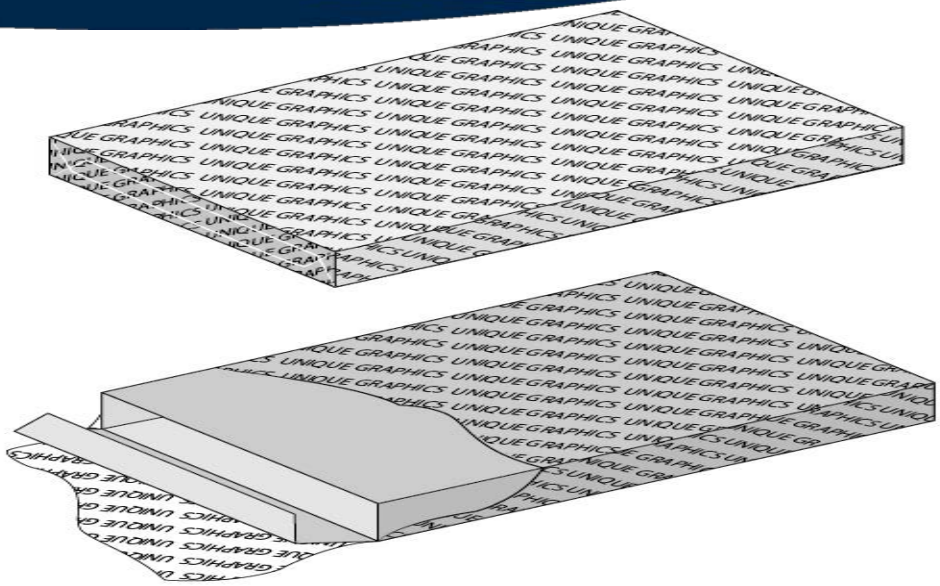
TGA Health Safety Regulation



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Introduction

This code of practice is for sponsors, manufacturers, component suppliers and members of industry bodies who are involved in the design, selection and use of tamper-evident packaging for therapeutic goods.

Purpose

The purpose of tamper-evident packaging is to alert consumers of possible safety concerns before they purchase or use goods.

This code of practice provides guidance on tamper-evident packaging for therapeutic goods. Compliance with the code improves the security of therapeutic goods supplied in Australia and increases the likelihood that consumers can identify when a product has been tampered with.

The code is not mandatory, but it has been established as a condition for membership for some relevant industry associations.

The Code of Practice for the Tamper-Evident Packaging (TEP) of Therapeutic Goods was originally published in June 2003 by the Therapeutic Goods Administration (TGA) after consultation with key industry associations, state health authorities and consumers. In 2009, the code was reviewed by the Therapeutic Goods Committee with consultation with relevant stakeholders; no changes to the scope or technical requirements were identified.

This version of the code of practice does not introduce any new requirements for tamper-evident packaging but is an update that reflects contemporary practices.

Tamper evident packaging (TEP) means packaging that has an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible or audible evidence to consumers that tampering may have occurred.

How to use the code of practice

Use the code of practice as a guide for the design, selection and validation of tamper-evident packaging. It can also be used as a reference for selecting appropriate tamper-evident labelling statements.

What the code applies to

This code of practice is intended for any therapeutic good that is claiming or presented as being supplied in tamper-evident packaging. In particular, it should be applied to therapeutic goods that can be accessed by the general public before purchase. These include medicines, devices and other therapeutic goods that are either:

- unscheduled

  OR

- subject to Schedule 2 or Schedule 3 to the Poisons Standard

  AND are:

- ingested orally
- administered transdermally
- applied to, or come into contact with, mucous membranes, including tampons, lubricants with/without spermicide/viricide, and condoms with/without spermicide or viricide
- for ophthalmic use or for use with contact lenses

If sponsors choose to use tamper-evident packaging for medical devices that are not available to the general public, they must use an acceptable form of packaging that will meet the essential principles relating to product safety outlined in the *Therapeutic Goods (Medical Devices) Regulations 2002*.

Requirements for tamper-evident packaging

To comply with this Code of Practice, tamper-evident packaging must:

- be designed to remain intact when the goods are handled in a reasonable manner, including during manufacture, distribution and retail display
- include a tamper-evident statement on the package (see Labelling)
- not obscure or destroy any mandatory label information (see Labelling)

In addition, for two-piece capsules (i.e. where the capsule shell is composed of two pieces - a body and a cap), the packaging must:

- use a minimum of two tamper-evident packaging features (see Tamper-evident features)

For all other products, the packaging must:

- use a minimum of one tamper-evident packaging feature (see Tamper-evident features)

Tamper evident packaging does not replace or obviate the need for child-resistant packaging where the law requires such packaging (Therapeutic Goods Order No .80). If child-resistant packaging is required, then use tamper evident packaging in conjunction with child-resistant packaging.

