CASE AUTH/2619/7/13

NOVO NORDISK v SANOFI

Breach of undertaking

Novo Nordisk alleged that a Lyxumia (lixisenatide) press release on Sanofi's website, breached the undertaking given by Sanofi in Case AUTH/2604/5/13.

As the complaint concerned an alleged breach of undertaking, it was taken up by the Director as it was the Authority's responsibility to ensure compliance with undertakings.

The detailed response from Sanofi is given below.

The Panel noted that an undertaking was an important document. Companies had to give an undertaking that the material in question and any similar material, if not already discontinued or no longer in use, would cease forthwith and give 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 that Case AUTH/2604/5/13 concerned an advertisement which featured the claims 'Lyxumia leads to even greater costs savings of' and 'Turn to the GLP-1 that minimises costs'. Novo Nordisk had alleged that the claims did not take into account the differences in efficacy and safety between Lyxumia and similar treatments. Sanofi had acknowledged that the claims might imply wider savings beyond the acquisition cost and had committed to amend such claims. However, a press release issued after the completion of inter-company dialogue featured the claim 'Lyxumia is a new, cost-effective option….'. The Panel considered that the term 'cost-effective' clearly implied savings beyond the acquisition cost alone and in that regard inter-company dialogue about the advertisement had been unsuccessful. The Panel had considered that without the benefit of more information, it was not clear that the claims in the advertisement were only based on acquisition costs and not a cost-effectiveness analysis or similar. The Panel considered that the claims were misleading and breaches of the Code were ruled.

In Case AUTH/2604/5/13 when considering the inter-company dialogue, the Panel referred to the press release now at issue in Case AUTH/2619/7/13 noting that it featured the claim 'Lyxumia is a new, cost-effective option'. In Case AUTH/2604/5/13, the Panel disagreed with Sanofi's submission that the press release made no explicit or implicit claim that Lyxumia would achieve 'cost savings' or 'cost minimisation' beyond the cost of the medicine itself. The Panel considered that the term 'cost-effective' clearly implied savings beyond the acquisition cost alone.

The Panel noted Sanofi's submission in Case AUTH/2604/5/13 that it had examined the press release before it was issued to ensure that, as per the company's inter-company commitment, claims, implicit or explicit, for wider savings than the cost of Lyxumia alone were not included.

Turning to the present case, Case AUTH/2619/7/13, the Panel noted that the heading of the press release stated that Lyxumia '… could save the NHS millions offering value and choice'. The first paragraph stated 'costing over 25% less than similar treatments…'. The claim 'Lyxumia is a new, cost-effective option' and 'The price is one that represents real value to both the NHS and Sanofi' appeared in the penultimate and final paragraph respectively. The Panel noted that Sanofi had removed the press release from the press section of its website. The Panel noted Sanofi's detailed account of its review and withdrawal of material which it undertook and completed following resolution of matters during inter-company dialogue and prior to notification of the ruling and provision of the undertaking in Case AUTH/2604/5/13. It appeared that when Sanofi provided its undertaking in Case AUTH/2604/5/13 it did not revisit the decisions it had made when it withdrew material following inter-company dialogue. The Panel was concerned that the press release in question had remained in the press section of the Sanofi website.

The Panel noted that there were differences between the claims at issue in the press release and those previously at issue in the advertisement. However, the Panel considered that neither of the claims at issue cited by Novo Nordisk 'Lyxumia is a new cost effective option' and 'The price is one that represents real value to both the NHS and Sanofi' in the press release made it sufficiently clear that it was based on the acquisition cost of the medicine alone. The term cost-effectiveness implied that indirect costs and efficacy had been taken into account and that was not so. The Panel considered that as the press release did not make it sufficiently clear that the claims in question related solely to the acquisition cost of Lyxumia, they were sufficiently similar to those at issue in Case AUTH/2604/5/13 to be covered by the undertaking in that case. The Panel therefore considered that each claim breached the undertaking previously given and a breach of the Code was ruled. High standards had not been maintained; a further breach of the Code was ruled.

