



## **Code of Practice**

for the

### **Manufacture, Labelling, Distribution and Marketing of Social Tonics in New Zealand**

The Social Tonic Association of New Zealand Inc, (STANZ) introduces this code of practice as a set of guidelines that are intended to introduce a high level of social responsibility to the manufacture, distribution and marketing of social tonics thereby ensuring that consumers have access to safe product and are able to make informed choices when purchasing and using social tonics.

The code of practice;

- has been agreed by consensus of STANZ members following extensive public consultation with health and law enforcement officials, consumers and other stakeholders,
- fills a void that exists relating to current legislation,
- fills a void created by lack of meaningful enforcement of legislation relating to manufacture, labelling, distribution, and marketing of products,
- sets industry standards for best practice to:
  - protect the health and safety of consumers,
  - enable consumers to make informed purchasing and use decisions,
  - promote fair and socially responsible trading, and to
  - prevent fraud,
- provides pragmatic frameworks to manage real or perceived safety concerns and disputes in a risk proportionate, fair and timely manner,
- is mandatory for STANZ members and should be adopted voluntarily by non-members.

Key features of the code of practice include:

- products will be manufactured and distributed in accordance with approved Good Manufacturing Practices (GMP) and legal requirements,
- distribution and marketing will be undertaken in a socially responsible manner,
- distribution and marketing will avoid targeting of under 18 year olds where risks are higher or significant uncertainty exists,
- introduction of a pragmatic risk classification system for ingredients,
- risk management decisions will be transparent, evidence-based, socially responsible and risk proportionate

The code of practice can be downloaded in PDF format from [www.stanz.org.nz](http://www.stanz.org.nz)

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## 1 Citation

This Code may be cited as the STANZ code of practice and is referred to in this document as “the code of practice.”

## 2 Preamble

Consumers and businesses alike are exposed on a regular basis to issues of fair trading, product safety, product quality, service performance, complaints and disputes resolution. To promote fair practices in these areas, business behaviour is often regulated which involves the process of making rules which govern behaviour and can mean one of, or a combination of, the following measures;

- formal government regulation to deal with serious, systemic, or chronic problems
- encouragement of self-regulation, including codes of practice, to deal with problems within a specific market, or with particular business activities
- education and other operational strategies to enhance consumer and trader understanding of acceptable trading standards
- a 'hands off' approach governed by the belief that the interaction between consumers and businesses will in itself ensure that problems will be reduced.

Codes of practice are often considered when;

- government regulation is unlikely to occur or is inappropriate, for example where only a segment of the market is affected,
- overarching legislation exists and the objective is to assist or promote compliance within a particular industry,
- there is widespread acknowledgment of the need for, and commitment to, the development of controls to improve trading standards within a particular industry,
- the objective is to provide customer focused benefits beyond the minimum standards provided by the law.

In this case, STANZ has developed the code of practice, in part, to bridge the gap in the regulation of non-mainstream products that are often perceived as exposing consumers to significant risk, even in the absence of evidence that they do. There are some critics of the social tonic industry that say that absence of evidence is not evidence of absence. STANZ not only argues that such a view is scientifically indefensible, but argues that absence of evidence is the only scientific way of validating evidence of absence. At the same time, STANZ accepts that current evidence is such that proof of safety is not possible. Having said that, STANZ notes by way of example that more than five million doses of benzylpiperazine (BZP) have been consumed by New Zealanders during the past few years with de minimis harm evident.

This absence of evidence of significant harm is in stark contrast to harm due to illegal products on the market. It follows then that based on available evidence, social tonics offer a much safer alternative to illegal products and therefore can be seen to help achieve the government’s stated harm minimisation policies.

The code of practice specifies various guidelines which should be adopted when manufacturing and marketing certain Social Tonic products under the Dietary Supplement Regulations 1985, the Food Act 1981, the Medicines Act 1981, and other relevant legislation. The focus is on improving and maintaining high standards of product and consumer information, thereby minimising the potential for harm.

Compliance with the code of practice will enable suppliers and retailers to be seen to be acting in a socially responsible manner in the marketing of Social Tonic products, and provide consumers with assurances regarding the quality of purchased product and enable them to make informed choices.

