

# GENERAL PRACTITIONER v PFIZER

## Lipitor journal advertisement

A general practitioner complained about a Lipitor (atorvastatin) journal advertisement issued by Pfizer. The advertisement showed a photograph of a fireman together with the text 'What's terrifying for them is everyday for me. I need to act quickly but decisions can never be rushed. You don't often get a second chance to rescue someone. For a few minutes, the family inside is more important than my own'. The product logo included the strapline 'My life. Your decision'.

Lipitor was indicated, *inter alia*, as an adjunct to diet for the reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotein B and triglycerides in primary hypercholesterolaemia, heterozygous familial hypercholesterolaemia or combined (mixed) hyperlipidaemia when response to diet and other non pharmacological measures was inadequate. It was also indicated for reducing the risk of cardiovascular events in certain diabetic patients.

The complainant stated that the advertisement had the potential to mislead with regard to Lipitor's role; was it for the acute management of coronary events such as myocardial infarction (MI) or the chronic management of raised cholesterol which aimed to reduce the lifetime risk of developing CHD? The image of a fireman associated with wording such as 'terrifying', 'act quickly', 'You don't often get a second chance to rescue someone' and 'few minutes' suggested that Lipitor was indicated not only for the chronic management of elevated cholesterol but was also for the management of acute cardiovascular events associated with elevated cholesterol. This was clearly not so.

The complainant agreed that 'decisions can never be rushed' but the advertisement implied that the failure to delay prescribing [sic] Lipitor somehow equated to a therapeutic crisis. To promote Lipitor by analogy to the work of the emergency fire rescue services was wholly inappropriate and misleading. Fireman often had to make split second life-or-death decisions often without recourse to second chances. However, in the complainant's experience, the treatment of raised cholesterol was not an acute condition/emergency situation and often offered the opportunity to revise/tailor treatment strategies which were not solely dependent on medicines but also involved dietary and lifestyle changes.

If one accepted the premise that Lipitor treatment was somehow analogous with an emergency rescue scenario where there might only be a 'few minutes' to make the right decision without recourse to a second chance, then one might ask

whether this advertisement invited prescribers to disregard the summary of product characteristics (SPC) which stated that 'Liver function tests should be performed before the initiation of treatment and periodically thereafter'. The SPC highlighted other equally important examples as to why Lipitor could not be considered to be an acute/rescue treatment and required prescribers to take a more thorough and responsible approach to implementing treatment. The advertisement was inconsistent with the licensed indications of Lipitor. It was also alarmist and irresponsible.

The Panel noted Pfizer's submission that the purpose of the advertisement was to position Lipitor as a cholesterol lowering agent for patients at high cardiovascular risk. Whilst the Panel accepted that there was a certain urgency attendant to lowering the cholesterol of such patients it did not accept, as implied by the advertisement, that the degree of urgency was immediate and similar to that faced by a fireman in an emergency. For patients with raised cholesterol levels (other than type 2 diabetics) Lipitor was indicated only when diet or other non-pharmacological measures had failed. The SPC referred to the need to perform liver function tests before the initiation of therapy. Prescribers would often have additional opportunities to tailor treatment ie a 'second chance'. The SPC stated that adjustment of dose should be made at intervals of 4 weeks or more. The Panel considered that the advertisement was misleading as alleged. Breaches of the Code were ruled.

Upon appeal by Pfizer, the Appeal Board noted that despite Pfizer's submission regarding the purpose of the advertisement, there was no reference to high risk patients; it appeared to be relevant to all patients with hypercholesterolaemia.

The Appeal Board considered that the advertisement exaggerated the urgency to prescribe which was incompatible with advice given to prescribers in the Lipitor SPC. For patients with raised cholesterol levels (other than type 2 diabetics) Lipitor was indicated only when diet or other non-pharmacological measures had failed and the SPC also referred to the need to perform liver function tests before the initiation of therapy. The degree of urgency was not similar to that faced by a fireman in an emergency.