The Panel was concerned that the documents provided to the Authority indicated that only promotional material was examined during the withdrawal of material following successful inter-company dialogue and that Sanofi had not reviewed these initial withdrawal decisions when it provided its undertaking to the Authority. In particular, the

Panel had noted that the press release in question was highlighted in the previous case wherein the similarity of the claims in the press release to those in the advertisement at issue was noted. In these circumstances the Panel was thus very concerned that Sanofi considered that the press release was beyond the scope of the undertaking. The Panel noted that the company's submission in this regard was inconsistent with its submission in Case AUTH/2604/5/13 wherein it stated that it had examined the press release prior to issue to ensure that it adhered to the company's commitment made in inter-company dialogue. The Panel noted its comments above about the importance of compliance with undertakings. The Panel considered that the conduct of Sanofi in this regard had brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

Novo Nordisk Limited alleged that Sanofi had breached its undertaking given in Case AUTH/2604/5/13.

COMPLAINT

Novo Nordisk noted that in Case AUTH/2604/5/13 it had raised concerns about the use of the following claims in a Lyxumia (lixisenatide) advertisement published in the Health Service Journal:

- 'Lyxumia leads to even **greater cost savings** of'
- 'Turn to the GLP-1 that minimises cost'

During inter-company dialogue Sanofi acknowledged that such cost saving comparisons might invite conclusions beyond acquisition cost alone and agreed to amend such claims. However, further to this commitment, Sanofi issued a press release on 1 May 2013, which featured similar claims to those in the advertisement. Novo Nordisk thus considered that inter-company dialogue had failed and it escalated the matter to the PMCPA.

Novo Nordisk stated that in Case AUTH/2604/5/13, the Panel considered that the inclusion of similar cost saving claims in the press release confirmed that inter-company dialogue had failed and that the complaint could proceed. This was confirmed in a letter dated 17 June 2013 which stated:

'The Panel further noted, however, that a press release which was embargoed until 00.01, Wednesday 1 May featured the claim 'Lyxumia is a new cost-effective option…'. The Panel thus disagreed with Sanofi's submission that the press release made no explicit or implicit claim that Lyxumia would achieve 'cost savings' or 'cost minimisation' beyond the cost of the medicine itself.'

Novo Nordisk noted that whilst it had not engaged in inter-company dialogue with Sanofi about the content of the press release *per se*, it contained claims that were similar to those in the Lyxumia advertisement in the Health Service Journal ie:

- 'Lyxumia is a new, cost effective option' (quotation by named health professional)
- 'The price is one that represents real value to both the NHS and Sanofi' (quotation by Sanofi employee)

Novo Nordisk noted that the press release was still accessible on www.sanofi.co.uk several days after Novo Nordisk was notified that Sanofi had accepted the ruling (9 July 2013) in Case AUTH/2604/5/13. Novo Nordisk understood that the undertaking signed by Sanofi requested that Sanofi no longer used the advertisement subject to the complaint, but also that the undertaking applied to any similar materials in circulation.

Novo Nordisk alleged that Sanofi had continued to make available an item which featured similar claims to those that had been deemed misleading by the Panel in Case AUTH/2604/5/13. Novo Nordisk alleged a breach of Clause 25. Given the seriousness of the matter, Novo Nordisk also alleged breaches of Clauses 2 and 9.1.

