



Australian Government
**Australian Communications
and Media Authority**

Investigation Report No. 1524

File no.	2005/0736
Licensee	Channel Seven Sydney Pty Ltd
Station	ATN
Type of service	Commercial Television
Name of program	<i>Today Tonight</i>
Date/s of broadcast	15 November 2004
Relevant legislation/code	Clauses 4.3.1, 4.3.2 and 7.9 of the Commercial Television Industry Code of Practice 2004

Investigation conclusion

The delegate finds that the licensee of ATN, Channel Seven Sydney Pty Ltd, in relation to the broadcast of *Today Tonight* on 15 November 2004:

- breached clause 4.3.1 of the Commercial Television Industry Code of Practice 2004 in relation to the accuracy of the reporter's statement that most doctors know nothing about the link between memory loss and statins
- breached clause 7.9 of the code by failing to provide a substantive written response to the complainant and
- did not breach clause 4.3.2 of the code in that it did not present material in a manner that created public panic.

The complaint

On 29 March 2005, the Australian Broadcasting Authority received a complaint from Pfizer Australia Pty Ltd regarding a segment broadcast by Channel Seven Sydney Pty Ltd (the licensee) on the *Today Tonight* program on 15 November 2004. The segment concerned a link between a cholesterol-lowering drug Lipitor, which is manufactured by Pfizer, and memory loss. From 1 July 2005, ACMA continued the investigation in accordance with clause 11 of Schedule 4 to the *Australian Communications and Media Authority (Consequential and Transitional Provisions) Act 2005*.

The complainant alleged that the licensee breached:

- clause 4.3.1 of the Commercial Television Industry Code of Practice 2004 (the code) by failing to present factual material accurately
- clause 4.3.2 of the code by presenting material in a manner that created public panic and
- clause 7.9 of the code by failing to provide a response to the complaint.

The program

The segment was introduced by the host, Naomi Robson, as follows:

But first, Australia's biggest selling drugs have been linked to memory loss. The hidden dangers have been exposed by NASA's top doctor who's linked the drug to amnesia and, as Dr John D'Arcy reports exclusively, millions of Australians are at risk.

The segment featured interviews with two men (Dr G and DS) who had suffered short-term memory loss as a result of taking the cholesterol-lowering drug Lipitor. One of the interviewees was a doctor at NASA, Dr G, who wrote a book about the connection between Lipitor and amnesia. The segment also included interviews with the wife of DS, a cardiologist and a cholesterol expert from the National Heart Foundation.

Assessment

The assessment is based on submissions from the complainant and the licensee and a copy of the relevant broadcast.

Issue 1: **Whether the licensee presented factual material accurately**

Clause 4.3.1 of the code states:

News and Current Affairs Programs

4.3 In broadcasting news and current affairs programs, licensees:

4.3.1 must present factual material accurately and represent viewpoints fairly, having regard to the circumstances at the time of preparing and broadcasting the program;

Complainant's submissions

The complainant submitted that:

- the reporter failed to convey the message that reports of memory changes associated with statin treatment (i.e. cholesterol-lowering medicines) occur very rarely
- the story failed to mention that medical evidence suggests that statins represent one of the most important classes of drugs for the prevention of cardiovascular events and that there is minimal medical evidence that links Lipitor to memory impairment
- the reporter failed to use a statement provided by Pfizer in its entirety, despite Pfizer's request to do so
- the reporter failed to mention that amnesia is listed in the Therapeutic Goods Administration (TGA) approved Lipitor Product Information. As amnesia is such a rare side effect, it is not required to be referred to in the Consumer Medication Information (CMI) leaflet approved for Lipitor
- the reporter failed to note that pharmacists have a professional duty of care to provide patients with information
- it was misleading to state that Dr G had 'exposed' the link between Lipitor and memory loss, which inferred that there had been a recent study or scientific evidence to support the licensee's claims and
- the story unfairly focused on Pfizer's drug Lipitor, despite the fact that memory loss is a rare condition associated with all statins.