The Appeal Board considered that the advertisement was misleading as alleged and upheld the Panel's rulings of breaches of the Code.

The Panel did not accept that the advertisement

**was inconsistent with the Lipitor SPC as alleged. It did not consider that it promoted Lipitor for an unlicensed indication ie that Lipitor was an acute/rescue treatment. No breach of the Code was ruled.**

A general practitioner complained about Lipitor (atorvastatin) journal advertisement (ref LIP2933e) issued by Pfizer Limited. The advertisement showed a photograph of a fireman together with the text 'What's terrifying for them is everyday for me. I need to act quickly but decisions can never be rushed. You don't often get a second chance to rescue someone. For a few minutes, the family inside is more important than my own'. In addition the product logo in the bottom right hand corner included the strapline 'My life. Your decision'.

Lipitor was indicated, *inter alia*, as an adjunct to diet for the reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotein B and triglycerides in primary hypercholesterolaemia, heterozygous familial hypercholesterolaemia or combined (mixed) hyperlipidaemia when response to diet and other non pharmacological measures was inadequate. It was also indicated for reducing the risk of cardiovascular events in diabetic patients with at least one additional risk factor without clinically evident coronary heart disease irrespective of whether cholesterol was raised.

## COMPLAINT

The complainant stated that it was widely recognised that the treatment of elevated cholesterol was an important risk factor in the management coronary heart disease (CHD) and that statins, such as Lipitor, had an important role to play. However, the advertisement had the potential for readers to be misled regarding what this precise role was; was it the acute management of coronary events such as myocardial infarction (MI) or the chronic management of raised cholesterol which aimed to reduce the lifetime risk of developing CHD?. The image of a fireman associated with wording such as 'terrifying', 'act quickly', 'You don't often get a second chance to rescue someone' and 'few minutes' suggested that Lipitor was indicated not only for the chronic management of elevated cholesterol but was also for the management of acute cardiovascular events associated with elevated cholesterol. This was clearly not the case and was not supported by the prescribing information.

Whilst the complainant agreed that 'decisions can never be rushed', he alleged that the advertisement clearly also aimed to create a misleading impression that the failure to delay prescribing [sic] Lipitor somehow equated to a therapeutic crisis. To promote Lipitor by analogy to the work of the emergency fire rescue services was wholly inappropriate and misleading. Yes, fireman often had to make split second life-or-death decisions to rescue individuals or families and often without recourse to second chances. However, in the

complainant's experience, the treatment of raised cholesterol to help reduce the risk of cardiovascular events was not managed as an acute condition/emergency situation and often offered the opportunity to revise/tailor treatment strategies which were not solely dependent on medicines but also involved dietary and lifestyle changes.

The complainant stated that if one accepted the premise that Lipitor treatment was somehow analogous with the emergency rescue scenario depicted in the advertisement, where there might only be a 'few minutes' to make the right decision without recourse to a second chance, then one might reasonably ask whether this advertisement invited prescribers to disregard Section 4.4 of the Lipitor summary of product characteristics (SPC) which stated 'Liver function tests should be performed before the initiation of treatment and periodically thereafter'. Indeed, consideration of the SPC in its entirety clearly highlighted other equally important examples as to why Lipitor could not be considered to be an acute/rescue treatment and required prescribers to take a more thorough and responsible approach to implementing this particular treatment. The advertisement was inconsistent with the licensed indications of Lipitor. It was also alarmist and irresponsible.

When writing to Pfizer, the Authority asked it to respond in relation to Clauses 3.2, 7.2 and 7.10 of the Code.

## RESPONSE

Pfizer noted that in the past, Lipitor advertisements had referred to the reduction in cholesterol in a broad spectrum of patients. In the context of increasing use of generic statins, Pfizer submitted that it was important to position Lipitor as a cholesterol lowering agent for particular patient groups rather than for everyone. The whole essence and concept behind this new advertisement was to position Lipitor as a cholesterol lowering agent for patients at high cardiovascular risk.

