

# MEDIA/DIRECTOR v ASTRAZENECA

## Disclosure of patient group involvement

An article in The Financial Times of 20 June claimed that two leading pharmaceutical companies, one of them AstraZeneca, were delaying disclosure of their funding of patient groups. In accordance with established practice the criticism was treated as a complaint under the Code of Practice.

The article stated that the companies were delaying disclosure of patient groups they funded for up to 18 months after the new Code called for publication of the data. The companies were quoted as stating that they believed that they did not have to reveal the list of patient groups they supported until their annual reports were released in Spring 2007.

The Panel noted that the supplementary information to the Code stated, *inter alia*, that:

'Any involvement a pharmaceutical company has with a patient organisation must be declared and transparent. Companies must make public by means of information on their websites or in their annual report a list of all patient organisations to which they provide financial support. This might include sponsoring materials and meetings.'

The two methods of disclosure provided for in the supplementary information were alternatives. A company could disclose the requisite information either on its website or in its annual report. Clearly the timeframe for first disclosure would be different in each case.

If a company disclosed the information on its website it would have to keep the information as up-to-date as possible. That is to say that the website would have to provide up-to-date information at all times. On the other hand, if a company disclosed the information in its annual report it would of necessity be retrospective as each annual report would cover a year ending some time earlier. That was an inevitable consequence of the wording of the supplementary information.

As far as the introduction of the requirement was concerned, the Panel considered that by 1 May 2006, the date when the transitional provisions in the new Code expired, a website providing the information would have to fully disclose all involvements with patient organisations which had been entered into on or after 1 January 2006, when the new Code became operative, or which had been entered into prior to that date but were still ongoing at that time.

If a company had decided to disclose the information in its annual report, the Panel considered that the information would have to appear for the first time in the first annual report which covered any period commencing on 1 January 2006. If a company's annual report was on a calendar year basis, this would be the annual report for 2006 which would be published in 2007. If a company's annual report was not on a calendar year basis it would be its annual report for 2005/2006. As with disclosure on a website, the information to be published in the first instance would be all involvements with patient organisations which had been entered into on or after 1 January 2006, or which had been entered into previously but were still ongoing at that date.

The Panel considered that some companies might initially decide to publish retrospective information about their involvement with patient organisations in their annual report but subsequently decide to publish up-to-date information on their website. It would thus be fundamentally unfair to rule such companies in breach of the Code for publishing data on their websites later than 1 May 2006 but sooner than would have been the case if they had waited for their annual report to be published.

In view of its interpretation of the requirement, the Panel considered that AstraZeneca's actions were not unacceptable. No breach the Code was ruled.

During its consideration of this case the Panel noted that companies were required to comply with both the spirit and the letter of the Code. In that regard, the Panel considered that companies which published retrospective details of their involvement with patient organizations in their annual reports must, nonetheless, be prepared to make available up-to-date information about such activities at any time in response to enquiries.

An article in The Financial Times of 20 June claimed that two leading pharmaceutical companies, one of them AstraZeneca UK Limited, were delaying disclosure of patient groups funded by them. In accordance with established practice the criticisms were treated as a complaint under the Code of Practice.

### COMPLAINT

The article stated that the companies were delaying disclosure of patient groups they funded for up to 18 months after the new Code called for publication of the data. The companies were quoted as stating that they believed that they did not have to reveal the list of patient groups they supported until their annual reports were released in Spring 2007.

When writing to AstraZeneca the Authority asked it to respond in relation to Clause 20.3 of the Code and its supplementary information.

### RESPONSE

AstraZeneca stated that it took corporate governance and compliance with both the letter and the spirit of the Code very seriously and as such had been working since late 2005 to ensure compliance with the 2006 Code.

AstraZeneca explained that an appropriate website design was identified in early 2006 and had been developed subsequently. Care had been taken to ensure listing of appropriate information within the site, within an easy to access format, to ensure compliance with the relevant elements of the Code.

The original planned release date was 1 August.

The website list of patient groups went 'live' on 20 June in response to the article in The Financial Times and consultation with the Authority.

AstraZeneca stated that it operated a number of different business arms within the UK. Its UK marketing company was based in Luton and was responsible for all the sales and marketing activities that took place with respect to UK health professionals. Some of AstraZeneca's global marketing teams were based in Cheshire, as were some of its research and development teams. Across the UK it also had a number of other research and science sites, such as those in Edinburgh, Loughborough and Brixham, and a number of pharmaceutical manufacturing and distribution sites. AstraZeneca's international corporate offices were based in London. All these businesses interacted with their local communities and customers in a wide range of activities.

Since January, as well as identifying its own relevant interactions, the UK marketing company had liaised with the global teams around the implications of the new Code requirements to ensure that it was provided with accurate details on any global activities with UK patient groups.

