

## “No Medicines are 100% Safe”

This official admission from our ever vigilant Ministry of health was announced in relation to the news from England that Bonjela used for painful gums had been withdrawn from sale due to the fact that it can lead to the development of Reye's syndrome (an often fatal encephalopathy especially of childhood) characterised by fever, vomiting, fatty infiltration of the liver and swelling of the kidney and brain.

### Unnecessary Iatrogenic Deaths

While the Ministry's announcement through the media can be applauded, it does raise the question as to how it is that a high number of scientifically developed, scientifically tested, scientifically approved and scientifically prescribed pharmaceutical medicines result in a high incidence of illness hospitalisation and iatrogenic (medical drug) deaths in New Zealand. Twelve to fourteen percent of hospital admissions are directly attributable to adverse reactions to pharmaceutical medicines. Alarming this figure is higher than hospital admissions from traffic accidents and illegal street drugs consumption combined.

Even though this high incidence of iatrogenic deaths was uncovered by a researcher investigating hidden Ministry of Health statistics in 2002 and subsequently presented to the Parliamentary Select Health Committee as well as the Ministry of Health, it appears that no action has been taken by the Ministry to rectify this situation and appallingly no action has been undertaken by any member of parliament.

The problem of these unnecessary and premature deaths starts at the pharmaceutical manufacturing level involving research, clinical trials and production and can be further compounded by prescribing errors plus the total reluctance of Ministry of Health bureaucrats to reverse a decision once a medicine has been accepted and registered. It requires an enormous amount of pressure and a high number of hospitalisations and deaths before a medicine is eventually withdrawn. The Ministry's position seems to be that the system that is in place leading up to registration of a medicine is perfect and infallible and that bureaucrats can never be seen to or admit to making an error in the first instance.

### Adverse Reaction Reporting

At the end of this corruptible chain the Ministry is responsible for overseeing the system and that it is supposedly monitoring registered medicines in the market place through “Adverse Reaction Reporting”.

Adverse Reaction Reporting is designed to gather statistical information on all medicines that are not up to standard *after* they have been released into the market place. This reporting procedure is supposed to be the “*safety valve*” for the whole operation, but the unnecessary number of deaths clearly indicates that the system is failing abysmally in its fiducial responsibility to protect public health.

Unfortunately there appears to be a high number of fraudulent practices at this level due in part to the enormous costs and expenditure of time in compliance relating to registration plus the lucrative potential of enormous excessive profits. The number of manufacturers who have faced extremely high fines for corrupt practice continues to grow annually and tighter controls are needed at these levels rather than the new and dubious fast track procedures that have been implemented overseas.

However having stated the obvious, possibly the most important area to protect public health is not only in tighter controls but also in strengthening the “safety valve” by making of adverse reaction reporting mandatory with input not only from medical prescribers but also from members of the public, with heavy fines for those practitioners that do not report Adverse Reactions.

The above procedure could go a long way to reducing unnecessary illness, hospitalisation and deaths if implemented in full and appropriately enforced.

### Risk Benefit Analysis

But wait! There is another important part to this pharmaceutical medicines regulations puzzle and that is the reliance on Risk Benefit Analysis in its present form. The use by the Ministry of Risk Benefit Analysis appears to place all the risk of illness, hospitalisation and unnecessary death on the patient and all the benefits to the pharmaceutical manufacturer and the medical prescriber.

### Overhaul Drastically Required

This overly one-sided arrangement needs a drastic overhaul. Independent researchers reporting to the Ministry are predominantly shrugged off with the statement that the risk benefit of the medicine is in the normal range. What is virtually stated here is that illness, hospitalisation and unnecessary death is normal. While such an eventuality may be normal to the pharmaceutical/medical and bureaucratic Ministry of Health administrators it most certainly is not normal to the victim, the victims’ family or loved ones.

Of all the suggestions outlined above the correction of risk benefit parameters in favour of the patient is possibly the most important starting point for health and wellness outcomes in relation to the use of pharmaceutical medicines.

I look forward to any suggestions that our readers have in relation to the above.

All Quiet on the Western Front

Anzac Day brings to mind the statement from World War II, "All Quiet on the Western Front." This phrase was used to indicate that at that particular time there was no hostile action on the Western Front.

At the present time all appears to be quiet on the political and persecution-prosecution front as far as Natural HealthCare Practitioners are concerned.

However we need to be constantly aware and past experience has repeatedly demonstrated that this is only the calm before the storm.

The current economic downturn has resulted in a drastic reduction in the number of government employed administrators. These reductions could result in increased actions to show that those who control health and advertising step up their accountability to prove to government that their continued tenure has affinity with what they perceive to be health and safety.