Pfizer addressed the complainant's four points as follows:

### **1 There was potential for readers to be misled about the role of Lipitor – Clause 7.2**

Pfizer submitted that the advertisement raised awareness of Lipitor. The analogy (to the work of the emergency fire rescue services) drew a comparison with the decision made by a health professional when considering cholesterol lowering treatment of patients at very high risk of a cardiovascular event. High risk patients with established cardiovascular disease and/or diabetes might benefit from the lipid lowering which Lipitor afforded. Lipitor should always be prescribed as an adjunct to dietary and lifestyle changes. However, in very high risk patients, dietary and lifestyle changes alone would not be adequate measures to lower

cholesterol. The encounter between the prescriber and the high risk patient presented an important opportunity for the initiation of lipid lowering therapy and in some high risk patients there was a role for Lipitor.

## **2 The advertisement was inconsistent with the licensed indication of Lipitor – Clause 3.2**

Pfizer submitted that the advertisement conveyed a very powerful and important message which was in line with the licensed indications of Lipitor. That message was about the importance of decision making when lowering cholesterol in patients at high risk of major cardiovascular events. There was a clearly identified role for Lipitor in reducing cholesterol in a high risk patient. The link between reducing cholesterol and lowering cardiovascular risk was well accepted. For example, the Cholesterol Treatment Trialists' meta-analysis suggested that a 1mmol/L reduction in LDL cholesterol could lead to a 21% reduction in major vascular events and a 12% reduction in all cause mortality (CTT Collaborators 2005).

## **3 The wording in the advertisement was inappropriate – Clause 7.10**

Pfizer submitted that the advertisement represented appropriately the sense of urgency and seriousness surrounding the prescribing decision undertaken by a health professional when treating a high risk patient with elevated cholesterol. The words 'act quickly' and 'few minutes' related to the fact that when faced with such patients, it was incumbent on the prescriber to consider prescribing a statin and that this decision had to be made within the available time of a typical consultation. The phrase 'You don't often get a second chance to rescue someone' suggested that making the decision to reduce cholesterol in high risk patients was something not to be complacent about and that care should be taken in selecting the right statin for each patient. The word 'terrifying' was not used in isolation, but in a sentence, the sentiment of which related back to the analogy of drawing a comparison to decisions made by a health professional when considering cholesterol lowering treatment of patients at very high risk of cardiovascular events.

Finally, although hypercholesterolemia was indeed a chronic condition, Pfizer considered and clinical evidence suggested that once a patient was identified as being at high cardiovascular risk, the decision to prescribe a statin was a serious and urgent one.

## **4 The advertisement invited prescribers to disregard Section 4.4 of the Lipitor SPC which stated 'Liver function tests should be performed before the initiation of treatment and periodically thereafter' – Clause 7.10**

Pfizer submitted that the advertisement did not invite prescribers to disregard Section 4.4 of the Lipitor SPC or their duties as a responsible prescriber. It would be wrong to assume that prescribing decisions which were made quickly, as most were whether managing acute or chronic illness, represented a less thorough and responsible approach on behalf of the prescriber. Pfizer upheld the ability and integrity of the medical profession in being able to consider the risks and benefits of the medicines they prescribed and to monitor treatment appropriately.

In summary, Pfizer submitted that advertising should never mislead or misinform, but argued that it could be creative. Pfizer had used the analogy of a fireman and his decision making in a risky situation to compare this to a prescriber managing a patient with hypercholesterolemia and at high cardiovascular risk. Lipitor might be an appropriate cholesterol lowering treatment in this situation. The fireman did not represent Lipitor. It was therefore not in breach of Clauses 3.2, 7.2 and 7.10.