Nothing in the code of practice usurps a member’s requirements to operate legally.

### 3 The Vision

#### 4 Statement of purpose

The code of practice has been produced by STANZ to ensure that industry exercises its duty of care that enables consumers who want to be better informed about the use of Social Tonics to be able to :

- a) Make informed choices
- b) reduce risks and maximise safety

The code of practice is to be seen as an important part of the social tonic industry's commitment to enabling people to exercise their human right to enjoy life without exposing themselves to excessive harm.

The code is wider than just focusing on good industry and consumer relations, it also refers, among other matters, to social responsibility issues such as harm reduction associated with other activities undertaken by a number of social tonic consumers.

STANZ will become a point of reference for officials and health practitioners wanting evidence based information on social tonics.

Adoption of the code of practice is intended to ensure that best practice is applied to the manufacture and marketing of social tonics in New Zealand in accordance with legal requirements.

Compliance with the code of practice will facilitate industry, regulators and other key stakeholders working together to ensure that consumers of social tonics are protected in terms of both the law and social responsibility.

The adoption and implementation of the code of practice is acknowledgement that the Social Tonic Industry is a legitimate and responsible industry but also desires to be recognised as such by all stakeholders.

#### 5 Why a code of practice?

A code of practice is a document which sets out standards of conduct for an industry sector in relation to its members, its customers, its regulators, other stakeholder groups and the public at large.

The code of practice is a way for STANZ and its members to make sure that they deliver high quality and appropriately labelled and marketed social tonics through adoption and implementation of a set of best practice procedures that protect the health and safety of consumers.

The code of practice specifies the agreed framework in which an activity or process should be conducted and becomes the standard against which deviation from best practice is assessed.

Whilst a code of practice can be used by the courts to test whether a supplier is complying with best practice and can also be approved as a food safety programme under the Food Act 1981, the code of practice is presently not law. To become law it would need to be mandated in legislation or regulation.

It will, however, be mandatory for existing STANZ members to fully comply with the code of practice within 12 months of it becoming operational and for new STANZ members to fully comply with the code of practice within 12 months of joining STANZ.

#### 6 Risk Classification System

STANZ is introducing a 5-bin risk classification system for social tonics which is adapted from a risk management framework developed jointly by the Ministry of Health and the Ministry of Agriculture and Fisheries and utilised by the New Zealand Food Safety Authority.

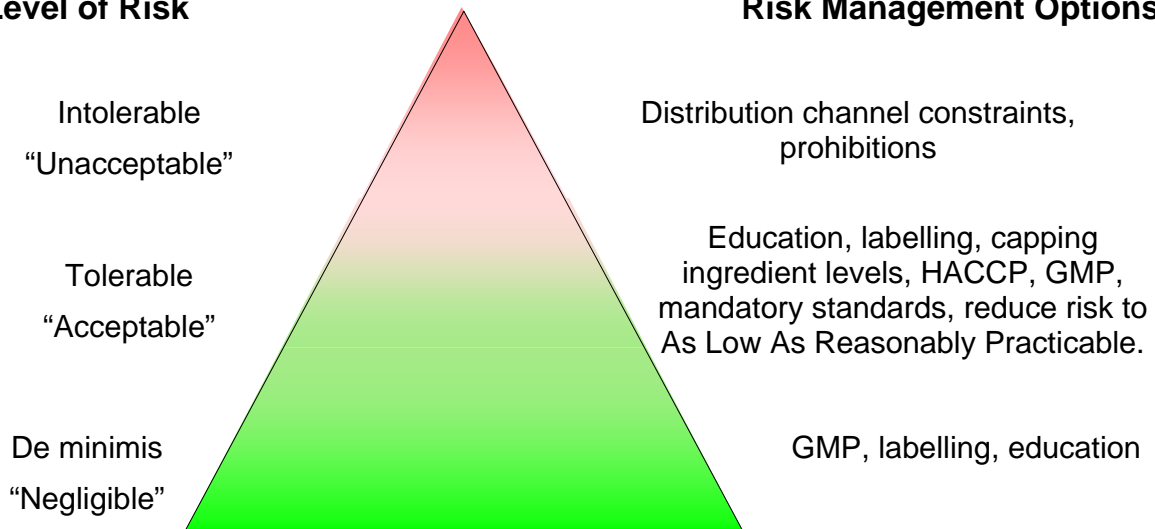
All products will be required to be notified for inclusion in a STANZ approved database that will be web-based and available to the public.