#### Lest We Forget

Our members must remember that any wording in their website or advertising can be construed to be a claim which could be open to prosecution. Therefore all members should review their advertising and past Charter newsletters to become familiar with those words that, in the past, have been taken to constitute a claim. As more words and phrases are added to these lists we will inform members accordingly.

#### An Important Reminder

All of our members have contractual obligations to the Charter and under our insurance policy must inform the Charter Office of any and all enquires from all government agencies– especially Medsafe, the Health and Disability Commission, any advertising authority and importantly any contact relating to the Fair Trading Act and/or the Commerce Commission, regardless as to how innocuous and innocent they may appear to be. Never respond to such enquires – report the incident to our office immediately!!!! An appropriate Charter representative will contact you with regard to the procedure to be undertaken.

The following have been extracted from the Fair Trading Act with our own emphasis added:

Full information on the Act can be obtained at

<http://www.consumeraffairs.govt.nz/businessinfo/fta.html>

The Act applies to a wide range of activities. Its primary focus is on anyone in trade. It applies to all aspects of the promotion and sale of goods and services – from advertising and pricing to sales techniques and financing. The Act also applies to certain activities whether or not the parties are ‘in trade’. In most cases it is not relevant whether a business intends to deceive or mislead, the issue is whether its conduct is liable or likely to deceive or mislead. Equally, someone does not need to have suffered or been directly affected by the behaviour of a business for a claim that there has been a breach of the Act.

Both businesses and individuals can be prosecuted for breaching the Act. When the Act is breached by a staff member, the company they work for can be held liable. The managers or directors, or anyone else, cannot simply say ‘staff acted without permission’, even if that statement is true.

Likewise, where a business acts unlawfully, its directors, managers, agents and employees, as well as anyone else involved in the offending conduct – such as wholesalers or retailers – can all be held liable.

A business making claims about products it supplies must remember that its audience will include those who may be gullible, of less than average intelligence or poorly educated. Some people, by reason of age, language difficulties or lack of education, can be more easily misled than others.

## The Fair Trading Act

This Act prohibits people in trade from engaging in misleading or deceptive conduct generally;

prohibits certain types of false or misleading representations about employment;

prohibits certain types of false or misleading representations about goods or services;

prohibits certain unfair trading practices; and

provides for consumer information and product safety standards regulations and unsafe goods notices.

## Definition of Fair Trading Act Terms

There are a number of terms used in the Fair Trading Act, and throughout this publication, which have been defined by both the Act and case law to have certain meanings, as discussed below:

**Deceive**

This means 'to cause to believe what is false, to mislead as to a matter of fact, to lead into error; to delude, take in'.

**False**

This means 'contrary to fact' and has been defined judicially to mean 'incorrect'. Making a false representation is likely to breach the Act even if a business incorrectly believed the representation to be true.

**In trade**

This term has a broad meaning, and covers all commercial activities. Few undertakings, except 'one-off' private transactions, escape the jurisdiction of the Act.

**Mislead**

This means 'to lead astray in action or conduct; to lead into error; to cause to err'. A representation may be literally true but misleading. For example, 'This product has been tested to the New Zealand Standard' implies the product passed the test. Even if the product was tested, this would be a misleading representation if the product had failed the test.

**False or misleading representations about goods or services****Availability of goods**

The Fair Trading Act requires businesses to supply advertised goods or services at the advertised price for a reasonable (or stated) period and in reasonable (or stated) quantities. Websites also need to be kept up-to-date so that stock that is no longer available is not promoted.

**Claims about qualifications and skills**

Any claims a business makes about qualifications or skills its employees possess must be truthful and accurate. Membership or approval of trade organisations should not be claimed unless that membership has been approved and is current. Claims should not be based on pending applications or part membership.

**Claims about success**

Businesses must not make misleading claims about their own success. Such claims may be designed to convince potential customers of the merits of going to that business for a particular product or service.

If a claim is made about the success of a certain product, service, or a business itself, this claim must be true. It must also be current. Any claims made relating to past success, such as an award won two years ago, must clearly state the date restrictions of that award – a restaurant claiming to be ‘best budget restaurant of the year’ when it was awarded the title five years ago, would breach the Fair Trading Act unless the date restriction was clearly stated.

### Comparative advertising

Promoting goods and services by comparing them to competing products and services is a common and accepted method of advertising. Comparisons can help consumers judge the relative merits of competing products and choose the one which best suits their needs and budgets.

As with all advertising, comparative advertising must not mislead or deceive. The comparisons made must be accurate, and must be of ‘like’ products or services available in the same market.

A business is in the best position to know whether its product can reasonably be compared to a competitor’s. If comparisons are used in advertising, they must tell the full story and not leave out information that is necessary for a true and fair comparison to be made.