## **PANEL RULING**

The Panel noted Pfizer's submission about the purpose of the advertisement. Whilst the Panel accepted that there was a certain urgency attendant to lowering the cholesterol of patients at very high risk of a cardiovascular event it did not accept, as implied by the advertisement, that the degree of urgency was immediate and similar to that faced by a fireman in an emergency. For patients with raised cholesterol levels (other than type 2 diabetics) Lipitor was indicated only when diet or other non-pharmacological measures had failed. The SPC referred to the need to perform liver function tests before the initiation of therapy. Health professionals prescribing Lipitor would often have additional opportunities to tailor treatment for example by increasing the dose ie a 'second chance'. The SPC stated that adjustment of dose should be made at intervals of 4 weeks or more. The Panel considered that the advertisement was misleading as alleged. Breaches of Clauses 7.2 and 7.10 were ruled. These rulings were appealed by Pfizer. The Panel did not accept that the advertisement was inconsistent with the Lipitor SPC as alleged. It did not consider that it promoted Lipitor for an unlicensed indication ie that Lipitor was an acute/rescue treatment. No breach of Clause 3.2 was ruled. The complainant did not appeal this ruling.

## **APPEAL BY PFIZER**

Pfizer noted that when taken in its entirety the advertisement stated: 'What's terrifying for them is everyday for me. I need to act quickly but decisions can never be rushed. You don't often get a second chance to rescue someone. For a few minutes, the family inside is more important than my own'. This wording sought to describe the role of the health professional in making decisions to treat patients.

Just as many would consider the role of a fireman was challenging, so would the role of a doctor be considered similarly; just as a fireman had to act quickly, so did a doctor. However, neither rushed a decision; both weighed the risks and benefits of a course of action. The advertisement represented the need for prescribers to decide to prescribe a statin without delay, but not with undue haste.

Pfizer submitted that the Panel's ruling was encouraging in that it accepted that there was a certain urgency attendant to lowering the cholesterol of patients at very high risk of a cardiovascular event. However, the advertisement did not imply an immediate emergency; it conveyed no more than the appropriate degree of urgency present in a doctor-patient consultation when addressing the need for treatment of high cholesterol levels in high risk patients. The advertisement creatively used an analogy (to the work of the emergency fire rescue services) to draw a comparison with the decision making process for a health professional when deciding to prescribe for a patient at high cardiovascular risk.

Pfizer submitted that the advertisement did not invite prescribers to disregard Section 4.4 of the Lipitor SPC or their duties as a responsible prescriber. The SPC stated 'Liver function tests should be performed before the initiation of treatment and periodically thereafter'. This advertisement portrayed the need for prescribers to decide to prescribe a statin without delay. Pfizer believed in the ability and integrity of the medical profession in carrying out the routine liver function tests after making this decision and issuing the statin prescription appropriately after receiving the test results. Therefore the advertisement, by highlighting a degree of urgency associated with the decision to prescribe Lipitor, could not be seen to mislead prescribers into not performing these tests. In addition, the degree of urgency represented in the advertisement had not invited prescribers to ignore diet or other non-pharmacological measures. In patients at very high risk of a cardiovascular event, it was likely that diet and non-pharmacological measures would be inadequate, hence the indication for the initiation of atorvastatin as an adjunct.

Pfizer submitted that a subjective view had been taken of what constituted a 'second chance'. Pfizer disagreed with the interpretation that a 'second chance' referred to the additional opportunities available to tailor Lipitor treatment by increasing the dose. In some patients at high risk of cardiovascular events, the opportunity to initiate Lipitor might not present itself again before the patient suffered a serious cardiovascular event. Hence, prescribers might not have a second chance to treat the high cholesterol levels of some of these very high risk patients and prevent them from having a cardiovascular event.

Finally, Pfizer noted that Lipitor was licensed for the reduction of cholesterol in 1997. Since then, it had

been used widely by primary and secondary care physicians to treat hypercholesterolemia. Thus, from a practical viewpoint, the majority of doctors knew when and in whom Lipitor should be prescribed. It was very unlikely that this advertisement would mislead any prescribers in the UK and suggest any change to the established clinical practices associated with prescribing Lipitor.