Ingredients not specifically listed in the risk classification schedule will be assumed to be safe, although it will be mandatory for new ingredients to be notified for risk classification which will be assessed systematically and in a socially responsible manner.

**A Risk Management Framework for Social Tonics**

**Level of Risk**

**Risk Management Options**



\* Source: [Modified and contextualized] MOH/MAF

<http://www.nzfsa.govt.nz/policy-law/harmonisation/rmgmtp.pdf>

<b>STANZ Risk Classification System</b>	
<b>Risk Classification</b>	<b>Specific Risk Management Response [examples]</b>
<b>RC1</b> = de minimis [acceptable level of risk if any]	None required
<b>RC2</b> = Potential risk that is ill defined but acceptable	Voluntary advisory statements & education. STANZ will issue publicly available web-based material for generic use
<b>RC3</b> = Sufficient evidence of risk or significant public concern to warrant mandatory risk management response	Mandatory advisory/caution or warning statements and/or ingredient limits per serving [and/or amount per package], and/or special GMP requirements
<b>RC4</b> = Sufficient evidence of mild risk or associated with significant social responsibility issues to warrant controls on accessibility of ingredient	Age and/or distribution restrictions and/or professional guidance and/or professional supervision required
<b>RC5</b> = Sufficient evidence of risk to restrict availability of ingredient	Prohibition is the only reasonable risk management option after having considered potential moral hazards

**7 STANZ Quality Marks**

STANZ introduces a Quality Mark that will only be available for use by STANZ members upon payment of any licensing fees (which will be used to administer the code of practice) and assure compliance with the code of practice as follows;

- Gold STANZ Quality Mark; **fully compliant** members will be able to use the Gold STANZ Quality Mark.
- Silver STANZ Quality Mark; members who have in place **notified recall protocol**, who have provided **certificates of analysis** from an approved testing laboratory for their products, and **are committed to and actively working towards full compliance** with the code of practice will be permitted to use the Silver STANZ Quality Mark for a period of 12 months whilst they implement the code of practice.

## 8 Synergy with Existing Government Policy

As noted, the risk classification system is an adaptation of the Ministry of Health's Risk Management Framework for other orally consumed substances; namely foods.

In part, social tonics are consumed as part of a harm minimisation strategy so therefore, these guidelines are therefore to be seen as an adjunct to the Ministry of Health's stated Harm Minimisation Policy<sup>1</sup> and Guidelines For Safe Dance Parties<sup>2</sup>.

The principles of harm minimisation are defined by the National Drug Policy 1998 as:

“An approach that aims to minimise the adverse health, social and economic consequences of drug use, without necessarily ending such use for people who cannot be expected to stop their drug use immediately. The primary goal of this approach is a net reduction in drug-related harm rather than becoming drug-free overnight, although harm minimisation strategies often lead to a reduced number of people who use drugs over time.”<sup>3</sup>

“Dance Clubs” will be encouraged to fully comply with the current Ministry of Health Guidelines For Safe Dance Parties.

The code of practice has been developed to fill a risk management void in compliance with and enforcement of regulation of the manufacture, distribution and marketing of these products.

This risk management option includes the establishment of clear ‘flags’ between which safe commercial activity can be undertaken and within which these products can be safely used.

Whilst operating outside of the code of practice does not necessarily imply illegal activity, operating within the code of practice is likely to be a defence or mitigating factor should a complaint be made.

The government has indicated that it will consider introducing a class ‘D’ in the Misuse of Drugs Act to enable selected compounds to be marketed with aged and distribution restrictions. In essence, the code of practice pre-empts such a classification.

