CASE AUTH/2269/9/09

DIRECTOR v NOVO NORDISK

Breach of undertaking

The Constitution and Procedure was such that when the Director received information from which it appeared that a company might have contravened the Code the company concerned was requested to provide a complete response to the matters of complaint.

From the information received it appeared that Novo Nordisk had continued to use a supplement to The Times contrary to its undertaking given in Case AUTH/2202/1/09. The matter was taken up by the Director as it was the responsibility of the Authority itself to ensure compliance with undertakings.

The matter had come to light as part of preparation for the consideration of the report in Case AUTH/2234/5/09 by the Code of Practice Appeal Board. It was raised with the Director by an independent member of the Appeal Board but played no part whatsoever in the Appeal Board's consideration of the report in that case.

The detailed response from Novo Nordisk is given below.

The Panel noted Novo Nordisk's submission that there was an error in its response of 20 February to the Panel in Case AUTH/2202/1/09. In response to a request for information about the use of the supplement Novo Nordisk had submitted that in addition to its distribution with The Times on 14 November, eighty copies had been distributed by the clinical research group on World Diabetes Day. No copies had been distributed by the sales and marketing teams and there were no plans for further dissemination.

The Panel was now extremely concerned to note that, in addition to the above, the supplement had been put on to the Novo Nordisk UK website on 4 December 2008. This had not been mentioned previously by Novo Nordisk. This was an extremely serious matter; it was of paramount importance that submissions to the Authority were checked for complete accuracy as the effectiveness of self regulation relied upon the integrity of the information provided by pharmaceutical companies. Novo Nordisk had not provided complete information to the Panel.

The Panel noted that in Case AUTH/2202/1/09 it had considered that Novo Nordisk was responsible for the content of the supplement. Novo Nordisk had full editorial control, owned the copyright and was part of the editorial team.

The article at issue, 'Gut protein drug expected to help improve control' recorded an interview with Novo Nordisk's chief science officer. The Panel considered that the inclusion of this article showed that Novo Nordisk had contributed material about liraglutide and so in that regard had been able to influence the content of the supplement in a manner which favoured its interests.

In his interview, Novo Nordisk's chief science officer stated, *inter alia*, that clinical trials of liraglutide had shown that not only did people maintain better control of their blood glucose levels but that it also helped them to lose weight. The Panel considered that patients would read the article and see liraglutide, with its 'single daily injection' and 'better glucose control' as a possible improvement on their current therapy and thus be encouraged to ask their health professional to prescribe it. In this regard the Panel considered it irrelevant that the product was yet unavailable to prescribe. The Panel further considered that the article promoted liraglutide to the public prior to the grant of a marketing authorization. High standards had not been maintained. Breaches of the Code were ruled. Companies should take particular care when producing materials for the public and in this regard the Panel considered that Novo Nordisk had failed to exercise due diligence and thus brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 had been ruled.

Turning to the case now before it, Case AUTH/2269/9/09, the Panel noted that liraglutide (Victoza) was granted a marketing authorization at the end of June 2009. However as the supplement had been ruled in breach of the Code for encouraging patients to ask their health professional to prescribe liraglutide and for advertising a prescription only medicine to the public, these rulings were still relevant. The Panel noted that following the rulings in Case AUTH/2202/1/09 Novo Nordisk removed the flash banner advertising the supplement from its website on 27 March; however an error resulted in the supplement still being available on the website in September 2009. The form of undertaking for Case AUTH/2202/1/09, signed on 9 March 2009, stated that the last time the supplement was distributed was 14 November 2008. This was not so. Novo Nordisk had instructed the communications department to remove the supplement from its website on 3 March 2009. Novo Nordisk then thought that the supplement had been removed from its website on 27 March.

The Panel noted that Novo Nordisk had failed to provide accurate information about the distribution of the supplement in its response to Case

AUTH/2202/1/09 and had failed to provide accurate information about the last date of use of the supplement in its undertaking. The fact that Novo Nordisk thought the supplement was removed from the website on 27 March was too long given the undertaking was dated 9 March 2009. Such a delay was inexcusable. This was compounded by the fact that the supplement had not been removed successfully and that Novo Nordisk had clearly stated that the supplement was last used on 14 November 2008.

