NUMBER 88 May 2015

CODE OF PRACTICE REVIEW

PMCPA | Prescription Medicines Code of Practice Authority

The Prescription Medicines Code of Practice Authority was established by The Association of the British Pharmaceutical Industry (ABPI) in 1993 to operate the ABPI Code of Practice for the Pharmaceutical Industry independently of the Association itself.

COMPLAINTS AND NUMBER OF CASES CONSIDERED IN 2014

In 2014 the PMCPA received 51 complaints compared with 80 in 2013. There were 78 complaints in 2012, 84 complaints in 2011, 86 complaints in 2010, 92 complaints in 2009 and 112 in 2008.

There were 49 cases to be considered in 2014, compared with 105 in 2013. The number of cases usually differs from the number of complaints because some complaints involve more than one company and others for a variety of reasons do not become cases at all.

The number of complaints from health professionals in 2014 (18) was more than the number from pharmaceutical companies (both members and non members of the ABPI) (8). In addition there were six complaints from anonymous health professionals. The more complex cases considered by the Authority are generally inter-company complaints which often raise a number of issues.

There was one complaint made by a member of the public and two by employees/ex-employees.

Seven complaints were nominally made by the Director and all arose from voluntary admissions by companies. There were no cases arising from alleged breaches of undertakings.

There were nine anonymous complaints in addition to the six from anonymous health professionals. One was from an anonymous employee and another from an anonymous ex-employee.

The details will be included in the PMCPA 2014 Annual Report which will be published shortly.

YELLOW CARD WEB ADDRESS

Please note that, www.mhra.gov.uk/yellowcard is the correct web address for the reporting of adverse events as stated in Clause 4.10 of the 2015 Code.

PUBLIC REPRIMAND FOR SANOFI

Sanofi has been publicly reprimanded by the Code of Practice Appeal Board for the breadth and scale of its failings to disclose and document its interactions with numerous patient organisations (Case AUTH/2736/9/14).

Sanofi had voluntarily admitted its failings in process and procedure, however, given the time period and the extent to which such failings had gone undetected, the Panel considered that its concerns about the company's procedures warranted consideration by the Appeal Board. The systemic failure with respect to the whole process of working with patient organisations was of grave concern.

The Panel reported Sanofi to the Appeal Board. On consideration of that report in December 2014, the Appeal Board noted that the transparency of a pharmaceutical company's interactions with patient organisations was critical. Whilst interactions with patient organisations was a legitimate activity, the arrangements in place at Sanofi at the relevant time were shambolic and shocking. The Appeal Board was extremely concerned about Sanofi's conduct and it decided to require an audit of its procedures in relation to the Code.

The audit, conducted in March 2015, was combined with the re-audit in Case AUTH/2620/7/13. Upon consideration of that audit report, the Appeal Board noted some concerns with the company's activities which should be addressed as a priority. In addition, it considered that, provided a company-wide focus and responsibility for compliance was maintained, no further action was required.

Full details of Case AUTH/2736/9/14 can be found on page 19 of this issue of the Review.

* REMINDER *

ABPI Unaccredited Examination to end this year.

Clause 16.3 of the Code requires representatives to take an appropriate examination within their first year of employment and pass it within two years. The ABPI has been offering either the unaccredited examination or the more recently introduced accredited examination.

Please note that the unaccredited ABPI examination finishes on 31 December 2015. Staff currently studying for this examination need to pass it by the end of 2015. From 1 January 2016 the ABPI will only offer the accredited examination.

FORWARDING PROMOTIONAL EMAILS

It has come to the Authority's attention that some promotional emails include the statement 'Forward to a colleague' or similar. The Authority is concerned that suggesting to recipients the possibility of forwarding the email to a colleague does not comply with Clause 9.9 and the need to ensure prior permission from the onward recipient before the promotional email is resent. In forwarding the email, original recipients would be acting at the company's direction in that regard and so the company would be responsible under the Code for their action. In the Authority's view, companies should not encourage recipients to forward promotional emails.

Companies are also reminded that permission to receive promotional emails has to be obtained from the recipient of the material; such permission cannot be given, or assumed, by a third party on the recipient's behalf.

COMPARISON OF SELF REGULATION IN SWEDEN AND THE UK

A study based, in part, on data from the PMCPA website, comparing the regulation of the pharmaceutical industry in the UK and Sweden, was published recently (Zetterqvist *et al* 2015). The study included a comparison of the sanctions imposed and number of breaches in each country.

The findings were not shared with the PMCPA in advance. There were some details that were inaccurate, including the nature of sanctions in the UK and the arrangements for pre-vetting of material.

The study was primarily concerned with financial penalties under the codes etc. It did not acknowledge the cost to the company such as preparing new materials and undergoing an audit. The PMCPA role in providing informal guidance and training about the Code was overlooked. Also there was no mention of the requirement in the Code for two senior staff, including either a medical practitioner or a pharmacist, to certify material prior to use.

The PMCPA responded to media and other enquiries by making it clear that if a company brought discredit upon, or reduced confidence in, the industry it would be ruled in breach of Clause 2, and this was a serious matter leading to the PMCPA placing advertisements in the BMJ, The Pharmaceutical Journal and the Nursing Standard to ensure that health professionals, and others, were aware that they could find details of the cases on the PMCPA website.

The additional sanctions in the UK were referred to in the study as 'non-economic'. We made it clear that his is not so, as there are charges for audits. If a company is ruled in breach of Clause 2, or is the subject of a public reprimand, or required to issue a corrective statement, then it has to pay toward the cost of that advertising. These sanctions have an indirect financial impact on companies in addition to the actual charge, as company staff have to spend time dealing with complaints, preparing fresh materials, preparing for an audit etc. This in addition to the administrative charges paid by pharmaceutical companies.

CODE IN CONTEXT

The PMCPA has launched the first 'Code in Context' module. The aim of this toolkit is to help in-house compliance specialists in pharmaceutical companies to run interactive workshops which will increase the value that staff attach to self-regulation and encourage positive engagement with the Code. Companies who sent staff to be trained (over 30 so far) have now received a toolkit and can deliver sessions to their colleagues.

The training session included much lively discussion about who owns the Code and debate about the impact of breaches on the industry, health professionals, the media and ultimately patients. It was received positively and another session has been arranged for June. We are asking for feedback to see what further improvements we can make.

Module 2 is being developed with the involvement of the PMCPA Compliance Network and it will look in more detail at specific challenges facing the industry.

Anyone interested in further detail on the toolkits can contact Elly Button on 0207 747 8884 or ebutton@pmcpa.org.uk.

MHRA ANNUAL MEETING AND REPORT 2014

The Advertising Standards Unit of the Medicines and Healthcare Products Regulatory Agency has published its annual report for 2014 (available from www.gov.uk). The report showed, there was a small increase in inter-company complaints made to the MHRA. There was also an increase in the number of cases upheld in the prescription sector from 4 in 2012 to 10 in 2013 and 12 in 2014. The report states that three of these related to one product area, but otherwise there was no consistent pattern. The MHRA required two corrective statements to be issued following publication of cases dealt with by the PMCPA.

NON MEMBER COMPANIES AND THE MHRA

The MHRA is supportive of self regulation and the annual report referred to the two non member companies which were recently removed from the PMCPA list of non member companies (those that had agreed to comply with the Code and accept the jurisdiction of the PMCPA), Galderma and Pharmacosmos. The MHRA has advised that both companies informed the MHRA that they were following the Code but were not subject to the complaints procedure. The MHRA required Galderma to issue a corrective statement in relation to one of the matters considered by the PMPCA. In addition that company is now required to submit all of its advertising to the MHRA for pre-vetting.

REVIEW OF THE CODE

A review of the Code is ongoing and the next version will be dated 1 January 2016. As part of this work informal guidance on the provision of items by pharmaceutical companies in connection with the sale, purchase and promotion of medicines and the requirement of the current (2015) Code is being agreed and will shortly be published on the PMCPA website.

CODE OF PRACTICE TRAINING

Training seminars on the Code of Practice, run by the Prescription Medicines Code of Practice Authority and open to all comers, are held on a regular basis in central London.

These full day seminars offer lectures on the Code and the procedures under which complaints are considered, discussion of case studies in syndicate groups and the opportunity to put questions to the Code of Practice Authority.

The next Code of Practice seminar dates on which places remain available are:

Friday 16 October 2015
Monday 14 December 2015

Short training sessions on the Code, or full day seminars, can be arranged for individual companies, including advertising and public relations agencies and member and non member companies of the ABPI. Training sessions can be tailored to the requirements of the individual company.

For further information regarding any of the above, please contact Nora Alexander (020 7747 1443 or nalexander@pmcpa.org.uk).

HOW TO CONTACT THE AUTHORITY

Our address is:
Prescription Medicines Code of Practice Authority
7th Floor, Southside, 105 Victoria Street, London
SW1E 6QT

www.pmcpa.org.uk

Telephone:	020 7747 8880
Facsimile:	020 7747 8881

Copies of the Code of Practice for the Pharmaceutical Industry and of this Review can be obtained from Lisa Matthews (020 7747 8885 or lmatthews@pmcpa.org.uk).

Direct lines can be used to contact members of the Authority.

Heather Simmonds:	020 7747 1438
Etta Logan:	020 7747 1405
Jane Landles:	020 7747 1415

The above are available to give informal advice on the application of the Code of Practice.

The PMCPA not the ABPI is the contact point for information on the application of the Code.

CASE AUTH/2620/7/13

NOVO NORDISK/DIRECTOR V SANOFI

Breach of undertaking

Novo Nordisk alleged that a claim for Lyxumia (lixisenatide) in a journal supplement about diabetes management, breached the undertaking given by Sanofi in Case AUTH/2604/5/13.

As the complaint was about an alleged breach of undertaking, it was taken up by the Authority in the name of the Director as the Authority was responsible for ensuring 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 disagreed with Sanofi's submission that the supplement was entirely different from the advertisement previously at issue and the implication that it was thus not covered by the undertaking in Case AUTH/2604/5/13. The undertaking covered all closely similar materials.

The Panel noted that Case AUTH/2604/5/13, concerned an advertisement which, *inter alia*, claimed that 'Lyxumia is the only once-daily GLP-1 receptor agonist licensed for type 2 diabetes mellitus patients not optimally controlled on oral antidiabetic drugs and/or basal insulin'. The claim now at issue, 'Lyxumia is the *only once-daily* GLP-1RA that is licensed for use in combination with basal insulin and/or oral glucose lowering agents', was worded differently and 'only once-daily' was not emboldened.

Lyxumia and Novo Nordisk's product Victoza (liraglutide) were both licensed as adjunctive therapy – to be added to existing antidiabetic therapy to achieve improved glycaemic control. Both medicines could be added to existing oral antidiabetic (OAD) therapy but only Lyxumia was also indicated to be added to an existing treatment regimen which included basal insulin. The Panel considered that the use of 'and/or' in the claim did not make this distinction between the two medicines entirely clear. The claim meant that Lyxumia was the only once-daily GLP-1 RA that was licensed for use in combination with basal insulin alone, in combination with OADs and basal insulin and in combination with OADs. The Panel accepted that, in the round, this claim was true, but considered that the 'and/or' made it unclear as to what 'only' referred to. Whilst the earlier two treatment scenarios were correct in that only Lyxumia could be added to existing basal insulin therapy, the last was not; both Victoza and Lyxumia could given in combination with OAD therapy. The Panel considered that the claim was misleading and ambiguous and sufficiently similar to that at issue in Case AUTH/2604/5/13 to be covered by the previous undertaking. The Panel therefore ruled a breach of the undertaking. High standards had not been maintained and a breach was ruled. These rulings were appealed.

The Panel noted Sanofi's account of its review and withdrawal of material 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 Sanofi had not validated the decisions made during its withdrawal process after providing its undertaking in Case AUTH/2604/5/13 dated 25 June 2013. The Panel was concerned that the supplement in question had appeared in the Nursing Times on 10 July 2013. The copy deadline for the journal to receive the supplement was after Sanofi had signed its undertaking in Case AUTH/2604/5/13 and as such Sanofi could have prevented the supplement from being published.

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. This ruling was appealed.

The Panel noted that this was the second time that Sanofi had breached the undertaking given in Case AUTH/2604/5/13 (Case AUTH/2619/7/13). The Panel was very concerned as it appeared Sanofi had not paid sufficient attention to ensure that its materials were comprehensively reviewed. The Panel considered Sanofi's conduct warranted further consideration and reported the company to the Code of Practice Appeal Board under Paragraph 8.2 of the Constitution and Procedure for it to consider whether further sanctions were necessary.

The Appeal Board noted that the claim at issue in Case AUTH/2604/5/13, 'Lyxumia is the only once-daily GLP-1 receptor agonist licensed for type 2 diabetes mellitus patients not optimally controlled on oral antidiabetic drugs and/or basal insulin' appeared in an advertisement. The claim now at issue 'Lyxumia is the only once-daily GLP-1RA that is licensed for use in combination with basal insulin and/or oral glucose lowering agents' appeared in a promotional supplement in a non-specialist journal. The Appeal Board noted that although the claims were not identical they were very similar; both contained 'and/or' which made the meaning of

'only' unclear. The Appeal Board noted that whilst Lyxumia was the only GLP-1RA that could be added to basal insulin it was not the only GLP-1RA that could be added to existing oral antidiabetic (OAD) therapy and thus the claim was misleading in that regard.

The Appeal Board considered that the claim in the supplement was so similar to that in the advertisement that it was covered by the undertaking given in Case AUTH/2604/5/13 and it upheld the Panel's ruling in that regard. In addition high standards had not been maintained and the Appeal Board upheld the Panel's ruling of a breach. The appeal on both points was unsuccessful.

In failing to comply with its undertaking the Appeal Board considered that Sanofi had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Appeal Board upheld the Panel's ruling of a breach of Clause 2. The appeal on this point was unsuccessful.

The Appeal Board noted that the journal supplement at issue had been certified the day after the undertaking in Case AUTH/2604/5/13 had been signed. Sanofi submitted that it had used the claim at issue in full knowledge of the undertaking and of the Panel's ruling in that case. In the Appeal Board's view, it should have been obvious to Sanofi that the claim in the supplement was so similar as to be almost the same as the claim at issue in Case AUTH/2604/5/13. That the claim was approved for use subsequent to the outcome of Case AUTH/2604/5/13, led the Appeal Board to query the rigour with which Sanofi had examined relevant materials to ensure compliance with its undertaking. After signing the undertaking, Sanofi had had time to cancel publication of the supplement. The Appeal Board noted that this was the second time that Sanofi had breached its undertaking given the Case AUTH/2604/5/13 (Case AUTH/2619/7/13) and so it decided, in accordance with Paragraph 11.3 of the Constitution and Procedure, to require an audit of the company's procedures in relation to the Code. The Appeal Board noted that Sanofi had already embarked on a programme of corrective measures and so it requested that the audit take place in March 2014 when the results of some of those measures should be obvious. In the meantime Sanofi should confirm in writing the measures it had implemented. On receipt of the audit report and Sanofi's comments upon it, the Appeal Board would consider if further sanctions were necessary.

Upon receipt of the March 2014 audit report, the Appeal Board noted a number of serious concerns regarding Sanofi's procedures and materials; the company had begun to address the issues including a change to the structure of company reporting, increasing compliance resource, training and updating its procedures and materials.

The Appeal Board decided that Sanofi should be re-audited in October 2014 at which point it expected to see changes implemented and significant progress made. Upon receipt of the report and Sanofi's comments upon it, the Appeal Board would decide whether further sanctions were necessary.

Upon receipt of the October 2014 audit report the Appeal Board noted that some progress had been made. However, the Appeal Board considered that there was still a lot of work to do and concerns to address. In addition the Appeal Board noted the recent issues raised concerning Sanofi's interaction with patient organisations (Case AUTH/2736/6/14). In relation to the re-audit in Case AUTH/2620/7/13, the Appeal Board decided to require a re-audit of Sanofi in March 2015 at the same time as the audit required in Case AUTH/2736/9/14; it would expect to see the recommendations of the October 2014 audit report implemented and significant progress made. On receipt of the re-audit report and Sanofi's comments upon it, the Appeal Board would consider whether further sanctions were necessary.

On receipt of the March audit report the Appeal Board noted that Sanofi had made progress since the audit in October 2014; a new, senior manager was fully involved and leading many of the company's compliance initiatives.

The Appeal Board however, noted its concern about some of the company's activities and considered that Sanofi should address the matters raised as a priority. On the basis that this work was completed, the progress otherwise shown in the March 2015 audit was continued and a company-wide focus and responsibility for compliance was maintained, the Appeal Board decided that no further action was required.

Novo Nordisk Limited alleged that, with regard to the promotion of Lyxumia (lixisenatide), Sanofi had breached its undertaking given in Case AUTH/2604/5/13. Lyxumia was a glucagon-like peptide-1 (GLP-1) receptor agonist (GLP-1RA) for the management of type 2 diabetes.

As the complaint was about an alleged breach of undertaking, it was taken up by the Authority in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

COMPLAINT

Novo Nordisk noted that in Case AUTH/2604/5/13, the claim 'Lyxumia is the only once-daily GLP-1 receptor agonist licensed for type 2 diabetes mellitus patients not optimally controlled on oral antidiabetic drugs and/or basal insulin' was found to be misleading and ambiguous in breach of Clause 7.2. Novo Nordisk was informed by the PMCPA that Sanofi had signed its undertaking in relation to this matter on 25 June 2013.

Novo Nordisk noted that on 10 July 2013 a supplement entitled 'Lantus (insulin glargine) and the evolution of diabetes management' was published in the Nursing Times. A sentence on the front page of the supplement stated: 'This promotional supplement has been produced by Sanofi'. Page 5 of the supplement included the claim 'Lyxumia is the only once-daily GLP-1RA that is licensed for use in combination with basal insulin and/or oral glucose lowering agents'. This claim was similar to that previously ruled in breach of the Code

(PMCPA letter of 17 June 2013); the Panel stated 'use of "and/or" in the claim did not make the distinction between the two medicines entirely clear'. The Panel also considered that 'use of "and/or" made it unclear as to what "only" referred to'.

Novo Nordisk stated that the Nursing Times had confirmed that the supplement was published 10 July 2013; the copy deadline for the journal to receive the supplement was 1 July 2013. Novo Nordisk submitted that as the copy deadline was nearly a week after the undertaking was signed by Sanofi, it appeared that Sanofi had continued to use the claim at issue despite the Panel's ruling. Novo Nordisk considered that there was sufficient time for Sanofi to have removed the claim from the supplement before the journal's copy deadline (1 July 2013), in light of its undertaking signed on 25 June 2013.

Novo Nordisk alleged that Sanofi had made available an item which featured a similar claim to that deemed misleading by the Panel, and after the signing of its undertaking. Novo Nordisk alleged a breach of Clause 25. Given the seriousness of such a matter, Novo Nordisk also alleged breaches of Clauses 2 and 9.1.

RESPONSE

Sanofi submitted that the Lyxumia advertisement (ref GBIE.LYX.13.02.11) at issue in Case AUTH/2604/5/13 was published in the Health Service Journal in March 2013. Before this complaint was made to the PMCPA, Sanofi and Novo Nordisk had participated in inter-company dialogue about the advertisement and Sanofi had agreed on 29 April 2013 to withdraw the item. This agreement was honoured in a timely fashion through the identification and withdrawal of the item, and all similar items. This was achieved through: a review of active Lyxumia materials within the validated approval system (Zinc), a review of active items on the iPad Catalogue system, and through instructions to the creative agency. The advertisement at issue was part of a campaign that ended by 29 April; however, the review identified additional materials which need to be withdrawn. The following detailed actions were undertaken as a result:

- The agency was advised verbally and in writing of the immediate withdrawal of two advertisements (Lyxumia Payor Advertisement ref GBIELYX.13.02.11 and Lyxumia Clinical Advertisement ref GBIE.LYX.13.02.12). The email notification sent on 29 April with the agency's response was provided. The agency was asked to identify the journals to which these items had been submitted as part of the advertising schedule and advised that no further submissions must be made with these items. A new brief was confirmed for a revised advertisement which did not have 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 without need to involve the sales force. The items were withdrawn from Zinc.
- A leavepiece (ref GBIE.LYX.13.01.13), similar to the advertisement at issue was identified for withdrawal through the review of materials. Following discussion within Sanofi, it was agreed to withdraw within two weeks despite the fact that this piece was not the subject of the inter-company agreement. A revised leavepiece was produced (ref GBIE.LYX.13.04.14) which fully met the terms of the agreement with Novo Nordisk. 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 2013: A brief for developing the revised leavepiece was provided to the agency.
  – 9 May: The sales force was notified that the leavepiece would be withdrawn from use on 13 May and briefed on the process for its return of the item and that each person should return signed declaration forms confirming his/her actions. Signed declarations were subsequently returned and logged.
  – The sales force was provided with a briefing document explaining the changes incorporated in the revised leavepiece (ref GBIELYX.13.04.14).
  – 9 May: Sanofi distribution centre was instructed to quarantine and destroy the original leavepiece (ref GBIE.LYX.13.01.14). It was also 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 quarantine of the withdrawn items.
  – 23 May: Distribution centre confirmed that the withdrawn items (including returns from the field) were queued for destructions.

To manage these actions efficiently, a log of all the resulting unscheduled work was initiated and maintained.

In summary, as a result of the inter-company dialogue Sanofi had removed the advertisement and all similar material, before Case AUTH/2604/5/13 was referred to the Panel in the same manner and using the same process as if it had been the subject of an undertaking to the PMCPA.

The Panel notified Sanofi of the outcome of Case AUTH/2604/5/13 on 17 June 2013. The Panel found that the claims in the advertisement, 'Lyxumia is the only once-daily GLP-1 receptor agonist licensed for type 2 diabetes mellitus patients not optimally controlled on oral antidiabetic drugs and/or basal insulin' and 'Lyxumia leads to even greater cost savings of' and 'Turn to the GLP-1 that minimises costs' were in breach of the Code.

Sanofi singed a written undertaking dated 25 June 2013 to accept the Panel's rulings 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

containing the claims at issue in that case. Sanofi noted that in the complaint now at issue (Case AUTH/2620/7/13) Novo Nordisk did not submit any evidence that Sanofi had issued or persisted to use any advertisement which contained the claims which were the subject of Case AUTH/2604/5/13.

Sanofi noted that Novo Nordisk had stated that Sanofi had breached its undertaking because 'Sanofi had made available an item which featured a similar claim to that deemed misleading by the Panel, and after the signing of its undertaking'.

The item referred to by Novo Nordisk (ref GBIE. DIA.13.05.03; 'Lantus (insulin glargine) and the Evolution of Diabetes Management') was a promotional 6 page supplement (including reference citations) published in the Nursing Times on 10 July 2013. Sanofi confirmed that the copy deadline for the supplement was 28 June 2013. As clearly indicated in its title, the supplement was about treatment with Lantus and most of the content was about Lantus monotherapy. However, the text also referred to other insulins and contained 1½ pages which introduced the paradigm of adding Lyxumia to treatment with Lantus. There was no consideration of Lyxumia, save in this context.

Lyxumia was first mentioned on page 4 of the supplement, which referred to the effects of GLP-1RAs and the benefits of combining 'prandial GLP-1RAs with a basal insulin'. The text stated that Lyxumia was one of 'four main GLP-1RAs available in the UK market'; all such products were listed. The opening paragraph of page 5 explained that 'Addition of Lyxumia to Lantus, the cornerstone of insulin therapy, is a new paradigm that will help your patients achieve glycaemic targets more sympathetically for years to come'. The second paragraph described the efficacy of the combination of Lantus and Lyxumia and stated that 'Lyxumia is also effective in combination with oral glucose lowering agents, or with both basal insulin and oral glucose lowering agents' before concluding 'Lyxumia is the only once-daily GLP-1RA that is licensed for use in combination with basal insulin and/or oral glucose lowering agents'. It was this final statement which Novo Nordisk alleged was similar to a claim considered in Case AUTH/2604/5/13.

Sanofi did not consider that Novo Nordisk's complaint was justified or that the claim at issue represented a breach of the undertaking provided by Sanofi. The wording of the claim now at issue which was not the same as that which was the subject of Case AUTH/2604/5/13 and the type of promotion and the context in which information was provided in the supplement was qualitatively different from the advertisement considered in Case AUTH/2604/5/13.

In Case AUTH/2604/5/13, the claim 'Lyxumia is the only once-daily GLP-1 receptor agonist licensed for type 2 diabetes mellitus patients not optimally controlled on oral antidiabetic drugs and/or basal insulin' was ruled in breach of the Code by the Panel. The reasons given in the case report were that (a) 'by emboldening "only once-daily" there was an implication that Lyxumia was the only once-daily GLP-1 receptor agonist which was not so …'; and (b) while 'the Panel accepted that, in the round, the quoted claim was true', it considered 'the "and/or" made it unclear what "only" referred to' and noted that 'both Victoza and Lyxumia could be given to patients not currently controlled on [oral antidiabetic] therapy'. The claim at issue in this case was 'Lyxumia is the only once-daily GLP-1RA that is licensed for use in combination with basal insulin and/or oral glucose lowering agents'. This claim was not similar to that in Case AUTH/2604/5/13 because:

- There were no emboldening and the clear construction of the text made clear that 'only' related to Lyxumia's authorization particulars, rather than its status as a GLP-1RA. Furthermore, the supplement expressly stated that Lyxumia was one of four main GLP-1RAs on the UK market.

- The use of 'and/or' appeared in a different context in the claim now at issue
  - In Case AUTH/2604/5/13, 'and/or' related to the types of diabetes patients who could receive Lyxumia and the ambiguity arose because some of these patients could also receive Victoza.
  - In this case use of 'and/or' related to the details of the licensed indication for Lyxumia. It was clearly the case that Lyxumia was the only once-daily GLP-1RA that was licensed for use 'in combination with basal insulin and/or oral glucose lowering agents' (the precise wording of the marketing authorization).

- Applying the test suggested by Novo Nordisk in Case AUTH/2604/5/13 and removing the alternative 'and' or 'or', the text remained accurate:
  - Lyxumia was the only once-daily GLP-1RA that was licensed for use in combination with basal insulin or oral glucose lowering agents.
  - Lyxumia was the only once-daily GLP-1RA that was licensed for use in combination with basal insulin and oral glucose lowering agents.

Sanofi submitted that due to the nature, content, context, distribution and focus of the promotional supplement and the claims therein, it was entirely different from the advertisement at issue in Case AUTH/2604/5/13 and the subsequent undertaking not to use that advertisement or similar materials.

The claim now at issue should be considered in the context in which it appeared. The supplement clearly focussed on providing great detail on the use of Lantus, and Lyxumia was referred to in the context of an add-on to treatment with Lantus; the first 3 pages were devoted to information on Lantus and page 4 opened with an introduction to the concept of adding a GLP-1RA to Lantus. There was no suggestion that Lyxumia was the only GLP-1RA; the text stated explicitly that Lyxumia was one of four main products of this type available in the UK.

In summary, Sanofi considered that, taken as a whole, the supplement was not ambiguous or misleading and did not represent a breach of the undertaking provided pursuant to Case AUTH/2604/5/13.

Even if, contrary to Sanofi's position, the claim now at issue was considered in isolation, it was materially different from that which was the subject of Case AUTH/2604/5/13 and simply comprised a direct quotation from the Lyxumia marketing authorization. Sanofi considered that it was entirely appropriate to inform health professionals, quite correctly, that Lyxumia was the only GLP-1RA with that particular licensed indication.

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 disagreed with Sanofi's submission that due to the nature, content, context, distribution and focus of the promotional supplement and the claims therein, it was entirely different from the advertisement at issue in Case AUTH/2604/5/13 and the implication that it was therefore not covered by the subsequent undertaking in that case. The undertaking covered all closely similar materials.