STANZ is cognisant of the fact that the government has signed a treaty with Australia regarding the possibility of a joint regulatory scheme for therapeutic products. Given the findings and recommendations of the Health Select Committee and opposition parties, there is no certainty that the proposed regulatory changes will proceed in the proposed form.

On the STANZ website there are links to support documents such as a list of more than 20 Acts, regulations, standards, and codes of practice that apply in some form or other to the regulation of Social Tonics. Commentators who say that these products are not regulated are simply not speaking the truth.

## 9 Application and Coverage

- a) This Code applies to the relationship between Social Tonic companies and their distributors, retailers and consumers.
- b) This Code covers all Social Tonic Association of New Zealand (inc) (STANZ)] members, their staff, contractors, distributors, agents and salespersons, for the sale of either products or services.
- c) A member of the STANZ may terminate their membership and their obligation to comply with the Code by resigning formally from STANZ giving fourteen days notice. This however does not negate the obligation by the member to fulfil obligations incurred while a member under the code.
- d) Obligations to comply with the code of practice shall not cease until the last obligation to do anything required by the Code has been performed.

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<sup>1</sup> Ministry of Health. 1998. New Zealand National Drug Policy, 1998 – 2003. Wellington: Ministry of Health. Cited In Ministry of Health, 1999, Guidelines For Safe Dance Parties: The Big Book,

<sup>2</sup> Guidelines promote safer dance parties, (1999) Ministry of Health, accessed from <http://www.ndp.govt.nz/media/moh6dec1999.html>; Ministry of Health's Guidelines for Safe Dance Parties, Ministry of Health Guidelines For Safe Dance Parties: The Big Book, 1999, [http://www.moh.govt.nz/moh.nsf/0/77e8b252dfab984b4c25683f001425b9/\\$FILE/DANCEPARTY.pdf](http://www.moh.govt.nz/moh.nsf/0/77e8b252dfab984b4c25683f001425b9/$FILE/DANCEPARTY.pdf)

<sup>3</sup> Ministry of Health. 1998. New Zealand National Drug Policy, 1998 – 2003. Wellington: Ministry of Health. Cited In Ministry of Health, 1999, Guidelines For Safe Dance Parties: The Big Book,

- e) Dance Clubs will be able to join STANZ and use the STANZ Quality Mark if they can show that they fully comply with the current Ministry of Health Guidelines For Safe Dance Parties.<sup>4</sup> Consideration should be given to getting the guidelines registered with the Department of Labour under the HSE Act.<sup>5</sup>

Retailers are encouraged to join STANZ and use STANZ Quality Mark accordingly.

## 10 Principles

The principles in the code of practice set down the basic values which STANZ will apply to meet the intentions expressed in code of practice.

### **10.1 Principle 1. Social Responsibility**

STANZ members will comply with the laws of New Zealand and all appropriate industry agreed codes of practice.

Claims must at all times be clear and truthful and not present a product in a way that could mislead or harm the consumer or other distributors.

It is acknowledged that the very nature of some social tonics can mean that they straddle the interface between legal and illegal products and often have perceived, rather than real risks. Such ingredients will be risk managed accordingly,

Social Responsibility implies that in adopting risk management options, decisions will not create moral hazards.

### **10.2 Principle 2 Accessibility**

STANZ will ensure that the code of practice is pragmatic and readily available to industry, distributors, customers and other stakeholders by promoting knowledge of its existence and ensuring that it is available online, and equitably administered.

A user-friendly website will be provided for simple communication, access to relevant public health information, and enable lodgement of product information, complaints, adverse effect reports and other concerns.

The administration of the code of practice will have no cost barriers for consumers.

### **10.3 Principle 3 Independence**

The decision-making processes relating to the administration of the code of practice are, wherever practicable independent from scheme members.

Where independence is not practicable, independent audits will be undertaken at regular intervals to ensure objectivity and transparency. Such reports will be published online.

### **10.4 Principle 4 Fairness**

The administration of the code of practice produces decisions which are fair and seen to be fair by observing the principles of natural justice and procedural fairness, by making decisions on the information before it and by having specific criteria upon which its decisions are based.

