

Background to ruling that AstraZeneca insert broke ABPI's Code of Practice

Steven Gray discusses the background to the investigations over an AstraZeneca sponsored insert that was distributed with *The Journal*

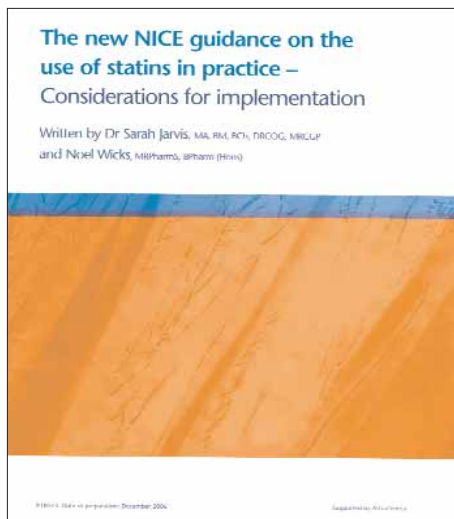
In January and February this year, readers of *The Pharmaceutical Journal* reacted angrily to an educational insert distributed within the same wrapper as *The Journal*. Entitled 'The new NICE guidance on the use of statins in practice — Considerations for implementation', the insert (cover picture, right) was included with the 20 January issue. The NICE guidance referred to in the insert had been published the same month ("Statins for the prevention of cardiovascular events"; Health Technology Appraisal 94).

Readers complained that the insert was, in effect, disguised promotion for AstraZeneca's statin, Crestor (rosuvastatin). The insert was subsequently the focus of a complaint to the Medicines and Healthcare products Regulatory Agency and, last week, the Prescription Medicines Code of Practice Authority, that enforces the the Association of the British Pharmaceutical Industry's code of practice, published the results of its own investigations.

The MHRA ruled that there had been no breach of medicines advertising legislation; the PMCPA found that AstraZeneca's actions had brought the industry into disrepute. So, with hindsight, was the *PJ* right to publish the insert? Did the authors act appropriately in writing it? And should AstraZeneca be castigated for its actions in this episode?

Clearly, mistakes were made, but was there really any deliberate intent to mislead? The risk now is that any material that has sponsorship from a pharmaceutical company is treated with suspicion and that sponsorship from the industry is shunned. It is therefore worth moving past the inevitable headline reactions and investigating some of the detail of the investigations — particularly those of the PMCPA because they transparently publish the representations of all parties involved in their investigations.

In March, the MHRA published the results of its investigation and ruled that the insert was not a breach of the medicines advertising Regulations because, in its opinion, editorial control rested with the two authors and the insert was therefore not considered to be an advertisement. The MHRA noted, however, that it was aware of the ongoing PMCPA investigation. Additionally, the MHRA declared publicly that it



had subsequently provided advice to *The Pharmaceutical Journal*, and to the authors, on the need to include relevant declarations of interest and also to bear in mind the need for relevant safety precautions when medicines are discussed.

The PMCPA investigation was not published until the end of August; the PMCPA found that AstraZeneca breached seven clauses of the ABPI Code of Practice as a result of this insert, including "failing to maintain high standards" and "bringing the industry into disrepute".

The PMCPA investigated the complaints in five letters published in *The Journal* about the insert. The key aspect the PMCPA had to consider was the degree of AstraZeneca's involvement. If AstraZeneca was deemed to have been influential in the placing of the insert or its content, then the insert was subject to the full weight of the code. If not, then the content would be deemed to be entirely appropriate because it is perfectly acceptable under the code for companies to provide financial sponsorship to support the development of independent educational material.

There are several key factors that determine whether material is independent and merely "sponsored" by a pharmaceutical company or whether the material is "promotional" in nature. These factors include:

- The existence (or lack) of a formal agreement between the authors and the company stating that the arrangement is one of arm's-length support.
- Whether the company initiated the project or responded to a request for help
- Whether the company or the third party selects the authors

- Whether the company supplies any content and under what circumstances
- Whether the company is able to influence the content in anything other than a correction of factual inaccuracies
- How the authors receive payment (it is difficult to claim an arm's-length agreement if a company pays the authors directly)
- Payment of any kind by the company for the placing of the document; this effectively makes it an advertisement and therefore promotional
- Having the final say about whether the material is published certainly implies the company has a promotional interest in it.