### Fine print

With all advertising, the first or overall impression made on a potential customer is very important. People reading, seeing or hearing an advertisement can react to and make decisions based on that first or overall impression. In making that impression, sometimes what is not said is just as important as what is said.

Many advertisements include fine print sections containing details of conditions and qualifications. Fine print should not be used to conceal important information which would be critical to a person’s decision to buy goods or services. Fine print cannot be used to modify, in an unexpected manner, the overall impression given by the ‘big print’ or headline.

If the overall impression given by an advertisement is misleading, it will breach the Fair Trading Act no matter what information is provided in fine print. If there are important qualifying, limiting or unusual conditions on a sale, or on other transactions such as finance agreements, these should be shown in a bold, clear and compelling way in the advertisement which cannot be easily overlooked.

The courts have indicated that they will not take into account the confines of any advertising medium in deciding whether a particular advertisement is misleading. Businesses need to ensure that the main message conveyed in any advertisement –

whether it be in print, on TV or radio, or on a website – is accurate rather than relying on the fine print to correct a misleading impression.

Stating that ‘Special Conditions Apply’ will not protect a business when the conditions are unusual, inconsistent with, or modify, in an unexpected manner, the main message. Fine print can elaborate on the main selling message, but not contradict it.

### Image advertising

Image advertising is the use of appealing images to influence how consumers view products on the basis that people will buy a product because they associate it with a memorable, appealing image.

A business may seek to convey an image of being environmentally friendly by using scenery in advertising, or designs featuring dolphins or plants, or may use a well-known personality, with appropriate associations, to promote its product and strengthen its image.

If a representation has been made, it may be in breach of the Fair Trading Act if it is found to create an impression which cannot be substantiated.

Advertising should not be used to create an image for a product or service which cannot be backed up by the facts. The image must be accurate. However, the Act does not prohibit ‘puffery’ – exaggerations which are so obvious that they are unlikely to mislead anyone.

### Internet advertising and transactions

The Fair Trading Act applies to representations and transactions made electronically, including those made over the internet.

All companies incorporated in New Zealand or which carry on a business in New Zealand are subject to the Act. This applies whether they are dealing with local customers, or trading with customers overseas, or whether the website is overseas. Businesses should take care to ensure all representations made online are accurate and do not mislead potential customers.

Because websites can be accessed by consumers anywhere in the world, it is important that local businesses that trade internationally through their websites are aware that laws in other jurisdictions may also apply to them. Whether a business will also be subject to legislation in other countries will depend on the laws in those countries.

The Commission has well-established relationships with its international counterparts to tackle consumer problems connected with cross-border transactions in both goods and services.

### **Puffery**

The Fair Trading Act does not prohibit 'puffery' – exaggerations which are so obvious that they are unlikely to mislead anyone. Humorous and imaginative advertisements often use this technique. Often no objective test can be used to determine their truth or otherwise, or the statements are obvious exaggerations.

Businesses should be careful when using exaggerated statements. Representations and claims that appear to relate to facts rather than opinion, particularly regarding quality and price, such as that a product is 'the fastest' or 'the most economical' will breach the Act if they are not accurate. The more factual or seemingly factual (and therefore the more capable of being proved or disproved) a claim is, the more likely it is to be a representation which, if misleading or deceptive, could breach the Act.

Businesses should also bear in mind the sophistication or otherwise of the potential audience when making exaggerated claims which seem to be obvious puffery.

It is important that any representations made do not mislead consumers as to the nature, extent or standard of any test or survey.

### **Words with special meanings**

Businesses should avoid using jargon or 'trade terms' with special meanings without adequate explanation if the average consumer is unlikely to be familiar with them.

Businesses must also ensure that technical words are easily understood and not used in a false or misleading way.

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Reading the above one is struck by the fact that it all appears so simple and innocuous. In reality prosecutions under this act are very complex.

### **A Reasonable Person**

A reasonable person of average intelligence could view your advertisement and find it perfectly acceptable – but investigators are not reasonable persons. They attribute deceitful interpretations on the most innocent of statements. I recently sat through a prosecution where the learned Judge in effect stated that as no one had purchased the



product advertised that the public had been too sophisticated to be taken in. However he did support the charges against the defendant and the local paper proudly proclaimed that the defendants were guilty of fraud.

When our members are under investigation we need to remember that we are not dealing with reasonable people we are dealing with people that will misconstrue the most simple of statements in order to win a conviction.

For this reason alone our members need to critically examine all their advertising from every angle possible so as to minimize the possibility of an investigation and a prosecution.

As I said earlier it has been a very quiet month it is now over to our members to ensure that the coming months be equally quiet – legally speaking not economically.

Without Prejudice

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