

# MEDIA/DIRECTOR v NOVARTIS

## Disclosure of patient group involvement

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

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 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 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 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.

In view of its interpretation of the requirement, the Panel considered that Novartis was entitled to defer disclosure until such time as it published an annual report covering from 1 January 2006 on. No breach of 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 Novartis Pharmaceuticals UK Ltd, were delaying disclosure of patient groups funded by them. In accordance with established practice the criticisms were treated as a complaint under the Code.

### COMPLAINT

The article stated that the companies were delaying disclosure of patient groups they funded for up to 18 months after a 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 Novartis the Authority asked it to respond in relation to Clause 20.3 of the Code and its supplementary information.

### RESPONSE

Novartis questioned the Authority’s decision to interpret the Financial Times article as a complaint against the company; it appeared to Novartis that the article was more a criticism of the ABPI and the current lack of clarity around the Code than a specific criticism of any of the companies mentioned. Novartis trusted that this would be taken into consideration in the assessment of its response.

The issue raised by the journalist was about the interpretation of the supplementary information to Clause 20.3 of the 2006 Code that ‘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 wording did not specify that the information had to appear on the company’s web site by 1 May as suggested in the Financial Times article, but implied that companies could choose to include this information in accordance with their publication schedule for their annual reports. As the Authority would be aware, companies’ annual reports were published in the subsequent year to the generation of the financial data. Companies choosing this route to publicise information on their patient organisations interactions as permitted by the Code would only be able to do so annually and retrospectively.

Although the article referred specifically to Novartis and AstraZeneca, Novartis considered that the lack of

clarity around this area of the Code was shared by the industry as a whole. Indeed Novartis noted that this confusion was shared by the ABPI. An article on the PMLive.com web site (provided) in response to the Financial Times article quoted Richard Ley, Head of Media Relations at the ABPI, as stating 'The Code of Practice is very clear in that companies have to make public on their website or in their annual review their involvement with patient groups. However for those companies that choose to reveal this in their annual report alone this could mean April 2007'.

Novartis stated that there had been no intention on its part to delay disclosure of this information; it had always intended to provide a comprehensive listing of the year's interactions in its annual report. Novartis believed that this would better serve the intention of this new requirement of the Code than including incomplete or out of date information on the company's website as suggested by the article in The Financial Times.

It appeared that the Authority's request to Novartis to explain which patient organisations the company supported, and how much support was made public, in Novartis' response to this complaint, implied that its interpretation of the Code had already been ruled as incorrect. This directly conflicted with Richard Ley's statement which had publicly confirmed Novartis' own interpretation of the Code in this context. Novartis noted that providing this information to the complainant would result in the selective disclosure of the company's interactions with patient groups. Novartis preferred not to include this information in the response to this complaint but to await the formal consideration of the case by the Panel and make such information fully public on the company's website if that was the ruling. Novartis hoped that whatever the ruling the Authority made would recognise this shared industry confusion and would publish clear guidance to all companies, including those not contacted for the article in The Financial Times.

Novartis was committed to complying with the Code and it hoped that this information would serve to clarify the company's position in relation to this issue.

#### **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.'

As regards the timing and method of making this information public, the Panel noted that the ABPI was reported as having given its own view on the matter. The interpretation of the Code was for the Authority and it was the practice of the Authority to qualify any guidance it gave. If any doubt existed over the meaning of a requirement, it could be definitively resolved only by the Code of Practice Appeal Board and so far there had been no cases in this area as the requirement was new.

The Panel rejected Novartis' assertion that the Authority's initial letter on the matter implied that Novartis' interpretation of the Code had already been ruled as incorrect. The Panel had not previously considered the matter and had now come to it for the first time.

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 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.

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In view of its interpretation of the requirement, the Panel considered that Novartis was entitled to defer disclosure until such time as it published an annual report covering from 1 January 2006 on. 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**