Early in 2006, the UK marketing company established a process to ensure that it did not make any payments to UK patient groups until a transparency agreement had been signed. This agreement detailed the principles on which the two organisations would work together and included the need to comply with all aspects of the Code. The transparency agreement included consent to publish details on the AstraZeneca website, as it would be inappropriate to list organisations without their permission. Therefore no publications could be made until the transparency agreements had been signed. No financial support was released to any patient group until the agreement was signed. On 23 February 2006 the first transparency agreement was signed.

Three examples of signed transparency agreements were provided and all were available for scrutiny.

The process supporting the transparency agreements had evolved during the early part of 2006 to ensure its effectiveness and robustness and now included a certified template for the agreement; early versions were certified individually. Emails pertaining to the new process were provided as was a copy of the certified template.

As at 3 July, 18 transparency agreements had been signed and the relevant patient groups were now listed at [www.astrazeneca.co.uk/responsibility/patient-groups.asp](http://www.astrazeneca.co.uk/responsibility/patient-groups.asp).

AstraZeneca had a comprehensive sponsorship policy, which was last revised in June 2005. This required all sponsorship applicants (including patient groups) to supply written details of specific projects requiring financial or other support and to sign an undertaking that the project was in keeping with the Code. Two nominated registered signatories, one of whom must be a physician, then approved the details of the project.

All projects over £5,000 (including more complex projects) were also formally reviewed by a sponsorship panel which comprised the legal director, the head of medical specialist care, the company compliance lead, the head of meetings management, the UK marketing company financial controller and an experienced senior physician.

AstraZeneca considered that The Financial Times had misrepresented the company's position with respect to compliance with Clause 20.3. Details of the written interaction with the journalist were provided.

With regards to the allegations made in the articles concerning the timing of the publication of patient group relationships, AstraZeneca stated:

- The supplementary information to Clause 20.3 clearly stated that a company must provide a list of patient groups either within the annual report or on a website. Thus, it could be considered acceptable for pharmaceutical companies to provide a list of those organisations supported in 2006 in their 2006 annual report – which would be published during 2007.
- There was no specific requirement in the Code to publish a list of those organisations historically supported by the company during 2005 or earlier.
- AstraZeneca believed this interpretation was in line with the Authority's own interpretation of the Authority's Constitution and Procedure Paragraph 13.6, which required all *prima facie* cases to be listed on the PMCPA website – this was updated periodically rather than daily (provided was a print out from the website on 27 June) and only listed cases since 1 January 2006).

As requested by the Authority, a full list of patient organisations which had received support from AstraZeneca in 2006 was provided. Currently only the list of names was made public. Copies of the signed transparency agreements would shortly appear on the AstraZeneca website next to the name of the patient group. At this stage AstraZeneca did not publicly declare the details of the specific interactions with each group, however these activities were of course available to the Authority on request.

In summary, as of 1 May 2006, AstraZeneca had not published on a website a list of all patient organisations due to its interpretation of the Code. However, it had undertaken a wide range of activities to ensure proper compliance with the Code in a reasonable and timely fashion, as detailed above. Finally, The Financial Times misrepresented the company's position opposite this issue.

AstraZeneca denied any breach of Clause 20.3 of the Code.

## PANEL RULING

The Panel noted that the supplementary information to Clause 20.3 of the Code stated, *inter alia*, that:

'Any involvement a pharmaceutical company has with a patient organisation must be declared and transparent. Companies must make public by means of information on their websites or in their annual

report a list of all patient organisations to which they provide financial support. This might include sponsoring materials and meetings.'

The two methods of disclosure provided for in the supplementary information to Clause 20.3 were alternatives. That is to say that a company could disclose the requisite information either on its website or in its annual report. Clearly the timeframe for first disclosure would be different in each case.

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As far as the introduction of the requirement was concerned, the Panel considered that by 1 May 2006, the date when the transitional provisions in the new Code expired, a website providing the information would have to fully disclose all involvements with patient organisations which had been entered into on or after 1 January 2006, when the new Code became operative, or which had been entered into prior to that date but were still ongoing at that time.

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The Panel considered that some companies might initially decide to publish retrospective information about their involvement with patient organisations in their annual report but subsequently decide to publish up-to-date information on their website. It would thus be fundamentally unfair to rule such companies in breach of the Code for publishing data on their websites later than 1 May 2006 but sooner than would have been the case if they had waited for their annual report to be published.

In view of its interpretation of the requirement, the Panel considered that AstraZeneca's actions were not unacceptable. No breach of Clause 20.3 was ruled.

During its consideration of this case the Panel noted that companies were required to comply with both the spirit and the letter of the Code. In that regard, the Panel considered that companies which published retrospective details of their involvement with patient organizations in their annual reports must, nonetheless, be prepared to make available up-to-date information about such activities at any time in response to enquiries.

**Proceedings commenced 20 June 2006**

**Case completed**

**22 August 2006**