RESPONSE

Sanofi noted that Case AUTH/2604/5/13 was about a Lyxumia (lixisenatide) advertisement issued by Sanofi and published in the Health Service Journal in March 2013 (ref GBIE.LYX.13.02.11). Prior to that complaint being made to the PMCPA, Sanofi and Novo Nordisk had participated in inter-company dialogue specifically about the advertisement. During the course of that dialogue, Sanofi agreed on 29 April 2013 to withdraw the advertisement, and all similar items. That was achieved through a review of the active Lyxumia materials within the electronic review system, by reviewing the active items on the iPad catalogue system and through direction issued to Sanofi's creative agency. The advertisement which was the subject of the inter-company dialogue was part of a campaign that had come to an end by 29 April; however, as a result of a thorough review, Sanofi identified additional materials containing similar claims to those within the advertisement at issue. The following detailed actions were undertaken as a result:

- Sanofi's creative agency was advised verbally and in writing of the immediate withdrawal of two advertisements (Lyxumia payor advertisement (ref GBIE.LYX.13.02.11) and Lyxumia clinical advertisement (ref GBIE. LYX.13.02.12) (a copy of the email notification with the agency response was provided). The agency was asked to identify the journals to which these items had been submitted as part of Sanofi's advertising schedule and advised that no further submissions be made with these items. Sanofi stated that it had confirmed a new brief for a revised advertisement which did not include the claims concerned.

- A range of 'payor' materials were identified for withdrawal including 'awareness mailers'. These were all head office-led initiatives and the materials were withdrawn with no need to involve the sales force. The items were withdrawn from the electronic review system by the originator, or (as one of the originators was

no longer in the company) via direct request to electronic review system company's staff.

- A leavepiece (ref GBIE.LYX.13.01.14), similar to the advertisement at issue was identified for withdrawal. Following internal discussion, an acceptable timeframe was agreed to withdraw this item. Regardless of the fact that this piece was not the subject to the agreement during inter-company dialogue, a timeframe of two weeks was set. A revised leavepiece was produced (ref GBIE.LYX.13.04.14) which fully met the terms of the inter-company agreement. Given that this involved material in circulation with a sales force, the following detailed actions were taken to ensure the complete withdrawal of the leavepiece and replacement with the revised item:

  - 29 April: A brief for developing the revised leavepiece was provided to the creative agency.
  - 9 May: The sales force was notified that the leavepiece would be withdrawn from use on 13 May, and was briefed on the process for returning the item; members of the sales force were required to return signed declaration forms confirming their actions (signed declarations were subsequently returned and logged).
  - The sales force was provided with a briefing document which explained the changes incorporated in the revised leavepiece (ref GBIE.LYX.13.04.14) (email provided).
  - 9 May: Sanofi distribution centre was advised on the need to quarantine and destroy the original leavepiece (ref GBIE.LYX.13.01.14) (email provided). It was advised of the timeframe for the despatch of the revised leavepiece (ref GBIE.LYX.13.04.14) to the sales force.
  - 12 May: Distribution centre confirmed that the withdrawn items had been quarantined (email provided).
  - 23 May: Distribution centre confirmed that the withdrawn items (including returns from the field) were queued for destruction (email provided).

To manage these actions efficiently, a log of all the resulting unscheduled work was initiated and maintained. This was recorded in an internal web-based workspace ('eRoom') to support transparency across the team that worked on the brand (a copy of the unscheduled work log from the eRoom was provided).

In summary, as a result of inter-company dialogue, Sanofi had removed the advertisement and all similar material, before the case was referred to the Panel, in the same manner and using the same processes as if it had been the subject of an undertaking made to the PMCPA.

Following the Panel's review and notification to Sanofi of its findings in Case AUTH/2604/5/13, Sanofi signed a written undertaking dated 25 June 2013 in which it accepted the decision of the Panel and undertook that 'Use of the advertisement in question and any similar material, if not already discontinued or no longer in use, will cease forthwith'. When Sanofi signed the undertaking, the actions as detailed above had been completed. Furthermore, Sanofi had not issued any further advertisements or similar promotional items containing the claims that were at issue in this case. Sanofi noted that in the current complaint (Case AUTH/2619/7/13) about the alleged breach of undertaking, Novo Nordisk did not submit any evidence that Sanofi had issued or continued to use any advertisement or similar promotional item containing the claims at issue.