Novo Nordisk had failed to comply with its undertaking and thus the Panel ruled a breach of the Code. The Panel considered that high standards had not been maintained and ruled a breach of the Code. The Panel further considered that by not taking sufficient steps to comply with its undertaking, and providing inaccurate information in that undertaking, Novo Nordisk had brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel was extremely concerned about Novo Nordisk's conduct in relation to the Code; the company had twice provided inaccurate information and had not complied with its undertaking given in Case AUTH/2202/1/09. The Panel decided to report the company to the Code of Practice Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

The Appeal Board noted that in its presentation, Novo Nordisk focussed on the three week delay between asking for the supplement to be removed from its website (3 March) and it being removed (27 March) (although it could still be accessed by using the search term liraglutide). In the Appeal Board's view the more serious error was the inaccurate information provided to the Panel about the use of the supplement in its response to the complaint and in its undertaking. Self regulation relied upon full and frank disclosure. With regard to the distribution of the supplement, the Appeal Board noted with concern Novo Nordisk's submission at the consideration of the report, that it did not regard the provision of the supplement via its website as 'distribution' or 'promotion'. Novo Nordisk did not appear to appreciate the utmost seriousness of the situation.

The Appeal Board considered that events at Novo Nordisk regarding the provision of inaccurate information, the delayed withdrawal of the supplement and its continued availability on the website despite the efforts to withdraw it demonstrated poor management practices. The company representatives stated that the standard operating procedure (SOP) for withdrawal of material had not been followed. Responsibility for withdrawal of the supplement had been delegated downwards with an apparent abrogation of responsibility. The undertaking in Case AUTH/2202/1/09 had been signed based on inaccurate information provided by a senior manager. In the Appeal Board's view there appeared to be no inherent sense of personal responsibility for compliance with the Code or a full understanding of what that meant. The Appeal Board considered that responsibility for the company culture in that regard resided with the senior management and was apparently lacking. The Appeal Board also expressed concern about the apparent lack of leadership from the medical department.

The Appeal Board noted Novo Nordisk's apology at the consideration of the report; poor communication within the company had caused some of the problems. A number of new senior managers had been appointed and a compliance team had been formed. The company had initiated a major review of its compliance systems, procedures and training. It had undertaken extensive remedial action and there appeared to be a commitment to improvement. A number of new SOPs would be rolled out in December 2009 with staff training in January 2010. The remaining SOPs would be rolled out in April 2010 with training scheduled for May 2010.

The Appeal Board decided in accordance with Paragraph 11.3 of the Constitution and Procedure to require an audit of Novo Nordisk's procedures in relation to the Code to be carried out by the Authority in March 2010. The Appeal Board would look for reassurance that the audit demonstrated a deeper understanding of the Code and that compliance with it was embedded into the company's culture. The audit required in this case would take place at the same time as the re-audit required in Case AUTH/2234/5/09. On receipt of the audit report the Appeal Board would consider whether further sanctions, including a report to the ABPI Board of Management, were necessary.

The Appeal Board further decided that, given its provision of inaccurate information, Novo Nordisk should be publicly reprimanded.

Upon receipt of the March 2010 audit report the Appeal Board considered that Novo Nordisk's progress was not sufficiently rapid. It still had serious concerns about the company's approach and attitude to the Code. There were still significant problems with certification. Not all the standard operating procedures (SOPs) had been completed and trained out. This was now due to happen at the May sales conference (other than the SOP for medical and educational goods and services).

Overall, the Appeal Board considered that Novo Nordisk still did not appear to appreciate the seriousness of the situation. The Appeal Board considered requiring Novo Nordisk to submit material for pre-vetting as set out in Paragraph 11.3 of the Constitution and Procedure and/or report the company to the ABPI Board of Management. The Appeal Board decided to require another audit in June/July. On receipt of that audit report the Appeal Board would decide whether further

sanctions, such as pre-vetting and/or a report to the ABPI Board, were necessary.