The Panel noted that the previous case, Case AUTH/2604/5/13, concerned an advertisement which, *inter alia*, featured the claim 'Lyxumia is the **only once-daily** GLP-1 receptor agonist licensed for type 2 diabetes mellitus patients not optimally controlled on oral antidiabetic drugs and/or basal insulin'.

Turning to the claim at issue in this case, 'Lyxumia is the only once-daily GLP-1RA that is licensed for use in combination with basal insulin and/or oral glucose lowering agents' the Panel noted that the wording of the claim was different from that of the claim at issue in Case AUTH/2604/5/13 as 'only once-daily' was not emboldened in the claim now at issue.

The Panel noted Sanofi's submission that the claim was a direct quote from the marketing authorization. The Panel had not seen the marketing authorization but noted that the indication in the summary of product characteristics (SPC) was for the treatment of adults with type 2 diabetes mellitus to achieve glycaemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, did not provide adequate glycaemic control. The SPC indication did not state that Lyxumia was the 'only' medicine licensed as such.

The Panel noted that Lyxumia and Victoza were both licensed as adjunctive therapy – to be added to existing antidiabetic therapy to achieve improved glycaemic control. Both medicines could be added to existing oral antidiabetic (OAD) therapy but only Lyxumia was also indicated to be added to an existing treatment regimen which included basal insulin. The Panel considered that the use of 'and/or' in the claim did not make this distinction between the two medicines entirely clear. The claim meant that Lyxumia was the only once-daily GLP-1 RA that was licensed for use in combination with basal insulin alone, in combination with OADs and basal insulin and in combination with OADs. The Panel accepted that, in the round, this claim was true, but considered that the 'and/or' made it unclear as to what 'only' referred to. Whilst the earlier two treatment scenarios were correct in that only Lyxumia could be added to existing basal insulin therapy, the last was not; both Victoza and Lyxumia could given in combination with OAD therapy. The Panel considered that the claim was misleading and ambiguous and on the basis that the 'and/or' made it unclear as to what 'only' referred to and the claim did not make the distinction between the two medicines entirely clear, it was sufficiently similar to that at issue in Case AUTH/2604/5/13 to be covered by the undertaking in that case. The Panel therefore ruled the claim to be in breach of 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. These rulings were appealed.

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 Sanofi had not validated the decisions made during its withdrawal process after providing its undertaking in Case AUTH/2604/5/13 dated 25 June 2013. The Panel was concerned that the supplement in question had been submitted to Nursing Times for publication on 10 July 2013. The Panel noted that Novo Nordisk had stated that the Nursing Times had confirmed that the copy deadline for the journal to receive the supplement was 1 July 2013 whereas Sanofi submitted that the copy deadline was 28 June 2013. Both of these dates were after the date on which Sanofi had signed its undertaking in Case AUTH/2604/5/13 and as such Sanofi could have prevented the supplement from being published.

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. This ruling was appealed.

The Panel noted that this was the second time that Sanofi had breached the undertaking given in Case AUTH/2604/5/13 (Case AUTH/2619/7/13). The Panel was very concerned as it appeared Sanofi had not paid sufficient attention to ensure that its materials were comprehensively reviewed following the provision of an undertaking. The Panel considered Sanofi's conduct warranted consideration by the Code of Practice Appeal Board and decided to report the company to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure for it to consider whether further sanctions were warranted.

APPEAL BY SANOFI

Sanofi submitted that the context and specific nature of the claim in the supplement was significantly different to the advertisement at issue in Case

AUTH/2604/5/13. The journal supplement was significantly different as demonstrated by the greater depth, comprehensive nature of the information and different method of distribution to the intended audience. As such Sanofi concluded that use of the supplement was not subject to the obligations set out in its undertaking which covered the use of 'similar materials'. In addition, Sanofi was confused by the additional clarification provided in the Panel ruling that the undertaking applied to '… closely similar materials'. Sanofi submitted that the undertaking which it signed on 25 June 2013 stated that 'Use of the advertisement in question and any similar material, if not already discontinued or no longer in use, will cease forthwith'. The undertaking did not refer to the claim which was considered in Case AUTH/2604/5/13.

Sanofi stated that it was a well-established principle in the application of the Code that the context and method of use of promotional material was of considerable relevance when deciding the acceptability of any activity, claim, or information provided; this was referred to in the context of certification in the supplementary information to Clause 14.1.

Sanofi submitted that the nature, content, context, distribution and focus of a piece were all important when determining what was and was not 'similar' or 'closely similar' material and that the Panel had not given sufficient consideration to how a company might determine what was and what was not 'similar material' when interpreting the nature of any undertaking it agreed to be bound by.

Sanofi stated that it had considered the Panel ruling and concluded that the six page supplement for a portfolio of diabetes products containing detailed information on the treatment of diabetes with both insulin and Lyxumia and whether it could be considered 'similar' or 'closely similar' to a simple, one page Lyxumia advertisement. Just as a mouse and an elephant were easy to identify they were difficult to define. In Sanofi's view, a one page advertisement and a six page journal supplement were clearly promotional items, just as a mouse and an elephant were mammals, but were equally quite dissimilar in many important ways, such as depth and breadth of content, overall context, delivery and the inherent understanding of the intended audience.

Sanofi submitted that the Panel had not given due consideration to how the wording of the undertaking agreed by Sanofi could be reasonably considered alongside the Panel's ruling concerning the claim at issue which stated that 'The Panel accepted that, in the round, this claim was true but that the "and/or" made it unclear as to what "only" referred to'.

Sanofi submitted that in the light of this clear position and the wording of the undertaking, it was reasonable to conclude that providing greater context about what 'and/or' referred to would satisfy the Panel's concern. Sanofi submitted that the undertaking did not prohibit a modified version of this claim being used in materials that were sufficiently dissimilar to the advertisement considered in Case AUTH/2604/5/13. Sanofi assured the Appeal Board that it would have acted differently had the undertaking stated that it must not use the claim, or if the Panel had not stated that 'The Panel accepted that, in the round, this claim was true but that the "and/or" made it unclear as to what "only" referred to'.

In summary, Sanofi did not believe that the meaning of what was, and importantly what was not considered 'similar material', as stated in the undertaking had been given due consideration in the Panel's ruling and therefore Sanofi appealed the ruling of a breach of Clause 25.

Sanofi noted the claim at issue 'Lyxumia is the only once-daily GLP1-RA that is licensed for use in combination with basal insulin and/or oral glucose-lowering agents' and that in its ruling the Panel re-iterated its findings concerning the claim from the previous case (Case AUTH/2604/5/13) and stated the use of a 'sufficiently similar claim' as rationale for ruling a breach of Clauses 9.1 and 25.

Sanofi submitted that its understanding of the undertaking was that it referred to the use of the claim in 'similar materials' and not to the claim itself. Notwithstanding this, Sanofi understood why the Panel has revisited this issue and welcomed the Appeal Board's deliberation on whether this case centred on a 'similar claim' or use in 'similar materials'.

Sanofi submitted that it appeared from Case AUTH/2604/5/13, that the claim *per se* was accepted but that the concern was its context 'The Panel accepted that, in the round, this claim was true, but considered that the "and/or" made it unclear as to what "only" referred to'.

Sanofi noted out that in the preceding sentence of the paragraph of the promotional supplement at issue, Lyxumia was described as being '…effective in combination with oral … glucose lowering agents or with both basal insulin and oral glucose lowering agents'. This sentence was followed by 'Lyxumia is the only once-daily GLP-1RA that is licenced for use in combination with basal insulin and/or oral glucose lowering agents'. Sanofi submitted that the Panel had given insufficient consideration to the context which the preceding sentence gave the claim. Whilst Sanofi understood that the use of 'and/or' as a conjunction that was contained in the relevant section of the SPC, might produce debate as a point of grammar, the sentence immediately preceding the claim provided absolute clarity as to the inclusivity of the 'and/or' conjunction. As such it was clear that 'only' in the claim referred to the whole inclusive list of presented scenarios as one entity.

Sanofi submitted that insufficient consideration had been given to the fact that '…in combination with basal insulin and/or oral glucose lowering agents…' was the exact wording taken from the therapeutic indications section of the SPC. No other once-daily GLP-1RA had a marketing authorization for once-daily use in all of the indications linked by the conjunction 'and/or' in the claim.

Sanofi submitted that it always sought to act within the spirit as well as the letter of the Code. In particular it understood that the context in which a claim was made and the way in which it was presented was key to determining its acceptability. For example, although an SPC was not considered a promotional item *per se*, as stated in Clause 1.2 of the Code, it could be considered a promotional item if given to inappropriate recipients in a promotional manner.

Sanofi appealed the ruling that the claim at issue was a 'sufficiently similar claim', given the context to the claim that was provided, as per the advice of the Panel and that this therefore constituted a breach of Clauses 9.1 and 25.

Sanofi noted the Panel's rationale for ruling a breach of Clauses 25 and 2 and as evidence that its conduct warranted consideration by the Appeal Board. Namely that it appeared that Sanofi: had not validated the decisions made in its withdrawal process after providing its undertaking; could have prevented the supplement from being published after the undertaking was signed, and had paid insufficient attention to ensuring that materials were comprehensively reviewed following the provision of an undertaking. Given the detailed account of Sanofi's approach to the withdrawal of its materials provided above, Sanofi submitted that these assertions were not valid.

Sanofi submitted that it decided to use the claim in the journal supplement in the full knowledge of the undertaking and the information contained in the Panel's ruling. Indeed it was the specifics of the wording of the ruling and the undertaking that guided Sanofi to modify the claim and allow its use in a clearly dis-similar piece from that which it undertook not to use.

Sanofi submitted that the supplement was comprehensively reviewed by its scientific service and then by both signatories of the promotional certificate.

Sanofi denied breaches of Clauses 2, 9.1 and 25.

COMMENTS FROM NOVO NORDISK

Novo Nordisk noted that in Case AUTH/2604/5/13 the Panel had ruled that the claim 'Lyxumia is the only once-daily GLP-1 receptor agonist licensed for type 2 diabetes mellitus patients not optimally controlled on oral antidiabetic drugs and/or basal insulin', which appeared in an advertisement, was misleading and ambiguous in breach of Clause 7.2. Sanofi had accepted this ruling and signed an undertaking. To use a similar claim again in another form of promotional material such as a supplement should not negate the Panel's original decision about this claim.

Novo Nordisk did not accept Sanofi's submission that the supplement was 'significantly different' to the advertisement. Both items were promotional and the supplement (which featured a misleading claim) was made available after Sanofi had signed its undertaking. Referring to Paragraph 7 of the Constitution and Procedure, Novo Nordisk failed to see how this supplement could not be covered by Sanofi's undertaking given in Case AUTH/2604/5/13.

APPEAL BOARD RULING

The Appeal Board noted that the claim at issue in Case AUTH/2604/5/13, 'Lyxumia is the only once-daily GLP-1 receptor agonist licensed for type 2 diabetes mellitus patients not optimally controlled on oral antidiabetic drugs and/or basal insulin' appeared in an advertisement. The claim at issue in the current case 'Lyxumia is the only once-daily GLP-1RA that is licensed for use in combination with basal insulin and/or oral glucose lowering agents' appeared in a promotional supplement in a non-specialist journal. The Appeal Board noted that although the claims were not identical they were very similar; both contained 'and/or' which made the meaning of 'only' unclear. The Appeal Board noted that whilst Lyxumia was the only GLP-1RA that could be added to basal insulin it was not the only GLP-1RA that could be added to existing oral antidiabetic (OAD) therapy and thus the claim was misleading in that regard.

The Appeal Board considered that the claim at issue in the supplement was so similar to that in the advertisement that it was covered by the undertaking given in Case AUTH/2604/5/13 and it upheld the Panel's ruling of a breach of Clause 25. The Appeal Board considered that high standards had not been maintained and it upheld the Panel's ruling of a breach of Clause 9.1. The appeal on both points was unsuccessful.

The Appeal Board noted that an undertaking was an important document. In failing to comply with its undertaking the Appeal Board considered that Sanofi had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Appeal Board upheld the Panel's ruling of a breach of Clause 2. The appeal on this point was unsuccessful.

COMMENTS FROM SANOFI ON THE REPORT

At the consideration of the report, Sanofi submitted that in response to the issues in these cases, it had compiled a file of disallowed claims, reviewed its compliance procedures, introduced a monitoring process and investigated the procurement of external compliance expertise.

APPEAL BOARD CONSIDERATION OF THE REPORT FROM THE PANEL

The Appeal Board noted that the journal supplement at issue had been certified the day after the undertaking in Case AUTH/2604/5/13 had been signed. Sanofi had submitted that it had decided to use the claim at issue in full knowledge of the undertaking and of the Panel's ruling in that case. In the Appeal Board's view, it should have been obvious to Sanofi that the claim in the supplement was so similar as to be almost the same as the claim at issue in Case AUTH/2604/5/13. That the claim was approved for use subsequent to the outcome of Case AUTH/2604/5/13, led the Appeal Board to query the rigour with which Sanofi had examined relevant

materials to ensure compliance with its undertaking. After signing the undertaking, Sanofi had had time to cancel publication of the supplement. The Appeal Board noted that this was the second time that Sanofi had breached its undertaking given the Case AUTH/2604/5/13 (Case AUTH/2619/7/13) and so it decided, in accordance with Paragraph 11.3 of the Constitution and Procedure, to require an audit of the company's procedures in relation to the Code. The Appeal Board noted that Sanofi had already embarked on a programme of corrective measures and so it requested that the audit take place in March 2014 when the results of some of those measures should be obvious. In the meantime it requested the Authority to ask Sanofi to confirm in writing the measures it had implemented. On receipt of the audit report and Sanofi's comments upon it, the Appeal Board would consider if further sanctions were necessary.

APPEAL BOARD FURTHER CONSIDERATION

Sanofi was audited in March 2014 and on receipt of the audit report, the Appeal Board noted a number of serious concerns regarding Sanofi's procedures and materials; the company had begun to address the issues including a change to the structure of company reporting, increasing compliance resource, training and updating its procedures and materials.

The Appeal Board decided that Sanofi should be re-audited in October 2014 at which point it expected to see changes implemented and significant progress made. Upon receipt of the report for the re-audit and Sanofi's comments upon it, the Appeal Board would decide whether further sanctions were necessary.

Sanofi was audited in October 2014 and on receipt of the audit report, the Appeal Board noted that some progress had been made; the company had a new general manger and there had been an increased focus on compliance. However, the Appeal Board considered that there was still a lot of work to do and concerns to address. In addition the Appeal Board noted the recent issues raised concerning Sanofi's interaction with patient organisations (Case AUTH/2736/6/14. In relation to the re-audit in Case AUTH/2620/7/13, the Appeal Board decided to require a re-audit of Sanofi in March 2015 at the same time as the audit required in Case AUTH/2736/9/14; it would expect to see the recommendations of the October 2014 audit report implemented and significant progress made. On receipt of the re-audit report and Sanofi's comments upon it, the Appeal Board would consider whether further sanctions were necessary.

Sanofi was audited in March 2015, and on receipt of the audit report the Appeal Board noted that Sanofi had made progress since the audit in October 2014; a new, senior manager was fully involved and leading many of the company's compliance initiatives.

The Appeal Board however, noted its concern about some of the company's activities and considered that Sanofi should address the matters raised as a priority. On the basis that this work was completed, the progress otherwise shown in the March 2015 audit was continued and a company-wide focus and responsibility for compliance was maintained, the Appeal Board decided that no further action was required.

Complaint received	**29 July 2013**
Undertaking received	**20 December 2013**
Appeal Board Consideration	**27 November 2013, 9 April and 10 December 2014, 16 April 2015**
Interim Case Report first published	**5 February 2014**
Case completed	**16 April 2015**

ANONYMOUS v MERCK SERONO

Sponsorship to attend, and subsistence at, an international meeting

An anonymous, non-contactable, fertility health professional complained about the conduct of Merck Serono personnel at the European Society of Human Reproduction and Embryology (ESHRE) conference in Munich. The complainant alleged that a named company employee and a sales team were in hotel restaurants and bars with fertility health professionals drinking alcohol into the early hours of the morning every night; this created an inappropriate and unprofessional impression of the pharmaceutical industry.

The complainant submitted that Merck Serono hosted the same health professionals at ESHRE year after year, ie those who used Merck Serono products, which was not in the spirit of supporting appropriate education for the wider profession. The complainant alleged that he/she was told by his/her local sales representative that he/she did not prescribe enough Gonal-f (follitropin alpha) to warrant an invitation to attend ESHRE with Merck Serono.

The detailed response from Merck Serono is given below.

The Panel noted the complainant was anonymous. As stated in the introduction to the Constitution and Procedure, such complaints were accepted and like all complaints, judged on the evidence provided by both parties. Complainants had the burden of proving their complaint on the balance of probabilities; as the complainant was also non-contactable it was not possible to ask him/her for further information.

The Panel noted that the Code allowed companies to provide limited hospitality to members of the health professions and appropriate administrative staff in association with scientific meetings, promotional meetings, scientific congresses and other such meetings, and training. The Panel also noted that the provision of hospitality and other interactions between the pharmaceutical industry and health professionals outside the formal congress proceedings at international congresses was a subject that attracted much public scrutiny and criticism. Companies should be mindful of the impression given by such interactions and ensure that when applicable, such activity complied with the UK Code.

The Panel noted that the Merck Serono policy document 'Congresses/Meetings and Hospitality FAQ' reflected the requirements of the Code and stated, *inter alia*, that outside of subsistence provided in association with appropriate meetings 'it is not appropriate to go to the hotel bar or other venue and buy alcoholic drinks for customers'. The Panel accepted that company employees would want to wind down away from health professionals at the end of a full congress day. However, company employees were in the conference city as representatives of their company for business reasons and as such they must be mindful of the impression created by their behaviour beyond the formal conference proceedings and associated subsistence. This was especially so in a late night social environment.

The Panel noted the complainant's allegation that a named employee and Merck Serono staff, together with health professionals, drank alcohol into the early hours of the morning at hotel restaurants and bars. No supporting evidence had been provided by the complainant.

The Panel noted that a buffet at the hotel restaurant where sponsored delegates were staying was provided on Sunday, 29 June at a cost of €60 per delegate. A set meal at an external restaurant was provided on Monday, 30 June at a cost of €55 per head. The company's responses and invoices did not quantify the amount of alcohol that was provided in relation to either event. In the absence of such information, the Panel considered that it was difficult to see how the arrangements could have been approved. On Tuesday, 1 July, dinner at an external restaurant included a beverage package which included two glasses of wine, one coffee and half a bottle of water at €22 per delegate. Whilst noting its comments above, the Panel considered that there was no evidence to indicate whether the consumption of alcohol at restaurants on 29 and 30 June was inconsistent with the Code. The complainant bore the burden of proof in this regard. Consumption on 1 July appeared to be consistent with the relevant requirements. The Panel ruled no breach of the Code.

In relation to hotel bars, the Panel noted Merck Serono's submission that health professionals were taken back to the hotel after dinner where some might have remained in the bar, but if they did so, it was at their own account. The Panel noted that on each night, staff incurred bar expenses at the hotel bar. The Panel noted that according to Merck Serono, on Sunday, 29 June a bar tab for employee drinks (nine staff) for €217.10 was settled at around midnight. The Panel queried whether it was appropriate to choose the hotel bar for a late night staff drink given one could reasonably assume that health professionals staying at the hotel would also be present. The Panel noted Merck Serono's submission that whilst health professionals were in the bar, they did not participate in the staff social activity nor were they seated nearby. The Panel queried whether this distinction would be clear to third parties or to those health professionals who had dined with the employees earlier that

evening. The Panel had no information about the layout of the bar nor whether at the relevant times it was a quiet or noisy environment. Similar comments applied to Monday, 30 June and Tuesday, 1 July although the monies spent and numbers of employees involved were less. Whilst the Panel was concerned as outlined above it noted that the complainant bore the burden of proof. Taking all the circumstances into account the Panel noted that although Merck Serono employees had consumed alcohol in the hotel bar late at night, there was no evidence that they had bought drinks for any of the health professionals present or otherwise socialised with them as alleged and thus no breach of the Code was ruled.

The Panel noted its rulings above and considered that there was no evidence that the conduct of the Merck Serono staff had created an inappropriate and unprofessional impression of the pharmaceutical industry nor that the company had brought the industry into disrepute. No breaches of the Code were ruled.

In relation to the allegation that the same health professionals were hosted year after year by Merck Serono and that the complainant had been told by his/her local representative that he/she did not prescribe enough Gonal-f to warrant an invitation to attend ESHRE with the company, the Panel noted emails from all relevant representatives which stated that none of them had ever had such a discussion with any of their health professionals. The Panel considered that on the information before it there was no evidence that a representative had told the complainant that only good prescribers of Gonal-f would be sponsored to attend. No breaches of the Code were ruled.

An anonymous fertility health professional complained about the conduct of Merck Serono personnel at the European Society of Human Reproduction and Embryology (ESHRE) 2014 conference in Munich.

COMPLAINT

The complainant alleged that a named employee and his/her sales team were in hotel restaurants and bars with fertility health professionals drinking alcohol into the early hours of the morning every night. In the complainant's view their actions created an inappropriate and unprofessional impression of the pharmaceutical industry.

The complainant further alleged that Merck Serono hosted the same health professionals who used Merck Serono products at ESHRE year after year. This was not in the spirit of supporting appropriate education for the wider profession. The complainant stated that he/she was told by his/her local sales representative that he/she did not prescribe enough Gonal-f (follitropin alpha) to warrant an invitation to attend ESHRE with Merck Serono.

When writing to Merck Serono, the Authority asked it to consider the requirements of Clauses 2, 9.1, 18.1 and 19.1 of the Code.

RESPONSE

Merck Serono explained that the ESHRE conference was an annual and preeminent, key, scientific and clinical meeting for fertility specialists and other affiliated specialities globally. Sponsorship of UK health professionals to ESHRE complied with the requirements of the Code, and all arrangements were formally certified in advance. Additionally the conference met the required standard for education and scientific content such that sponsorship of health professionals for attendance outside of the UK was not deemed inappropriate.

Merck Serono submitted that the employee named by the complainant, had many years' experience and had passed the ABPI examination and a copy of his examination certificate was provided together with a summary of the related expenses from the ESHRE meeting.

Before the ESHRE meeting, the named employee and the sales team were briefed with regard to meetings and hospitality frequently asked questions (FAQ). Merck Serono noted in particular a section of the FAQ briefing which stated:

> 'Q When can I provide refreshments for health professionals ?
>
> A Subsistence can be provided in association with appropriate meetings (which have an educational content) and the arrangements (content, venue and cost) are examined via the Zinc process. Depending upon the event, refreshments range from a buffet to a meal and up to half a bottle of wine per person. It should not include alcoholic spirits, liquors or sparkling wine. It's not appropriate to serve alcoholic drinks during lunchtime meetings. Outside of this, it is not appropriate to go to the hotel bar or other venue and buy alcoholic drinks for customers. We should be sensitive to the external perception of our interactions with customers, particularly late at night in social environments such as bars, even if we have not paid for their drinks or had any involvement with arranging hospitality.'

It was clear from the above that Merck Serono prohibited activities such as those alleged. There was no evidence from analysis of the expenses of the Merck Serono personnel that they were in hotel restaurants and bars with fertility health professionals drinking alcohol as alleged. The named employee and the sales team categorically denied the allegations and Merck Serono was absolutely confident in their responses.

Merck Serono noted that the complainant had offered no evidence as to the veracity of the events; standard instructions to sales representatives were clear on these matters, and receipts showed that such activity could not have occurred.

Merck Serono's representatives who attended the ESHRE conference were instructed about appropriate conduct during conferences and interactions with health professionals before the meeting.

Merck Serono stated that 68 UK health professionals were selected for sponsorship on the basis of their 'expertise, knowledge, experience and profile within their designated geography'. Those sponsored to attend the ESHRE conference were all considered to be regional leaders within their area of speciality (ie nursing, embryology, specialists in reproductive medicine) and were selected in accordance with Merck Serono's standard operating procedure (SOP). Health professionals selected to attend were emailed a certified invitation which was co-ordinated by an events agency and Merck Serono's medical department. Any correspondence regarding invitations and sponsorship were communicated solely by the events agency and Merck Serono's medical department. Neither the sales team nor the named employee were involved in the invitation process and any queries from invitees were directed to the medical department.

Merck Serono submitted that in the previous four years (2010-2013), 4 of the 68 delegates to the 2014 ESHRE meeting had been sponsored by the company every year, 3 had been sponsored 3 times, 10 had been sponsored twice, 14 had been sponsored once before and 34 (50%) had never been sponsored before. Full delegate data was also provided.

Delegates were provided with economy flights, hotel accommodation and subsistence in a manner consistent with the Code. Supporting documentation was provided which Merck Serono stated was evidence of compliance.

In summary, Merck Serono denied allegations of inappropriate hospitality and inappropriate sponsorship of health professionals to attend the ESHRE conference, and contended that no breaches of Clauses 2, 9.1, 18.1, or 19.1 had occurred.

In response to a request for further information, Merck Serono submitted a full list of the eleven Merck Serono employees and the two third party agency personnel who attended the ESHRE conference in 2014, their job titles and the reason for their attendance at the conference. Merck Serono submitted that attending the conference was crucial for the development of its employees who worked within the medical department and fertility business franchise; they could update their knowledge and understanding of current trends within reproductive health and to discuss, review and understand newly presented data. The two events agency staff who attended were responsible for managing all onsite logistics and liaison with third party vendors including; transport providers for all airport and dinner transfers; managing the restaurants for offsite dinners; the hotel team in relation to accommodation and the congress team in relation to collection of congress passes. Agency personnel were also involved in the management of communication to attendees via the information desk at the hotel.

Merck Serono provided a full account of all expense claims (including those related to ESHRE) for each named Merck Serono employee, expenses for the agency personnel, which were included on the final hotel master invoice (provided). Expenses included accommodation and some extra costs for telephone calls, food and beverages for their personal subsistence. A summary was provided. In addition agency personnel also incurred some expenses travelling to and from the hotel, airport and congress centre. Merck Serono stated that this was a full account of all expenses incurred by the events agency personnel engaged on behalf of Merck Serono in relation to the ESHRE meeting.

Merck Serono confirmed that all expenses relating to the ESHRE meeting for all staff that attended (and agency personnel) had now been submitted. A full and detailed account of all expenses relating to ESHRE for the named employee and the sales team had already been provided; Merck Serono initially responded with information limited to these employees because the complaint specifically stated '[named employee] and his sales team were in the hotel restaurants and bars with fertility healthcare professionals'.

The details provided reflected all expenses submitted relating to ESHRE 2014. All hospitality and subsistence arrangements for staff and delegates were organised before the meeting via the events agency. Therefore, the vast majority of expenses for all staff and delegates was included in the overall master bill which Merck Serono paid directly to the events agency. Staff thus only submitted minor incidental expenses that were outside of the overall service agreement with the agency (which covered evening subsistence for 3 nights 2014).

A full detailed account of the individual hospitality provision for each night was provided:

Sunday, 29 June 2014

Rolling buffet dinner (8-10pm) in the hotel restaurant, based on a maximum allowance of €60 per person for 90 people, which included beverages. The relevant extract from the master hotel bill and copy of the master invoice was provided.

Monday, 30 June 2014

Dinner at a city centre restaurant – set dinner menu with drinks, €55/person for 89 people. A copy of the master invoice was provided.

Tuesday, 1 July

Dinner at a city centre restaurant – set dinner menu with drinks for 80.

A breakdown (including reference to 2 glasses of wine, ½ bottle of water and 1 coffee per person @ £22) and a master invoice was provided.

Wednesday, 2 July

No hospitality was provided; delegates departed throughout the course of the day.