In summary, Pfizer reiterated that advertising should never mislead or misinform, but argued that it could be creative in an established, widely used, mature medicine. Pfizer had used the analogy of a fireman and his decision making in a work situation to compare this to a prescriber managing a high risk patient with hypercholesterolemia. Lipitor might be an appropriate cholesterol lowering treatment in this situation.

For all the reasons given above, Pfizer submitted that the advertisement was not in breach of Clauses 7.2 and 7.10.

## COMMENTS FROM THE COMPLAINANT

The complainant considered that Pfizer's argument that the advertisement simply aimed to highlight to doctors that their role was analogous to that of a fireman was not only patronising to both professions but also sought to obfuscate from the main issue which that this advertisement had only one function which was to promote the prescribing of Lipitor.

The complainant alleged that the depiction of a fireman, apparently stressed and in action and the associated wording clearly and deliberately set out to create an impression of 'immediate emergency'. If this was not the intention then why not consider depicting an alternative professional or indeed a fireman obviously shown not to be dealing with a life and death situation...such as giving members of the general public demonstrations on fire prevention and safety? Arguably, the latter was a more relevant situational analogy between doctors and the fire-service, with respect to the managing life-time risks of cardiovascular disease associated with raised cholesterol....but obviously not quite as alarmist or off-licence as Pfizer would prefer!

The complainant alleged that the advertisement did not state that the information was only to be considered with particular respect to patients with high cholesterol levels at very high risk of a cardiovascular event. Pfizer's appeal relied entirely on this qualification. Therefore, in the absence of a similar caveat in the advertisement one could reasonably assume that the claims could be attributed to all hypercholesterolaemic patients, even those with modestly elevated cholesterol levels and relatively low cardiovascular risk profile. The alarmist nature of the advertisement and the intentional focus on acute management of cardiovascular events was clearly not consistent

with the medicine's licensed indications or relevant to all patients with raised cholesterol.

The complainant also considered that, in the absence of any clarification that this advertisement was specific to patients with high cholesterol levels and at very high risk of a cardiovascular event, the wording 'second chance' promoted the message, as intended, that managing raised cholesterol was a therapeutic crisis and one which afforded no additional opportunities to consider treatment response/management and that not prescribing Lipitor was equivalent to signing a patient's death warrant. This wording was applicable to all patients, irrespective of the severity of their cardiovascular risk or degree of hypercholesterolaemia, and most definitely had not referred to missed opportunities to prescribe Lipitor and treat high cholesterol levels of some of these very high risk patients as suggested by Pfizer.

Intended or otherwise, the complainant considered that when taken in its entirety the advertisement clearly sought to communicate that Lipitor was indicated not only for the chronic management of elevated cholesterol but also for the management of acute cardiovascular events associated with hypercholesterolaemia.

Finally, given Pfizer's confidence that the majority of doctors knew when and in whom Lipitor should be prescribed the complainant questioned the need to continue advertising and promoting this medicine to an already well informed audience. This was precisely the cynical argumentation in support of misleading advertising that most healthcare now

came to expect from companies like Pfizer; this not only served to irritate but also bring the industry into disrepute.

## **APPEAL BOARD RULING**

The Appeal Board noted Pfizer's submission that the purpose of the advertisement was to re-position Lipitor as a treatment to lower cholesterol in patients at high cardiovascular risk. There was however no reference in the advertisement to high risk patients; it appeared to be relevant to all patients with hypercholesterolaemia.

The Appeal Board considered that the advertisement exaggerated the urgency to prescribe which was incompatible with advice given to prescribers in the Lipitor SPC. For patients with raised cholesterol levels (other than type 2 diabetics) Lipitor was indicated only when diet or other non-pharmacological measures had failed and the SPC also referred to the need to perform liver function tests before the initiation of therapy. The degree of urgency was not similar to that faced by a fireman in an emergency.

The Appeal Board considered that the advertisement was misleading as alleged and upheld the Panel's rulings of breaches of Clauses 7.2 and 7.10. The appeal was unsuccessful.

<b>Complaint received</b>	<b>31 January 2008</b>
<b>Case completed</b>	<b>15 May 2008</b>

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