Tamper-evident features

Tamper-evident features are barriers or devices on the packaging, which if breached or missing, reveal irreversibly to consumers that tampering may have occurred.

The features can be used on primary packaging, the container or both.

Acceptable forms of tamper-evident features

Examples of acceptable forms of tamper-evident features are described below. Other forms of tamper-evident packaging may also be acceptable, provided they are appropriate for the product and suitably validated.

The feature used must be appropriate for the product in question and validated in accordance with design and validation principles.

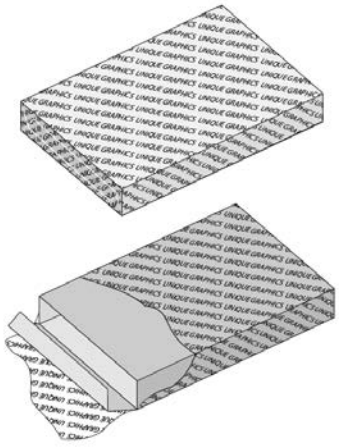
In selecting a tamper-evident feature, consider the special needs of some consumers, such as arthritic, manually impaired or elderly persons.

Film wrappers, transparent

A transparent film with distinctive design is wrapped securely around the entire product pack ensuring that it is completely sealed and a secure, tight fit is achieved.

- The wrapper must be ripped or broken to gain access to the product
- Sealing of a film wrapper with overlapping end flaps is acceptable only if the ends cannot be opened and resealed without leaving visible evidence of entry
- Tinted wrappers without a distinctive design are unacceptable because of the possibility that their material may be readily available and can be potentially substituted for the original wrapper
- The use of cellophane wrappers to provide tamper-evidence is not acceptable because of the possibility that their material may be readily available and can be potentially substituted for the original wrapper. It is also difficult to achieve a weld seal on cellophane

Figure 1 Transparent film wrapper



Blister or strip packs

Individual doses (for example, capsules or tablets) are sealed in pockets between a pre-formed tray and a lidding material, or between two layers of material bonded together to form a continuous strip, so that the dosage units are separated and individually protected.

- The blister or strip pack seals around individual compartments and the strip as a whole, must be intact and complete
- The individual compartment of the pack must be ripped or broken to gain access to the product

- The layers forming the blister or strip pack cannot be separated or replaced without leaving visible evidence of entry

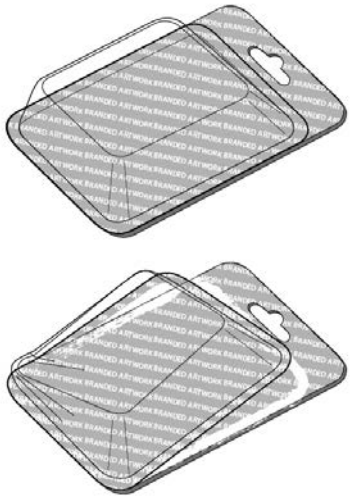
Figure 2 Blister pack

Bubble packs

The product and container are sealed in a plastic bubble and mounted in or on a display card.

- The plastic and/or card must be ripped or broken to gain access to the product
- The backing material cannot be separated from the bubble or replaced without leaving visible evidence of entry
- Bubble pack seals must be intact, complete and sealed all the way around

Figure 3 Bubble pack



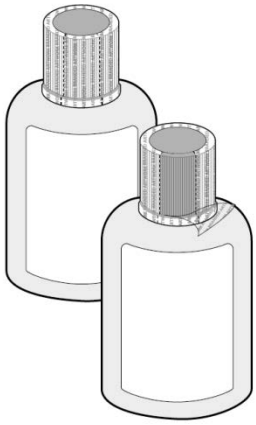
Heat shrink bands or wrappers

Bands or wrappers with a distinctive design are shrunk by heat to tightly seal the union of the cap and container.

- The seal must be ripped or broken to gain access to the product
- The band or wrapper cannot be removed and reapplied without visible damage
- Use of a perforated tear strip can enhance tamper evidence

- Cellulose wet shrink seals are not acceptable because of the reversible nature of these seals
- Tinted bands without a distinctive design are unacceptable because of the possibility that their material may be readily available as a substitute band or wrapper

Figure 4 Heat shrink band or wrapper

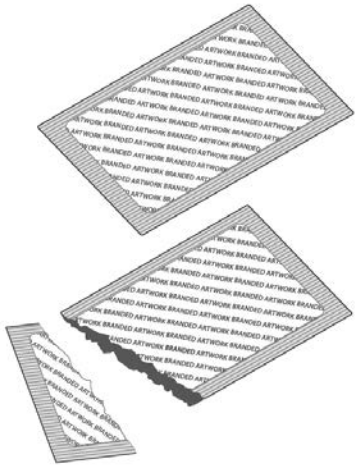


Pouches, sachets and form-fill seal packs

The product is enclosed in an individual pouch or sachet that must be ripped, peeled open or broken to gain access to the product.