In accordance with Clause 14.2 of the Code, the full meeting arrangements for the ESHRE 2014 conference, including the hospitality arrangements, were formally certified in advance. A copy of the

relevant Zinc certificate was provided. In particular, the hospitality arrangements were certified with a maximum allowance of €60/person for food and drink. Merck Serono noted that on the final night (Tuesday, 1 July) this maximum allowance was increased to €63 per person (detailed above) based on the set menu options provided by the restaurant. This increase was approved by a final signatory who deemed that this was an acceptable level of subsistence and still within the maximum allowance (£75) set out in Clause 19.2.

Merck Serono advised there were no planned after dinner events or activities during the ESHRE meeting. Health professionals were taken back to the hotel after dinner where some might have decided to remain in the hotel bar, but if they wished to do so, it was on their own account.

Prior to attending ESHRE, all Merck Serono employees were given guidance on appropriate conduct during meetings as provided previously in the 'Meetings and Hospitality FAQ, the relevant extract was provided.

> 'It is not appropriate to go to the hotel bar or other venue and buy alcoholic drinks for customers. We should be sensitive to the external perception of our interactions with customers, particularly late at night in social environments such as bars, even if we have not paid for their drinks or had any involvement with arranging hospitality.'

The 'Meetings and Hospitality FAQ' was sent out to all Merck Serono employees. Further training of the Merck Serono Global Policies relating to 'Meetings' was also provided via WebEx to all relevant sales and marketing employees. This was the only briefing specifically given to representatives about their conduct and activities during the ESHRE meeting.

All relevant Merck Serono representatives involved with the meeting strongly denied that the comments, 'Sponsorship was denied by the local Merck Serono representative because [the complainant] did not prescribe enough Gonal F' were mentioned and indeed that they would never have this conversation with a health professional. Copies of emails from all relevant representatives were provided. Merck Serono confirmed that the sales force had never been asked to make such a comment.

Merck Serono provided further explanation regarding its initial response which indicated that health professionals were selected for sponsorship on the basis of expertise, knowledge, experience and profile within their designated territory. The company explained that the comment 'profile within their designated territory' referred to a health professional's seniority and influence with his/her designated area (ie his/her specific fertility clinic, or regional area). The two objectively defined criteria used for selection were:

> Senior fertility specialists recognised as local/ regional/national influencers.
> No more than two customers per centre.

All sales and marketing employees were briefed on the selection and invitation process for ESHRE 2014 at a team meeting in January (Zinc certified slides used at the meeting were provided). The briefing provided an overview of the arrangements at that point in time and the slides confirmed the following details to all staff involved in the fertility franchise:

- Progress and arrangements with regard to the ESHRE meeting so far
- A 'Save the Date' flyer would be sent out to customers (once selected) to encourage earlier registration for the meeting
- The medical team were to have primary responsibility for selection of delegates for sponsorship to ESHRE
- The overall number of delegates to be sponsored across UK and Ireland
- The objectively defined criteria that would be used for selection (senior fertility specialists recognised as regional/national/international influencers and no more than 2 per centre)
- Finally, the sales team was asked to nominate potential delegates for sponsorship to the medical team for consideration based on the criteria above as well as any direct requests for sponsorship they might have already received from health professionals.

Further to the above, names and contact details of potential delegates were forwarded to the medical team for consideration, which then reviewed the details based on the two criteria and directly invited selected health professionals to register. The sales and marketing team was informed of who had been selected for invitation but was not involved in the selection process. Furthermore, all communications regarding sponsorship selection and invitations were coordinated solely by the medical department with no involvement of the sales representatives. Sales representatives were instructed to channel all queries about invitations and sponsorship to the medical department. A copy of a relevant slide from the January team meeting was provided.

Merck Serono provided copies of ABPI certificates for the relevant sales employees.

In response to a further request for information, Merck Serono confirmed that there were no after dinner events, hospitality or activities either planned or unplanned during the ESHRE 2014 conference.

Further to the Panel's request Merck Serono had asked the hotel in Munich to provide a detailed breakdown including original receipts.

Merck Serono confirmed that one named employee did not incur any incidental expenses related to the ESHRE conference and therefore no information was previously provided on her behalf. The company provided the expense reports (with receipts) for this member of staff which related to June and July 2014 to substantiate this.

Finally, Merck Serono explained that the 13 additional names from the master bill which did not match the previous list of UK delegates provided were health professionals from the Republic of

Ireland. Furthermore, two rooms which appeared in the master bill as Merck Serono bedrooms were not for Merck Serono employees as the named persons were health professionals.

Merck Serono subsequently provided timed receipts for employees staying at a hotel in Munich.

In response to a further request for further information, Merck Serono stated that it had endeavoured to provide all the relevant materials to the review of this case and had supplied thus far all the specific items requested by the PMCPA.

As stated previously, the hotel had only been able to provide receipts based on what was logged on its accounts system, and the original bar receipts were not retained. It should also be noted that the times logged on the receipts provided to the Panel were the times that the expenses were logged on the hotel accounts system and not when the final bills were paid at the bar. This was confirmed during subsequent interviews with each staff member who attended ESHRE.

An advanced party of Merck Serono staff arrived in Munich on Saturday, 28 June 2014 due to their involvement in various briefing meetings the following day. The staff present had arranged to meet in the hotel restaurant for dinner (Merck Serono referred to a hotel invoice for a named employee dated 28 June 2014 for €183.70). Merck Serono stated that no health professionals were present at this dinner only 6 named Merck Serono staff: [The six staff named included two who Merck Serono had not previously identified as attendees].

A full account of expenses relating to activities on this day and early hours on Sunday, 29 June was described below:

Time	Amount	No of staff	Explanation
6.17pm	€3.90	1	1 tea
7.11pm	€183.70	6	Evening meals and drinks
7.37pm	€42.40	1	Evening meal and drinks
2.05am (29/06/2014)	€36.00	2	4 x drinks

Merck Serono submitted that these expenses related purely to those of Merck Serono staff only.

Sunday, 29 June 2014

There were various Merck Serono meetings (for staff only) planned on this day. Some staff attended a training session on a medical technology at the International Convention Centre (ICC) from 12 noon to 3pm. The designated stand crew attended the 'Stand Crew Training' from 1.30-3.30pm at a nearby hotel and then returned to the hotel. The final meeting was a general briefing for all Merck Serono staff attending ESHRE (excluding those who attended the Stand Crew Training). These staff then went back to the hotel and gathered at the bar briefly before departing to prepare for the planned dinner in the hotel restaurant with the invited delegates. At this time, a bar tab was opened by a named employee to cover the costs of staff only subsistence throughout the evening.

The next scheduled activity was the buffet dinner in the hotel restaurant which was the first planned interaction with any sponsored health professional delegates. Health professional delegates had arrived throughout the day and could attend the buffet dinner from 8pm. This was the only planned event for health professional delegates that day (Merck Serono referred to the delegate welcome letter previously submitted for health professionals' itinerary).

Merck Serono had previously submitted the master bills in relation to the planned hospitality for that evening. After dinner, some staff returned to the hotel bar where they remained until the bar tab was settled by a named employee around midnight (Merck Serono referred to the hotel invoice for the named employee dated 29 June 2014, €217.10). Merck Serono stated that whilst some health professional delegates were in the hotel bar and restaurant, no health professionals were involved or participated in the staff entertaining activities in the bar relating to this expense. Furthermore, no health providers were seated in the vicinity of the staff present in the hotel bar. Merck Serono listed staff who were present during this 4-5 hour period relating to the €217.10 expense claim [this list included a future employee who was to Merck Serono on 1 July 2014]. Additionally, throughout the evening, one employee bought three drinks for him/herself. As previously explained Merck Serono believed the times shown on the printouts provided by the hotel ideally did not accurately represent the time the order was settled at the bar. The receipts provided showed the time that the expenses were added to the hotel accounting system against each room.

A full account of expenses relating to activities on this day and the early hours of Monday, 30 June as described above were listed in the table below:

Time	Amount	No of staff	Explanation
5.51pm	€7.80	2	2 teas
6.48pm	€22.40	5	5 drinks
12.47am (30/06/2014)	€217.10	9	Drinks before and after dinner
12.53am (30/06/2014)	€3.90	1	1 tea
12.59am (30/06/2014)	€12.60	1	3 drinks before/ after dinner

There were no further planned or unplanned activities or events that evening.

Monday, 30 June 2014

The ESHRE main scientific programme started at 8.30am. All health professional delegates and staff travelled to and from the ICC by public transport.

The delegate welcome letter again showed that health professionals and staff were due to meet in the hotel lobby at 7.30pm before an organised coach transfer took them to dinner at a restaurant in central Munich. After dinner, all delegates (health professionals and staff) were taken back to the hotel by coach (approximately 10pm-11pm). There were no further planned or unplanned activities or events that evening and all delegates (health professionals and staff) were free upon arrival back to the hotel; some staff went to the bar for drinks but again, they did not buy any drinks for health professionals.

As previously explained, Merck Serono believed the times shown on the printouts provided by the hotel did not accurately represent the time the order was settled at the bar. The receipts provided showed the time that the expenses were added to the hotel accounting system against each room.

A full account of expenses relating to activities on this day and early hours of Tuesday, 1 July as described above were summarised in the table below:

Time	Amount	No of staff	Explanation
4.37pm	€39.90	1	Subsistence and drinks
2.35am (01/07/2014)	€14.00	2	2 drinks
2.37am (01/07/2014)	€14.00	1	2 drink after dinner
2.39am (01/07/2014)	€12.00	1	2 drinks and a snack purchased from mini bar in room
12.59am (30/06/2014)	€12.60	1	3 drinks before/ after dinner

There were no further planned or unplanned activities or events that evening.

Tuesday, 1 July

Again, health professionals and staff travelled to and from the ESHRE conference by public transport. The planned evening hospitality was similar to the previous day. Staff and health professional delegates met at 7.30pm for transfers to a restaurant in central Munich before returning to the hotel. Again, no further planned or unplanned activities or events took place.

Full account of expenses relating to activities on this day and early hours of Wednesday, 2 July (described above):

Time	Amount	No of staff	Explanation
1.11am (02/07/2014)	€8.40	3	3 drinks

Merck Serono noted that the complainant did not provide any examples of what was considered inappropriate or unprofessional behaviour by any member of staff during ESHRE 2014 and in that regard questioned the authenticity of this complaint. All staff that attended ESHRE had been interviewed and had confirmed that no inappropriate or unprofessional behaviour took place. Merck Serono referred to statements provided which acknowledged this fact.

PANEL RULING

The Panel noted the complainant was anonymous. As stated in the introduction to the Constitution and Procedure, such complaints were accepted and like all complaints, judged on the evidence provided by both parties. Complainants had the burden of proving their complaint on the balance of probabilities; as the complainant was also non-contactable it was not possible to ask him/her for further information.

The Panel noted that Clause 19.1 required that companies must not provide hospitality to members of the health professions and appropriate administrative staff except in association with scientific meetings, promotional meetings, scientific congresses and other such meetings, and training. Meetings must be held in appropriate venues conducive to the main purpose of the event. Hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting, ie subsistence only. The level of subsistence offered must be appropriate and not out of proportion to the occasion. The supplementary information to that clause noted, *inter alia*, that the impression created by the arrangements for any meeting must always be kept in mind.

The Panel noted that the provision of hospitality and other interactions between the pharmaceutical industry and health professionals outside the formal congress proceedings at international congresses was a subject that attracted much public scrutiny and criticism. Companies should be mindful of the impression given by such interactions and ensure that when applicable such activity complied with the UK Code.

The Panel noted the Merck Serono policy document 'Congresses/Meetings and Hospitality FAQ' reflected the requirements of Clause 19 (2014 Code) and stated, *inter alia*, that outside of subsistence provided in association with appropriate meetings 'it is not appropriate to go to the hotel bar or other venue and buy alcoholic drinks for customers'. The Panel accepted that company employees would want to wind down away from health professionals at the end of a full congress day. However, company employees were in the conference city as representatives of their company for business reasons and as such they must be mindful of the impression created by their behaviour beyond the formal conference proceedings and associated subsistence. This was especially so in a late night social environment.

The Panel noted the complainant's allegation that a named employee and Merck Serono staff, together with health professionals, drank alcohol into the

early hours of the morning at hotel restaurants and bars. No supporting evidence had been provided by the complainant. The Panel noted that it had been difficult to extract the relevant information from the material provided by Merck Serono. Consequently, the Panel had been obliged to ask the company for more information on several occasions. The Panel considered that its management of the case would have been greatly assisted if Merck Serono had provided a clear explanation of all expenses incurred at ESHRE and a comprehensive list of staff attendees at the outset.

The Panel noted that a buffet at the hotel restaurant where sponsored delegates were staying was provided on Sunday, 29 June at a cost of €60 per delegate. A set meal at an external restaurant was provided on Monday, 30 June at a cost of €55 per head. The company's responses and invoices did not quantify the amount of alcohol that was provided in relation to either event. In the absence of such information, the Panel considered that it was difficult to see how the arrangements could have been approved. On Tuesday, 1 July, dinner at an external restaurant included a beverage package which included two glasses of wine, one coffee and half a bottle of water at €22 per delegate. Whilst noting its comments above, the Panel considered that there was no evidence to indicate whether the consumption of alcohol at restaurants on 29 and 30 June was inconsistent with the Code. The complainant bore the burden of proof in this regard. Consumption on 1 July appeared to be consistent with the relevant requirements. The Panel ruled no breach of Clause 19.1 of the Code.

In relation to hotel bars, the Panel noted Merck Serono's submission that health professionals were taken back to the hotel after dinner where some might have remained in the bar, but if they did so, it was at their own account. The Panel noted that on each night, staff incurred bar expenses at the hotel bar. The Panel noted that according to Merck Serono, on Sunday, 29 June a bar tab for employee drinks (nine staff) for €217.10 was settled at around midnight. The Panel queried whether it was appropriate to choose the hotel bar for a late night staff drink given one could reasonably assume that health professionals staying at the hotel would also be present. The Panel noted Merck Serono's submission that whilst health professionals were in the bar, they did not participate in the staff social activity nor were they seated nearby. The Panel queried whether this distinction would be clear to third parties or to those health professionals who had dined with the employees earlier that evening. The Panel had no information about the layout of the bar nor whether at the relevant times it was a quiet or noisy environment. Similar comments applied to Monday, 30 June and Tuesday, 1 July although the monies spent and numbers of employees involved were less. Whilst the Panel was concerned as outlined above it noted that the complainant bore the burden of proof. Taking all the circumstances into account the Panel noted that although Merck Serono employees had consumed alcohol in the hotel bar late at night, there was no evidence that they had bought drinks for any of the health professionals present or otherwise socialised with them as alleged and thus no breach of Clause 19.1 was ruled.

The Panel noted its rulings above and considered that there was no evidence that the conduct of the Merck Serono staff had created an inappropriate and unprofessional impression of the pharmaceutical industry or otherwise brought the industry into disrepute. No breach of Clauses 2 and 9.1 was ruled.

In relation to the allegation that the same health professionals were hosted year after year by Merck Serono and that the complainant had been told by his/her local sales representative that he/she did not prescribe enough Gonal-f to warrant an invitation to attend ESHRE with Merck Serono, the Panel noted emails from all relevant Merck Serono sales representatives which stated that none of them had ever had such a discussion with any of their health professionals. The Panel considered that on the information before it there was no evidence that a sales representative had stated to the complainant that only good prescribers of Gonal-f would be sponsored to attend. No breach of Clauses 18.1, 9.1 and 2 was ruled.

Complaint received **9 September 2014**

Case completed **14 January 2015**

CASE AUTH/2736/9/14

VOLUNTARY ADMISSION BY SANOFI

Relationships with patient organisations

Sanofi voluntarily admitted breaches of the Code in relation to its conduct and disclosure of interactions with patient organisations in 2013 and 2014. The company also voluntarily admitted a potential breach of the Code concerning its support of scientific meetings organised by patient organisations.

In accordance with Paragraph 5.6 of the Constitution and Procedure, the matters were treated as a complaint.

Sanofi referred to media interest in the way that patient organisations interacted with the pharmaceutical industry and it recognised that disclosure was important in ensuring that all such interactions were transparent. Prompted by this, Sanofi examined the disclosures made for patient organisation interactions and discovered that the support which it provided in 2013 had not been disclosed alongside other disclosures that were made for the same year. There were also no written agreements in place for the support provided. Sanofi immediately contacted the relevant organisations and disclosed the support provided.

Sanofi reviewed the disclosure and documentation concerning all support it provided to patient organisations in 2013 and 2014 and discovered that due process was not followed and correct disclosure did not occur, in breach of the Code.

In addition, Sanofi noted that it had sponsored some professional meetings organised by patient organisations but that such sponsorship had not been disclosed as an interaction with those organisations.

The detailed response from Sanofi is given below.

The Panel noted that Sanofi's voluntary admission related to its interactions with patient organisations in 2013 and 2014. Activities carried out in 2013 were subject to the Second 2012 Edition of the Code. That Code required companies which worked with a patient organisation to have a detailed written agreement agreed and certified in advance. Similarly, before a patient organisation provided a service to a pharmaceutical company, a detailed written contract or agreement was needed. Companies were required to make publicly available a list of patient organisations to which they provided support to include a description of the support which was sufficiently complete for readers to understand the significance of the support. Companies were also required to make publicly available a list of patient organisations engaged to provide significant, contracted services to include a description of the nature of the services which was sufficiently complete for readers to understand the arrangement without the need to divulge confidential information; the total amount paid per patient organisation over the reporting period must be declared. Both lists must be updated at least once a year.

The Panel noted that Sanofi had referred to interactions with patient organisations which had occurred before 2013. In that regard, from 1 July 2008 Sanofi would have had to annually publish a list, by no later than 31 March 2009, to cover activities commenced on or after 1 January 2008 or ongoing on that date, of patient organisations to which it had provided support in the previous year. A list of patient organisations engaged to provide significant contracted services had to be declared for the first time by 31 March 2013 to cover activities commenced on or after 1 January 2012 or ongoing on that date. Given the requirement to update its declarations at least once a year, Sanofi would have to amend the lists by no later than 31 March each year for activities carried out in the previous calendar year.

With regard to the activities carried out in 2014 the requirements of the 2014 Code were identical to those of the Second 2012 Edition of the Code except that the clauses had different numbers.

The Panel considered Sanofi's relationship with each patient organisation in turn.

The Panel noted Sanofi's submission that there was no written agreement to cover relationships with a number of patient organisations and breaches of the Code were ruled. The company had also failed to certify sponsorship arrangements with a number of patient organisations and further breaches were ruled. In addition breaches of the Code were ruled with regard to failures to disclose and certify fee for service arrangements.

A breach was ruled with regard to the interaction with one patient organisation as Sanofi had not accurately disclosed the amount paid and the information given was not sufficient for the reader to understand the significance of the support.

The Panel ruled further breaches of the Code as Sanofi's sponsorship of health professional's meetings organised by patient associations had not been publicly declared as interactions with the relevant associations.

The Panel noted the sensitivities surrounding the pharmaceutical industry working with patient organisations; robust agreements setting out the arrangements, and certification of agreements were important steps in ensuring that such interactions complied with the Code and in that regard they underpinned the self-regulatory compliance system. That projects and sponsorship were able

to go ahead without a certified agreement in place was unacceptable. Further, public disclosure of support was an important means of building and maintaining confidence in the industry. The Panel noted that Sanofi had either sponsored or engaged thirteen patient organisations without first having agreements in place to cover more than twenty activities. The company's support for the patient organisations in 2013, although now disclosed (apart from its support for health professionals' meetings) were disclosed six months late in September 2014; some original disclosures had been inaccurate or lacking in detail. The Panel considered that high standards had not been maintained and a breach was ruled.

The systemic failure with respect to the whole process of working with patient organisations was of grave concern. The voluntary admission submitted by Sanofi set out, and to a degree remediated, the situation with respect to patient organisations in 2013 and to date in 2014 however it was clear that Sanofi thought activities in 2012 could also be affected. For the lack of due process to be followed and for it to have gone undetected by the company for such a considerable period of time was totally unacceptable and brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

The Panel noted its comments and rulings above. The Panel appreciated that Sanofi had voluntarily admitted its failings in process and procedure, however given the time period and the extent to which such failings had gone undetected, the Panel considered that its concerns about the company's procedures warranted consideration by the Appeal Board. The Panel thus reported Sanofi to the Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

The Appeal Board considered that the transparency of a pharmaceutical company's interactions with patient organisations was critical. Whilst interactions with patient organisations was a legitimate activity, the arrangements in place at Sanofi at the relevant time were shambolic and shocking. The Appeal Board noted that Sanofi's voluntary admission was prompted by media criticism in summer 2014 about the relationships between the pharmaceutical industry and patient organisations. The Appeal Board was concerned that the failure had not been discovered earlier, for example as part of the company's preparation for the audit in March 2014 (Case AUTH/2620/7/13). It noted Sanofi's response that the area was part of its work programme. The company was still investigating to see what other interactions had not been disclosed.

The Appeal Board was extremely concerned that such a long term systemic failure across the entire Sanofi business regarding multiple payments to multiple patient organisations had occurred. Staff had failed to follow the relevant standard operating procedure (SOP) and Sanofi's governance of its SOP was very poor. This was a very serious matter.

The Appeal Board was extremely concerned about the breadth and scale of the failings and decided that, in accordance with Paragraph 11.3 of the Constitution and Procedure, the company should be publicly reprimanded.

The Appeal Board also decided to require an audit of Sanofi's procedures in relation to the Code. Given the company's ongoing and planned compliance activities, the Appeal Board decided that the audit should be conducted in March 2015 at the same time as the re-audit required in Case AUTH/2620/7/13. On receipt of the audit report and Sanofi's comments upon it, the Appeal Board would consider whether further sanctions were necessary.

On receipt of the March audit report the Appeal Board noted that Sanofi had made progress since the audit in October 2014; a new, senior manager was fully involved and leading many of the company's compliance initiatives.

The Appeal Board however, noted its concern about some of the company's activities and considered that Sanofi should address the matters raised as a priority. On the basis that this work was completed, the progress otherwise shown in the March 2015 audit was continued and a company-wide focus and responsibility for compliance was maintained, the Appeal Board decided that no further action was required.

Sanofi voluntarily admitted breaches of the Code in relation to its conduct and disclosure of interactions with patient organisations in 2013 and 2014. The company also voluntarily admitted a potential breach of the Code concerning its support of scientific meetings organised by patient organisations.

In accordance with Paragraph 5.6 of the Constitution and Procedure, the matters were treated as a complaint.

VOLUNTARY ADMISSION

Sanofi stated that it was currently undertaking a comprehensive project to review and improve procedures relating to compliance with the Code. The company stated it was committed to ensuring that a robust infrastructure existed, supported by a culture in which compliance with the Code was seen to enable business activity. In line with this strong leadership position, Sanofi submitted that it took immediate steps to prevent breaches of the Code as soon as the issues outlined below were realised, performed a thorough investigation, implemented robust corrective actions and submitted this voluntary admission.

Sanofi was aware of the recent media interest in the way that patient organisations interacted with the pharmaceutical industry and it recognised that disclosure was important in ensuring that all such interactions were transparent. Prompted by this, Sanofi examined the disclosures made for patient organisation interactions in 2013 and on 9 July 2014 discovered that the support which it provided in 2013 to Beating Bowel Cancer and the Rarer Cancers

Foundation had not been disclosed alongside other disclosures that were made for the same year. It was also apparent that there were no written agreements in place for the support provided.

Sanofi stated that it immediately contacted those patient organisations and requested permission to disclose the support provided. In both cases the disclosure was made as soon as possible after permission was granted, on 18 July 2014.

Having identified that no written agreement was in place before providing support and the failure to disclose that support, Sanofi realised that it was important to review the disclosure and documentation concerning the provision of all support it provided to patient organisations in 2013 and 2014. The review revealed that on a number of occasions due process was not followed, correct disclosure did not occur, and this had led to breaches of the Code.

As a result of this finding, Sanofi instigated an investigation reporting to the general manager and medical director, to identify the root cause and corrective actions that needed to be implemented. This revealed that although there was a properly defined process which clearly identified the steps to be taken when supporting or engaging patient organisations, this was not widely understood nor adequately trained to existing or new staff. There was also a process failure in that the financial systems allowed payment to be made without confirmation that all the requirements of the Code had been met.

This combination of factors had resulted in the following failures with regard to interactions with patient organisations in 2013: 2 disclosures referred to an incorrect financial figure; 3 disclosures contained no financial information; 15 activities were not disclosed and 16 activities were undertaken without a signed agreement outlining the nature of the support/service. Twelve disclosures met all the requirements of the Code.

In addition, although disclosure for activities undertaken in 2014 were not yet due, it was clear that five activities had been supported without a signed agreement in place.

Relationships with patient organisations subject to the Second 2012 Edition of the Code

Sanofi submitted that the following declarations all concerned payments made to patient organisations for activities undertaken in 2013. Although disclosure of payments was due in 2014, Sanofi had considered the requirements of the Second 2012 Edition of the Code on the basis that it was this version of the Code which was effective when the sponsorship/fees for service were provided.

The Second 2012 Edition of the Code required disclosure by the end of the first quarter of the following year. Where disclosure occurred after 31 March 2014 a breach of the Second 2012 Edition of the Code was declared.

A moot point was whether the disclosure should be judged by the 2014 Code which had removed a specific date by which disclosure should occur and instead required this to be 'at least once a year'. Sanofi's previous disclosure was 28 March 2013 – if the declarations were considered against the 2014 Code the disclosures would be similarly late. The clauses cited below were therefore from the Second 2012 Edition of the Code.

1 In 2013 Sanofi paid Team Blood Glucose £2,500 to support participation in the Richmond Park 5K/10K run to raise awareness of diabetes and the importance of regular exercise. In addition, Sanofi paid Team Blood Glucose to provide a motivational speaker for an internal meeting. As no formal written agreements were in place between the two organisations for either activity, Sanofi had thus failed to certify such agreements in advance in breach of Clauses 14.3 and 23.3. Furthermore, although disclosed in September 2014, the sponsorship and service fee were not disclosed within the required timeline in breach of Clauses 23.7 and 23.8 respectively.

2 In 2013 Sanofi paid Heart UK £12,000 to sponsor four continuing professional development accredited articles on hypercholesterolaemia published in the Primary Care Cardiovascular Journal. Heart UK was also paid a further £31,143 in sponsorship of a Royal College of General Practitioners' online training programme in lipid management.

   Sanofi submitted that the public disclosure of support to Heart UK was inaccurate in that the level of funding was incorrect (£24,000 as opposed to £12,000, and £42,958 as opposed to £31,143 respectively). Furthermore, in one instance the disclosure contained insufficient detail to enable the reader to understand the significance of the support (disclosed only as 'Direct project funding').

   Written agreements were produced and certified before the activity took place in accordance with the requirements of the Code.

   Sanofi admitted breaches of Clause 23.7 in respect to the inaccurate and insufficient disclosure of the support it had provided.

3 In 2013 Sanofi paid the Rarer Cancers Foundation £5,000 to support the Foundation's public affairs campaign. The lack of a formal written agreement between the two organisations governing this sponsorship meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3. Furthermore, although disclosed in September 2014 the sponsorship and service fee [sic] were not disclosed within the required timeline in breach of Clause 23.7.

4 In 2013 Sanofi paid Leukaemia Care £10,000 to support patient support events. The lack of a formal written agreement between the two organisations governing this sponsorship meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3.

Furthermore, although disclosed in September 2014 the sponsorship and service fee [sic] were not disclosed within the required timeline in breach of Clause 23.7.

5 In 2013 Sanofi paid the National Kidney Federation £14,000 in unrestricted sponsorship of the Foundation's general charitable objective of supporting patients with kidney disease. The lack of a formal written agreement between the two organisations governing this sponsorship meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3. Furthermore, although disclosed in September 2014 the sponsorship and service fee [sic] were not disclosed within the required timeline in breach of Clause 23.7. [Post consideration of the case Sanofi advised that £4,100 was paid to the National Kidney Federation not £14,000 as previously stated].