Sanofi noted that Novo Nordisk had alleged a breach of undertaking because 'Sanofi has continued to make available an item **which contains similar claims as those which have been deemed misleading …'.**

Sanofi noted that its signed undertaking explicitly referred to 'Use of the advertisement in question and any similar material …'. The undertaking did not refer to any specific claim or claims.

Sanofi acknowledged that the press release (ref GBIE.LYX.13.03.12) was accessible in the press section of its website (www.sanofi.co.uk) when Novo Nordisk stated it was and as demonstrated in its letter by way of a screen shot. Sanofi stated that the press release had been examined and approved within its validated approval system (Zinc) for use as a press release and was issued once (30 April 2013) to health journalists of national and regional newspapers and to pharmaceutical trade press. This was the only occasion and the only purpose for which it was used, but it was subsequently placed in the press section of the Sanofi website. Following the initial use as described above, the press release had only ever been accessible in the press section of the Sanofi website. It was not distributed or available in any other format or medium. In particular, it had never been submitted for publication as an advertisement or been distributed in any promotional medium.

Sanofi considered that a press release, which was examined and used as such in full compliance with the Code, could not be considered to be an advertisement or similar material. An advertisement and similar material would be certified as promotional material in accordance with Clause 14 and would be proactively distributed through a variety of appropriate promotional channels in accordance with the use for which it was certified. By its very nature, a press release was inherently dissimilar to an advertisement and similar promotional material. In that regard, and because the undertaking was not to use the advertisement and any similar materials, Sanofi did not consider that the availability of the press release constituted a breach of the undertaking. The company denied breaches of Clauses 25, 9.1 and 2. However, to demonstrate its commitment to conclude this issue, Sanofi stated that it had removed the press release from its website when it received the complaint about it.

Sanofi noted that it had not engaged in inter-company dialogue with Novo Nordisk on the subject of any press release (as confirmed by Novo Nordisk in its complaint). Sanofi recognised that the content of the press release was referred to in Case

AUTH/2604/5/13; however, it noted that this was in the context of whether that case should proceed and that the final Panel ruling on the claims at issue were explicitly referenced to the advertisement. The first notification Sanofi received about the ongoing availability of the press release was when it was notified of this complaint. Given that the lack of inter-company dialogue on the press release, Sanofi submitted that it would have been more constructive and in keeping with both the spirit and letter of the Code for Novo Nordisk to raise this as a new issue directly with Sanofi as soon as it had identified it, enabling the issue to be resolved through inter-company dialogue without the need for recourse to the PMCPA.

PANEL RULING

The Panel noted that an undertaking was an important document. Companies had to give an undertaking that the material in question and any similar material, if not already discontinued or no longer in use, would cease forthwith and give 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 that the undertaking was not limited to promotional material as inferred by Sanofi; it covered all similar materials irrespective of their promotional status including press releases and such like.

The Panel noted Sanofi's comments about the absence of inter-company dialogue on this matter. The Panel noted that Paragraph 5.3 of the Constitution and Procedure provided that the requirements for inter-company dialogue did not apply where the allegation was that a company had failed to comply with its undertaking and was in breach of Clause 25 of the Code. Novo Nordisk was therefore not required to engage in inter-company dialogue on this matter.

The Panel noted that the previous case, Case AUTH/2604/5/13, concerned an advertisement which, *inter alia*, featured the claims 'Lyxumia leads to even greater costs savings of' and 'Turn to the GLP-1 that minimises costs'. Novo Nordisk had alleged, *inter alia*, that whilst the claims in question were correct when the pack price of Lyxumia was compared to the pack price of similar treatments, this comparison did not take into account the differences in efficacy and safety between Lyxumia and similar treatments. Sanofi had acknowledged that the claims might imply wider savings beyond the acquisition cost and had committed to amend such claims. The Panel had considered that without the benefit of more information, it was not clear that the claims in the advertisement were only based on acquisition costs and not a cost-effectiveness analysis or similar. The claims were considered to be misleading and breaches of Clauses 7.2 and 7.3 were ruled.