Upon receipt of the July 2010 audit report the Appeal Board was concerned that it had taken some time but considered that significant progress had now been made. This must be maintained. The Appeal Board considered carefully all the options available noting that it had already decided that both cases (Cases AUTH/2234/5/09 and AUTH/2269/9/09) should be the subject of a public reprimand. It decided that no further action was necessary.

COMPLAINT

The Constitution and Procedure was such that when the Director received information from which it appeared that a company might have contravened the Code the company concerned was requested to provide a complete response to the matters of complaint (Paragraph 5.1 of the Constitution and Procedure referred).

From information received it appeared that Novo Nordisk had continued to use a supplement to The Times, contrary to its undertaking given in Case AUTH/2202/1/09. The matter was taken up by the Director as it was the responsibility of the Authority itself to ensure compliance with undertakings. Novo Nordisk was accordingly asked to comment in relation to Clauses 2, 9.1 and 25 of the Code.

The matter had come to light as part of preparation for the consideration of the report in Case AUTH/2234/5/09. It was raised with the Director by an independent member of the Code of Practice Appeal Board but played no part whatsoever in the Appeal Board's consideration of the report in that case.

RESPONSE

Novo Nordisk stated that it seemed the supplement was put onto the company website on 4 December 2008 pursuant to the instructions of a senior manager.

It seemed that there was an error in Novo Nordisk's letter of 20 February 2009 to the PMCPA about Case AUTH/2202/1/09. This letter stated that the supplement was only distributed in The Times, and that the clinical research group distributed 80 copies of it on 14 November 2008 and at that point there were no plans for further dissemination, when in fact it had also been put onto Novo Nordisk's website.

On receipt of the PMCPA ruling on 3 March 2009, the senior manager was instructed to arrange for all copies of the supplement held by Novo Nordisk's external agencies to be destroyed, for the website copy to be deleted and to generally ensure that the supplement was recalled and removed from circulation. Unfortunately due to sickness and holiday absences within the communications department the flash banner advertising the supplement was not removed from the front page of the company's website until 27 March 2009.

As such, Novo Nordisk assumed that the supplement had been successfully removed from circulation on 27 March 2009. The company was therefore surprised and shocked to learn from the PMCPA's letter dated 18 September 2009 that the supplement could still be viewed on Novo Nordisk's website. Immediate action was taken to remedy this situation, and an investigation commenced.

It transpired that although the supplement was removed from the website on 27 March 2009 by deleting the front page flash banner and a copy of the pdf version was deleted via a function on the content manager system 'inactive with attachments', the supplement could still be found in the event of a search. On enquiry with Novo Nordisk's technical IT support function in headquarters, it seemed that the supplement was not permanently removed from the 'back pages' of the website due to it being a pdf document which was manually uploaded to the live server when the page was created.

Novo Nordisk deeply regretted that although the supplement was deleted on 27 March 2009, and the links to it were removed, a technical glitch caused the supplement to re-embed itself into the website on a re-boot, despite being previously deleted. Hence the supplement could still be viewed if 'liraglutide' was used as a search term on the website. Novo Nordisk confirmed that this technical abnormality had been investigated and solved and the supplement could no longer be viewed on the UK website.

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Novo Nordisk enquired whether the complaint had been raised by a competitor company. The Director had informed Novo Nordisk that the matter was raised with her by an independent member of the Appeal Board during preparation for the consideration of the report in Case AUTH/2234/5/09. It had played no part whatsoever in the Appeal Board's consideration of that report. Novo Nordisk was invited to submit any further comment. None was received.

PANEL RULING

The Panel considered that an undertaking was an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in the future. It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted Novo Nordisk's submission that there was an error in its response of 20 February to the Panel in Case AUTH/2202/1/09. In response to a request for information about the use of the supplement Novo Nordisk had submitted that in addition to its distribution with The Times on 14

November, eighty copies had been distributed by the clinical research group on World Diabetes Day. No copies had been distributed by the sales and marketing teams and there were no plans for further dissemination.