In this case, AstraZeneca's own evidence confirmed that none of the required conditions were actually met. They commissioned the insert, they paid the authors, they paid *The Journal* to distribute it, they reviewed the document and they provided information for inclusion (albeit at the request of the authors). Taken together, the circumstances were such that it became impossible for AstraZeneca to argue that the insert was independently produced as far as the Code of Practice was concerned.

This case has resulted in one of the highest number of upheld complaints ever recorded for a single item, 27 in all:

- Three breaches of Clause 2 (for bringing the industry into disrepute)
- Five breaches of Clause 9.1 (for not maintaining high standards)
- Five breaches of Clause 10.1 (for conducting disguised promotion)
- One breach of Clause 7.10 (for failing to encourage the rationale use of a medicine)
- Three breaches of Clause 4.1 (for not including prescribing information in the insert)
- Eight breaches of Clauses 7.2 (for making various misleading claims)
- Two breaches of Clause 7.4 (for making claims that were not capable of substantiation).

Some readers might be puzzled that the same breaches were not consistently applied to all five complaints. This is because of the way the code is applied. Essentially, each complaint is considered individually on the alleged breaches raised by that complainant. Therefore if the complainant does not list a particular allegation it is not considered for that specific case. So, three of the complainants raised issues relating to patient safety

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and the apparent advocating of the 40mg dose of Crestor without reflecting the need for specialist supervision and regular monitoring of patients treated with that dose. This, combined with the encouragement to follow guidelines that were contrary to national policy was stated as the main reason for ruling breaches of Clause 2 in those three complaints. Because the other two complainants did not raise those points the PMCPA did not find enough evidence in those complaints to rule that AstraZeneca brought the industry into disrepute.

A number of the breaches related to the use of the Joint British Societies guidelines. The NICE guidance had declined to comment on treatment targets, however the authors of the insert chose to draw practical conclusions arising from the NICE guidelines in the context of cholesterol targets. Unfortunately, in the few months between the document being written and it being published, the Department of Health's cardiovascular tsar (Professor Roger Boyle) issued national policy targets, which were different from the JBS targets quoted in the article. While the code recognises, and allows for, publishing delays, it was decided that AstraZeneca would have had sufficient time to withdraw the document before publication once the targets were announced.

Some readers might also be confused about why AstraZeneca appealed the original

decisions of the PMCPA. Clearly AstraZeneca would not have welcomed the rulings on Clause 2 and Clause 9.1 in particular and, given the reasoning of the PMCPA that the insert was not independent, it was always likely that AstraZeneca would lose any appeal. Regardless of AstraZeneca's actual reasons, there may be a firm constitutional rationale to the decision.

There is an important element of the ABPI constitution that effectively means that if a company does not appeal a breach of the code, any subsequent complaints about the same matter can be considered again — and can be ruled in breach again. Effectively, without an appeal, if 1,000 pharmacists decided to complain independently in a year's time about this insert, AstraZeneca could have been ruled in breach another 1,000 times. It is also worth pausing to note that all of the breaches ruled arose from a single (albeit fundamental) error on the part of AstraZeneca. The company failed to recognise its involvement in the insert was enough to turn it from being arm's-length sponsorship to one where the document was deemed to be promotional. There has never been any suggestion that AstraZeneca intended to mislead or to risk patient safety in any way.

Nor should we think negatively of the authors; they were commissioned to write an educational insert and they delivered a thoughtful and challenging document, which

in the absence of pharmaceutical sponsorship would possibly have been received very differently.

It is also inappropriate to cast any blame on *The Journal*; while there was a vocal response when the insert was first released, the *PJ* acted in good faith and should not be expected to know the detail of the Code of Practice which governs the pharmaceutical industry — that is a matter for pharmaceutical companies and the PMCPA. Company involvement was, after all, declared prominently on the front cover of the insert. The *PJ* has a remit to deliver challenging and useful content, and it should be complimented for transparently publishing the initial criticism and the outcome of the complaints.

It is important to ensure that in the response to this incident, health care professionals do not risk losing the valuable (and valued) support of the industry. In general, the attitude of the industry towards compliance is not a negative one; since the current code was published at the beginning of 2006, pharmaceutical companies have "self reported" breaches on at least nine occasions. The rulings by the PMCPA were no less forgiving for the fact that the case was raised by self-admission. In any event, the rulings of the PMCPA concerning the statins insert certainly underline that while pharmaceutical marketing may be controversial, it is effectively policed.