6 In 2013 Sanofi paid Beating Bowel Cancer the following: £5,000 to support a public affairs campaign in the devolved nations (unspecified); £5,000 to support an 'Access for All' campaign in Scotland; £10,000 to further support its public affairs campaign in the devolved nations (specifically Scotland and Wales) and £110 to purchase tickets for Sanofi personnel to attend a Beating Bowel Cancer fund-raising event.

In the same period Sanofi paid Beating Bowel Cancer to provide the following: a speaker for an internal Sanofi meeting; support for the development of a patient pathway document for use by Sanofi internally and with health professionals and a presentation from the chief executive at a Sanofi internal meeting.

The lack of any formal written agreements between the two organisations governing these interactions meant that Sanofi had failed to certify such agreements in advance in breach of Clauses 14.3 and 23.3. Furthermore, although disclosed in September 2014 the sponsorship and service fees were not disclosed within the required timeline in breach of Clauses 23.7 and 23.8 respectively.

7 In 2013, Sanofi organised a national competition for patient organisations and invited applications in open competition for three bursaries to be awarded by an independent panel of judges. Three bursaries were awarded as follows: Anaphylaxis Campaign received £25,000 to develop support groups for parents of children with severe food allergies; the Brittle Bone Society received £15,000 to establish support groups for children with osteogenesis imperfecta and Tommy's received £10,000 to support education on mental wellbeing during pregnancy.

The lack of formal written agreements between the company and any of the three organisations meant that Sanofi had failed to certify such agreements in advance in breach of Clauses 14.3 and 23.3. Furthermore, although these bursaries were disclosed in an area of Sanofi's public UK website, this was separate to the section in which disclosure to patient organisations was made and, regardless, failed to include the financial sums paid to each organisation in breach of Clause 23.7.

8 In 2013 Sanofi paid £1,500 to Diabetes Flight Project Ltd in support of a 'Flying with Diabetes Day' to provide education on diabetes and flight experience for people with diabetes, their friends and families. Diabetes Flight Project was a private company that raised awareness of diabetes and worked with other patient organisations to support their objectives.

The lack of a formal written agreement between the two organisations governing this sponsorship meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3. Furthermore, although disclosed in September 2014, the sponsorship and service fee [sic] were not disclosed within the required timeline in breach of Clause 23.7.

Relationships with patient organisations subject to the 2014 Code

1 In 2014 Sanofi paid Diabetes UK £20,000 in sponsorship of patient care events, to provide support to individual patients with diabetes. The lack of a formal written agreement between the two organisations for this activity meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3.

2 In 2014 Sanofi paid Heart UK £23,000 in sponsorship of a familial hypercholesterolaemia (FH) audit project, aimed at systematically improving the diagnosis of FH within primary care. The pilot offered a model that could be implemented by other Clinical Commissioning Groups in England. The lack of a formal written agreement between the two organisations for this activity meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3.

3 In 2014 Sanofi paid Database of Individual Patient Experience (DIPEx) £2,000 in sponsorship of the Launch of Healthtalk at the House of Lords. Healthtalk was an online resource for patients and medical professionals. The lack of a formal written agreement between the two organisations for this activity meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3.

4 In 2014 Sanofi paid Arthritis and Musculoskeletal Alliance (AMRA) £5,000 in sponsorship of its core capacity building and advocacy activities and to help to initiate new activities. The lack of a formal written agreement between the two organisations for either activity meant that Sanofi had failed to certify such an agreement in advance in breach of Clauses 14.3 and 23.3.

Sanofi submitted that senior managers were in no doubt that this failing required immediate and decisive action. When the failure of process was identified, all payments to patient organisations were immediately suspended and where disclosure had not been made or was incorrect the relevant

organisations were contacted to confirm agreement for disclosure to occur. All disclosures from 2013 interactions were now, belatedly, correctly disclosed.

Patient organisation payments were unable to be processed unless scrutinised and approved by the head of promotional affairs, pending the implementation of a new management process, which was being developed taking into account the findings of the compliance officer's investigation.

Sanofi submitted that it had created a new position of transparency manager, within the medical division, to oversee all processes which supported transparency, including the disclosure of patient organisation interactions. Interactions would be managed and captured within a bespoke electronic system that would support comprehensive, accurate and timely disclosure for 2015. Payments to patient organisations would be flagged in financial systems making it mandatory for compliance with the Code to be checked and completed before payment was released. Finally, comprehensive training would be provided for all company personnel.

In conclusion, Sanofi stated that it had identified a failing in its processes governing disclosure of interactions with patient organisations which had led to numerous breaches of the Code. Sanofi considered that this clearly indicated that it had not maintained high standards in breach of Clause 9.1.

Sanofi contended that this had not, however, brought discredit on the industry, and through the actions it had taken in both making a voluntary admission and immediately strengthening its procedures to ensure compliance, it had supported the transparency standards that the public deserved. On this basis, Sanofi denied a breach of Clause 2.

Finally, Sanofi confirmed that this declaration was specific to 2013/14. The same processes that caused failings in this period existed before 2013. The voluntary admissions above were the result of several weeks' investigation, and were made now so as to avoid any delay that would occur if earlier periods were to be examined. Given that the deficiencies had been identified, acted upon and were being addressed as a result of the investigation conducted, Sanofi asked what the PMCPA expected with regard to investigating further historical cases of failure of process before 2013.

Support to meetings organised by patient organisations

In addition to the voluntary admissions above, Sanofi queried how a professional meeting organised by a patient organisation should be treated as regards compliance with the Code. These were principally meetings of health professionals and to date had been approved and supported in accordance with the requirements of the Code with respect to sponsorship of meetings.

Sanofi had supported several professional conferences during 2013/14 and had managed these as 'Meetings', in keeping with the requirements of Clause 19. Reviewing other member companies' disclosure sites, it was clear that there was no consistent pattern of disclosure when a health professional meeting was organised by a patient organisation. For example, two named companies declared their sponsorship of the Heart Rhythm Conference organised by the Arrhythmia Alliance, whereas another did not disclose its sponsorship of the Diabetes UK Professional Conference.

Sanofi therefore asked the PMCPA to consider the following professional meetings which took place in 2013 and which it sponsored in accordance with Clause 19 of the Code, but had not disclosed as an interaction with a patient organisation. Sanofi therefore asked the PMCPA to consider whether these were in breach of Clause 23.7 of the Second 2012 Edition of the Code:

With regard to the Diabetes UK Annual Professional Conference 2013, Sanofi had paid: £55,440 to be platinum sponsors; £11,340 for a second small exhibition space; £10,450 for two satellite symposia; £2,000 for freestanding screen advertising and £825 for sponsorship of delegate bags. Sanofi stated that it had also paid Diabetes UK the following: £13,704 to sponsor the Diabetes Innovator Meeting 2013; £20,000 to sponsor the Young Diabetologists Forum Meeting; £4,000 to sponsor the Young Diabetologists Forum Caledonian Meeting; £15,000 to sponsor the Young Diabetologists Forum Retinopathy Meeting and £600 to sponsor exhibition space at the South West Professional Meeting.

In conclusion, Sanofi saw that the industry was undecided as to whether support of a professional meeting, organised by a patient organisation, fell within the disclosure requirements relating to the latter. Sanofi would appreciate the PMCPA's determination on this matter.

Sanofi remained committed to its programme of review and improvement in both cultural and process aspects of Code compliance, and was determined to work with the Authority to conclude a review and determination in both of these matters.

Sanofi was advised that, in accordance with Paragraph 5.6 of the Constitution and Procedure, the matter would be treated as a complaint and it was asked to comment in relation to the requirements of Clauses 2, 9.1, 14.3, 23.3, 23.7 and 23.8 of the Second 2012 Edition of the Code (amended) and Clauses 2, 9.1, 14.3 and 24.3 of the 2014 Code.

RESPONSE

Sanofi stated that it had no further comment.

In response to specific questions from the case preparation manager, Sanofi provided further information as follows:

1 Material sent to patient organisations to inform them of the payment and disclosure

Sanofi provided a template letter used by its communications team (responsible for the process) with the individuals accountable for interactions with each of the patient organisations which were to have

support disclosed in March 2013. It was intended that the template would be adapted to include specific detail for each organisation and then sent by the accountable individuals. Sanofi had no record of the actual materials that were sent.

Sanofi also provided a print out from its patient group database which listed interactions in 2013; this was used by the communications team to track support provided to patient organisations in order to enable disclosure at the appropriate time.

2 Payments to patient associations

Sanofi stated that payments were initiated by the individual who was responsible for leading the respective interaction with the patient organisation. The Sanofi finance system operated a 'delegation of authority level' which meant that a payment initiated by an individual needed to be approved by someone in their management line, but whether this was done by the first or second line manager depended on the level of authority granted to the manager. The higher the sum, the more senior the approver must be. These delegations of authority were applied to all payments, but there was no functionality in the system to flag patient organisations as a distinct group to the approver, so that even if fully aware of the required process (Sanofi referred to Point 4 below concerning why the standard operating procedure (SOP) was not followed), the approver was not always clear that additional requirements were in place for that particular payee. When the current issues concerning payment were uncovered, an immediate preventative action was implemented such that only one individual in the UK company could initiate a payment to a patient organisation. That individual sat in the medical department and now used one consistent financial code which indicated the payment was to a patient association. This provided an additional check to track payments for disclosure. In addition, the relevant members of the procurement and finance teams had been fully orientated to the requirements and questioned any payment being raised to an organisation that might be a patient group, raising it to the medical team for confirmation of due process.

Sanofi stated that prior to a raised final payment being triggered, the head of promotional affairs reviewed all paperwork to ensure the correct documentation was in place.

Sanofi submitted that it was currently in the final stages of procuring and implementing a single automated information technology system (iDisclose) to process and manage all transfers of value to health professionals, healthcare organisations and patient groups in order to comply with the requirements of the 2014 Code for disclosures of transfers of value made from 1 January 2015. The iDisclose system and associated workflows would mandate that all payments to individuals or organisations which required disclosure under the Code would be managed by a new transparency team (incremental resource) which was currently being recruited (three full-time equivalent staff members). Sanofi referred to Point 4d below.

3 The SOP in use when the Code was breached

Sanofi stated that there were two relevant published SOPs in use at the time of the breaches. The first SOP, PA SOP-003-v02, 'Review and Approval of proposed projects or support involving patient or professional groups', was under the authorship and accountability of the promotional affairs team and effective from 10 May 2011. This policy stated that a defined project specific project owner was accountable for documentation relating to that project. This was replaced by COMMS-SOP-001-v01.1, 'Patients Associations', under the accountability and authorship of the communications team; it was available in the Sanofi Document Control Portal (DCP) and effective from 2 April 2013. It stated 'The Communications and Government Affairs teams have overall accountability for the strategic management and co ordination of our relationships with UK patient organisations, consistent with Global Sanofi guidance. They also have accountability in terms of our interface with Global on patient group activity and in relation to compliance and corporate audit. As such, the Communications and Government Affairs teams should be engaged in any review/approval processes'. Sanofi stated that the author of the SOP was the communications director, UK and Ireland, who left the organisation in June 2014.

As a result of the findings of the Sanofi investigation the SOP was under significant revision and was being moved to the medical department for oversight. The SOP was being updated to take on board all that had been found and ensure that what happened could not happen again.

4 Reasons the SOP was not followed

Sanofi stated that due to the seriousness of the breach, it had reviewed events so as to fully understand why the SOP was not followed, to inform the action plan required by Sanofi UK and ultimately to ensure these breaches could not occur again.

The points of relevance and the remedial action taken were as follows:

a) Training

The quality team within the medical function managed the organisation's SOP repository relating to regulated systems. The defined protocol for the inclusion of an SOP was that key stakeholders needed to have been trained on it by the author and subsequently evidenced by way of a formal training record.

The training records of the SOP showed that only three people had been trained on it in April and May 2013. It was clear that not enough people were trained in the SOP. To correct this, relevant staff had been trained on the interim solution which was co-ordinated by medical (see Point 4b below) and once the updated SOP was finalised, a group of senior individuals had been identified as requiring training along with all final medical and non-medical signatories. This training would take place in October.

b) Clarity in roles and responsibilities

Details of the responsibilities of the SOP were provided and the conclusions was that responsibilities for patient association oversight were only partly adhered to.

As a result of this, the medical director called a mandated meeting of all senior leaders of departments (commercial divisions, government affairs, communications, promotional affairs, financial controlling, medical and procurement) who could have been involved in patient organisations, to inform them of the findings and the actions that were being taken to rectify the situation moving forward. This group was made accountable for communication within their teams to ensure no payments were made except via the one person charged with this, and re-iterated exactly what was needed to work with patient organisations in a compliant way as per Clauses 14.3 and 24. All ongoing work was requested to be reviewed and to ensure that the appropriate review and written contracts were in place.

The revised SOP was currently being written and would ensure greater role clarity and accountability at each step. In addition, only individuals deemed competent after formal training and assessment would be able to lead interactions with patient organisations in future (and this point was captured in the revised SOP).

c) Oversight

As already indicated, it was agreed that the owner of the process and respective SOP was moved to a function that had greater oversight and was more closely aligned to the Code. The medical function (promotional affairs) had taken this responsibility immediately as an interim measure and it would be confirmed in the updated SOP which would move to the oversight of the transparency team.

d) Automation of capture and consistency in capture of information on patient organisation financial transactions

Sanofi recognised that it needed to strengthen internal controls in order to ensure that payments to patient organisations could only be made once all the necessary documentation required for the Code and internally defined policies and procedures had been met.

Measures had already begun to restrict such payments to patient organisations and filter these through one department within medical as an interim ahead of the revised SOP being trained and in place. Similarly, in the interim and in collaboration with procurement, additional controls were being developed around the financial processes including:

i) Identification of patient organisations through a specific type of vendor account
ii) Modification of the vendor account form to include identification of patient organisations
iii) Quarterly checks of the financial account types to ensure all patient organisations had been correctly identified and tagged
iv) Attachment of the contracts and supporting documentation with all purchase requisitions
v) A recommendation to complete a six monthly report based upon the patient association 'grouping' from the company's computer system to identify all payments made to those vendor accounts had also been made and agreed. This report could then be reconciled to the manual 'tracker' in the short-term in order to ensure that no payments to patient organisations were made outside of the newly defined processes.

In the longer term an internal control framework around patient association payments would be incorporated within the iDisclose system. The processing of payments made to support patient organisations would be met through iDisclose. This system would be configured so that only individuals with a pre-specified authority could initiate a patient association transaction, allowing strict control of who accessed that part of the system, which in turn enabled a tight control of the training of those who were given such access. In addition, the automated workflow would only permit progress to payment if all requirements built into the system were met, and oversight of this would be managed by the dedicated transparency team.

Summary

Sanofi stated that it took this matter extremely seriously as evidenced by the investigation and the immediate, interim and long-term corrective and preventive actions described. The company was fully aware of the importance of transparency to the reputation of the pharmaceutical industry and this was why it had given the management of this issue the utmost priority. Sanofi believed that it had demonstrated a clear and unwavering commitment to transparency in its approach to addressing the breaches in this case, making a voluntary admission, and importantly, in identifying, contracting for, and disclosing all payments made to patient organisations in 2013 and 2014. In this regard, transparency had been achieved, albeit outside of the required timeframe. Whilst Sanofi understood that lack of transparency in financial interactions with patient organisations might bring discredit upon the industry, and in such cases a breach of Clause 2 might be warranted, it believed that in this case the fact that it achieved transparency together with the robustness of its approach meant that it had not breached Clause 2 of the Code.

PANEL RULING

The Panel noted that Sanofi's voluntary admission related to its interactions with patient organisations in 2013 and 2014. Activities carried out in 2013 were subject to the Second 2012 Edition of the Code. Clause 23.3 of that Code required companies which worked with a patient organisation to have a written agreement in place which set out exactly what had

been agreed, including funding, in relation to every significant activity or on-going relationship. Clause 14.3 required such agreements to be certified in advance. When a patient organisation provided a service to a pharmaceutical company then Clause 23.8 required a written contract or agreement to be agreed in advance of the commencement of the services which specified the nature of the services to be provided and the basis for payment of those services. Clause 23.7 of the Second 2012 Edition of the Code required companies to make publicly available a list of patient organisations to which they provided support to include a description of the support which was sufficiently complete to enable the average reader to understand the significance of the support. The list of organisations being given support must be updated at least once a year. Clause 23.8 required each company to make publicly available a list of patient organisations it had engaged to provide significant, contracted services. The list must include a description of the nature of the services which was sufficiently complete to enable the average reader to form an understanding of the arrangement without the need to divulge confidential information; the total amount paid per patient organisation over the reporting period must be declared. The list of patient organisations engaged must be updated at least once a year. The Panel noted that Sanofi had referred to interactions with patient organisations which had occurred before 2013. In that regard, from 1 July 2008 Sanofi would have had to annually publish a list, by no later than 31 March 2009, to cover activities commenced on or after 1 January 2008 or ongoing on that date, of patient organisations to which it had provided support in the previous year. A list of patient organisations engaged to provide significant contracted services had to be declared for the first time by 31 March 2013 to cover activities commenced on or after 1 January 2012 or ongoing on that date. Given the requirement to update its declarations at least once a year, Sanofi would have to amend the lists by no later than 31 March each year for activities carried out in the previous calendar year.

With regard to the activities carried out in 2014 the requirements of the 2014 Code were identical to those of the Second 2012 Edition of the Code except that Clause 24, not Clause 23, of the 2014 Code governed relations with patient organisations.

The Panel considered Sanofi's relationship with each patient organisation in 2013 in turn. The following rulings were made under the Second 2012 Edition of the Code:

1 The Panel noted that Sanofi had paid Team Blood Glucose £2,500 to support one of its activities. The organisation had also been paid to provide a motivational speaker for a Sanofi internal meeting. The Panel noted Sanofi's submission that there was no written agreement to cover either relationship. A breach of Clause 23.3 and thus also of Clause 14.3 was ruled with regard to the sponsorship arrangement. A breach of Clause 23.8 and thus also of Clause 14.3 was ruled with regard to the fee for service. Further, Sanofi had not disclosed its sponsorship by 31 March 2014 and so the Panel ruled a breach of Clause 23.7 and similarly ruled a breach of Clause 23.8 for the late disclosure of the service provided by Team Blood Glucose.

2 In 2013 Sanofi paid Heart UK £12,000 to sponsor four continuing professional development accredited articles on hypercholesterolaemia published in the Primary Care Cardiovascular Journal. Sanofi also paid Heart UK a further £31,143 in sponsorship of a Royal College of General Practitioners online training programme in lipid management. The Panel noted Sanofi's submission that it had not accurately disclosed the amount paid in sponsorship for either activity and in one instance the information given was not sufficient for the reader to understand the significance of the support. The Panel thus ruled a breach of Clause 23.7 with regard to each disclosure.

3 In 2013 Sanofi paid the Rarer Cancers Foundation £5,000 to support a public affairs campaign. The Panel noted Sanofi's submission that there was no written agreement to cover this support. A breach of Clause 23.3 and thus also of Clause 14.3 was ruled. Further, as Sanofi had not disclosed its support by 31 March 2014, a breach of Clause 23.7 was ruled.

4 In 2013 Sanofi paid Leukaemia Care £10,000 to support patient support events. The Panel noted Sanofi's submission that there was no written agreement to cover this support. A breach of Clause 23.3 and thus also of 14.3 was ruled. Further, as Sanofi did not publicly disclose its support by 31 March 2014, a breach of Clause 23.7 was ruled.

5 In 2013 Sanofi paid the National Kidney Federation an unrestricted grant of £14,000. The Panel noted Sanofi's submission that there was no written agreement to cover such support. A breach of Clause 23.3 and thus also of Clause 14.3 was ruled. Further, as Sanofi did not publicly disclose its support by 31 March 2014 a breach of Clause 23.7 was ruled. [Post consideration of the case Sanofi advised that £4,100 was paid to the National Kidney Federation not £14,000 as previously stated].

6 In 2013 Sanofi paid the charity £20,110 in sponsorship for four activities; the company had also paid the charity to provide three services. The Panel noted Sanofi's submission that there were no written agreements to cover its support for and provision of services by the organisation. Breaches of Clause 23.3 were ruled with regard to each of the four sponsorship activities and breaches of Clause 23.8 were ruled in relation to the fees for service. Breaches of Clause 14.3 were ruled with respect to each of the seven activities. Further, as Sanofi had not publicly declared its sponsorship by 31 March 2014 the Panel ruled four breaches of Clause 23.7; it similarly ruled three breaches of Clause 23.8 for the late disclosure of the three services provided by Beating Bowel Cancer.

During its consideration of this matter, the Panel noted that Sanofi had paid Beating Bowel Cancer £110 for tickets for Sanofi personnel to attend a fund raising event. The Panel had no details as to the arrangements for the event or who attended but it requested that Sanofi's attention be drawn to Clause 23.2 of the Second 2012 Edition of the Code which stated that the requirements of Clause 19 of the Code applied to companies supporting patient organisation meetings. The supplementary information to Clause 19.1 of that Code stated that meetings which were wholly or mainly of a social or sporting nature were unacceptable. The Panel queried the acceptability under the Code of Sanofi's attendance at the fund raiser and asked that Sanofi be advised of its concerns in this regard.

7 In 2013 Sanofi organised a national competition for patient organisations the outcome of which was that the Anaphylaxis Campaign was awarded £25,000, the Brittle Bone Society was awarded £15,000 and Tommy's was awarded £10,000. The Panel noted Sanofi's submission that there were no written agreements to cover these bursaries. A breach of Clause 23.3 and thus also of Clause 14.3 was ruled with regard to each bursary. Further, as Sanofi had not disclosed the amount paid per organisation three breaches of Clause 23.7 were ruled.

8 The Panel noted that in 2013 Sanofi paid £1,500 via Diabetes Flight Projects Ltd to support a 'Flying with Diabetes Day' which provided education on diabetes and flight experience for people with diabetes, their friends and families. Although Diabetes Flight Projects Ltd was not a patient organisation the money given to it by Sanofi was used to support a patient activity day. In that regard the Panel considered that Diabetes Flight Projects Ltd had acted in support of patients and families and so Sanofi's sponsorship of the company for that activity was covered by the Code. The Panel noted Sanofi's submission that there was no written agreement to cover its support. A breach of Clause 23.3 and thus also of Clause 14.3 was ruled. Further, as Sanofi had not publicly disclosed its support before 31 March 2014, a breach of Clause 23.7 was ruled.

The Panel considered Sanofi's relationship with each patient organisation in 2014 in turn. The following rulings are made under the 2014 Code:

1 In 2014 Sanofi paid Diabetes UK £20,000 to sponsor patient care events. The Panel noted Sanofi's submission that there was no written agreement for this sponsorship. A breach of Clause 24.3 and thus also of Clause 14.3 was ruled.

2 In 2014 Sanofi paid Heart UK £23,000 to sponsor a familial hypercholesterolaemia audit project. The Panel noted Sanofi's submission that there was no written agreement for this sponsorship. A breach of Clause 24.3 and thus of Clause 14.3 was ruled.

3 In 2014 Sanofi paid DIPEx £2,000 to sponsor an online resource for patients and medical professionals. The Panel noted Sanofi's submission that there was no written agreement for this sponsorship. A breach of Clause 24.3 and thus of Clause 14.3 was ruled.

4 In 2014 Sanofi paid AMRA £5,000 to sponsor its core capacity building and advocacy activities and to help to initiate new activities. The Panel noted Sanofi's submission that there was no written agreement for this sponsorship. A breach of Clause 24.3 and thus also of Clause 14.3 was ruled.

The Panel noted Sanofi's submission that the process failings that had resulted in the voluntary admissions regarding the above, existed before 2013. Sanofi had queried what it should do about any historical cases of failure of process. In the Panel's view the company should review all of its historical interactions with patient organisations and take whatever remedial action seemed appropriate to ensure compliance with the relevant Codes, company procedures and any undertaking given in this case. Whether the matter subsequently became the subject of another voluntary admission would be for Sanofi to decide.

The Panel noted Sanofi's voluntary admission with regard to its sponsorship of health professionals' meetings organised by patient organisations; the company had supported several such meetings during 2013/14. In the Panel's view, such sponsorship was covered by Clause 23 of the Second 2012 Edition of the Code and Clause 24 of the 2014 Code. Both clauses referred to relationships with patient organisations and did not exempt sponsorship of meetings held for health professionals. In order for a company to be transparent about its interactions with patient organisations it was important that all such interactions were publicly declared – the required description of the nature of the support would show why the support was given.

The Panel noted that in 2013, Sanofi had paid Diabetes UK a total of £80,055 with regard to its Annual Professional Conference. The monies had been paid to enable Sanofi to be a platinum sponsor, have a second exhibition space, hold two satellite symposia, have some free standing screen advertising and sponsor delegate bags. Further, Sanofi had sponsored five other meetings in 2013 for a total of £53,304. The Panel noted Sanofi's submission that none of the above had been disclosed as an interaction with a patient organisation. Breaches of Clause 23.7 of the Second 2012 Edition of the Code were ruled with regard to each sponsorship arrangement.

During its consideration of this matter, the Panel noted that Sanofi had paid Diabetes UK £825 to sponsor delegate bags at its 2013 Annual Professional Conference. The Panel noted from Clause 18.3 that the items which might be provided to health professionals and appropriate administrative staff attending scientific meetings and conferences were limited to inexpensive notebooks, pens and pencils; conference bags were thus outside that limit. The Panel was concerned that

the sponsorship of the delegate bags was not in line with the requirements of the Code and it asked that Sanofi be so advised.

The Panel noted the sensitivities surrounding the pharmaceutical industry working with patient organisations; robust agreements setting out the arrangements, and certification of those agreements were important steps in ensuring that such interactions complied with the Code and in that regard they underpinned the self-regulatory compliance system. That projects and sponsorship were able to go ahead without a certified agreement in place was unacceptable. Further, public disclosure of support was an important means of building and maintaining confidence in the industry. The Panel noted that Sanofi had either sponsored or engaged thirteen patient organisations without first having agreements in place to cover more than twenty activities. The company's support for the patient organisations in 2013, although now disclosed (apart from it support for health professionals' meetings) was disclosed six months late in September 2014; some original disclosures had been inaccurate or lacking in detail. The Panel considered that high standards had not been maintained. A breach of Clause 9.1 of the 2014 Code was ruled (the requirements of Clause 9.1 in the 2014 Code and in the Second 2012 Edition of the Code were identical and so the Panel did not make separate rulings in that regard).

The Panel noted compliant and robust processes and procedures, which were appropriately trained into an organisation were the basics of any compliance program. The systemic failure with respect to the whole process of working with patient organisations was of grave concern. The voluntary admission submitted by Sanofi set out and to a degree remediated the situation with respect to patient organisations in 2013 and to date in 2014 however it was clear that Sanofi thought activities in 2012 could also be affected. For the lack of due process to be followed and for it to have gone undetected by the company for such a considerable period of time was totally unacceptable and brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 of the 2014 Code was ruled (the requirements of Clause 2 in the 2014 Code and in the Second 2012 Edition of the Code were identical and so the Panel did not make separate rulings in that regard).

The Panel noted its comments and rulings above. The Panel appreciated that Sanofi had voluntarily admitted its failings in process and procedure, however given the time period and the extent to which such failings had gone undetected, the Panel considered that its concerns about the company's procedures warranted consideration by the Appeal Board. The Panel thus reported Sanofi to the Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

During its consideration of this case the Panel noted the template letter that had been sent to patient organisations to inform them that Sanofi intended to publicly disclose the specific amount of financial support provided in 2013. The letter informed the recipient that a brief description of the nature of the support would be published; that brief description was not included in the letter itself. The Panel was very concerned that Sanofi had stated that it had no record of the actual materials which were sent. In the Panel's view, each letter, given that it was material related to working with patient organisations, should have been certified according to Clause 14.3 of the Code. The Panel requested that Sanofi be advised of its concerns in this regard.

