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THE PROPRIETARY MEDICINES ASSOCIATION OF AUSTRALIA INC.
BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

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To : Gary Hones	Date : 8 September 1993
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Originator : Liz Simpson-Booker	No of pages : 7 (incl cover sheet)



THE PROPRIETARY MEDICINES ASSOCIATION OF AUSTRALIA INC.
BETTER HEALTH THROUGH RESPONSIBLE SELF-MEDICATION

GUIDELINES FOR TAMPER RESISTANT PACKAGING
OF PROPRIETARY MEDICINES

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1. BACKGROUND

- 1.1 The tragic events arising from the criminal tampering with certain OTC medications in the United States, late in 1982, focussed the attention of manufacturers and health authorities around the world on means whereby product packaging design can minimise, or at least reveal, criminal tampering and thus reduce the risk of a repetition of such events.
- 1.2 Whilst the United States Health Authorities have legislated for the use of tamper resistant systems of packaging of certain classes of goods, such action has not yet been proposed in Australia, because the local industry has taken prompt and adequate steps to implement such systems on its own initiative.
- 1.3 These guidelines, based on the US experience and approach to TRP, have been prepared by the Proprietary Medicines Association of Australia in collaboration with officers of the Department of Community Services and Health.
- 1.4 Whilst compliance with these guidelines is not a legal requirement, at this point in time, self-regulation in this matter will only remain viable if the level of compliance is high.
- 1.5 The Proprietary Medicines Association of Australia believes that compliance with these guidelines is in the interests of the community, the proprietary medicines industry and individual companies alike.
- 1.6 Accordingly, the Association's Board of Directors resolved in 1985 that compliance with these Guidelines should be a requirement of membership of the Association.

2. DEFINITIONS/CONCEPTS

Whilst the "tamper-evident" characteristic remains a fundamental goal in any of the packaging systems referred to in this context, the FDA has ruled to adopt the term "tamper-resistant".

For the sake of uniformity, the term "tamper-resistant", is used in this guideline.

- 2.1 A tamper-resistant package has been defined as :

* - one having an indicator or barrier to entry which, if breached or missing, can reasonably be expected to provide visible evidence to consumers that tampering has occurred".

- 2.2 The above definition has been further expanded, viz:

"Tamper-resistant packaging may involve immediate-container/carton systems or any combination thereof, intended to provide a visual indication of package integrity, when handled in a reasonable manner during manufacture, distribution and retail display. The visual indication is required to be accompanied by appropriate illustrations, or precautionary statements, to describe the safe-guarding mechanism to the consumer and to warn that the absence of or damage to such mechanism at the time of purchase is an indication of possible tampering with the product".

- 2.3 "Tamper-proof" (as distinct from tamper-resistant packaging) is not possible and, therefore, any suggestion that a package is tamper-proof, in contrast to tamper-resistant, must be seen to be deliberately misleading.

3. PACKAGING SYSTEMS WHICH ARE ACCEPTABLE

The packaging technologies listed below have been identified by the US Food & Drug Administration as being capable of meeting the requirements for TRP provided that they are properly designed and appropriately used.

Whilst these classes of packaging are acceptable to Australian authorities they should not be seen to be exclusive of other classes or to preclude technological innovation.

Tamper-resistant packaging must not be regarded as replacing or obviating the need for Child Resistant Closures wherever such closures are required by law.

In selecting/developing tamper-resistant packaging, manufacturers are urged to give serious consideration to the needs of arthritic or manually impaired persons.

- 3.1 **FILM WRAPPERS** : A transparent film with distinctive design is wrapped securely around a product container. The film must be cut or torn to open the container and remove the product. The wrapper must have an identifying characteristic (e.g. a pattern, name, registered trademark, logo, or picture) that cannot be readily duplicated.

Tinted wrappers are no longer acceptable as an identifying characteristic because of the possibility that their material or a facsimile may be available to the public. A distinctive design that is proprietary and different for each product size is recommended.

A reasonably tight "fit" of the film around the container must be achieved, e.g., by a heat shrink-type process. 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 tampering.

The use of cellophane with overlapping end flaps is no longer acceptable because of the possibility that the ends can be opened and resealed without leaving visible evidence that tampering has occurred.

- 3.2 **BLISTER OR STRIP PACKS**: Dosage units (for example, capsules or tablets) are individually sealed in clear plastic or foil. The individual compartment must be torn or broken to obtain the product. The backing materials cannot be readily separated from the blisters or easily replaced without leaving evidence of tampering.
- 3.3 **BUBBLE PACKS**: The product and container are sealed in plastic and mounted in or on a display card. The plastic must be torn or broken to remove the product. The backing material cannot be readily separated from the bubble or easily replaced without leaving evidence of tampering.
- 3.4 **HEAT SHRINK BANDS OR WRAPPERS**: Bands or wrappers with a distinctive design (e.g., a pattern, name, registered trademark, logo, or picture) are shrunk by heat to seal the union of the cap and container. A distinctive design that is proprietary and different for each product size is recommended.

The seal must be cut or torn to open the container and remove the product. The band or wrapper cannot easily be worked off and reapplied without visible damage to the band. Use of a perforated tear strip can enhance tamper resistance.

Cellulose wet shrink seals are not acceptable as the knowledge of how to remove and reapply these seals without evidence of tampering is widespread.