### **10.5 Principle 5 Accountability**

The Administrator of the code of practice publicly accounts for its operations by publishing its determinations and information about complaints and highlighting any systemic industry problems.

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<sup>4</sup> Guidelines promote safer dance parties, (1999) Ministry of Health, accessed from <http://www.ndp.govt.nz/media/moh6dec1999.html>; Ministry of Health's Guidelines for Safe Dance Parties, Ministry of Health Guidelines For Safe Dance Parties: The Big Book, 1999, [http://www.moh.govt.nz/moh.nsf/0/77e8b252dfab984b4c25683f001425b9/\\$FILE/DANCEPARTY.pdf](http://www.moh.govt.nz/moh.nsf/0/77e8b252dfab984b4c25683f001425b9/$FILE/DANCEPARTY.pdf)

<sup>5</sup> Some concern has been expressed that some dance clubs have deliberately turned off water supply to cold water taps in washrooms in order to encourage patrons to buy expensive bottled water at the bar. This is unsafe practice and is contrary to the MOH guidelines which states "Cold, clean drinking-water should be available, free of charge, at all times... Cold water supplies should never be shut off."

**10.6 Principle 6 Efficiency**

The administration of the code of practice will operate efficiently by establishing a database of complaints, keeping track of complaints, ensuring complaints are dealt with appropriately within an agreed time-frame and regularly reviewing its performance. STANZ will also review the performance of both the code of practice and the administration of it at least annually.

**10.7 Principle 7 Effectiveness**

The effectiveness of the administration of the code of practice will be reviewed at least annually against appropriate and agreed terms of reference. An independent review of its performance and relevance will be undertaken every two years or sooner if there are obvious deficiencies.

**10.8 Principle 8 Proportionality**

All decisions will be proportionate to the magnitude of the problem.

**10.9 Principle 9 Timeliness**

Complaints and disputes will be handled promptly.

## 11 Objectives of the code

The adoption and application of the code of practice:

- applies evidence-based and risk proportionate risk management strategies to the manufacture, distribution, and marketing of appropriately regulated social tonics in New Zealand,
- improves and clarifies standards of socially responsible behaviour within the Social Tonic industry,
- ensures that consumers are provided with accurate and timely information to enable them to make informed choices,
- ensures that manufacturing quality is commensurate with best practice
- addresses safety concerns including reporting, analysis of and response to reports of adverse events,
- ensures that complaints are addressed fairly and timely,
- provides an equitable disputes resolution mechanism for industry,
- allows policy makers and law compliance officers access to industry to review best practice in terms of overall government policy.

### 11.1 General

In order to manage the code of practice in a socially responsible manner it is important that both STANZ and regulators know “who” and “what” are in the market so that emerging safety issues or recalls are able to respond appropriately. To this end, STANZ members will;

- a) provide to the Administrator full company contact details as determined by STANZ, from time to time, for posting on the STANZ website.
- b) as soon as reasonably practicable, enter required details of all products on to the STANZ approved web-based product database for public access.

### 11.2 Specific Risk Management Requirements

STANZ will maintain a five category Risk Classification Schedule that provides specific risk management requirements for ingredients with identified risks. The five categories will be known as RC1, RC2, RC3, RC4, and RC5.

Risk management options will vary according to the evidence-based level of risk and/or degree of uncertainty and/or social responsibility factors.

- a) All products are to be distributed in compliance with the STANZ 5-category risk classification schedule.

- b) Ingredients listed in risk classifications RC3, RC4 and RC5 have been placed their by STANZ in consultation with industry, consumers and regulators, as requiring special labelling, restricted distribution or, in extreme cases, as being inappropriate for distribution at all.
- c) Risk analysis will be based on good regulatory practice and include good risk management practice and may be undertaken due to any one or more of the following reasons;
  - i. documented or emerging safety concerns, or
  - ii. perception of emerging safety concerns, or
  - iii. agreed social responsibility concerns, or
  - iv. dispute between stakeholders as to whether risks are real or perceived, or
  - v. uncertainty regarding risk profile of ingredient.
- d) Risk management options may include;
  - i. status quo,
  - ii. specific professional, industry and/or consumer education,
  - iii. voluntary or mandatory advisory, cautionary, or warning statements on labels,
  - iv. maximum per-serving amounts of ingredient,
  - v. maximum per package amounts of ingredient,
  - vi. requirement for synergistic ingredients to be present in the product formula,
  - vii. age restrictions on product sale,
  - viii. accessibility to product in certain retail outlets,
  - ix. prohibition,
  - x. any other agreed risk management option based on good regulatory practice and good risk management practice.