COMMENTS FROM SANOFI ON THE REPORT

At the consideration of the report Sanofi stated that the company fully recognised the severity of this case which was why, when it discovered the issues all interactions with patient organisations were immediately stopped and it self reported the matter to the Authority. The failings highlighted by this case reflected how the company had historically dealt with compliance. It was now introducing wide ranging changes in company infrastructure and culture to address these issues. Details were given. Sanofi was confident that major compliance failures would no longer go unnoticed.

APPEAL BOARD CONSIDERATION OF THE REPORT FROM THE PANEL

The Appeal Board considered that the transparency of a pharmaceutical company's interactions with patient organisations was critical. Whilst interactions with patient organisations was a legitimate activity, the arrangements in place at Sanofi at the relevant time were shambolic and shocking. The Appeal Board noted that Sanofi's voluntary admission was prompted by media criticism in summer 2014 about the relationships between the pharmaceutical industry and patient organisations. The Appeal Board was concerned that the failure had not been discovered earlier, for example as part of the company's preparation for the audit in March 2014 (Case AUTH/2620/7/13). It noted Sanofi's response that the area was part of its work programme. The company was still investigating to see what other interactions had not been disclosed.

The Appeal Board was extremely concerned that such a long term systemic failure across the entire Sanofi business regarding multiple payments to multiple patient organisations had occurred. Staff had failed to follow the relevant SOP and Sanofi's governance of its SOP was very poor. This was a very serious matter.

The Appeal Board was extremely concerned about the breadth and scale of the failings and decided that, in accordance with Paragraph 11.3 of the Constitution and Procedure, the company should be publicly reprimanded.

The Appeal Board also decided to require an audit of Sanofi's procedures in relation to the Code. Given the company's ongoing and planned compliance activities, the Appeal Board decided that the audit in this case should be conducted in March 2015 at the same time as the re-audit required in Case

AUTH/2620/7/13. On receipt of the audit report and Sanofi's comments upon it, the Appeal Board would consider whether further sanctions were necessary.

APPEAL BOARD FURTHER CONSIDERATION

Sanofi was audited in March 2015, and on receipt of the audit report the Appeal Board noted that Sanofi had made progress since the audit in October 2014; a new, senior manager was fully involved and leading many of the company's compliance initiatives.

The Appeal Board however, noted its concern about some of the company's activities and considered that Sanofi should address the matters raised as a priority. On the basis that this work was completed, the progress otherwise shown in the March 2015 audit was continued and a company-wide focus and responsibility for compliance was maintained, the Appeal Board decided that no further action was required.

Complaint received	**26 September 2014**
Undertaking received	**10 November 2014**
Appeal Board consideration	**10 December 2014, 16 April 2015**
Interim Case Report first published	**12 February 2015**
Case completed	**16 April 2015**

CASE AUTH/2739/11/14

PFIZER/BRISTOL MYERS SQUIBB v DAIICHI-SANKYO

Satellite symposium to provide advance budgetary notification

Pfizer complained on behalf of both Bristol-Myers Squibb and itself (the Alliance) about a proposed Daiichi-Sankyo UK satellite symposium to be held at the Pharmacy Management National Forum, November 2014, entitled 'Financial and Policy Planning in Partnership with the NHS - A New Oral Treatment for the prevention of stroke in atrial fibrillation (AF) and treatment and secondary prevention of venous thromboembolism (VTE) in 2015 - Advance Budgetary Notification'. The symposium would be presented by a regional healthcare director. The new oral treatment at issue was edoxaban, an anticoagulant which was expected to be available in 2015.

Pfizer noted that the proposed symposium was advertised on the Forum's website which was publicly accessible. The symposium would be run three times during the course of the main meeting.

The synopsis used to promote the symposium contained the following statement: 'In Quarter 1 of financial year 2015/16, and subject to marketing authorisation approval, Daiichi-Sankyo UK Ltd will be introducing a new oral direct factor Xa inhibitor for anticoagulation in the prevention of stroke in atrial fibrillation (AF), and in the venous thromboembolism (VTE) disease area'. Pfizer alleged that the synopsis and the proposed symposium promoted edoxaban prior to the granting of a marketing authorization in breach of the Code.

Although in Daiichi-Sankyo's opinion the material and activities constituted advance budgetary notification, Pfizer considered that the requirements listed in the supplementary information to the Code, which needed to be met before pre-licence activities could be classified as such, had not been met. The synopsis was published on a website which was accessible to all; it was not restricted to those involved in budget planning or those with responsibility for making policy decisions on budgets. In Pfizer's view, a significant number of the health professionals who were likely to look at this website would not be responsible for making policy decisions on medicines budgets.
This lack of specificity in targeting the messages was further evidenced by the delegate list; many of the delegates did not have the required budgetary responsibilities to receive advance budgetary notification. Further, the synopsis on the website did not make it clear that attendees had to be budget holders and if they were not they would not be able to attend. During inter-company dialogue Daiichi-Sankyo stated that this could be changed quickly. However, this had been out there, people had registered, and Pfizer did not believe changing it now would make it compliant.

During inter-company dialogue Daiichi-Sankyo explained that to register for the symposium delegates to self-certify that advance budgetary notification content was relevant and appropriate to their role. Daiichi-Sankyo relied on Pharmacy Management to check the registration and oversee the sign in sheet on the day. In addition Pfizer questioned how much control there was with the sign in sheet. Attendees might sign, thinking it was an attendance register. It did not appear that anyone took them through the requirements for attendance before they signed.

Materials provided by Daiichi-Sankyo stated that people must register for the meeting in advance, and yet people could turn up on the day without registering. Pfizer was concerned that the sign in sheet just before the symposium was about to start was not a sufficient control. The group nature of the meeting could encourage 'casual attendance' from people who would otherwise not engage on a 1:1 basis; the nature of the meeting meant that attendees might not have the opportunity to reflect on whether they could genuinely influence budgets at this late stage and might just attend 'out of interest' – this would be hard to control.

In addition Pfizer was concerned about the group nature of the advance budgetary notification because attendees would be from across the UK. The advance budgetary notification discussion should be about the significant budgetary impact locally for a payor. Everyone's budget would be impacted differently. The local specifics (and the service model varied widely) could never be addressed in this type of meeting so the potential budget impact in reality would be impossible to quantify for any individual.

Pfizer questioned whether there was adequate time to influence the budget if the licence and launch was in quarter 1 of 2015, 6 weeks after the symposium. Attendees were not asked to confirm that they would have sufficient time to be able to act on the information and influence their budgets.

During the symposium, Daiichi-Sankyo explained that a medical liaison scientist (MSL) would be present which could be viewed as inviting questions on the clinical data prior to marketing authorization. If the requests were to be unsolicited and handled outside the meeting via MSLs or medical information, Pfizer questioned why the MSL was on the agenda along with the regional business director. The chairman's briefing document outlined these arrangements.

In summary, Pfizer alleged that the satellite symposia and associated advertising on the Forum website did not comply with strict advance

budgetary notification requirements and thus promoted edoxaban prior to the grant of a marketing authorization in breach of the Code. Given the seriousness of promoting prior to marketing authorization, Pfizer also alleged that this activity failed to maintain high standards and brought the industry into disrepute, in breach of the Code.

The detailed response from Daiichi-Sankyo is given below.

The Panel noted that the marketing authorization for edoxaban was expected at the earliest in April 2015. The Panel also noted Daiichi-Sankyo's submission about the approval dates of bodies such as NICE but considered that such approval dates were not relevant to the provision of advance notification.

The Panel noted that Daiichi-Sankyo appeared to accept that a satellite symposium was a novel format for the provision of advance notification. Although the company had tried to restrict access to the session itself and to ensure that it was individualised, the Panel queried whether a company-sponsored meeting would ever satisfy the requirements of the Code with regard to the provision of advance notification of new products and product changes, particularly the need to restrict the distribution of such information to those responsible for making policy decisions on budgets. In addition the relevant supplementary information only referred to a presentation being made on request.

The Panel noted that the forum website contained information and a brief synopsis of all of the satellite symposia. That information was available to all delegates whether or not they had any budgetary responsibility and if they did whether or not it was in stroke prevention in AF and/or the treatment or secondary prevention of VTE. In that regard the Panel noted that some attendees were pharmacy technicians and others included students and locum pharmacists. Although, as noted by Daiichi-Sankyo, the vast majority of delegates held senior positions within their organisations, it was clear that some did not and in that regard, although possibly interested in budgets, they were unlikely to be responsible for budgetary decisions. In addition, not all of the delegates in senior positions would be responsible for budgets or budgets relevant to the use of edoxaban. By reading the title and description of the session, every delegate would know that Daiichi-Sankyo expected to launch a new oral anticoagulant. Although such information was already in the public domain, the information provided on the Forum website had been approved by and specifically placed by Daiichi-Sankyo. In the Panel's view, the information provided on the website was not solely directed to those responsible for making policy decisions on budgets as required and so in that regard it promoted edoxaban prior to the grant of its marketing authorization. A breach of the Code was ruled which was upheld on appeal by Daiichi-Sankyo.

The Panel noted that it was important that advance notification of new products was only provided to those responsible for making policy decisions on budgets. In the Panel's view, a company had to make sure that those to whom it provided such information were appropriate. The Panel noted that Daiichi-Sankyo had asked potential attendees to self declare and to sign a symposium attendance sheet stating that they had appropriate and relevant budgetary responsibility. In the Panel's view, this was not sufficient – the company had to take responsibility for the provision of the information to appropriate personnel and exercise due diligence in that regard, not pass that responsibility to the attendee. Relying on self declaration alone was inadequate. Although some potential attendees had been declined entry to the symposium before it started, Daiichi-Sankyo still considered it necessary for the chairman to reiterate to the audience that if anyone did not fulfil the entry requirements, they should leave immediately. The Panel did not accept Daiichi-Sankyo's submission that because no-one did leave at that point, everyone in the room had appropriate and relevant budgetary responsibility.

The Panel noted that each satellite symposium lasted 40 minutes. The first 20 minutes consisted of two presentations; one from the regional business director (10 minutes) and one from an MSL (10 minutes). Together the two speakers had 38 slides, some of which were quite detailed and in that regard the Panel doubted that they could have all been presented in 20 minutes. In addition the Panel considered that the presentation went beyond the provision of a succinct account of the product's properties as set out in the Code. Whilst many of the slides provided background information and referred to budget impact, 14 of the slides provided in-depth information about a clinical trial for edoxaban. The final 20 minutes of the symposium was for 1:1 individualised discussion around the local budget impact using the cost model. The Panel did not have a copy of the cost model. The Panel noted, however, that this was not the subject of complaint. Pfizer had alleged that given the local variability in budgets, the impact on budgets could not be addressed in this type of meeting. The Panel noted Daiichi-Sankyo's submission that there were other agents of the same class as edoxaban on the market and that there was a great variability in uptake across the UK; the DoH had reported that the ratio of novel oral anticoagulant (NOAC)/ warfarin prescriptions could vary up to 86 fold across the country. The final slide in the formal part of the symposium stated that the local impact [of the introduction of edoxaban] would depend upon population size, disease incidence and prevalence and NOAC uptake, 'Please let the facilitator at your table know what the level of uptake is as this has a significant impact on your potential budget'. In that regard the Panel assumed that unless the attendees had all the necessary information with them then the 20 minute 1:1 exchange would not be detailed enough such that each would leave the symposium knowing how the introduction of edoxaban would significantly affect budgets in his/her area. In the Panel's view without providing delegates with that piece of information, then any discussion of edoxaban would not meet the requirements of advance budgetary notification.

The Panel considered that bearing in mind all of the points above, on the balance of probabilities the symposium had not met the requirements for advance notification and in that regard it had amounted to the promotion of edoxaban before the grant of a marketing authorization. A breach of the Code was ruled.

Upon appeal by Daiichi-Sankyo the Appeal Board did not consider on the information before it, bearing in mind the controls put in place to ensure that only those suitably qualified to receive advance budgetary information had been allowed into the symposium, that the symposium itself had promoted edoxaban prior to Daiichi-Sankyo receiving a marketing authorization. No breach of the Code was ruled. The appeal on this point was successful.

The Panel noted its rulings above and considered that high standards had not been maintained. A breach of the Code was ruled which was upheld on appeal by Daiichi-Sankyo.

The Panel noted its comments above in relation to the widespread notification of and the format, content and arrangements for the symposium and ruled a breach of Clause 2.

Upon appeal by Daiichi-Sankyo the Appeal Board noted that it considered each case on its merits. In this instance, it considered that its rulings of a breach in relation to the invitation to the meeting did not warrant a ruling of Clause 2 which was a sign of particular censure and reserved for such use. The Appeal Board therefore ruled no breach of Clause 2. The appeal on this point was successful.

Pfizer complained on behalf of both Bristol-Myers Squibb and itself (the Alliance) about a proposed Daiichi-Sankyo UK Ltd satellite symposium to be held at the Pharmacy Management National Forum, 18 November 2014. The satellite symposium was entitled 'Financial and Policy Planning in Partnership with the NHS - A New Oral Treatment for the prevention of stroke in atrial fibrillation (AF) and treatment and secondary prevention of venous thromboembolism (VTE) in 2015 - Advance Budgetary Notification'. The symposium would be presented by a regional healthcare director. The new oral treatment at issue was edoxaban, an anticoagulant which was expected to be available in 2015.

COMPLAINT

Pfizer noted that the proposed symposium was advertised and publicly accessible on the Forum's website. The symposium would be run three times during the course of the main meeting.

In addition to the title stated above, the synopsis used to promote the symposium contained the following statement: 'In Quarter 1 of financial year 2015/16, and subject to marketing authorisation approval, Daiichi-Sankyo UK Ltd will be introducing a new oral direct factor Xa inhibitor for anticoagulation in the prevention of stroke in atrial fibrillation (AF), and in the venous thromboembolism (VTE) disease area'. Pfizer alleged that both the synopsis and the proposed symposium clearly promoted edoxaban prior to the granting of a marketing authorization in breach of Clause 3.1.

Although in Daiichi-Sankyo's opinion the material and activities constituted advance budgetary notification, Pfizer considered that the requirements clearly listed in the supplementary information to Clause 3.1, which needed to be met before pre-licence activities could be classified as such, had not been met. The synopsis was published on a website which was accessible to all; it was not restricted to those involved in budget planning or those with responsibility for making policy decisions on budgets. In Pfizer's view, a significant number of the health professionals who were likely to look at this website would not be responsible for making policy decisions on medicines budgets.

This lack of specificity in targeting the messages was further evidenced by the delegate list; many of the delegates did not have the required budgetary responsibilities to receive advance budgetary notification. A copy of the delegate list for the Forum, available on the Forum website, was provided.

In addition, the synopsis on the website did not make it clear that it was mandatory that attendees were budget holders and if they were not they would not be able to attend. During inter-company dialogue Daiichi-Sankyo stated that this could be changed quickly. However, this had been out there, people had registered, and Pfizer did not believe changing it now would make it compliant.

During inter-company dialogue Daiichi-Sankyo provided information on the registration process for the symposium which required delegates to self-certify that advance budgetary notification content was relevant and appropriate to their role. Daiichi-Sankyo relied on Pharmacy Management to check the registration and oversee the sign in sheet on the day. In addition Pfizer questioned how much control there was with the sign in sheet. Attendees might sign thinking it was an attendance register. It did not appear that anyone took them through the requirements for attendance before they signed. Copies of materials provided by Daiichi-Sankyo during inter-company dialogue were provided.

The documents stated that people must register for the meeting in advance, and yet people could turn up on the day without registering. Pfizer was concerned that the sign in sheet just before the symposium was about to start was not a sufficient control. The group nature of the meeting could encourage 'casual attendance' from people who would otherwise not engage on a 1:1 basis; the nature of the meeting meant that attendees might not have the opportunity to reflect on whether they could genuinely influence budgets at this late stage and might just attend 'out of interest' – this would be hard to control.

In addition Pfizer was concerned about the group nature of the advance budgetary notification because attendees would all be from different locations around the UK. The advance budgetary notification

discussion should be about the significant budgetary impact locally for a payor. Everyone's budget would be impacted differently. The local specifics (and the service model varied widely) could never be addressed in this type of meeting so the potential budget impact in reality would be impossible to quantify for any individual attendee.

Pfizer questioned whether there was adequate time to influence the budget if the licence and launch was in quarter 1 of 2015 which was only 6 weeks away from the symposium. Attendees were not asked to confirm that they would have sufficient time to be able to act on the information and influence their budgets.

During the symposium, Daiichi-Sankyo outlined that a medical liaison scientist (MSL) would be present. Having the MSL there could be viewed as inviting questions on the clinical data prior to grant of the marketing authorization. If the requests were to be unsolicited and handled outside the meeting via MSLs or medical information, Pfizer questioned why the MSL was there on the agenda along with the regional business director. The chairman's briefing document provided during inter-company dialogue outlined these arrangements.

In summary Pfizer alleged that the satellite symposia and associated advertising on the Forum website did not comply with strict advance budgetary notification requirements and thereby promoted edoxaban prior to the grant of a marketing authorization in breach of Clause 3.1. Given the seriousness of promoting prior to marketing authorization, Pfizer also alleged that this activity failed to maintain high standards and brought the industry into disrepute, in breach of Clauses 9.1 and 2.

RESPONSE

Daiichi-Sankyo robustly defended the alleged breaches of Clauses 3.1, 9.1 and 2 and wished to prove that the satellite session at the Pharmacy Management National Forum was a *bona fide* form of advance budgetary notification and that it complied with the Code.

Website Synopsis

Daiichi-Sankyo noted that a series of recent cases (eg Case AUTH/2575/2/13) had clearly established that it was not unreasonable for a website connected with a meeting to bear the title of that meeting, so long as it did not itself constitute promotion. The website, for this recognised group of relevant decision makers was dedicated solely to the Pharmacy Management National Forum, itself organised by the organisation Pharmacy Management and was very unlikely to attract the attention of a member of the public but was targeted at the payor audience ('pharmacy managers'), akin to any website of a scientific congress. Access to information about the satellite session was not freely available, but required the user to voluntarily book. Subsequent to this, the information was only available through either registration, or by clicking on a further link to access information about all the symposia running at the Forum. Hence, Daiichi-Sankyo did not consider that it had promoted to the public for three reasons: firstly, the website was intended for a pharmacy manager audience only (and not the public); secondly, the information had to be actively sought (one of around 33 satellite sessions) and was not freely available on entering the site and lastly, Daiichi-Sankyo did not consider that the synopsis would promote an unlicensed product.

Daiichi-Sankyo firmly believed that the activity carried out during the Forum sessions was genuine advance budgetary notification. As such, it had to provide enough information for a person judging whether to attend the symposium.

- In the satellite session synopsis, it was stated that the factor Xa inhibitor was currently unlicensed, and subject to marketing authorization approval; the relevant timings for marketing authorization approval and approval by the National Institute for Health and Care Excellence (NICE) approval were given. Daiichi-Sankyo knew that there were other agents of the same class on the market and that there was a great variability in uptake across the country. According to the Department of Health (DoH) pilot dashboard of prescriptions for novel oral anticoagulants (NOACs), the ratio of NOAC/warfarin prescriptions could vary up to 86 fold. Hence if a payor had already made budgetary provisions for this class, he/she could make the informed decision not to attend. If on the other hand they had poor uptake, the budget impact might vary considerably. The synopsis had to give enough information for the payor to be able to decide whether attendance was appropriate.

- As a result of inter-company dialogue with Pfizer on 5 November, Daiichi-Sankyo asked the Forum organisers to add the extra statement in bold on the website "**Please note that only those responsible for making policy decisions on budgets for anticoagulation in the prevention of stroke in AF and in VTE in order to assist in the NHS financial planning for the financial year 2015/16 will be allowed to attend this session**" and this was actioned by 6 November in addition to the other measures Daiichi-Sankyo had in place.

Daiichi-Sankyo considered that it had taken care to provide sufficient information to an appropriate and self-selected group of people who would attend the Pharmacy Management National Forum so they could make an appropriate decision whether to attend the satellite session. Daiichi-Sankyo denied breaches of Causes 3.1 and 9.1.

Ensuring appropriate attendees

- Daiichi-Sankyo submitted that information was directed to those making policy decisions on budgets. The Pharmacy Management National Forum was intended for managers from primary and secondary care, with key stakeholders with an interest in medicines optimisation being invited to join the event this year, for example lead GPs from clinical commissioning groups (CCGs). These were exactly the types of individuals who would be responsible for making policy

decisions on budgets within their respective NHS organisations. The list of titles of attendees was available on the Forum website from last year and this year and it was clear that the vast majority of attendees were in senior positions within their organisations.

- Unlike the Alliance description of a 'symposium', these satellite sessions were designed to be workshops where only a small number of appropriate attendees were expected. There were 32 concurrent sessions. With 700 expected attendees and the very specific topic Daiichi-Sankyo had chosen, it did not expect there to be more than 10 people per session. In fact, the company only had 28 pre-registered and 12 attendees in all. The sign in sheets were provided and Daiichi-Sankyo submitted that they confirmed that those attending were responsible for making policy decisions on budgets in AF and VTE.

- Daiichi-Sankyo submitted that the only way to find out about the satellite session before the meeting was through the Forum website, where it was listed amongst 32 other concurrent sessions. A printout of the website page was provided and Daiichi-Sankyo noted that it was 14 pages long, with no particular emphasis on its session. A printed programme was also provided which was a replica of the website provided by the Forum organisers. The printed version had the additional disclaimer that only those with express budgetary responsibility in the field of AF and VTE would be admitted. Again, there was no emphasis on the Daiichi-Sankyo session in the printed programme. Daiichi-Sankyo personnel were specifically briefed not to talk to any attendees at the Forum about the advance budgetary notification session outside of the satellite session rooms.

- To register for the session, attendees had to confirm their budgetary responsibility in the specific domains of AF and VTE and confirm they were still financially planning for 2015/16. This was by means of a pop up that appeared when choosing the Daiichi-Sankyo session. Screenshots of the pop up were provided.

- Daiichi-Sankyo stated that it actively monitored who had registered for the session with a list sent to it a week before the event, a day before and on the morning of the event. If an attendee was thought to be inappropriate from their job title, an email was sent to him/her to make sure he/she was appropriate. For example, two attendees were from pharmaceutical companies and were asked to attend alternative sessions. A third delegate pre-registered and when they confirmed to Pharmacy Management that they were not a budget policy decision maker, their attendance was checked with Daiichi-Sankyo and they were consequently declined.

- The session itself was held two floors above the main meeting area in clearly labelled rooms. Forum personnel were positioned at the door to ensure attendees were on the registered list and a further check was carried out by Daiichi-Sankyo personnel to check that the attendees had pre-registered and were appropriate for the session. One person who had not pre-registered was allowed in as she job shared with a colleague who had registered and was attending in her place. Another person who had not registered stated that she did not have direct budgetary responsibility in the field of AF and VTE and was turned away.

- At the beginning of the session itself, the chairman explained the nature of advance budgetary notification and the importance that the information only be directed to budget holders. He asked any attendees who felt that the meeting was not appropriate for them to leave. As a sign of the rigorous process Daiichi-Sankyo had in place, no attendees left the session at that stage.

Daiichi-Sankyo therefore strongly refuted the claim that the meeting encouraged 'casual attendance' and it considered that it had demonstrated that the intent was always to invite the appropriate individuals and that it had put several barriers and showed due diligence in ensuring only the appropriate people attended. Daiichi-Sankyo therefore refuted breaches of Clauses 3.1 and 9.1.

Timing of advance budgetary notification

Daiichi-Sankyo stated that it would introduce a new factor Xa inhibitor, edoxaban ie a product with a new active substance. While the regulatory process was unpredictable, Daiichi-Sankyo had made public that regulatory filing occurred in January 2014 and assuming the usual time course of 12-15 months, the medicine was only likely to receive a marketing authorization in April 2015 at the very earliest (ie the first financial quarter in 2015). Daiichi-Sankyo noted that the uptake of new medicines in the UK was not very quick and was very much dictated by approval from bodies such as NICE or the Scottish Medicines Consortium (SMC). NICE guidance for the use of edoxaban in AF was only planned to be available in September 2015 and in October 2015 for VTE (www.nice.org.uk). NICE implementation only became mandatory ninety days after the publication of guidance. Therefore Daiichi-Sankyo believed that the financial impact of the introduction of edoxaban in the UK was only likely to be felt in December 2015/January 2016, more than a year after the satellite session at issue and at the end of the financial cycle of 2015/16.

Daiichi-Sankyo stated that the Alliance clearly misunderstood the situation when it stated that edoxaban could be launched in quarter 1 of 2015, 6 weeks after the symposium, implying January 2015. As stated above and in materials, no approval was expected until at least quarter 1 of the financial year 2015 and any financial impact was not expected until at least a year after the satellite session. This was made clear to the Alliance several times during inter-company dialogue, but it had nonetheless raised the issue.

Daiichi-Sankyo noted that Prescribing Outlook 2014, issued in September 2014, contained information about edoxaban. This document was produced by UK Medicines Information (UKMi) which aimed to provide advance information about new medicines

and new licensed indications or formulations for the purpose of planning for the following financial year. The content was not comprehensive but focused on medicines with the potential for significant clinical or financial impact on the NHS.

Furthermore, the component documents of the Prescribing Outlook series were published each autumn in line with annual budget planning timeframes. Hence, Daiichi-Sankyo considered that the timing of the Forum was in line with NHS budget planning cycles. Daiichi-Sankyo provided an Internet link to the document.

Daiichi-Sankyo stated that as part of the meeting it collected feedback on the structure, content and timing of the session in relation to the financial planning cycle; there were 9 responses from 12 attendees. No-one thought the information received was too late. In fact, a third thought it was too early. Daiichi-Sankyo stated that this further strengthened its claim around the appropriate timing of this activity.

Daiichi-Sankyo submitted that the timing of the advance budgetary notification session was entirely appropriate and in keeping with the NHS financial planning cycle 2015/16; the company denied breaches of Clauses 3.1 and 9.1.

Content of advance budgetary notification and role of MSL

The session was structured as follows:

- Presentation of environmental factors and the policy environment concerning AF related stroke and VTE (10 minutes) by a regional healthcare director

- A brief presentation of the top line pivotal clinical trial data supporting the edoxaban application in AF and VTE with the relevant efficacy and safety endpoints for a payor audience (10 minutes) by an MSL

- 1:1 individualised discussion around the local budget impact using the cost model (20 minutes).

Daiichi-Sankyo submitted that all of its personnel were briefed on what was appropriate to discuss in the context of an advance budgetary notification meeting. It was made clear during the presentation that the clinical presentation was a summary only and no data on competitor products would be presented or discussed. There were a couple of instances where the data presented had to be clarified by the MSL but these were within the parameters briefed out previously. The MSL also had to ensure that the discussion did not go into inappropriate clinical detail. While medical information forms were available to capture requests from attendees, none were received at the session nor since.

With regard to the 'group nature' of this session, Daiichi-Sankyo accepted that this was a novel format for such an activity. However, it had taken great care to ensure that the session was interactive and as individualised as possible. The environmental/ policy presentation showed information that was relevant across the health service but sufficient time was built into the agenda (around half of the session) to discuss local factors that would directly influence budgets such as prevalence of AF/VTE and NOAC uptake. Daiichi-Sankyo did not expect to have a huge audience and had planned to have enough personnel to deliver a near 1:1 discussion with payors in attendance. Ten people per session were registered to attend. Taking into account non attendance, Daiichi-Sankyo had 7 people capable of delivering advance budgetary notification at the session who were regionally based and therefore were familiar with the regional environment. There was a much lower turn out than expected, especially in the first session where only two registered attendees arrived. All extra Daiichi-Sankyo staff left the room for that session. So, in all, Daiichi-Sankyo was able to deliver a short upfront presentation with the majority of time dedicated to a 1:1 discussion with a local company employee.