The Panel was now extremely concerned to note that, in addition to the above, the supplement was put on to the Novo Nordisk UK website on 4 December 2008; a fact not previously mentioned by Novo Nordisk. The Panel considered that this matter was extremely serious. It was of paramount importance that submissions to the Authority were checked for complete accuracy as the effectiveness of self regulation relied upon the integrity of the information provided by pharmaceutical companies. Novo Nordisk had failed to provide complete information to the Panel.

The Panel noted that in Case AUTH/2202/1/09 it had considered that Novo Nordisk was responsible for the content of the supplement. Novo Nordisk had full editorial control, owned the copyright and was part of the editorial team.

The article at issue, 'Gut protein drug expected to help improve control' recorded an interview with Novo Nordisk's chief science officer. The Panel considered that the inclusion of this article showed that Novo Nordisk had contributed material about liraglutide and so in that regard had been able to influence the content of the supplement in a manner which favoured its interests.

In his interview, Novo Nordisk's chief science officer referred to liraglutide stating that clinical trials of the product had shown that not only did people maintain better control of their blood glucose levels but that it also helped them to lose weight. The article stated that the medicine was currently lodged with the relevant authorities in Europe and the US and, if approved, would be expected to be available from mid 2009. In its consideration of Case AUTH/2202/1/09 the Panel did not accept that the supplement in The Times was an acceptable forum to publish the results of clinical trials as submitted by Novo Nordisk. The Panel considered that patients would read the article and see liraglutide, with its 'single daily injection' and 'better glucose control' as a possible improvement on their current therapy and thus be encouraged to ask their health professional to prescribe it. In this regard the Panel considered it irrelevant that the product was yet unavailable to prescribe. A breach of Clause 22.2 was ruled. The Panel further considered that the article promoted liraglutide to the public. A breach of Clause 22.1 was ruled. Further, the product had, in effect, been promoted prior to the grant of a marketing authorization. A breach of Clause 3.1 was ruled. The Panel considered that high standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel further considered that companies should take particular care when producing materials for the public. The Panel considered that in this regard Novo Nordisk had failed to exercise due diligence and thus brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 had been ruled.

Turning to the case now before it, Case AUTH/2269/9/09, the Panel noted that liraglutide (Victoza) was granted a marketing authorization at the end of June 2009. However as the supplement had been ruled in breach of the Code for encouraging patients to ask their health professional to prescribe liraglutide and for advertising a prescription only medicine to the public, these rulings were still relevant. The Panel noted that following the rulings in Case AUTH/2202/1/09 Novo Nordisk removed the flash banner advertising the supplement from its website on 27 March however an error resulted in the supplement still being available on the website in September 2009. The form of undertaking for Case AUTH/2202/1/09, signed on 9 March 2009, stated that the last time the supplement was distributed was 14 November 2008. This was not so. Novo Nordisk had instructed the communications department to remove the supplement from its website on 3 March 2009. Novo Nordisk then thought that the supplement had been removed from its website on 27 March.

The Panel noted that Novo Nordisk had failed to provide accurate information about the distribution of the supplement to the Panel in its response to Case AUTH/2202/1/09. The company had failed to provide accurate information about the last date of use of the supplement in its undertaking. The fact that Novo Nordisk thought the supplement was removed from the website on 27 March was too long given the undertaking was dated 9 March 2009. Such a delay was inexcusable. This was compounded by the fact that the supplement had not been removed successfully and that Novo Nordisk had clearly stated that the supplement was last used on 14 November 2008.