### **11.3 Manufacture/Distribution**

#### **11.3.1 Good Manufacturing Practice (GMP)**

All products will be manufactured according to an approved code of good manufacturing practice (GMP).

- a) STANZ will maintain a schedule of approved GMP codes of practice.
- b) All member's premises and their manufacturer(s) sites are to comply with approved GMP requirements (for example; standards of cleanliness, quality-assurance, record-keeping, recall procedures, etc) within one year of implementation of the code of practice or acceptance for membership.

#### **11.3.2 Quality assurance**

Product will be subject to regular and random quality assurance testing to assure consumers that every effort has been made to maintain product quality.

- a) Suppliers marketing products containing ingredients placed in the RC3 or higher risk classification will be required to submit an appropriate certificate of analysis to the administrator of the STANZ code of practice for each batch of product marketed.
- b) Members will pay STANZ, upon invoice, for the independent testing of two products per year or 10% of their product range, whichever is larger.

### **11.4 Product and Consumer information**

Consumers are to have sufficient information to be able to make informed purchasing and consumption choices. As such;

- a) all product labelling will conform with legal and GMP requirements,
- b) suppliers will have appropriate product information freely available via 0800 numbers or website,
- c) all labelling requirements of the Risk Classification Schedule will be required to be placed on the labels of distributed product as soon as reasonably practicable following STANZ classification and notification,
- d) over stickers may be used for existing stock,
- e) retailers are to be provided with over stickers for their existing stock as soon as reasonably practicable,

### **11.5 Marketing Claims and Advertising**

STANZ accepts that all marketing and advertising claims must be truthful and socially responsible, and comply with specific requirements of the code of practice.

STANZ does not accept that social tonics have a legal or moral requirement to be pre-vetted. However, STANZ will maintain a database of TAPS<sup>6</sup> approved claims. As such;

- a) Use of TAPS approved claims by members will provide strong defence of compliance with the code of practice and legislative requirements if challenged by compliance regulators.
- b) members who use such claims will be strongly supported by STANZ. In their defence;
- c) use of other claims are not prohibited, but such claims are likely to expose members to closer scrutiny by compliance officers and are less likely to be defended by STANZ.

Members **shall** ensure that;

- a) Every advertisement, brochure, leaflet, website or other means of publication of consumer information shall include contact details for purposes such as obtaining detailed product information, or reporting an adverse event.

Members shall **not**:

- a) Make false or misleading comparisons about efficacy, safety, price or quality of product
- b) quote or imply scientific or technical data in support of a claim unless the data can be readily substantiated and is readily available for verification.
- c) use false, fabricated or misleading testimonials.
- d) promise outcomes where those outcomes have no safe scientific, medical, history of use or performance basis.
- e) use comparisons which are likely to mislead and which are incompatible with the principles of fair competition. Points of comparison shall not be unfairly selected and shall be based on facts which can be substantiated.
- f) unfairly denigrate other companies or products directly or by implication.

### **11.6 Recalls**

STANZ believes that it is socially responsible for distributors of social tonics to be able to quickly identify where product is in the distribution chain and to be able to recall product without delay when required.

- a) Within six months of implementation of the code of practice or joining STANZ, all members will have established an appropriate product recall system, and
  - lodged copies of the system with the Administrator of this Code, and
  - provided the appropriate regulator [presently being the New Zealand Food Safety Authority] with required contact details.

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<sup>6</sup> Therapeutic Advertising Pre-Vetting Service, a commercial division of the Advertising Standards Association.

### **11.7 *Dispute resolution and consumer complaints***

STANZ acknowledges that from time to time disputes between industry members and between industry members and their consumers occur. When these are resolved to all parties satisfaction the integrity of both the member and the social tonic industry itself can be enhanced.