Licensee's submissions

The licensee submitted that:

- it does not believe that the segment portrayed memory loss as being common or likely. The segment specifically described the link to memory loss as only 'a possible link' and emphasised that it was rare. It also included a statement from Pfizer that memory loss was very rare
- no information regarding possible memory loss was given at the time the drug was prescribed or purchased
- given that the CMI for Lipitor does not list amnesia as a possible side effect of the drug, the licensee does not understand Pfizer's comment that pharmacists have a duty of care to provide customers with the CMI
- Pfizer's assertion that large numbers of queries were received as a result of the program would appear to support the view that patients, pharmacists and doctors were not aware that memory loss could be caused by statin drugs
- the segment did not suggest that Dr G's experience with Lipitor was recent. Rather, it specifically noted that he ceased taking Lipitor four years ago, and
- the segment did not unduly focus on Lipitor as it specifically mentioned other drugs such as Pravachol and Zocor. The interviewees happen to be taking the particular drug Lipitor.

In response to the preliminary finding in relation to the reporter's statement, the licensee submitted that:

Seven notes Pfizer's submission that doctors 'should' be aware of the side effect of Lipitor and that amnesia is listed in the TGA approved Lipitor Production Information. However, whether doctors 'should' be aware, is different to whether or not doctors 'are' in fact aware.

The reality of medical practice is that many doctors do not have the capacity and time to avail themselves of all possible information in relation to each and every drug they prescribe. In particular, where Product Information is altered after a product has been approved for use in Australia, many doctors will not subsequently review the Product Information and update their knowledge.

...
... the statement that many doctors were unaware of the link was a fair and reasonable comment made by a medical practitioner himself, on the basis of his understanding and experience and the experience of the [couple interviewed].

Finding

The delegate finds that the licensee breached clause 4.3.1 of the code in the *Today Tonight* broadcast on 15 November 2004 in relation to the accuracy of the reporter's statement that most doctors know nothing about the link between memory loss and statins.

Reasons

Omission of factual material

Licensees are not required to include all factual material available to them; however, the omission of factual material that could substantively alter the presentation of the report may be sufficient to constitute a breach. Whether a particular omission has this effect is determined by ACMA on a case-by-case basis.

The rare occurrence of memory loss

Pfizer has submitted that the licensee failed to convey the message that memory loss is very rare. Rather, the story inaccurately suggested that memory loss was a common occurrence with Lipitor and that 'millions of Australians were at risk' of amnesia.

The delegate notes that the reporter indicated that there was only a 'possible link' between Lipitor and memory loss:

REPORTER: ... but we'll reveal what doctors and pharmaceutical companies will never tell you, a possible link to memory loss and amnesia.

The segment also indicated that the condition was rare:

REPORTER: When we approached Pfizer, the manufacturer of Lipitor, they did admit that memory loss is associated with statins but that it is rare and reversible once the medication is stopped...

The delegate is therefore satisfied that the story included references to the fact that memory loss was rare.

Further, the delegate does not consider that the omission of information relating to the importance of statins and the minimal evidence linking Lipitor to memory loss substantively altered the presentation of the report. One of the major purposes of the report was to highlight the lack of available information advising statin-users and

health professionals of the possible side effect of amnesia. The omission of the information identified by Pfizer does not detract from this theme.

Statement provided by Pfizer

Pfizer contended that the reporter failed to use the statement it provided to the licensee in its entirety, despite Pfizer's request to do so. Pfizer provided a copy of this statement to ACMA:

Several studies have indicated that taking a statin may actually reduce dementia risk. Preliminary data from a clinical trial reported last week showed that more Alzheimer's Disease patients had their condition stabilized when Lipitor was added to their treatment, than when placebo was added. Statins however are not indicated for the treatment or prevention of dementia. Reports of memory loss associated with any statin treatment occur very rarely. In the majority of these cases the memory changes were reversible when the medicine was stopped. If patients have any concerns or questions they should speak to their doctor.

Whilst the omission of salient facts can result in inaccuracy, it is not the case here. The delegate is satisfied that the material relating to statins reducing dementia is not essential to the major purpose of the report.

Pharmacists' duty of care

Pfizer submitted that the reporter failed to note that pharmacists have a professional duty of care to provide patients with information. In order to ensure that the most up-to-date CMI is provided to the patient, Pfizer stated that it makes the CMI electronically available to pharmacists who are able to provide the most current version to the patient at the time of dispensing. Pfizer contends that a high percentage of pharmacists have signed a Medicines Information to Consumers agreement, which is a Pharmacy Guild initiative that requires pharmacists to provide the CMI to patients in various situations.