- The pouch or sachet must have a distinctive design
- Seals of the pouch or sachet cannot be separated and resealed without showing visible evidence of entry

Figure 5 Pouches and sachets



Container mouth inner seals

Paper, thermal plastic, polystyrene foam, plastic film, foil, or combinations thereof, with a distinctive design is sealed to the mouth of a container under the cap.

- The seal must be ripped or broken to open the container and gain access to the product
- The seal cannot be removed without showing visible evidence of entry, and once removed, seals cannot be reapplied without showing visible evidence of entry

- The seal must be intact, complete and sealed all the way around
- Seals applied by heat induction appear to offer a higher degree of tamper-evidence than those that depend on an adhesive to create the bond
- Pressure sensitive adhesives may not offer adequate evidence of entry

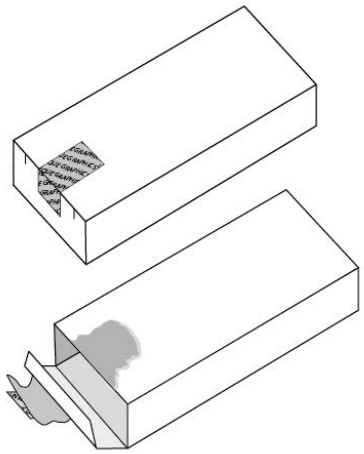
Figure 6 Container mouth inner seal

Tape seals

Paper, foil or plastic with a distinctive design is sealed over all carton flaps or a container cap.

- The seal or pack must be ripped or broken to gain access to the product
- The seal cannot be removed and reapplied, or the carton side-seam breached, without showing visible evidence of entry

Figure 7 Tape seal



Breakable caps

The plastic or metal cap has a portion (such as a ring) that breaks away on opening and remains on the neck of the container.

- The cap cannot be removed without the ring breaking away
- The cap cannot be reapplied in its original state

Figure 8 Breakable cap

Tear away caps

The plastic or metal cap has a portion that is torn away in order to allow the remainder of the cap to be removed to gain access to the product.

- The tear away portion must be clearly torn or missing once the package is opened
- The cap cannot be removed without the tear-away portion being broken
- The cap therefore cannot be reapplied in its original state

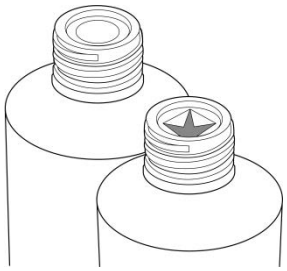
Figure 9 Tear away cap

Sealed metal tubes

The lower end is sealed by folding and/or crimping.

- That end must not be capable of being breached by unbending and refolding without visible evidence of entry
- The nozzle is blocked by seal or membrane. The nozzle seal or membrane must be broken or punctured to gain access to the product
- The seal cannot be punctured, or removed and reapplied without showing visible evidence of entry

Figure 10 Sealed metal tube

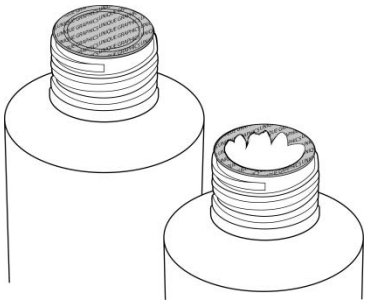


Sealed plastic and laminate tubes

The lower end of the tube is sealed by heat-sealing and crimping.

- That end must not be capable of being breached without visible evidence of entry
- The nozzle is blocked by a seal, membrane or twist off top and must be broken or punctured to gain access to the product

Figure 11 Sealed plastic and laminate tube



Cans, all metal and composite

The top and bottom of a can must be joined to the can walls in such a manner that they cannot be pulled apart and reassembled without visible evidence of entry.

- After opening, the can cannot be reclosed without visible evidence of entry

In-built tamper-evident controls

Products such as in-vitro diagnostics with in-built controls that indicate if the product is unacceptable for use (i.e. a test-method failure) are considered as having tamper-evident controls. Such products are considered to comply with the code of practice without needing additional packaging or labelling.

- The controls must be obvious to the user when trying to access the test results and from the packaging information and instructions

Sealed two-piece capsules

Two-piece capsules are sealed such that the two halves of the capsule cannot be separated or re-joined without leaving visible evidence of entry.