Conversely, inappropriately managed disputes or complaints can leave parties dissatisfied and bring the industry as a whole in to disrepute. Therefore disputes and consumer complaints will be managed;

- a) By observing the principles of natural justice and procedural fairness, and
- b) in a timely manner, and
- c) in accordance with current STANZ Dispute Resolution and Consumer Complaints policies.

### **11.8 *Adverse event monitoring***

Adverse events can be associated with social tonic use without being caused by social tonic use. For example, someone who is drunk and who uses a social tonic may well have a severe hangover... severe hangovers are common following alcohol use. An 'Event' does not necessarily imply an adverse reaction to a product. It would be unfair to blame the social tonic.

- a) STANZ acknowledges that whilst adverse event reports are to be considered 'suspected adverse reaction' until proven otherwise, sometimes communication of possible risk is an important and socially responsible risk management option.
- b) STANZ acknowledges that whilst individual 'suspected' reports in themselves are not evidence of harm, a cluster of similar reports will usually be seen as a "flag" requiring further investigation.
- c) Where concern is expressed regarding safety issues STANZ will liaise with the appropriate regulators to determine how best to establish whether there is actual cause for concern.
- d) Such action may require the undertaking of a risk assessment, and it may be prudent for STANZ and/or the regulator to issue a public statement advising consumers and other stakeholders that there is a concern being investigated, and what precautions they can apply in the meantime.
- e) In risk management terms, this risk communication process is often sufficient to educate people so that they can make informed choices regarding exposure to personal risk.
- f) It may be that STANZ determines that specific education via industry, or product information, temporary advisory/warning statements, or in extreme circumstances, temporary recall of product is warranted.

There is ample evidence, however, of a few stakeholders who take any opportunity to impugn social tonics for political or ideological reasons. Occasionally, this amplifies perceived risks to the point that risk seems real to those who are oblivious to the facts.

STANZ acknowledges that industry can sometimes be slow to respond to real risk and it is not in the social tonic industry's interests for perceived risks to be risk managed as if they were real risks. Therefore, in order to make an objective risk management response in a socially responsible manner, STANZ will ensure that a risk management system is implemented that;

- a) Enables on-line input of adverse event reports,
- b) utilises appropriate expertise to interpret the collected data and reports, and assesses the likelihood of causality,
- c) where risk profiling suggests there is possible cause for concern undertake evidence-based risk analysis,
- d) ensures that risk management responses are timely and proportionate to risk,

- e) provides meaningful and timely reports for both industry and public purposes to ensure that adverse events contribute towards better understanding and management of perceived or real risk,
- f) following review of reported adverse events, anonymised reports may be issued on-line where appropriate to ensure that industry, professionals and consumers learn from experience, and appropriate risk management options are utilised,<sup>7</sup>
- g) makes public specific product or member details if deemed necessary.<sup>8</sup>
- h) is independently moderated to ensure that risk analyses and risk management decisions are evidence-based, risk proportionate and timely.

Members are to;

- a) Maintain an adverse event log containing information prescribed by STANZ from time to time.
- b) report adverse events involving serious harm [normally defined as harm requiring admission to hospital] to the Ministry of Health as soon as practicable after the distributor or STANZ becomes aware of the adverse event,<sup>9</sup> and
- c) report the adverse event to the STANZ approved online adverse event database. [A current Adverse Event form will be available on the Internet as soon as developed and may be used for submitting adverse events electronically or by printed and submitted via fax or post.]

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<sup>7</sup> At the time of implementing the code of practice no such adverse event reporting system exists in New Zealand. STANZ is committed to ensuring that such a system is operational within 12 months of adoption of the code of practice.

<sup>8</sup> Adverse events can sometimes occur due to specific product or manufacturer/distributor deficiencies. It is appropriate that such information is made publicly available; it is unfair that a whole industry would be brought in to disrepute due to the failings of one member.

<sup>9</sup> A visit to the emergency department as a precautionary measure is no evidence of serious harm, nor causality and does not constitute an admission to hospital.