Novo Nordisk had failed to comply with its undertaking and thus the Panel ruled a breach of Clause 25. The Panel considered that high standards had not been maintained and ruled a breach of Clause 9.1. The Panel further considered that by not taking sufficient steps to comply with its undertaking, and providing inaccurate information in that undertaking, Novo Nordisk had brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel was extremely concerned about Novo Nordisk's conduct in relation to the Code; the company had twice provided inaccurate information and had not complied with its undertaking given in Case AUTH/2202/1/09. The Panel decided to report the company to the Code of Practice Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

APPEAL BOARD CONSIDERATION

The Appeal Board noted that in its presentation, Novo Nordisk focussed on the three week delay

between asking for the supplement to be removed from its website (3 March) and it being removed (27 March) (although it could still be accessed by using the search term liraglutide). In the Appeal Board's view the more serious error was the inaccurate information provided to the Panel about the use of the supplement in its response to the complaint and in its undertaking. Self-regulation relied upon full and frank disclosure. With regard to the distribution of the supplement, the Appeal Board noted with concern Novo Nordisk's submission at the consideration of the report, that it did not regard the provision of the supplement via its website as 'distribution' or 'promotion'. In the Appeal Board's view Novo Nordisk appeared not to appreciate the utmost seriousness of the situation.

The Appeal Board considered that events at Novo Nordisk regarding the provision of inaccurate information, the delayed withdrawal of the supplement and its continued availability on the website despite the efforts to withdraw it demonstrated poor management practices. The company representatives stated that the standard operating procedure (SOP) for withdrawal of material had not been followed. Responsibility for withdrawal of the supplement had been delegated downwards with an apparent abrogation of responsibility. The undertaking in Case AUTH/2202/1/09 had been signed based on inaccurate information provided by a senior manager. In the Appeal Board's view there appeared to be no inherent sense of personal responsibility for compliance with the Code or a full understanding of what that meant. The Appeal Board considered that responsibility for the company culture in that regard resided with the senior management and was apparently lacking. The Appeal Board also expressed concern about the apparent lack of leadership from the medical department.

The Appeal Board noted Novo Nordisk's apology at the consideration of the report; poor communication within the company had caused some of the problems. A number of new senior managers had been appointed and a compliance team had been formed. The company had initiated a major review of its compliance systems, procedures and training. It had undertaken extensive remedial action and there appeared to be a commitment to improvement. A number of new SOPs would be rolled out in December 2009 with staff training in January 2010. The remaining SOPs would be rolled out in April 2010 with training scheduled for May 2010.

The Appeal Board decided in accordance with Paragraph 11.3 of the Constitution and Procedure to require an audit of Novo Nordisk's procedures in relation to the Code to be carried out by the Authority in March 2010. The Appeal Board would look for reassurance that the audit demonstrated a deeper understanding of the Code and that compliance with it was embedded into the company's culture. The audit required in this case would take place at the same time as the re audit required in Case AUTH/2234/5/09. On receipt of the audit report the Appeal Board would consider whether further sanctions, including a report to the ABPI Board of Management, were necessary.

The Appeal Board further decided that, given its provision of inaccurate information, Novo Nordisk should be publicly reprimanded.

FURTHER APPEAL BOARD CONSIDERATION

Upon receipt of the March 2010 audit report the Appeal Board considered that Novo Nordisk's progress was not sufficiently rapid. It still had serious concerns about the company's approach and attitude to the Code. There were still significant problems with certification. Not all the standard operating procedures (SOPs) had been completed and trained out. This was now due to happen at the May sales conference (other than the SOP for medical and educational goods and services).

Overall, the Appeal Board considered that Novo Nordisk still did not appear to appreciate the seriousness of the situation. The Appeal Board considered requiring Novo Nordisk to submit material for pre-vetting as set out in Paragraph 11.3 of the Constitution and Procedure and/or report the company to the ABPI Board of Management. The Appeal Board decided to require another audit in June/July. On receipt of that audit report the Appeal Board would decide whether further sanctions, such as pre-vetting and/or a report to the ABPI Board were necessary.

Upon receipt of the July 2010 audit report the Appeal Board was concerned that it had taken some time but considered that significant progress had now been made. This must be maintained. The Appeal Board considered carefully all the options available noting that it had already decided that both cases (Cases AUTH/2234/5/09 and AUTH/2269/9/09) should be the subject of a public reprimand. It decided that no further action was necessary.

Proceedings commenced	**18 September 2009**
Undertaking received	**5 November 2009**
Appeal Board consideration	**11 November 2009, 21 April, 8 September 2010**
Interim case report published	**26 January 2010**
Case completed	**8 September 2010**