In Case AUTH/2604/5/13 when considering the inter-company dialogue, the Panel referred to the press release now at issue in Case AUTH/2619/7/13 noting that it featured the claim 'Lyxumia is a new, cost-effective option'. The press release had been issued after the completion of inter-company dialogue. In Case AUTH/2604/5/13, the Panel disagreed with Sanofi's submission that the press release made no explicit or implicit claim that Lyxumia would achieve 'cost savings' or 'cost minimisation' beyond the cost of the medicine itself. The Panel had considered that the term 'cost-effective' clearly implied savings beyond the acquisition cost alone.

The Panel noted Sanofi's submission in Case AUTH/2604/5/13, that it had examined the press release currently at issue, before it was issued to ensure that as per the company's commitment in inter-company dialogue claims in the advertisement which implied wider savings than the cost of the medicine alone were not used. Further that no explicit nor implicit claim that Lyxumia would achieve cost savings or cost minimisation beyond the cost of the medicine itself was made.

Turning to the present case, Case AUTH/2619/7/13, the Panel noted that the press release was headed 'Lyxumia (lixisenatide) – effective new Type 2 diabetes treatment could save the NHS millions offering value and choice'. The first paragraph stated 'costing over 25% less than similar treatments…'. The claims cited by Novo Nordisk 'Lyxumia is a new, cost-effective option' and 'The price is one that represents real value to both the NHS and Sanofi' appeared in the penultimate and final paragraph respectively. The Panel noted that Sanofi had now removed the press release from the press section of its website. The Panel noted Sanofi's detailed account of its review and withdrawal of material which it undertook and completed pursuant to resolution of matters during inter-company dialogue and prior to notification of the ruling and provision of the undertaking in Case AUTH/2604/5/13. It appeared that Sanofi had not validated the decisions made during its withdrawal process pursuant to inter-company dialogue when providing its undertaking in Case AUTH/2604/5/13 dated 25 June 2013. The Panel was concerned that the press release in question had remained in the press section of the Sanofi website.

The Panel noted that there were differences between the claims at issue in the press release and those previously at issue in the advertisement. However, the Panel considered that neither of the claims at issue cited by Novo Nordisk 'Lyxumia is a new cost effective option' and 'The price is one that represents real value to both the NHS and Sanofi' in the press release made it sufficiently clear that it was based on the acquisition cost of the medicine alone. Indeed, the term cost-effectiveness implied that indirect costs and efficacy had been taken into account and that was not so. The Panel considered that on the basis that the press release did not make it sufficiently clear that the claims in question related solely to the acquisition cost of the medicine, the claims at issue were sufficiently similar to those at issue in Case AUTH/2604/5/13 to be covered by the undertaking in that case. The Panel therefore considered that each claim breached the undertaking previously given. A breach of Clause 25 was ruled. High standards had not been maintained; a breach of Clause 9.1 was ruled.

The Panel was concerned that the documents provided to the Authority indicated that only promotional material was examined during the withdrawal of material pursuant to successful inter-company dialogue. The Panel was also concerned that Sanofi had not reviewed these initial withdrawal decisions when it provided its undertaking to the Authority. In particular, the Panel noted that the press release in question was highlighted in the previous case wherein the similarity of the claims in the press release to those in the advertisement at issue was noted. In these circumstances, the Panel was very concerned that Sanofi considered that the press release was beyond the scope of the undertaking. The Panel noted that the company's submission in this regard was inconsistent with its submission in Case AUTH/2604/5/13 wherein it stated that it had examined the press release prior to issue to ensure that it adhered to the company's commitment made in inter-company dialogue. The Panel noted its comments above about the importance of compliance with undertakings. The Panel considered that the conduct of Sanofi in this regard had brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

Complaint received **22 July 2013**

Case completed **10 September 2013**