In the feedback from the session, 8 of the 9 respondents reported that the session covered what they expected it to, and all rated the content and presentation as good or excellent.

In summary, Daiichi-Sankyo firmly believed that the advance budgetary notification delivered via voluntary attendance at a satellite session of a national meeting dedicated to medicines management and optimisation, which was specifically targeted at key stakeholders with an interest in medicines optimisation, was timely, appropriate in content, tone and delivery and was conducted to the highest standards within the spirit and letter of the requirements of the Code. The company denied breaches of Clauses 3.1 and 9.1. Daiichi-Sankyo did not consider that its actions had jeopardised the reputation of the industry and thus it denied a breach of Clause 2.

PANEL RULING

The Panel noted that Clause 1.2 defined promotion as any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines. Clause 3.1 stated that a medicine must not be promoted prior to the grant of the marketing authorization that permitted its sale or supply. The supplementary information to Clause 3.1, in recognition of the fact that NHS organisations and others had to plan estimated budgets in advance, allowed an exemption for advance notification of new products or product changes. The exemption was narrow: the information provided had to, *inter alia*, relate to a medicine which would have a significant budgetary impact, the likely cost and budgetary impact had to be stated and the information could only be directed to those responsible for making policy decisions on budgets. The supplementary information provided a list of requirements which had to be met to ensure that companies provided *bona fide* advance notification and thus did not promote their medicines prior to the grant of a marketing authorization. Only

factual information could be provided, limited to that sufficient to provide an adequate but succinct account of the product's properties. If requested, further information might be supplied or a presentation made.

The Panel noted that the marketing authorization for edoxaban was expected at the earliest in April 2015. The Panel also noted Daiichi-Sankyo's submission about the approval dates of bodies such as NICE but considered that such approval dates were not relevant to the provision of advance notification.

The Panel noted that Daiichi-Sankyo appeared to accept that a satellite symposium was a novel format for the provision of advance notification. Although the company had taken some steps to restrict access to the session itself and to ensure that it was individualised, the Panel queried whether a company-sponsored meeting would ever satisfy the requirements of the Code with regard to the provision of advance notification of new products and product changes, particularly the need to restrict the distribution of such information to those responsible for making policy decisions on budgets. In addition the relevant supplementary information only referred to a presentation being made on request.

The Panel noted that that the website for the Pharmacy Management National Forum 2014 contained information and a brief synopsis of all of the satellite symposia. That information was available to all delegates whether or not they had any budgetary responsibility and if they did whether or not it was in stroke prevention in AF and/or the treatment or secondary prevention of VTE. In that regard the Panel noted that some attendees were pharmacy technicians and others included students and locum pharmacists. Although, as noted by Daiichi-Sankyo, the vast majority of delegates held senior positions within their organisations, it was clear that some did not and in that regard, although possibly interested in budgets, they were unlikely to be responsible for budgetary decisions. In addition, not all of the delegates in senior positions would be responsible for budgets or budgets relevant to the use of edoxaban. By reading the title and description of the session, every delegate would know that Daiichi-Sankyo expected to launch a new oral anticoagulant for the prevention of stroke in AF and the treatment and secondary prevention of VTE. Although such information was already in the public domain, the information provided on the Forum website had been approved by and specifically placed by Daiichi-Sankyo. In the Panel's view, the information provided on the website was not solely directed to those responsible for making policy decisions on budgets as required and so in that regard it promoted edoxaban prior to the grant of its marketing authorization. A breach of Clause 3.1 was ruled.

The Panel noted that it was important that advance notification of new products was only provided to those responsible for making policy decisions on budgets. In the Panel's view, it was incumbent upon a company to make sure that those to whom it provided such information were appropriate.

The Panel noted that Daiichi-Sankyo had asked potential attendees to self declare and to sign a symposium attendance sheet stating that they had appropriate and relevant budgetary responsibility. In the Panel's view, this was not sufficient – the company had to take responsibility for the provision of the information to appropriate personnel and exercise due diligence in that regard, not pass all of that responsibility to the attendee. Relying on self declaration alone was inadequate. Although some potential attendees had been declined entry to the symposium before it started, Daiichi-Sankyo still considered it necessary for the chairman to reiterate to the audience that if anyone did not fulfil the entry requirements, they should leave immediately. The Panel did not accept Daiichi-Sankyo's submission that because no-one did leave at that point, everyone in the room had appropriate and relevant budgetary responsibility.

The Panel noted that each satellite symposium lasted 40 minutes. The first 20 minutes consisted of two presentations; one from the regional business director (10 minutes) and one from an MSL (10 minutes). Together the two speakers had 38 slides some of which were quite detailed and in that regard the Panel doubted that they could have all been presented in 20 minutes including a handover time from one speaker to the next. In addition the Panel considered that the presentation went beyond the provision of a succinct account of the product's properties as set out in the supplementary information to Clause 3.1. Whilst many of the slides provided background information and referred to budget impact, 14 of the slides provided in-depth information about a clinical trial for edoxaban. The final 20 minutes of the symposium was for 1:1 individualised discussion around the local budget impact using the cost model. The Panel did not have a copy of the cost model. The Panel noted, however, that this was not the subject of complaint. Pfizer had alleged that given the local variability in budgets, the impact on budgets could not be addressed in this type of meeting. The Panel noted Daiichi-Sankyo's submission that there were other agents of the same class as edoxaban on the market and that there was a great variability in uptake across the UK; the DoH had reported that the ratio of NOAC/warfarin prescriptions could vary up to 86 fold across the country. The final slide in the formal part of the symposium stated that the local impact [of the introduction of edoxaban] would depend upon population size, disease incidence and prevalence and NOAC uptake, 'Please let the facilitator at your table know what the level of uptake is as this has a significant impact on your potential budget'. In that regard the Panel assumed that unless the attendees had all the necessary information with them then the 20 minute 1:1 exchange would not be detailed enough such that each would leave the symposium knowing how the introduction of edoxaban would significantly affect budgets in his/her area. In the Panel's view without providing delegates with that piece of information, then any discussion of edoxaban would not meet the requirements of advance budgetary notification. The supplementary information to Clause 3.1 stated that the likely cost and budget implications must be stated.

The Panel considered that bearing in mind all of the points above, on the balance of probabilities the symposium had not met the requirements for advance notification and in that regard it had amounted to the promotion of edoxaban before the grant of a marketing authorization. A breach of Clause 3.1 was ruled. The Panel noted its rulings above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that the supplementary information to Clause 2 stated that one of the activities likely to be in breach of that clause was the promotion of a medicine prior to the grant of a marketing authorization. The Panel noted its comments above in relation to the widespread notification of and the format, content and arrangements for the symposium and ruled a breach of Clause 2.

APPEAL BY DAIICHI-SANKYO

Daiichi-Sankyo stated that the broader context was that the meeting in question took place during the Pharmacy Management National Forum, 18 November 2014. The one-day event ran from 9.30am-4.30pm and comprised a mixture of plenary sessions and workshops. Approximately 800 delegates who all had a self-selected interest in pharmacy management attended; over 65% were senior managers. Daiichi-Sankyo provided a copy of an email from the Forum organisers which explained how attendance to the Forum generally was controlled.

Daiichi-Sankyo submitted that three 45-minute sessions were allocated to small workshops on the day; the same workshops ran for all three sessions and delegates could choose which one to attend in each time slot by pre-registering. Delegates had 31 workshops to choose from, of which Daiichi-Sankyo hosted one.

General points

Daiichi-Sankyo submitted that the Panel rulings had focused on the innovative format of its approach, rather than the specific manner in which the advance budgetary notification was actually conducted. The Code did not preclude the provision of advance budgetary notification in a meeting environment, indeed there were some parallels in the way scientific exchange operated with scientific symposia. The Code did not require the recipient of advance budgetary notification to receive highly detailed localised information. Indeed, information had to be provided which facilitated understanding of the potential impact of advance budgetary notification so that recipients could decide whether they wanted to take any action. The provision of advance budgetary notification required appropriate recipients to be identified and steps taken to ensure that only those deemed to be appropriate were exposed to the material. Clearly, this needed to be informative in terms of budget impact and not promotional, *per se*, but the Code did not define how this was achieved.

Information on the website

Daiichi-Sankyo noted the Panel's statement that in its view 'the information provided on the website was not solely directed to those responsible for making prescribing decisions on budgets as required and so in that regard it promoted edoxaban prior to the grant of its marketing authorization'.

The company submitted the two following considerations in respect of this ruling:

i) Intended audience and who was likely to access the information on the website

Daiichi-Sankyo submitted that it was an established principle of the Code, that in considering the appropriateness of communications, the intended target audience should be noted. For example, although the public could buy copies of certain medical journals, such as the Health Service Journal, the intended audience was hospital management and therefore the Appeal Board had previously indicated that it was acceptable to publish advertisements for prescription medicines within that journal (Case AUTH/2426/8/11).

Daiichi-Sankyo referred to its comments above about the Pharmacy Management National Forum and provided a 2014 delegate list. It was clear from the Pharmacy Management National Forum website that the target audience was comprised of medicines payors and the attendee list further indicated the relevant nature of the delegates the overwhelming majority of whom were senior managers and senior pharmacists. Whilst a very small number of delegates fell outside the usual definition of senior managers, their roles justified their presence at the conference overall (eg, the two students were the leaders of the student pharmacist council, British Pharmaceutical Student's Association).

However, as a responsible company Daiichi-Sankyo took several additional steps to ensure that only appropriate individuals attended the session including clear statements on the registration forms and accompanying website text about the nature of the event. The filtration steps were further detailed below, however, it was appropriate here to examine the arrangements related to the text about the Daiichi-Sankyo workshop on the event website.

Daiichi-Sankyo submitted that the Appeal Board had ruled in Case AUTH/2580/2/13 that websites should be seen in the context of the intended target audience. The intended target audience was clearly pharmacy managers/payors. However, the descriptions related to the parallel workshops were not visible on the main pamphlets and areas of the website; they were only visible when the delegate was ready to select a workshop and they accessed a separate, specific area of the website.

Daiichi-Sankyo submitted that when they registered for the workshop, delegates were immediately shown a pop-up box which stated the nature of the workshop and asked them to confirm they were

appropriate attendees for the intended content. With so many parallel sessions to choose from, it was highly unlikely that individuals would attend the workshop unless they had an intense interest in this area, given the precious nature of NHS learning time. On registering, delegates were sent a further confirmation which clarified the nature of the workshop and asked them to confirm in writing that they were an appropriate delegate to attend the session. If that was not the case, the delegate would be deregistered.

Daiichi-Sankyo submitted that it was always in communication with the Forum staff to monitor the eligibility of those who registered. Hence a week before and four days before the event, a list of registered delegates along with their job title was circulated. If there was any doubt about the eligibility of the delegate, a further email was sent to the delegate to confirm suitability. Examples of such interactions with delegates were provided.

Finally, Daiichi-Sankyo submitted that the chairman of the session was specifically briefed to, and did use, clear statements on the slides about the nature of the workshop. It was difficult to see what else Daiichi-Sankyo could have done to ensure appropriate attendance. In fact the final number of attendees indicated the success of the filtering process: two in one of the workshops and five each in the other two, so twelve attendees in all.

Therefore, Daiichi-Sankyo submitted that the specific filtering of the potential audience combined with the additional precautions it had taken ensured that 12 delegates (~1.5% of attendees) attended its satellite sessions. Indeed random attendance spread across the 31 sessions would have led to more than double this attendance. Daiichi-Sankyo submitted that it did everything it could to ensure the highest possible standards that the industry would expect to ensure that appropriately qualified individuals were targeted and included in these sessions and that inappropriate individuals were not aware of and did not attend the session.

ii) Website content

Daiichi-Sankyo submitted that it was necessary (and appropriate) to describe the nature of the workshop. This was exactly the same as when pre-filtered payors were sent letters to ask them if they had a relevant interest in advance budgetary notification.

Daiichi-Sankyo submitted that the specific text used on the workshop abstract was carefully worded to ensure that edoxaban was not promoted *per se*. Neither the generic name nor the brand name was used. It was of course necessary to declare the therapy area and the nature of the session, and the Code required the company to declare its involvement. The text used was:

'**Financial and Policy Planning in Partnership with the NHS – A New Oral Treatment for the prevention of stroke in atrial fibrillation (AF) and treatment and secondary prevention of venous thromboembolism (VTE) in 2015**
Advance Budgetary Notification

[named], Regional Healthcare Director, Daiichi-Sankyo UK Ltd

Synopsis:
In Quarter 1 of financial year 2015/16, and subject to marketing authorisation approval, Daiichi-Sankyo UK Ltd will be introducing a new oral direct factor Xa inhibitor for anticoagulation in the prevention of stroke in atrial fibrillation (AF), and in the venous thromboembolism (VTE) disease area.

The Department of Health has requested NICE to carry out single technology appraisals for this product within each of its expected licensed indications, with guidance on the AF and VTE indications expected in September and October 2015 respectively.

This satellite will provide you with information to help you and your organisation plan for the potential budget impact of the introduction of this currently unlicensed product. If you are responsible for making policy decisions on budgets in these disease areas and feel that attending this symposium would be appropriate, please come along.

Please note that only those responsible for making policy decisions on budgets for anticoagulation in the prevention of stroke in atrial fibrillation and in the venous thromboembolism area in order to assist in the NHS financial planning for the financial year 2015/16 will be allowed to attend this session.

A symposium organised and funded by Daiichi-Sankyo UK Ltd.'

Daiichi-Sankyo submitted that the text on the website was appropriate in its placement, accessibility and content. The information conveyed appropriate information and did not promote a specific product; the content was no different to that used in order to determine whether specific payors were appropriate recipients of specific advance budgetary notification communications.

Daiichi-Sankyo appealed the Panel's ruling of a breach of Clause 3.1 because the audience was appropriate and the content was appropriate for the occasion.

Symposium

Daiichi-Sankyo noted that the Panel considered that, on the balance of probabilities, the symposium had not met the requirements for advance notification and in that regard it had amounted to the promotion of edoxaban before the grant of its marketing authorization.

Daiichi-Sankyo submitted that there were several considerations in respect of this ruling. Firstly,

what did the Code require for advance budgetary notification and secondly, what points did the Panel raise?

Advance budgetary notification requirements and Daiichi-Sankyo actions

Daiichi-Sankyo noted that:

> 'Non-promotional information can be provided as advance notification but it must:
>
> i) relate to:
>
> a) a product which contains a new active substance, or
> b) a product which contains an active substance prepared in a new way, such as by the use of biotechnology, or
> c) a product which is to have a significant addition to the existing range of authorised indications, or
> d) a product which is to have a novel and innovative means of administration.'

Daiichi-Sankyo submitted that in this regard, whilst not the subject of the complaint or any comments from the Panel, it was confident that its product met the requirements of advance budgetary notification.

> 'ii) only be directed to those responsible for making policy decisions on budgets and not those expected to prescribe.'

Daiichi-Sankyo submitted that in this regard, not only was the overall event clearly targeted at pharmacist payors, but also it had taken considerable steps to ensure that the delegates who attended its workshop were appropriate for advance budgetary notification. When they registered for the workshop, delegates were immediately shown a pop-up box which stated the nature of the workshop and asked them to confirm that they were appropriate attendees for the intended content. The pop-up text was:

> 'I confirm that I am responsible for making policy decisions on budgets for anticoagulation in the prevention of stroke in atrial fibrillation and in the venous thromboembolism disease area and agree to receive advanced notification of the new product from Daiichi-Sankyo UK Ltd in order to assist in the NHS financial planning for the financial year 2015/16.'

Daiichi-Sankyo submitted that the conference organisers were briefed to filter inappropriate attendees according to pre-defined criteria it had established. One week then four days before the event and on the morning of the event, the conference organisers sent Daiichi-Sankyo the list of registered delegates for the advance budgetary notification satellite sessions so that Daiichi-Sankyo signatories could determine the appropriateness of each individual and deregister any inappropriate delegates.

Daiichi-Sankyo submitted that for those who did not pre-register but tried to join the session on the day, its staff were briefed to discuss the nature of the symposium with the individual and if appropriate, to declare their suitability in writing. The chairman of the session was specifically briefed to, and had used clear statements on the slides about the nature of the workshop. It was difficult to see what else Daiichi-Sankyo could have done to ensure appropriate attendance. In fact the highly select number of attendees indicated the success of the filtering: two in one of the workshops and five each in the other two. The briefing for staff attending the workshop as facilitators, clearly indicated the requirement to check that delegates had indicated their suitability.

Daiichi-Sankyo submitted that it had clearly demonstrated accountability for the event and did not, as indicated by the Panel, abdicate responsibility to the organisers or the delegates themselves. Disappointingly, the Panel saw the chairman's statement at the beginning of the workshop in relation to the suitability of the audience as an admission of failure by Daiichi-Sankyo, rather than a responsible final check. Further, the Panel also failed to see the company's decision to exclude certain inappropriate delegates as an indication that it was in control and did not in any way abdicate responsibility for delegate selection. The final decision regarding attendees at the workshop rested with Daiichi-Sankyo.

Daiichi-Sankyo submitted that there was no evidence that anyone inappropriate attended the workshop.

> 'iii) state whether or not a new medicine or a change to an existing medicine is the subject of a marketing authorization in the UK.'

Daiichi-Sankyo submitted that this was clearly stated in the website text, on all forms, in the chairman's briefing and in the workshop materials. Unfortunately, the Panel noted that in making such a declaration (for example, on the abstract explaining the nature of the workshop) Daiichi-Sankyo had breached the Code. It was difficult to see how specifically meeting the requirements of the supplementary information was in breach of Clause 3.1.

> 'iv) state the likely cost or savings and budgetary implications which must be such that they will significantly change the organisation's likely expenditure.'

The workshops comprised of three elements:

- A ten minute presentation from the Daiichi-Sankyo regional business director to indicate the budgetary impact
- A ten minute presentation from a Daiichi-Sankyo medical science liaison explaining some top-line relevant clinical information to place the budget impact in context
- Twenty minutes where the delegates were able to discuss the local implications with an appropriately trained member of Daiichi-Sankyo staff who had access to a cost impact model.

Daiichi-Sankyo submitted that in order for the cost impact model to be most effective, the payor had to have specific detailed information. However, the

model was pre-populated with default numbers that clearly indicated the likely impact. This was in line with the custom and practice of nearly all advance budgetary notifications used by the pharmaceutical industry over many years. In addition, from the registration details, Daiichi-Sankyo knew where the delegates worked and it used this information to allocate a geographically relevant member of staff to the delegates.

Daiichi-Sankyo submitted that the Panel specifically commented that because the chairman explained that the impact could be dependent on 'population size, disease incidence and prevalence and NOAC uptake' and the delegates were unlikely to have this information with them, the requirements of advance budgetary notification could not be met. This was patently incorrect. All specifically qualified payors had a detailed knowledge of their local population dynamics and local demographics and all good budget impact models (including Daiichi-Sankyo's) allowed users to enter different ranges of information to determine the likely impact, typically based on varying the percentages attributable to different variable factors. The Daiichi-Sankyo model was able to pre-populate information down to CCG level and could incorporate local prevalence data as well as national data. In addition, Daiichi-Sankyo staff could show data about local NOAC/warfarin prescribing ratio as produced by the NHS England medicines optimisation dashboard by individual CCG to gain an idea of current level of uptake of this class of medicines.

Daiichi-Sankyo submitted that contrary to the Panel's comments, the Code did not require advance budgetary notification to use specifically localised data, only that the payor understood the likely local impact; in fact arguably, by doing so, there was a risk that the information became so specific it was effectively promotional. The Code only required the payor understood the likely impact; it was not unreasonable to expect that payors would be able to conclude impact from appropriately presented consensus information.

> 'v) be factual and limited to that sufficient to provide an adequate but succinct account of the product's properties; other products should only be mentioned to put the new product into context in the therapeutic area concerned.'

Daiichi-Sankyo noted in this regard that the Panel's comments went beyond the complaint. The complainant was concerned that the presence of the MSL might encourage off-licence questions. Given that every advance budgetary notification was about the unlicensed use a medicine this was a very strange comment, especially given that the MSL's role was broad and could encompass advance budgetary notification specifically as indicated in the PMCPA's Guidance about Clause 3.

Daiichi-Sankyo submitted that there was no complaint about the content of the workshop. Despite this, the Panel examined the content of the slides and drew conclusions. Daiichi-Sankyo considered that the conclusions were incorrect and that the Panel's comments in this regard were irrelevant because they exceeded the scope of the complaint. Daiichi-Sankyo submitted that nevertheless, the Panel ruled that the MSL presentation went beyond the scope of advance budgetary notification by explaining a relevant clinical trial 'in depth'. Given the wide nature of the potential audience, it was appropriate that the MSL had the ability to explain the context of the trials and to answer questions, however there was no evidence provided either that all the slides were actually used, or that any delegate received inappropriate information for his/her role. However, as this matter was not the subject of the complaint a ruling upon it was inappropriate.

Additional Panel comments

Daiichi-Sankyo noted the Panel's view that advance budgetary notification could not be conducted in a meetings format, partly because the supplementary information to Clause 3 stated that relevant supplementary information was available on request. This was an unexpected interpretation of the intention of that aspect of the supplementary information. The specific wording was right at the end of the supplementary information and stated 'If requested further information may be supplied or a presentation made'.

Daiichi-Sankyo submitted that this clearly meant that it was acceptable to return to the payor on a second occasion to elucidate a particular point. It was not a ban on the format of advance budgetary notification; if it were then given that the majority of discussions with payors used laptops or iPads, etc, nowadays, the use of PowerPoint-type media was widespread and in that sense presentations could be made on a 1:1 or group basis. The Code did not state that advance budgetary notification must be either conducted with individual payors, or limited to hard copy paper documents.

Further, Daiichi-Sankyo submitted that by registering for the workshop, delegates had effectively asked for a presentation (or at least accepted there would be one). Daiichi-Sankyo did not agree with or understand why this comment was made, especially because it was not mentioned anywhere by the Alliance and in that regard it was not appropriate for the PMCPA to make the case for the complainant.

Summary

Daiichi-Sankyo submitted that the text on the website was appropriate in its placement, accessibility and content. The information did not promote a specific product and the content was no different to that used in order to determine whether specific payors were appropriate recipients of specific advance budgetary notification communications.

Daiichi-Sankyo appealed the Panel's ruling of a breach of Clause 3.1 because the audience was appropriate and the content was appropriate for the occasion.

Clause 9.1

Daiichi-Sankyo submitted that as it had appealed the two rulings of breaches of Clause 3.1, upon which the ruling of the breach of Clause 9.1 was based, rather than anything additional, it also appealed the ruling of a breach of Clause 9.1.

In addition, while Daiichi-Sankyo accepted that the Panel had not previously considered the communication of advance budgetary notification at a meeting, this did not mean that Daiichi-Sankyo had failed to maintain high standards. In fact Daiichi-Sankyo submitted that its actions indicated a high degree of responsibility and control. Even if the Appeal Board upheld one or both of the Panel's rulings of breaches of Clause 3.1, Daiichi-Sankyo did not agree that its actions reflected a lack of high standards for the reasons outlined above. In particular, Daiichi-Sankyo submitted that it fully controlled all aspects of the workshop and the text used to communicate the content. The only debate was about the format of the meeting, not Daiichi-Sankyo's actions *per se*.

Clause 2

Daiichi-Sankyo submitted that the ruling of the breach of Clause 2 was based on the Panel's view that edoxaban had been promoted prior to the provision of marketing authorization. Daiichi-Sankyo categorically denied that its actions had brought the industry into disrepute. Even if the Appeal Board ruled a breach of Clause 3.1, Daiichi-Sankyo did not agree that its actions reflected a lack of high standards; the arrangements were not such that the industry was brought into disrepute. In particular, the Panel commented on the 'widespread notification of and the format and arrangements for the symposium'.

Daiichi-Sankyo submitted that it had already commented that the communication about the specific nature of the workshop was neither widespread, nor inappropriate. In fact, visibility of the nature of the 31 workshops was achieved by accessing the website for the event itself, so only potential attendees would even know what the subjects of the workshops were. It might be appropriate to consider the wider parallels to this event, which would be the subject of some confusion as a result of this case. For example, it was an established principle that scientific exchange, another key component of Clause 3 and the PMCPA's Guidance about Clause 3 document could be conducted in a 1:1 and a meeting format. In that regard, it was appropriate to consider how sponsored symposia were conducted at scientific meetings – there was an agenda which defined the content, and a need to ensure that only appropriate attendees were aware of the symposium (given the widespread range of delegate types (including patients) attending some scientific events). Abstracts which indicated the nature of the workshop were widely publicised at such events, but there were very few companies who would apply the level of scrutiny and multiple checks on the symposium delegates that Daiichi-Sankyo applied to payors in the Pharmacy Management National Forum meeting.

Daiichi-Sankyo submitted that if the Appeal Board upheld one or more of the Panel's rulings, it would be appropriate to explain why group meetings and the accompanying communications were appropriate for one aspect of Clause 3, but not another owing to the potential for widespread confusion otherwise across the industry.

With regard to the Daiichi-Sankyo workshop, the company submitted that it carefully controlled the arrangements as reflected by the certified workshop content, briefings and text used in communications, and the certified processes for ensuring appropriate individuals attended, in addition to the professionalism of the Daiichi-Sankyo staff on the day itself.

Daiichi-Sankyo therefore strongly objected to the ruling of a breach of Clause 2 and thus appealed it.

RESPONSE FROM PFIZER

Pfizer responded on behalf of the Alliance to the points raised by Daiichi-Sankyo in the order raised.

Pfizer noted Daiichi-Sankyo's submission that over 65% of the attendees at the Pharmacy Management National Forum were 'senior managers'. This assertion, or versions of it, appeared to be central to Daiichi-Sankyo's appeal. Pfizer alleged that it was not clear how the term 'senior manager' was defined. However, not all senior managers, however defined, would be responsible for making policy decisions on budgets for anticoagulants or anticoagulation services. This was even more likely to apply to the 35% of attendees who were not 'senior' managers. The delegate list confirmed that not all attendees at the meeting were suitable recipients of pre-licence advance budgetary notification information about edoxaban. Pfizer listed the job descriptions of a number of attendees including, *inter alia*, Clinical Director & Sexual Health Consultant, Director of Marketing & Membership, Director International Business Development, Fundraiser and Nutritional Medicine Consultant.

However, Pfizer alleged that in addition to those who attended the Forum, a number of others would have read the website but not registered to attend. As a result they would also have had access to the information about the Daiichi-Sankyo meeting which included the promotional statement about its unlicensed medicine ie:

> 'In Quarter 1 of financial year 2015/16, and subject to marketing authorisation approval, Daiichi-Sankyo UK Ltd will be introducing a new oral direct factor Xa inhibitor for anticoagulation in the prevention of stroke in atrial fibrillation (AF), and in the venous thromboembolism (VTE) disease area.'

In summary, Pfizer alleged that Daiichi-Sankyo had broadcast the information about the anticipated launch of its unlicensed medicine in such a way that it could reasonably be assumed to have been read by people with no responsibility for making policy decisions on budgets relating to anticoagulants or the provision of anticoagulation services. Pfizer

alleged that this promoted a medicine prior to the grant of its marketing authorization, failed to maintain high standards and brought the industry into disrepute in breach of Clauses 3.1, 9.1 and 2.

General Points

Pfizer disagreed with Daiichi-Sankyo's view that the Panel had focused on the 'innovative format' of this advance budgetary notification approach. In the UK, the promotion of an unlicensed medicine was considered to be a very serious matter and the exception provided by the Code for advance budgetary notification was therefore allowed only within specific and defined parameters. The Panel's review of these arrangements had been conducted appropriately and with these considerations in mind.