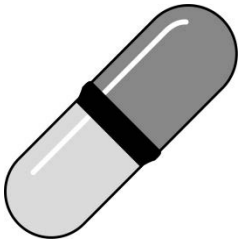
- Capsules may be sealed by means such as banding, sonic welding and sealing techniques employing solvents or low temperature heating

- The sealing of a two-piece capsule is considered to be a tamper-evident feature. However, to meet the requirements for two-piece capsules, sealed two-piece capsules are required to be supplied with a minimum of one **additional** tamper-evident packaging feature

Note

For unsealed capsules, the packaging requires two tamper-evident features.

Figure 12 Sealed two-piece capsule



Packaging that is not tamper-evident

Some packaging available for use with therapeutic goods is not considered to be tamper-evident. These types of packaging may be easily breached and/or do not provide an adequate indication of likely tampering.

Packaging examples which are not considered to be tamper-evident include:

- Paperboard cartons which have been sealed by gluing the end flaps and / or side-seam together without the addition of other tamper-evident features such as tape seals or film wrappers
- Tinted film wrappers or bands which are not distinctive by design
- Film wrappers manufactured from cellophane
- Cellulose wet shrink seals

Design and validation

The sponsor or manufacturer must have documented evidence to support the suitability of the tamper-evident packaging (TEP) that includes the:

- design qualification of the TEP and its suitability/compatibility of components with the product and compliance with required TEP statements
- specifications for the TEP including details of the approved supplier, functional /performance criteria and critical attributes
- validation of the effectiveness (function) of the TEP as wells as the manufacturing process used to apply the TEP to the goods
- requirements for routine sampling and testing of incoming TEP packaging componentry and applied (assembled) TEP devices

Labelling

All goods that are sold in tamper-evident packaging, must include a tamper-evident statement on the pack. This must:

- describe the tamper-evident feature(s) (including any identification characteristics)
- warn that the absence of, or damage to, such feature(s) at the time of purchase is an indication of possible tampering

Examples of acceptable wording for tamper-evident statements are below.

Any mandatory label information must not be destroyed or obscured by the use of tamper-evident packaging. Examples of mandatory labelling requirements for therapeutic goods include *Therapeutic Goods Order No. 69 – General requirements for labels for medicines, Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines* and the *Poisons Standard*.

Where to place the wording

The tamper-evident statement must be placed:

- on the package so that it will be unaffected if the tamper-evident feature is breached or missing

For products with a container and primary pack, the statement should be placed either:

- on both the container and primary pack

  OR

- on the container, alerting the consumer that the container should be inside a carton (or other primary pack) at the time of purchase

For sachets not for individual sale, blister or strip packs and small containers, it is acceptable for the tamper-evident packaging statement to be included only on the primary pack.

Due to the potential for paper labels to be removed and/or substituted, direct printing of the statement, or full label, on the container may be more effective than a paper label.

A primary pack, in relation to therapeutic goods, means the complete pack in which the goods, or the goods and their container, are to be supplied to consumers.

Examples of acceptable wording

Examples of acceptable wording are listed in the table below. Alternative wording that delivers equivalent consumer understanding is also acceptable e.g. some generic statements as supplied on packaging components by packaging material manufacturers. We encourage you to use performance-based labelling principles.

Tamper-evident feature	Examples of acceptable wording
Film wrappers	Do not use if film wrapper is damaged or missing
Blister or strip packs	Do not use if blister seal is broken Do not use if blister backing is damaged
Bubble packs	Do not use if blister seal is broken
Heat shrink bands or wrappers	Do not use if seal (around cap/under lid, etc.) is broken or missing Do not use if tape (band) around cap is damaged Band around cap must be present to ensure package security The seal over/around the cap is your assurance that the package has not been opened For your protection, this bottle has an imprinted seal around the neck
Pouches: foil, paper, or plastic	Do not use if pouch is torn
Bottle mouth inner seals	Do not use if inner foil liner is missing or broken Bottle sealed under cap for your protection
Tape seals	Now with tamper-evident carton seal Tape over carton flaps must be unbroken Use only if carton seal is unbroken Do not use if seals over carton ends are missing or broken
Breakable caps	Now with tamper-evident cap seal Bottle has been opened if cap is separated Use only if cap seal is unbroken The seal on the cap is your assurance that the package has not been opened Do not use if cap seal is broken
Tubes: sealed metal or plastic blind-end heat-sealed	Do not use if foil seal at mouth of tube is broken Do not use if sealed tip is cut
Cans (all-metal and composite)	Do not use if can is damaged

Tamper-evident feature	Examples of acceptable wording
In-built tamper-evident controls	Sterile if in unopened undamaged pack
Sterile medical devices	Sterile if in unopened undamaged pack

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA	June 2003
V2.0	Revised format	Scientific Evaluation Branch	March 2017

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