The licensee provided a copy of the CMI for Lipitor to ACMA. Given that it does not include a reference to amnesia as a side effect of using Lipitor, the delegate does not consider that the material relating to pharmacist's duty of care is essential to the story.

Presentation of inaccurate factual material

Listing of Lipitor in TGA's Product Information

Pfizer submitted that the reporter failed to mention that amnesia is listed in the TGA approved Lipitor Product Information. Pfizer has advised that the Product Information is a document that is specifically designed for doctors to refer to. It is made available to doctors through a variety of means, including bi-monthly MIMS publications, MIMS Annuals, Medical Director prescribing software and promotional materials. Pfizer advised that there is no requirement under the *Australian Regulatory Guidelines for Prescription Medicines (June 2004)* that the Product Information be supplied as a package insert in medicines taken orally such as Lipitor.

The segment reported that medical professionals were not aware of the link between Lipitor and memory loss as evidenced by the following statements:

REPORTER: ... but we'll reveal what doctors and pharmaceutical companies will never tell you, a possible link to memory loss and amnesia.
...

REPORTER: ... memory loss is associated with statins but that it is rare and reversible once the medication is stopped. The trouble is, no-one knows of this. When we bought Lipitor there was no information detailing the adverse side effects that was readily available. To make matters worse, *most doctors know nothing about it* [emphasis added].

The delegate has considered whether the licensee presented factual material accurately by making these statements. In light of Pfizer's submissions that doctors should be aware of the side-effects of Lipitor via the Product Information, the delegate considers that the last statement above stating categorically that most doctors know nothing about it, amounts to a breach of clause 4.3.1 of the code in relation to accuracy. The last statement clearly indicates that most doctors are not aware of the link between memory loss and statins, although this information is potentially available to doctors through the Product Information.

In response to the preliminary finding, the licensee submitted that the statement that most doctors were unaware of the link was a fair and reasonable comment made by a medical practitioner on the basis of his understanding and experience and the experience of the [couple interviewed]. It is clear that the reporter's statement was presented as a fact rather than an opinion. On this basis, the accuracy of the statement was assessed in light of the evidence available. Namely, that information about the side-effects of Lipitor is available to doctors. In light of this, the delegate is not persuaded to revise the preliminary finding.

'Exposure' of Lipitor

Pfizer submitted that it was misleading to state that Dr G had 'exposed' the link between Lipitor and memory loss, which inferred that there had been a recent study or scientific evidence to support the licensee's claims. The delegate does not consider that the use of the word 'expose' necessarily leads to the conclusion that a study has been conducted. In the context of the segment, the delegate finds that a reasonable viewer is likely to interpret this word to mean that Dr G had publicised his theory in his book, *Lipitor: Thief of Memory*. ACMA does not consider that the licensee has breached the code in this instance.

Unfair focus on Lipitor

It was also alleged that the story unfairly focused on Pfizer's drug Lipitor, despite the fact that memory loss is associated with all statins. It is noted that the segment clearly refers to other statin drugs:

REPORTER: They're hailed as the wonder drugs that lower cholesterol. Today two million Australians are popping them costing us \$820 million every year making these drugs Australia's top sellers. Names like Lipitor, Pravachol and Zocar...

It is also noted that the segment provided an alternative view to that presented by the interviewees who experienced memory loss. The story included an interview with a cholesterol expert from The National Heart Foundation who stated that:

DR S: I think statins are amongst our most important and best tolerated drugs. They have a very good safety profile and we're very keen for people not to stop for trivial reasons.
...

DR S: Look at your own individual situation, talk to your doctor if you are worried and hopefully you'll be able to continue what we think is a very valuable therapy.

The delegate is satisfied that the segment did not unfairly focus on Lipitor to the exclusion of other statin drugs.