Pfizer noted Daiichi-Sankyo's submission that there were similarities between the way that scientific exchange operated within a scientific symposium and its arrangements for delivering advance budgetary notification for edoxaban. In Pfizer's view, there were fundamental differences between the two and most pharmaceutical companies would be able to differentiate between them. Examples of how they differed were:

- A scientific exchange was exactly that, an exchange. There was intended to be a flow of information in both directions in a true scientific debate, discussion or discourse. However, advance budgetary notification was the provision of information to those responsible for making budgetary decisions. There was no true exchange of information or back and forth discourse as in a scientific debate. Indeed, to invite or solicit such exchange during the course of advance budgetary notification could stray into the realms of unlicensed promotion. This intention was reflected in the Code by the statement in the supplementary information to Clause 3.1 that 'only factual information must be provided which should be limited to that sufficient to provide an adequate but succinct account of the product's properties'.

- Acceptable meetings which involved a legitimate exchange of scientific and clinical information were likely to be initiated and run by a company's medical or research and development groups. However, the only speaker named on the Pharmacy Management National Forum website as a speaker at this meeting was a member of the Daiichi-Sankyo commercial organisation. It must therefore be clear to Daiichi-Sankyo that there was a difference between advance budgetary notification and legitimate scientific exchange or it would not have advertised a member of its commercial team as its main speaker.

With regard to Daiichi-Sankyo's submission that the Code did not require that advance budgetary notification information be localised and that group advance budgetary notification was therefore permissible, Pfizer stated that the arrangements for the delivery of anticoagulation services varied greatly on a geographical basis and might therefore need to be localised to be meaningful for the recipient such that the local budget impact of the new medicine was understood. Pfizer stated that the Panel's judgment was correct in that the arrangements for this meeting which involved group advance budgetary notification did not allow for such localised tailoring of the information for an individual budget holder.

Pfizer noted Daiichi-Sankyo's submission that beyond being appropriately targeted, informative in relation to budget impact and non-promotional, the Code gave no further guidance on how advance budgetary notification should be delivered. Pfizer stated that a great deal more information about how advance budgetary notification should be delivered was in the supplementary information to Clause 3.1. Pfizer alleged that Daiichi-Sankyo breached both the letter and the spirit of this supplementary information and thus also Clauses 9.1 and 2.

Who was likely to access the information on the website?

Pfizer stated that it had already addressed this question. However, in defence of its arrangements, Daiichi-Sankyo also stated that it was highly unlikely that individuals would attend the workshop unless they had an intense interest in this area. Pfizer was not sure what point Daiichi-Sankyo was trying to make as 'an intense interest in' was not the same thing as 'budgetary responsibility for'.

In addition, Daiichi-Sankyo had stated that as a responsible company it took several additional steps to ensure that only appropriate individuals attended the session. This included clear statements on the registration forms and accompanying website text about the nature of the event.

However, Pfizer stated that there must be some question as to when exactly some of these 'additional steps' were actually introduced. For example, when Daiichi-Sankyo referred to 'accompanying website text', Pfizer presumed it was referring to the following:

> 'Please note that only those responsible for making policy decisions on budgets for anticoagulation in the prevention of stroke in atrial fibrillation and in the venous thromboembolism area in order to assist in the NHS financial planning for the financial year 2015/16 will be allowed to attend this session.'

This statement was added to the website text only after inter-company dialogue in November 2014. Before Pfizer had complained to Daiichi-Sankyo it took screenshots of the website text in September 2014 which demonstrated that the following, very different, statement was included at that time:

> 'If you are responsible for making policy decisions on budgets in these disease areas and feel that attending this symposium would be appropriate, please come along.'

Pfizer alleged that this statement did not indicate that only those with budgetary responsibility would be allowed to attend. Instead it left the decision with

the readers and if they considered it was appropriate they were invited to 'come along'. The revised statement was added as a result of inter-company dialogue. This therefore led to two further questions: how many weeks or months had the non-compliant website text been in place and how many other 'additional steps' had been put in place only after Pfizer had complained?

Website content

Pfizer noted Daiichi-Sankyo's submission that it was necessary (and appropriate) to describe the nature of its workshop. Pfizer stated that this was supposed to be an advance budgetary notification activity. Given that, at this stage of the interaction, Daiichi-Sankyo would not know if the reader had any budgetary responsibility for anticoagulation, it was neither necessary nor appropriate that the information accessed should include detailed and specific information about the unlicensed medicine such that its identification, probable indications and anticipated date of launch were provided. Such information when provided to an individual who did not have the required specific budgetary responsibility constituted promotion of an unlicensed medicine, in breach of Clauses 3.1, 9.1 and 2.

Pfizer noted that Daiichi-Sankyo believed this was exactly the same as when pre-filtered payors were sent letters which asked them if they had a relevant interest in advance budgetary notification. Pfizer was confused as to what point Daiichi-Sankyo had tried to make here, what did it mean by 'pre-filtered'? Did it mean that the people to whom Daiichi-Sankyo had sent the mailing had already been identified as having budgetary responsibility? If so, then this was completely different from the website situation, as had been established that when readers accessed the website statement, Daiichi-Sankyo would not know if they had the appropriate budgetary responsibility.

Pfizer noted Daiichi-Sankyo's submission that the specific text of the workshop abstract was carefully worded to ensure that its medicine was not promoted because neither the brand nor generic names were used. The use or otherwise of the name of the medicine was irrelevant in this context. The wording of the statement contained a sufficiently detailed description of the medicine such that it could only apply to edoxaban. The text also included the proposed indications and the anticipated launch date of this unlicensed medicine. Pfizer thus alleged that this abstract had promoted edoxaban in advance of a marketing authorization, in breach of Clauses 3.1, 9.1 and 2 of the Code.

Symposium

Advance budgetary notification requirements and Daiichi-Sankyo actions

Pfizer alleged that many of the points made by Daiichi-Sankyo in its appeal, about inadequacies in the specific targeting of its messages and the arrangements for its workshop, had been addressed earlier. In addition, Daiichi-Sankyo stated that arrangements had been made for its signatories to review the list of delegates registered for its satellite session in order to determine the appropriateness of each individual and deregister any inappropriate delegates. This was an admission by Daiichi-Sankyo that inappropriate delegates might have read its website abstract and as a result registered for its satellite symposium. It was also not a defence to state that few delegates turned up to the symposium. Where promotion prior to marketing authorization was concerned this was a breach of the Code irrespective of the number of delegates and many people could have seen the website advertising whether they attended or not.

Pfizer noted Daiichi-Sankyo quoted the Code requirement that advance budgetary notification must '… state whether or not a new medicine or a change to an existing medicine is the subject of a marketing authorization in the UK'. However, Pfizer did not understand Daiichi-Sankyo's subsequent point. The quotation from the Code clearly referred to legitimate advance budgetary notification materials directed at appropriate recipients. The inclusion of this information in the website text, which would be accessed by inappropriate recipients, therefore did not specifically meet the requirements of the supplementary information as claimed. The Panel's ruling in this respect was entirely valid and this advertising represented a breach of Clauses 3.1, 9.1 and 2 as it was promotion of an unlicensed medicine prior to the grant of a marketing authorization, which failed to maintain high standards and brought the industry into disrepute.

Pfizer noted Daiichi-Sankyo's submission that because no complaint had been received about the workshop content, it was inappropriate for the Panel to have examined the content of the workshop. Pfizer noted that its complaint was initiated before the meeting had taken place and was based on its belief that the promotion of, and the arrangements for, this meeting were in breach of Clauses 3.1, 9.1 and 2. However, given the nature of the original complaint, and the non-compliant nature of other materials and arrangements associated with this project, the Panel was correct to ask to review the meeting materials and to make judgements about them.

Additional Panel comments

Daiichi-Sankyo sought to assert that the Code did not preclude conduct of advance budgetary notification by the means discussed here. In making its case Daiichi-Sankyo sought to claim that the wording of the Code was sufficiently unclear and ambiguous as to allow it to behave in this way. However, there was clearly a difference between a pharmaceutical company employee using a laptop to present advance budgetary notification information to an appropriate budget holder in an office at his/her place of work, and a satellite symposium at a major national congress involving numerous attendees, an external chairman and multiple speakers. Pfizer considered that both the letter and spirit of the Code was clear in this respect and that the Panel's interpretation was correct.

Clauses 9.1 and 2

Pfizer considered that all the points raised by Daiichi-Sankyo in these sections had already been addressed. Pfizer alleged that promotion prior to the grant of a marketing authorization was a clear example of inadequate standards and given its seriousness also brought the industry into disrepute in breach of Clauses 9.1 and 2.

Summary

In summary, Pfizer agreed that the Panel's rulings of breaches of Clauses 3.1, 9.1 and 2 were correct and should be upheld by the Appeal Board.

APPEAL BOARD RULING

The Appeal Board noted that the supplementary information to Clause 3.1, Advance Notification of New Products or Product Changes, referred to the introduction of new medicines or changes to existing medicines which might significantly affect the level of expenditure. The Appeal Board noted that advance budgetary information should be directed to those responsible for making policy decisions on budgets rather than those expected to prescribe. There was no complaint about whether the introduction of edoxaban would have a significant budgetary impact and in that regard the Appeal Board had no detail of the Daiichi-Sankyo cost model or the content of the company's presentation slides about budget impact. It could make no ruling on this aspect.

The Appeal Board noted that Daiichi-Sankyo accepted that a satellite symposium was a novel way to provide advance budgetary information. The Appeal Board noted that normal custom and practice in the industry for providing advance budgetary information was to identify appropriate individuals who would be expected to be responsible for making relevant policy decisions on budgets and provide them with written information and perhaps offer a follow-up meeting. In this regard the Appeal Board noted that in response to a question the Daiichi-Sankyo representatives at the appeal stated that the company had also undertaken this approach for edoxaban.

The Appeal Board noted the Pharmacy Management National Forum website page 'Who attends' stated that 'The audience for the Forum is made up of Medicines Payers from primary and secondary care setting along with pharmaceutical company personnel'. The website contained information and a brief synopsis of all of the satellite symposia. That information was available to all delegates whether or not they had any budgetary responsibility and if they did whether or not it was in stroke prevention in AF and/or the treatment or secondary prevention of VTE. By reading the title and description of the Daiichi-Sankyo session, every delegate would know that the company expected to launch a new oral anticoagulant for the prevention of stroke in AF and for use in VTE. The information provided on the Forum website had been approved by and specifically placed by Daiichi-Sankyo.

The Appeal Board noted that the initial website synopsis of the symposium contained an open invitation to all the meeting attendees which included students and a fundraiser who would never be responsible for making policy decisions on budgets. It was also unclear if many others on the list would be appropriate given the restrictions in the supplementary information to Clause 3.1. The Appeal Board noted from Daiichi-Sankyo representatives at the appeal that the company had seen the delegate lists from 2013 and thus should have known that not all of the attendees would be suitably qualified to receive advance budgetary information. Daiichi-Sankyo appeared to have relied on the mistaken assumption that the Pharmacy Management National Forum 2014 would only be attended by delegates responsible for making policy decisions on budgets. The Appeal Board considered that Daiichi-Sankyo had not undertaken due diligence to ensure that its invitation had only been sent to those responsible for policy decisions on budgets in the relevant therapeutic area.

In the Appeal Board's view, the information provided on the website had not been sufficiently targeted solely to those who could be assumed to be responsible for making policy decisions on budgets and thus, given the content of the material, Daiichi-Sankyo had promoted edoxaban prior to the grant of its marketing authorization. The Appeal Board upheld the Panel's ruling of a breach of Clause 3.1. The appeal on this point was unsuccessful.

The Appeal Board then considered the actual symposium. It noted the arrangements made by Daiichi-Sankyo to ensure that the attendees were appropriate. The Appeal Board examined the agenda for the 45 minute symposium. There were three parts to the symposium, firstly a presentation each from the regional business director and the MSL with the final 20 minutes given over to a 1:1 discussion between the attendees and their local Daiichi-Sankyo regional account manager. The Appeal Board noted again that it was not making any decisions about whether the introduction of edoxaban would have a significant budgetary implication. Although it had not seen the Daiichi-Sankyo cost model the Appeal Board considered that it was likely that it would be pre-populated with data specific to various geographical locations.

The Appeal Board did not consider on the information before it, bearing in mind the controls put in place to ensure that only those suitably qualified to receive advance budgetary information had been allowed into the symposium, that the symposium itself had promoted edoxaban prior to Daiichi-Sankyo receiving a marketing authorization. No breach of Clause 3.1 was ruled. The appeal on this point was successful.

The Appeal Board noted its ruling of a breach of Clause 3.1 above and considered that by posting a blanket invitation on the Forum website, without recognising that it would not be appropriate to provide all of the delegates for the Pharmacy Management National Forum advance budgetary information about edoxaban, Daiichi-Sankyo had

not maintained high standards. The Appeal Board upheld the Panel's ruling of a breach of Clause 9.1. The appeal on this point was unsuccessful.

The Appeal Board noted that the supplementary information to Clause 2 stated that one of the activities likely to be in breach of that clause was the promotion of a medicine prior to the grant of a marketing authorization. The Appeal Board considered each case on its merits. In this instance, it considered that its rulings of a breach in relation to the invitation to the meeting did not warrant a ruling of Clause 2 which was a sign of particular censure and reserved for such use. The Appeal Board therefore ruled no breach of Clause 2. The appeal on this point was successful.

Complaint received **14 November 2014**

Case completed **24 February 2015**

CASE AUTH/2741/12/14

REPRESENTATIVE v CHIESI

SOP training

A representative complained that standard operating procedure (SOP) training for a primary care sales team, which was run by a regional business manager (RBM), was such that it failed to maintain high standards and did not help Chiesi be more code compliant.

The complainant stated that the SOP training took place because Chiesi was to be audited by the PMCPA; delegates were told that the training was a 'tick box exercise to get [the PMCPA] off [Chiesi's] backs'. The RBM also said that he/she was one of the managers who would be interviewed by the PMCPA but that he/she was 'more than ready for it' and was looking forward to it. This might have just been bravado, but all of the delegates thought it was a strange way to talk about a PMCPA audit.

The complainant stated that the training was very rushed because there was a lot to get through. The delegates completed a multiple choice test and then passed their sheet to a colleague for marking and the RBM read out the answers. The complainant alleged that all of the delegates got some answers wrong but that the RBM gave instructions to rub or score out the wrong answers and then re-tick the correct box. The RBM then collected the answer sheets and stated 'but of course you all got these right, 100% otherwise we would have to do this training all again'. After the event everyone considered that the training was inadequate and a waste of time, especially as they were made to cheat to pretend that they had passed an examination that actually most of them failed.

The complainant alleged that the SOP training was inadequate and was merely a 'tick box' exercise; it showed that Chiesi was not very ethical and did not take its SOP training seriously and was more worried about passing an audit than training its staff to a sufficient level in order to be an ethical pharmaceutical company and make its representatives fully conversant with the Code.

The detailed response from Chiesi is given below.

The Panel noted that the training in question had been run by an RBM who, 8 days before the event, emailed the attendees to remind them of the importance of complying with the company SOPs, in particular those governing the support of meetings. The RBM was clear in the email that the correct application of processes was a personal responsibility as was improving compliance skills, knowledge and attitude and helping colleagues to do the same. The Panel did not consider that the email had set the training up as a tick box exercise. It was of course impossible to know what was said at the training event itself but Chiesi submitted that during its investigation the RBM denied referring to the training as a tick box exercise and none of the eight delegates interviewed had heard the training be so described. The Panel noted, however, that in the RBM's interview notes, he/she stated that he/she might have referred to the validation test as a tick box exercise as he/she needed to show that the training had been delivered and that people understood the training. Chiesi submitted that many of those interviewed had stated that they recognised the importance of the training and had left the event with a good understanding of the SOPs. The Panel was concerned that the running order provided by Chiesi failed to include the validation of the meetings SOP.

The Panel noted that the delegates were trained on six SOPs; three were updates from versions on which the delegates had been previously trained and validated (recall procedure, information requests and UK meetings) and three were new SOPs for which there had been no previous training or validation, (distribution of material, use of electronic communications and use of consultants and speakers). The Panel was concerned that delegates were only formally re-validated on their understanding of two SOPs at the meeting and their understanding of the other four SOPs, including three new ones, was only validated verbally. The formal validation of the two SOPs was by way of two multiple choice test papers, one for the meetings SOP (13 questions) and the other on the sales procedure for handling on- and off-label requests for information (7 questions). The Panel queried, given the length of the meetings SOP (12 pages) and its related guidance notes (34 pages), whether being required to answer 13 multiple choice questions in 15 minutes with a further 15 minutes for discussion was a sufficiently rigorous test of understanding. The Panel noted in that regard Chiesi's submission that the delegates had been trained and validated on the previous meetings SOP and the new version was not significantly different from the old one. Nonetheless, given the content of the day and the extent to which delegates were tested on six SOPs, three of which were new, the Panel queried the validation exercise and whether it would withstand external scrutiny. In that regard, it disagreed with Chiesi's submission that the training and validation was robust.

The Panel noted that the multiple choice papers were swapped between delegates for marking and the marked papers showed that every delegate scored 100% in both tests. The Panel was concerned, however, that three of the validation papers relating to the meetings SOP appeared to show that answers had been changed – three answers on one paper, two on another and one on the third. One of the test papers for the procedures for handling information requests showed that

one answer had been changed. The Panel noted that as only four of the validation papers overall showed that initial answers had been changed, there was insufficient evidence to support the complainant's allegation that all of the delegates got some answers wrong and that everyone was a bit confused.

The Panel noted that Chiesi had provided copies of the interview sheets from December 2014 and January 2015 for each delegate and in that regard it was concerned that each delegate was not asked a standard set of questions. For instance, in the December interviews, only three delegates were asked 'Did anyone get a question wrong?' and some were asked 'Was anyone asked to *change their answers*?' whilst others were asked 'Was anyone asked to change *an answer*?' (emphasis added). The Panel noted that a number of the interviewees stated that during the marking procedure, if any wrong answers were noted the matter was discussed in detail to ensure the correct answer was understood. Further, the RBM stated in his/her interview that where a question was answered incorrectly he/she sought to clarify the issue and then in light of discussions, in order to revalidate their understanding, the delegates were asked to identify and highlight the correct answer on the sheet. The RBM referred to the changes being evident on the hand written score sheets. The Panel considered that there was thus some evidence to support the complainant's allegation that original answers were changed but noted Chiesi's submission that this was only done after discussion so that those who had answered a question incorrectly understood the correct answer. In the Panel's view this was not necessarily unacceptable as the discussion and clarification of points could be regarded as training in itself. However, the amount of discussion needed was an important aspect and measure of the effectiveness of the initial training and in that regard the Panel considered that it would have been clearer if the results included each delegate's initial score as well as their final score. This would give a more accurate reflection of the position. The Panel appreciated that the RBM would not want anyone leaving the training without knowing all of the correct answers.

The Panel noted its concerns above and considered that based on the material before it, in so much as the validation of the six SOPs was inadequate, on the balance of probabilities, this aspect of the training had been a tick box exercise and in that regard it considered that high standards had not been maintained. A breach of the Code was ruled. The Panel noted its concerns above about the possibility of answers being changed or inserted but considered that as training had been given there was no breach of the Code.

The Panel noted its comments above and considered that the complainant had not shown that the SOP training was inadequate. No breach of the Code was ruled.

The Panel noted the complainant's serious allegations; representative training was important for the reputation of the industry as a whole. However, although noting its rulings above, the Panel considered that overall the training was not such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. The Panel ruled no breach of Clause 2.

A representative complained about standard operating procedure (SOP) training for a primary care sales team which took place in October 2014.

COMPLAINT

The complainant stated that the training was run by a named regional business manager (RBM). Eight named individuals attended the training. An attendance sheet was signed by all present before the training commenced.

The complainant stated that the SOP training took place because Chiesi was shortly to be audited by the PMCPA; delegates were told that the training was a 'tick box exercise to get [the PMCPA] off [Chiesi's] backs'. The RBM also said that he/she was one of the managers who would be interviewed by the PMCPA but that he/she was 'more than ready for it' and actually he/she was looking forward to it. This might have just been bravado, but all of the delegates thought it was a very strange way to talk about a PMCPA audit.

The SOPs being covered at the meeting were: SOP13 meetings organised field force personnel – 38 pages; SOP252 safety event reporting – 6 pages; SOP247 electronic communication – 7 pages; SOP7 recall of materials – 9 pages; and SOP10 handling customer requests – 5 pages.

The RBM stood at the front of the room and all of the representatives sat around a table. The RBM used a projector and basically read through all of the SOPs. This was very rushed because there was a lot to get through. The RBM read through the SOPs from 10am until 1pm with a 15 minute coffee break.

There were two coffee breaks as well as lunch. At around 2pm the delegates were split into pairs and given an example of a promotional meeting that was carried out and they had to state if it fitted the meetings SOP. The delegates then discussed this as a group and it was quite unclear how this fitted into the SOP. As there was so much within the SOP, rushing once through the slides was not enough to have a full understanding. Everyone was a bit confused.

The complainant stated that delegates were then tested on the SOP training at 2:30pm. The delegates completed the multiple choice test and then had to pass their sheet to a colleague for marking and the RBM read out the answers. The complainant alleged that all of the delegates got a number of the answers wrong but that the RBM gave instructions to rub out or score out the wrong answers and then re-tick the correct box. The RBM then collected the answer sheets and stated 'but of course you all got these right, 100% otherwise we would have to do this training all again'. After the meeting everyone

considered that the training was inadequate and a waste of time, especially as they were basically made to cheat to pretend that they had all passed an examination that actually most of them failed.

The complainant alleged that the SOP training was inadequate and was merely done as a 'tick box' exercise; it showed that Chiesi was not very ethical and did not take its SOP training seriously and was more worried about passing an audit than training its staff to a sufficient level in order to be an ethical pharmaceutical company and make its representatives fully conversant with the Code. Other people that attended the meeting also considered that it was very unethical that they were made to change answers and they felt quite uncomfortable about this, but were too scared about any repercussions to say anything.

The complainant alleged that the training was such that it failed to maintain high standards, in breach of Clause 9.1, or to help Chiesi to be more Code compliant, in breach of Clause 16.1.

When writing to Chiesi, the Authority asked that in addition to the clauses cited by the complainant, it also consider the requirements of Clauses 15.1 and 2.

RESPONSE

Chiesi stated that it was disappointed to receive any complaint, more so when it was from an employee. Chiesi had a confidential 'Raising an Internal Concern' facility, available to all employees. If this had been raised through internal processes at the time, the matter would have been brought to the attention of senior managers to be fully investigated and, where required, immediate action taken.

Background

Chiesi stated that it had worked hard over recent years to enhance the compliance culture and structure within its business. One of the key changes was to ensure operational managers were focused on compliance which was afforded the same, if not greater, importance than commercial performance. The changes had been driven by Chiesi's desire for continuous improvement, as well as acting upon recommendations made following recent PMCPA audits. A key area of Chiesi's focus had been to review the overall compliance framework, develop SOPs and change the responsibility for SOP development from central medical/compliance led, to operational management led. As a result, new SOPs had been created and existing ones revised.

SOP training

Chiesi stated that on two successive days in October 2014 SOP training took place for head office employees and field based sales managers, including RBMs respectively. The training was delivered by the SOP authors.

The training for the field based managers and RBMs was designed to ensure that attendees could train the SOPs to their teams. The field based team was trained on an additional SOP (UK-SOP-0247 Use of Electronic Communication by Salesforce). The agenda had already been compiled and a late decision was taken to include UK-SOP-0247 as the final draft was then available. Following the SOP training for the field based managers, RBMs were given materials in order to train their respective teams. RBMs were instructed to deliver a similar full day event and to conduct written validations for all attendees to check understanding.

Response to complaint

Chiesi submitted that it conducted a full investigation, checked training records and reviewed the training process. Investigation meetings had been conducted with all the delegates and the RBM, with the exception of one person who had worked under contract to Chiesi at the time but no longer worked for the company; he/she had declined an invitation to be involved with an investigation meeting.

Chiesi acknowledged that it was due to be audited by the PMCPA shortly after the SOP training in question; this was a re-audit from the previous PMCPA audit conducted on 13 March 2014. Chiesi confirmed that the RBM who delivered the training was scheduled to be interviewed by the PMCPA for the audit.

Sales team training

Chiesi stated that the training at issue for eight attendees was led by the RBM; Chiesi confirmed that all those named by the complainant, including the RBM, were present at the training. The RBM had passed the APBI examination; he/she had an impeccable record and was a mentor within the RBM team. The objective for the event was to train the regional sales team on the newly created SOPs and revised SOPs applicable to their role.

In preparation the RBM met the regional compliance champion on the evening before the event to explain the format of the following day's training as they would both be present to support the event. The purpose of the meeting was to alert the compliance champion as to the questions that were likely to arise. The meeting was informal, hence no agenda was produced, and lasted for approximately 2 hours.

The training in question started at 10am and finished at 4pm. There was a scheduled coffee break at 11:15am with lunch scheduled at 12:30pm and a further coffee break at 2:30pm. The SOPs trained that day were:

UK-SOP-0007	Procedure for recall for promotional and non-promotional materials
UK-SOP-0010	Sales procedure for handling on and off-label requests for information
UK-SOP-0013	Meetings organised by field force personnel
UK-SOP-0237	Material distribution (not stated by the complainant)
UK-SOP-0247	Use of electronic communication by salesforce

UK-SOP-0253 Use of consultants and speakers (not stated by the complainant).

The complainant also incorrectly stated that 'SOP 252' on safety event reporting was trained; UK-SOP-0252 was not an allocated number for current SOPs. UK-SOP-0251 Safety Event Reporting for Chiesi Workers was referenced as part of the presentation for UK-SOP-0010 to add context but was not trained on the day.

At the start of the training session the RBM delivered a presentation to set the scene using approved training slides. This was followed by presentations on the SOPs UK-SOP-0007, UK-SOP-0010, UK-SOP-0013 (no presentation, SOP and guidance notes used), UK-SOP-0237, UK-SOP-0247 (no presentation, SOP and guidance notes used) and UK-SOP-0253. These presentations were examined only and therefore no certificates were available. Current SOPs UK-SOP-0007, UK-SOP-0010, UK-SOP-0237 and UK-SOP-0253 were provided.

The RBM provided context to the attendees by explaining how the company was performing which included reference to the March 2014 audit and the upcoming audit. The RBM explained to attendees that as part of any training the company had to provide evidence of how it had trained its representatives and that it had to confirm that individuals had received and understood the SOP training. As the RBM was scheduled to be interviewed by the PMCPA the RBM knew what documents had to be provided to demonstrate how and what had been trained. The RBM refuted the allegation that he/she had implied the training was merely a tick box exercise 'to keep the PMCPA off [Chiesi's] backs'. Chiesi confirmed that none of those interviewed heard the RBM make the alleged statement which fully corroborated the RBM's account. Many of those interviewed stated that they recognised the importance of the training.

The RBM could not remember if he/she stated that he/she was 'more than ready for the audit'. None of those interviewed could remember this being stated either. The RBM confirmed that he/she had informed the group that he/she was to be interviewed at the audit. However, this was in the context of considering that the company was in a really good place to demonstrate change and to emphasise how seriously Chiesi took compliance. Commercial activities and compliance were seen to be of equal importance to the business. None of those interviewed remarked that they considered this statement was inappropriate.

Timings

Chiesi noted the complainant's suggestion that the training was rushed with insufficient time to understand it and that everyone was a bit confused. Chiesi further noted that three SOPs already existed and therefore the training was to update the attendees on the changes. All attendees had already been trained on the previous versions. With the exception of the format of the SOPs (separated out into SOPs and guidance notes) there was no significant changes to these SOPs compared with the previous versions. UK-SOP-0237, UK-SOP-0247 and UK-SOP-0253 were new SOPs for which there was neither previous training nor validation.