- 3.5 FOIL, PAPER, OR PLASTIC POUCHES:** The product is enclosed in an individual pouch that must be torn or broken to obtain the product. The pouch should have a distinctive design (e.g. a pattern, name, registered trademark, logo, or picture).

The end seals of the pouches cannot be separated and resealed without showing visible evidence of entry.

- 3.6 BOTTLE MOUTH INNER SEALS:** Paper, thermal plastic, polystyrene foam, film, foil, or combinations thereof, with a distinctive design (e.g., a pattern, name, registered trademark, logo, or picture) is sealed to the mouth of a container under the cap. The seal must be torn or broken to open the container and remove the product.

Seals applied by heat induction to plastic bottles appear to offer a higher degree of tamper-resistance than those that depend on an adhesive to create the bond.

- 3.7 TAPE SEALS:** Paper or foil with a distinctive design is sealed over all carton flaps or a bottle cap. The seal must be torn or broken to open the container and remove the product.

Tape seals are acceptable only if they contain a unique feature that makes it apparent if the seals have been removed and reapplied.

- 3.8 BREAKABLE CAPS :** The container is sealed by a plastic or metal cap that either breaks away completely when removed from the container or leaves part of the cap attached to the container. The cap, or a portion thereof, must be broken in order to open the container and remove the product. The cap cannot be reapplied in its original state.

- 3.9 SEALED METAL TUBES OR PLASTIC BLIND-END HEAT-SEALED TUBES:** Both ends of the tube are sealed. The mouth or blind-end must be punctured to obtain the product.

A tube with a crimped end is acceptable if the crimped end cannot be breached by unfolding and refolding without showing visible evidence of tampering.

- 3.10 AEROSOL CONTAINERS:** Aerosol containers are believed to be inherently tamper-resistant because of their particular design.

Direct printing of the label on the container (e.g. lithographing) , is preferred to using a paper label which could be removed and substituted.

- 3.11 CANS (BOTH ALL-METAL AND COMPOSITE) :** The top and bottom of a composite 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. Rather than attaching a separate label, direct printing of the label onto the can (e.g., lithographing) is preferred.

4. PACKAGING SYSTEMS WHICH ARE UNACCEPTABLE

- 4.1 **SEALED CARTONS** : Sealed paperboard cartons as currently available in the marketplace (e.g., cartons sealed by gluing the end flaps together) are unacceptable. However, the Agency recognises that future technological advances may provide sealed paperboard packages that meet the intent of the TRP regulation.
- 4.2 **SEALED TWO-PIECE HARD GELATIN CAPSULES** : Sealed capsules are not tamper resistant packages. They must be packaged in an acceptable TRP technology.

Technologies for sealing two-piece hard gelatin capsules are available which provide evidence if the capsules have been tampered with after filling. The sealing technologies currently in use for two-piece hard gelatin capsules include sonic welding, band, and sealing techniques employing solvents and/or low temperature heating. These examples are not intended to rule out the development and use of other capsule sealing technologies.

5. APPLICATION TO OTC PRODUCTS

It is recommended that tamper-resistant packaging be applied to "all non-prescription therapeutic goods which consist of a substance for human use (other than dermatologics, dentifrices, insulin and lozenges), cosmetic liquid oral hygiene preparations, vaginal products and to contact lens solutions and tablets used to make these solutions if such goods are accessible to the public while being held for retail sale".

The PMAA is aware that Australian packaging technologies have, to some extent, lagged behind those used in the United States, and that some members have encountered difficulties in transferring particular products to TRP technologies.

For this reason, the Association conducts an annual audit of member companies to ensure that positive action is being taken to solve those difficulties and to keep a record of compliance.

New members of the Association are granted a maximum 24 months from the date of acceptance of their membership application by the Committee of Management, to comply with these requirements.

6. LABELLING

- 6.1 Obviously a fundamental requirement for any tamper-resistant packaging system is the provision of appropriate advice to the intending consumer as to the nature of the specific tamper-resistant characteristic.
- 6.2 That advice must at least be displayed on either the retail carton, primary package or container - wherever the tamper-resistant characteristic is located.
- 6.3 The US Food and Drug Administration (FDA) labelling requires that each package should :

* - contain a statement that is prominently placed so that consumers are alerted to the specific tamper-resistant feature of the package. The labelling statement is required to be so placed that it will be unaffected if the tamper-resistant feature of the package is breached or missing. If the tamper-resistant feature chosen is one that uses an identification characteristic, that characteristic is required to be referred to in the Labelling Statement".

- 6.4 Within those parameters manufacturers are free to exercise their initiative. However, the requirements of Commonwealth and State labelling legislation should also be observed.
- 6.5 As a guide to members, the following are examples of American pack copy and of statements believed to be acceptable to the FDA :
- "Now with tamper-resistant cap/carton seal"
 - "Do not use if seal (around cap/under lid, etc.) is broken or missing"
 - "Foil sealed for your protection"
 - "Do not purchase if carton is torn"
 - "Bottle sealed under cap for your protection"
 - "Individually sealed in (foil, plastic, paper, etc.) for your protection"
 - "Band around cap must be present to ensure package security"
 - "Tape over carton flaps must be unbroken"
 - "Do not use if tape around cap is damaged"
 - "Bottle has been opened if cap is separated"
 - "Use only if (carton/package/cap) seal is unbroken"
 - "The seal (on/over/around) the cap is your assurance that the package has not been opened".