Issue 2: Whether the licensee presented material in a manner that created public panic

Clause 4.3.2 of the code states:

News and Current Affairs Programs

4.3 In broadcasting news and current affairs programs, licensees:

4.3.2 must not present material in a manner that creates public panic;

Complainant's submissions

The complainant submitted that:

- the story caused considerable public panic and unnecessary alarm among patients who stopped taking Lipitor to the detriment of their health. It is of significant concern that the licensee has put the health of Australians at risk by engaging in scare-mongering tactics which can only be seen as socially irresponsible
- Pfizer's Head Office received more than 250 queries from patients, pharmacists and doctors about Lipitor and memory loss over a five day period. There were also numerous additional queries and queries to health professionals across the country
- the day after the broadcast, Pfizer was forced to send a letter to tens of thousands of doctors to alleviate fears that Lipitor was likely to lead to memory loss. The National Prescribing Service was also forced to send a letter to doctors,¹ and
- of particular concern is that a qualified medical doctor reported the story which only served to give medical credibility to the story.

Licensee's submissions

The licensee submitted that the segment:

- specifically included the statement from Pfizer emphasising that memory loss was very rare and reversible once the patient stopped taking the drug
- included comments from Dr S from the National Heart Foundation who stressed:
 - the importance of statin drugs and that they are generally well tolerated and have a good safety profile
 - that people should not stop taking their medication for trivial reasons and
 - the benefits of statin drugs outweighs the chances of memory loss and
- rightly expressed concerns that patients taking statin drugs were not being given any information about the potential for sudden memory loss and that this

¹ A copy of the letter was provided to ACMA.

information was presented in a balanced and reasonable manner and was not unduly alarmist or exaggerated.

Finding

The delegate finds that the licensee did not breach clause 4.3.2 of the code in that it did not present material in a manner that created public panic in the *Today Tonight* broadcast on 15 November 2004.

Reasons

The intention of clause 4.3.2 is to prohibit licensees from presenting material that would cause widespread terror and panic in the general population.

Whilst some of the images may have been distressing to some viewers who used Lipitor, they were not, when viewed in the context of the overall presentation of the program, presented in a manner that would have created public panic. The delegate considers that the information was presented in a serious and considered manner and was not sensationalised in any way. Furthermore, the segment included an alternative viewpoint from a credible source, which balanced the views put forward by the two men who had experienced temporary memory loss.

Issue 3: Whether the licensee provided a substantive written response to the complainant

Clause 7.9 of the code states:

- 7.9 Where a Code complaint is made about material broadcast by a station within thirty days of its broadcast, the licensee must provide a substantive written response

Complainant's submissions

The complainant submitted that it did not receive a response from the licensee to its letter of complaint dated 24 November 2004.

Licensee's submissions

The licensee submitted that:

- it sincerely regrets that Pfizer was not provided with a substantive written response to their complaint
- Pfizer's letter was addressed personally to the Executive Producer of the program who was on leave for a number of weeks and on his return the letter from Pfizer was not amongst his unopened mail
- given that no procedures were in place to keep a record of the mail during his absence, the licensee is unable to confirm whether or not the letter was received by Seven
- as a result of this matter, all news and current affairs have now been issued with an instruction that appropriate and diligent procedures for written correspondence must be put in place prior to taking any leave. In particular, mail is to be opened

and potential code-related complaints are to be identified and immediately passed on to an appropriate staff member for response.

Finding

The delegate finds that the licensee breached clause 7.9 of the code by failing to provide a substantive written response to the complainant.

Reasons

The licensee has conceded that it failed to respond to the letter of complaint. The delegate notes the efforts of the licensee to rectify this failure in future.

Action taken by the licensee

The delegate notes that in relation to the complaints handling breach finding, the licensee has taken the following step:

- as a result of the failure to respond to Pfizer's complaint, all news and current affairs personnel have been issued with an instruction that appropriate and diligent procedures for written correspondence must be put in place prior to taking any leave.

ACMA considers this action addresses the compliance issue raised by the investigation and will continue to monitor the licensee's performance in this regard.

Decision

I, Andree Wright, Executive Manager, Industry Performance and Review Branch, being the appropriate delegated officer of the Australian Communications and Media Authority, determine for the above reasons that the licensee of ATN, Channel Seven Sydney Pty Ltd, in relation to the broadcast of *Today Tonight* on 15 November 2004:

- breached clause 4.3.1 of the Commercial Television Industry Code of Practice 2004 in relation to the accuracy of the reporter's statement that most doctors know nothing about the link between memory loss and statins;
- breached clause 7.9 of the code by failing to provide a substantive written response to the complainant; and
- did not breach clause 4.3.2 of the code in that it did not present material in a manner that created public panic.

Signed: -----
Andree Wright

dated this day of August 2005