The RBM delivered the presentation as briefed. This included an upfront presentation and group work to enable attendees to discuss the SOP content in detail. The SOP which was used most frequently by the field and contained the most content was UK-SOP-0013, Meetings organised by field force personnel. For this SOP the RBM had the SOP on screen and attendees had a printed copy to read. They reviewed it page by page, pausing for discussion and to clarify understanding. This was interactive with the attendees, but due to its content and more frequent use, the RBM decided to go through it as a group. For UK-SOP-0013 there was a workshop briefing presentation and three scenarios for the attendees to work through. The group re-convened to discuss and share answers.

During the investigation meetings all those interviewed were asked about the delivery and content of the training. None of those interviewed stated that the training was rushed nor left them confused. All those interviewed were asked whether they left the training with a good understanding of the SOPs and how to operate with them. All those interviewed were clear on the SOPs when they left the training. All those interviewed were asked for feedback on the training and Chiesi gave details of the comments made in this regard.

The RBM had run the same training the previous day with another group. Two attendees from that training day were also interviewed and they stated that they understood the SOPs and neither said that they were confused; their statements echoed those of the attendees, at the training in question.

Validations

Chiesi stated that the RBM gave the attendees a written validation to complete on two SOPs, UK-SOP-0010 (seven multiple choice questions (MCQs)) and UK-SOP-0013 (thirteen MCQs). The attendees were provided with validation questions and had to complete them under examination conditions. Once completed, the sheets were passed to a colleague to be marked. The RBM went through each of the questions as a group and asked the attendees in turn to answer a question. The marker then marked the sheet and passed it back to their colleague. The answers were discussed. All the interviewees confirmed that they were not asked to change the answers. However, one interviewee stated: 'I may have been cheeky as very competitive, I may have asked for my sheet back to amend an answer but [the RBM] wouldn't have been aware of this'. The answer sheets were then collected in by the RBM.

Chiesi stated that the complainant alleged that sheets were collected by the RBM with a comment 'but of course you all got these right, 100%'. The complainant also alleged that attendees were basically made to cheat to pretend that they had all passed an examination that actually most of

them had failed. The RBM confirmed that when the answer sheets were collected in, because of the training that was received on the day and the discussions that had taken place around the answers, he/she was confident that the attendees had 100% understanding. This comment was not said in the context that the complainant had stated but more as a reflection of how well the day had gone. Again, none of those interviewed stated that the comment was made in the way the complainant had implied.

Chiesi stated that it took Code compliance extremely seriously and strove to ensure that its employees were trained to the highest standard. It submitted that the RBMs were fully trained before they dedicated a full day of SOP training for their sales teams. The training sessions had a balance of upfront presentations and workshop discussions. When discussing the answers to the validations the RBM encouraged participation from the group to answer each question. Where there was any doubt or an incorrect answer the RBM clarified the point there and then. When an answer was given there was discussion and the RBM checked with the group that everyone understood the answer before moving to the next question. This was confirmed by those interviewed.

Chiesi strongly denied that the training was inadequate. Clause 15.1 stated 'Representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines which they promote'. As the complaint was not about training on medicines, and as Chiesi believed that the training on SOPs was adequate as detailed above, it strongly denied a breach of Clause 15.1.

Chiesi submitted that the SOP training at issue was in addition to training on the Code which all Chiesi representatives received. As the complaint referred to SOP training and not Code training, and as Chiesi believed that the training on SOPs was adequate as detailed above, it strongly denied a breach of Clause 16.1.

Chiesi reiterated its belief that the training and validation was adequate, conducted in the spirit of the Code and had maintained high standards. Chiesi therefore denied a breach of Clauses 9.1 and 2.

In response to a request for further information, Chiesi explained that two senior managers had conducted the initial investigation. Notes from the original investigation meeting held with those who had attended the training event in question were provided. To ensure that a thorough response was provided to the Authority's request for additional information, the same investigation team conducted further enquiries with the support of an additional member of staff. The notes from the additional investigation meeting held with some of the team that attended the training at issue were provided.

Chiesi reiterated that the RBM who had delivered the SOP training had also done so in a different region the previous day which was a much larger event with delegates from the primary care and the special care divisions. As it was a larger group, the session was primarily delivered by the RBM with support from the two other facilitators. The results for this SOP validation were provided together with a summary of all the validation scores for the SOP training session run by RBMs. Chiesi noted that of the fifteen training events held, ten achieved an overall validation result of 100% for UK-SOP-0013, the lowest average score was 90%; for UK-SOP-0010, eight achieved 100% and the lowest average score was 86%. Chiesi believed the results achieved by the RBM in question were achieved by other RBMs.

As noted in the investigation meeting notes, due to the length of time between the SOP training (October 2014) and the investigation meetings (December 2014 and January 2015), those interviewed consistently commented that they could not be certain about some of their responses. One representative in December 2014 stated 'I may have asked for my sheet back to amend an answer but [the RBM] wouldn't have been aware of this'. In January 2015, the representative was re-interviewed and asked 'When we spoke to you in December you made a statement that you may have changed one of your answers but that you were not sure. If you look at the papers that have been scanned and sent to you today there does appear to be amendments. Can you tell us when during the validation process you made these changes?' The representative responded 'It may have been when I was checking my answers before I finished the paper but I can't remember. I may have changed it at this point, it looks like I changed the answer'.

In January 2015, another representative was asked 'If you look at question 7 first, it looks like you have changed your answer, can you tell us when you made these amendments to the sheet?' The representative responded 'I can't remember when I made the change. Sometimes I circle the answer, then once finished I re-read the question and answer and then amend what I have put. I know I spent a long time on one of the questions as I couldn't decide from the options; I may have changed my mind from the original answer I selected'.

A third representative in January was asked 'When we spoke to you in December you made a statement that you may have got an answer wrong but your paper looks like you got everything correct, though question 6 looks like a circle may have been rubbed out, please comment?'. The representative responded 'It looks like I changed one of my answers by rubbing one out and selecting a different answer. With regards to getting one wrong, the question I thought I got wrong isn't even a question on the paper so I think I may have just mixed up with a question I may have asked regarding what to get signed off during the actual training delivery'.

Based on all the investigation meetings and despite individuals being directly asked to comment on the changes to their papers, Chiesi was unable to ascertain when, how or who amended the papers in question. However, it was clear from the investigation meetings held in December 2014 and January 2015 that those who attended the SOP

training event at issue believed it was professional and well delivered and nobody recalled or believed anyone was asked to amend their validation sheets. Examples of quotations to support this included: 'Nobody was asked to change an answer', 'Not at all, we went through the answers as a group, there was discussion around the answers, but no one was asked to change a response' and 'No one was advised to change an answer'.

In response to a request for more information about when the changes to the validation papers might have occurred, Chiesi explained that the papers were exchanged between colleagues for marking. The correct answers were provided by individual delegates after being asked a direct question by the RBM as to what he/she believed the correct answer was. Whilst running the marking session in this way both delegates and the RBM stated that further discussions took place in order to ensure everyone was clear and fully understood. In December 2014 the RBM stated;

> 'I didn't ask people to change their answers I asked people questions such as:
>
> "what is the correct answer?", "why have you put that?", "do you understand why the answer is X?" and "what is your understanding now based on our further discussion?". I then asked delegates to revisit their answers once I was comfortable that they had confirmed their understanding to me. I wanted to ensure everyone left the room knowing the correct answer, not the wrong answer.'

As everyone got 100% the RBM was asked in January 2015 'In December you commented that if someone got a question incorrect you sought to re-validate to ensure that everyone understood. Nobody got a question wrong, everyone got 100% so what did you mean by re-validation/your response?' The RBM responded;

> 'Question 9 caused confusion therefore at the point of going through the answers delegates asked for clarity regarding venues and I sought to provide the clarity. From memory I think [two delegates] asked questions in relation to this question, I can't remember if it was before marking and whilst completing their initial response or if it was discussed during the marking stage. People asked questions during the marking stage, it might not have been because they got a question wrong, it could have been to gain clarity prior to providing an answer, [one named delegate] is the type of person who seeks clarity on the question before providing an answer.'

The RBM was also asked in January 'Do you recall when you asked people to give you their verbal answer if anyone verbally gave you an incorrect answer?' The RBM responded 'I can't recall for sure. If anyone changed an answer during the marking stage I wouldn't necessarily be aware'.

Chiesi accepted that the papers could have been amended by delegates at any point.

In response to a question about why the validation of UK-SOP-0013 did not appear on the agenda, Chiesi submitted that this was an omission by the RBM. Chiesi submitted that when planning the SOP training events, given the importance of field based employees adhering to the requirements of UK-SOP-0010 (Sales procedure for handling on and off-label requests for information) and UK-SOP-0013 (Meetings organised by field force personnel) in their role, it was felt that a documented validation was required. A significant amount of time was spent on UK-SOP-0103 as it was regularly used by field force employees in their roles, providing the clarity and guidance required on how to conduct meetings and comply with the Code. The remaining SOPs trained at the event in question were validated verbally by the RBM by asking a series of questions to test delegate understanding and so that validation was not included as an item on the agenda.

Chiesi submitted that the training was well delivered and appropriate validations were completed. Those interviewed for the investigation did not corroborate the complainant's view and the investigation confirmed that the delegates believed that the training had been well delivered and that they understood the SOPs. The investigators did not believe that the training was a tick box exercise. In addition to the interviews, Chiesi noted that piror to the event, the RBM emailed the team to highlight his/her committment to the forthcoming training event and for individuals to improve their compliance skills, knowledge and attitude. This demonstrated the importance of the event. Chiesi considered the training and validation were robust and that the complainant's allegations did not suggest that there was a need for revalidation.

Chiesi noted that the RBMs were validated in the same way during their training, the results of which were provided.

With regard to the attendees at the training event in question, Chiesi listed when and on which date they had previously been trained on UK-SOP-0007, UK-SOP-0010 and UK-SOP-0013.

Chiesi explained that one of the representatives was absent from work for several months during 2014 and subsequently received 1:1 retraining from the RBM followed up in email correspondence on 1 October 2014.

Chiesi provided a copy of UK-SOP-0204, Training Procedure for Organising Initial Training Course. Chiesi noted that at the time of the training event at issue, a number of training SOPs were in draft and nearing completion. These were now effective.

Chiesi explained that in order to ensure consistent SOP training sessions were rolled out in October, a full day 'Train the Trainer' session was delivered by its head of learning and development early in the month. At the end of the session the RBMs were validated and then instructed to replicate the event with their teams.

Chiesi reiterated that it believed that the training and validation was adequate, conducted in the spirit of the Code and had maintained high standards. Chiesi therefore denied breaches of Clauses 15.1, 16.1, 9.1 and 2.

PANEL RULING

The Panel noted that in any complaint under the Code, the complainant had the burden of proving their complaint on the balance of probabilities. The complainant in this case had made a general allegation that the SOP training had been inadequate and presented to delegates as a tick box exercise. The complainant had further alleged that during the marking of the validation papers, delegates could amend their initial answers in order to ensure that they scored 100%; the complainant stated that in reality most had failed the test.

The Panel noted that the training in question had been run by an RBM who, 8 days before the event, emailed the attendees to remind them of the importance of complying with the company SOPs, in particular the processes governing the support of meetings. The RBM was clear in the email that the correct application of processes was a personal responsibility as was improving compliance skills, knowledge and attitude and helping colleagues to do the same. The Panel did not consider that the email had set the training up as a tick box exercise. It was of course impossible to know what was said at the training event itself but Chiesi had stated that during its investigation the RBM denied referring to the training as a tick box exercise and none of the eight delegates interviewed stated that they had heard the training be so described (one delegate no longer worked for the company and had declined to be interviewed). The Panel noted, however, that in the interview notes for the RBM, he/she did state that he/she might have referred to the validation test as a tick box exercise as he/she needed to be able to evidence that the training had been delivered and that people understood the training. Chiesi submitted that many of those interviewed had stated that they recognised the importance of the training and that they had left the event with a good understanding of the SOPs and how to operate them. The Panel was concerned that the running order provided by Chiesi failed to include the validation of the meetings SOP (UK-SOP-0013).

The Panel noted that the delegates were trained on six SOPs. Three of the SOPs were updates from previous versions on which the delegates had been previously trained and validated (UK-SOP-0007 (recall procedure), UK-SOP-0010 (information requests) and UK-SOP-0013 (meetings)) and three were new SOPs for which there had been no previous training or validation (UK-SOP-0037 (distribution of material), UK-SOP-0047 (use of electronic communications) and UK-SOP-0053 (use of consultants and speakers)). The Panel was concerned that delegates were only formally re-validated on their understanding of two SOPs at the meeting (UK-SOP-0010 and UK-SOP-0013) and their understanding of the other four SOPs, including three new ones, was only validated verbally. The formal validation of the two SOPs was by way of two multiple choice test papers, one for the meetings SOP (13 questions) and the other on the sales procedure for handling on- and off-label requests for information (7 questions). The Panel queried, given the length of the meetings SOP (12 pages) and its related guidance notes (34 pages), whether being required to answer 13 multiple choice questions in 15 minutes with a further 15 minutes for discussion was a sufficiently rigorous test of the delegates' understanding. The Panel noted in that regard Chiesi's submission that the delegates had been trained and validated on the previous meetings SOP and the new version was not significantly different from the old one. Nonetheless, given the content of the day and the extent to which delegates were tested on six SOPs, three of which were new, the Panel queried the validation exercise and whether it would withstand external scrutiny. In that regard, it disagreed with Chiesi's submission that the training and validation was robust.

The Panel noted that the multiple choice papers were swapped between delegates for marking and the marked papers showed that every delegate scored 100% in both tests. The Panel was concerned, however, that three of the validation papers relating to the meetings SOP appeared to show that answers had been changed – three answers on one paper, two on another and one on the third. One delegate had originally submitted that he/she might have asked for his/her sheet back (presumably after they were swapped for marking) to amend an answer. However, when questioned again about the matter the delegate stated that he/she might have changed the answer before he/she had finished the paper; he/she could not remember. Another delegate whose paper showed that an answer had been changed had stated that he/she could not remember when he/she made the change. One of the test papers for the procedures for handling information requests showed that one answer had been changed. The Panel noted that as only three of the nine validation papers relating to the meetings SOP, and only one relating to procedures surrounding requests for information, showed that initial answers had been changed, there was insufficient evidence to support the complainant's allegation that all of the delegates got a number of answers wrong and that everyone was a bit confused.

The Panel noted that Chiesi had provided copies of the interview sheets from December 2014 and January 2015 for each delegate and in that regard it was concerned that each delegate was not asked a standard set of questions. For instance, in the first round of interviews in December 2014, only three delegates were asked 'Did anyone get a question wrong?' and some were asked 'Was anyone asked to change *their answers*?' whilst others were asked 'Was anyone asked to change *an answer*?' (emphasis added). The Panel noted that a number of the interviewees stated that during the marking procedure, if any wrong answers were noted the matter was discussed in detail to ensure the correct answer was understood. Further, the RBM stated in his/her interview that where a question was answered incorrectly he/she sought to clarify the

issue and then in light of discussions, in order to revalidate their understanding, the delegates were asked to identify and highlight the correct answer on the sheet. The RBM referred to the changes being evident on the hand written score sheets. The Panel considered that there was thus some evidence to support the complainant's allegation that original answers were changed but noted Chiesi's submission that this was only done after discussion so that those who had answered a question incorrectly understood the correct answer. In the Panel's view this was not necessarily unacceptable as the discussion and clarification of points could be regarded as training in itself. However, the amount of discussion needed was an important aspect and measure of the effectiveness of the initial training and in that regard the Panel considered that it would have been clearer if the results included each delegate's initial score as well as their final score. This would give a more accurate reflection of the position. The Panel appreciated that the RBM would not want anyone leaving the training without knowing all of the correct answers.

The Panel noted its concerns above and considered that based on the material before it, in so much as the validation of the six SOPs was inadequate, on the balance of probabilities, this aspect of the training had been a tick box exercise and in that regard the Panel considered that high standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel noted its concerns above about the possibility of answers being changed or inserted but considered that as training had been given there was no breach of Clause 16.1.

Clause 15.1 of the Code required that representatives were adequately trained. The Panel noted its comments above and considered that the complainant had not shown that the SOP training in question was inadequate. No breach of Clause 15.1 was ruled.

The Panel noted the complainant's serious allegations; representative training was important for the reputation of the industry as a whole. However, although noting its rulings above, the Panel considered that overall the training was not such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. The Panel ruled no breach of Clause 2.

Complaint received **19 December 2014**

Case completed **12 February 2015**

CASE AUTH/2743/12/14

COMMUNITY PHARMACIST v AMDIPHARM MERCURY

Yellow card follow-up

A community pharmacist complained about the conduct of Amdipharm Mercury in relation to the follow-up to a yellow card report. The complainant explained that a patient asked for levothyroxine tablets from, *inter alia*, Teva UK as he had previously had issues with those made by Amdipharm Mercury. The pharmacy spoke to Teva which explained that it no longer made this medicine but outsourced it to Amdipharm Mercury and that it wanted to issue a yellow card warning based on the patient's account of 'issues'.

The pharmacy subsequently received a follow-up call from Amdipharm Mercury citing the call from Teva about the patient and requesting personal information about him such as contact details, date of birth etc. The pharmacy refused to answer despite the caller's insistence that he/she had to ask for this information. The complainant stated that the company should not have pressurised the pharmacy to supply this information which it felt unable to supply without the patient's prior permission.

The detailed response from Amdipharm Mercury is given below.

The Panel noted that the complaint had arisen following an exchange between the complainant, a superintendent pharmacist, and a pharmacovigilance (PV) associate from Amdipharm Mercury's PV provider. The PV associate was following up a report of a possible adverse event which had occurred in the patient who had taken levothyroxine manufactured by Amdipharm Mercury. The patient had told the pharmacist that he had had 'issues' with the medicine from Amdipharm Mercury. This information had been passed to Amdipharm Mercury via Teva and in line with Amdipharm Mercury's PV procedures, had been taken up as an adverse drug reaction report. The PV associate had tried unsuccessfully on two successive days to contact the pharmacist for details before he/she was able to speak to him on the third. The adverse event report had been given high priority by Amdipharm Mercury and in his/her conversation with the pharmacist it appeared that the the PV associate was anxious to collect as much information as possible and in that regard mistakenly asked for personal data about the patient which required the patient's prior consent. The Panel noted the complainant's reference to the PV associate's insistence in that regard and that in his view he should not have been put under pressure to provide such information without first gaining the patient's permission. Neither party had commented on whether the pharmacist had offered to get such permission during his conversation with the PV associate or to otherwise help with the collection of data. Overall, the Panel considered that the outcome of the exchange between the complainant and the PV associate was unfortunate – co-operation between the two should have been such that the patient's best interests were uppermost. Nonetheless, the Panel acknowledged that in his/her efforts to collect comprehensive data, the PV associate had asked a third party for the patient's personal details which could not be provided without the patient's consent as acknowledged by Amdipharm Mercury. The Panel noted its comments above and considered that, on the very narrow point of asking for too much personal data without prior consent from the patient, high standards had not been maintained. A breach of the Code was ruled.

The Panel noted that the PV associate had been trained in PV requirements. It was unfortunate that in following up one adverse event report the PV associate had asked a third party for more personal information than he/she should have done. Amdipharm Mercury referred to the incident as an isolated case but acknowledged that it had highlighted gaps in explicitly covering patient confidentiality. Given Amdipharm Mercury's submission in this regard the Panel considered that the PV associate's mistake meant that, on the balance of probabilities, he/she was not fully conversant with PV requirements in relation to patient confidentiality relevant to his/her work. A breach of the Code was ruled.

The Panel noted that the Code required companies to comply with all applicable codes, laws and regulations. As breaches of the Code had been ruled, the Panel also ruled a futher breach of the Code.

A community superintendent pharmacist complained about the conduct of Amdipharm Mercury Company Limited in relation to the follow-up to a yellow card report.

COMPLAINT

The complainant stated that the pharmacy took a query from a patient on 11 December 2014 about the brand of levothyroxine to be dispensed. The patient indicated that he had had issues previously with certain brands including Amdipharm Mercury and asked for tablets manufactured by others including Teva UK Limited. The pharmacy spoke to Teva which explained that it no longer made this medicine but outsourced it to Amdipharm Mercury and it wanted to issue a yellow card warning based on the patient's query.

On 18 December the pharmacy received a follow-up call from Amdipharm Mercury citing the call from Teva about the patient and requesting personal information about the patient such as his home

contact details, date of birth etc. The pharmacy refused to answer despite the caller's insistence that he/she had to ask for this information. The complainant stated that the company should not have put the pharmacy under pressure to supply this information which it felt unable to supply without the patient's prior permission.

When writing to Amdipharm Mercury, the Authority asked it to respond to Clauses 1.9, 9.1 and 16.2 of the Code.

RESPONSE

Amdipharm Mercury explained that it had outsourced its pharmacovigilance (PV) function to a provider for over 6 years. The dedicated teams responsible for pharmacovigilance and drug safety within both Amdipharm Mercury and the PV provider worked together in close partnership with well defined roles and responsibilities. Amdipharm Mercury provided details of the PV provider's role and responsibilities and stated that a technical agreement between Amdipharm Mercury and its PV provider detailed all of the contractual arrangements.

1 Process for handling adverse drug reactions (ADRs)

The main relevant features of receiving and processing an ADR in Amdipharm Mercury and its PV provider were as follows:

i Handling ADRs by Amdipharm Mercury:

ADRs were reported to the medical information (MI) team in Amdipharm Mercury which gathered as much information as it could about a particular ADR from the reporter. The ADR was logged in the MI database with a reference number generated in-line with Amdipharm Mercury's relevant standard operating procedure (SOP). This ADR was then shared with the PV team at the PV provider which was responsible for further follow-up.

ii Handling ADRs by the PV provider:

The follow-up of spontaneous ADRs received by Amdipharm Mercury was done in-line with its SOP 'Medical Information and Processing Medical Queries' and once an ADR was received from Amdipharm Mercury an ADR form and follow-up sheet were completed.

After receipt of initial information for a spontaneous ADR, follow-up activity was undertaken by the PV provider. At least three telephone follow-up attempts for a spontaneous ADR should be made, if initial attempts were not successful. Thereafter, an e-mail/fax/letter should be sent providing a response to a spontaneous ADR case if contact details were available. A list of data elements that determined what follow-up information was needed for particular types of ADR cases was included. These included as a minimum, an identifiable reporter, an identifiable patient, a suspect drug or drugs, one or more ADR, source type and country in which the event occurred. In the case of a patient, personal details such as name and address were not considered as identifier details. In cases of higher priority ie serious expected/serious unexpected cases, further details were also sought. Details were provided. The process for follow-up of a spontaneous ADR received from health professionals was provided.

iii Training

The PV provider ensured that all of its employees responsible for following up ADR reports were trained on the following SOPs: 'Medical Information and Processing Medical Queries' and 'Case Processing of Medical Inquires'.

iv Quality control measures at Amdipharm Mercury and its PV provider

Amdipharm Mercury audited annually; the last audit was in April 2014. Amdipharm Mercury self-inspection audits also look at various responsibilities that its PV provider performed on its behalf. The PV provider could record all telephone conversations related to ADRs for quality and training purposes. Details of this complaint were readily available through playing these recordings. Since July 2014 the PV provider managers had listened to 10% of all recordings. There was no record of any issues pertaining to patient confidentiality deviations in any of these recordings.

2 Details of events pertaining to this complaint

An adverse event was received by Amdipharm Mercury MI team via Teva on 12 December 2014, which was logged in the MI database. This case was then passed to the PV provider to gather further follow-up information as per the Amdipharm Mercury process for handling ADRs.
In line with the process for handling ADRs by the PV provider, follow-up attempts were made by one of the PV associates from at the PV provider to the reporting pharmacist. First and second follow-ups were made on 16 December 2014 and 17 December 2014. Contact could not be established with the pharmacist (reporter) and on both occasions a message was left requesting a call back. At the third follow-up attempt the same PV associate established contact and spoke with the pharmacist on 18 December 2014 to obtain the required information. During the call, the PV associate tried to obtain the patient's contact details for follow-up information. The reporter refused to give any contact details or information about the patient without the patient's consent as he was concerned about patient confidentiality. Call recordings supported the view of the reporting pharmacist that 'during a follow-up call from Mercury Pharmaceuticals the caller began requesting personal information about the patient, in particular his home contact details, date of birth etc. We refused to supply them despite the insistence from the caller that they had to ask for this information'.

Amdipharm Mercury provided details of the induction training and SOP training given to the PV associate at issue. Training records were provided.

Amdipharm Mercury submitted that in-line with the process of follow-up at the PV provider, the PV associate had tried to gather as much information as possible about the ADR because this was a high priority case. It had been identified that he/she should not have tried to obtain the patient's personal details and instead should have sought further information from the health professional. If vital information was still lacking, then the PV associate should have asked the health professional for help to get consent from the patient to disclose his personal details to the PV provider. Furthermore, the PV associate should have waited for patient consent from the health professional, if he agreed to have helped.

Amdipharm Mercury noted that the following measures had been undertaken both in-house and by the PV provider to avoid the recurrence of such instances in future:

- This case raised the need for specific training on patient confidentiality especially in this particular situation.
- All relevant SOPs in Amdipharm Mercury and the PV provider would be redrafted to explicitly cover this point.
- Importantly, once the SOPs were rewritten, they would be retrained to the entire team.
- In the interest of timely response, the entire PV provider team had been briefed and trained on patient confidentiality matters at an *ad hoc* training session. Re-training on the PV provider's SOPs for the entire team responsible for performing follow-ups for Amdipharm Mercury had been completed, with added attention to patient confidentiality. The record of this training was provided.
- Although 10% of all follow-up calls were reviewed for quality and training purposes by the PV provider, following this instance a further 15 were randomly reviewed. In none of these calls had an issue of patient confidentiality arisen.
- Amdipharm Mercury monitored the quality of MI calls by regular and independent 'mystery shopping exercises'; the last exercise was conducted in December 2014. The PV provider had previously been included in such independent activities and would continue to do so.

In conclusion, Amdipharm Mercury submitted that both it and its PV provider had robust PV processes and procedures in place, underpinned by training and quality control measures. This meant that the company had complied with the local requirements whilst keeping abreast of PV regulations. In doing so the company had maintained the necessary high standards.

However, this case had highlighted gaps in explicitly covering patient confidentiality which had led to a deviation by an individual. This had been manifested by falling short of necessary high standards in this particular case. Although there was no evidence (despite Amdipharm Mercury actively looking) to suggest anything more than a single isolated case, immediate and appropriate actions had been taken to strengthen processes and procedures, with more long-term definitive actions to follow soon.

Amdipharm Mercury therefore submitted there was no breach of Clauses 1.9 and 16.2, but acknowledged an isolated breach of Clause 9.1, where relevant actions had been undertaken already.

PANEL RULING

The Panel noted that the complaint had arisen following an exchange between the complainant, a superintendent pharmacist, and a pharmacovigilance (PV) associate from a PV provider. The PV associate was following up a report of a possible adverse event which had occurred in a patient who had taken levothyroxine manufactured by Amdipharm. The patient had told the pharmacist that he had had 'issues' with the medicine from Amdipharm Mercury. This information had been passed to Amdipharm Mercury via Teva and in line with PV procedures at Amdipharm Mercury, had been taken up as an adverse drug reaction report. The PV associate charged with following up the report had tried twice, on successive days, to contact the pharmacist for details but he/she had been unavailable and he/she had received no response to his/her request for him/her to return his/her calls. On the third day the PV associate was able to speak to the pharmacist. The adverse event report had been given high priority by Amdipharm Mercury and in his/her conversation with the pharmacist it appeared that the the PV associate was anxious to collect as much information as possible and in that regard made a mistake by asking for personal data about the patient which required the patient's prior consent. The Panel noted the complainant's reference to the PV associate's insistence in that regard and that in his view he should not have been put under pressure to provide such information without first discussing this with and gaining the patient's prior permission. Neither party had commented on whether the pharmacist had offered to get such permission during his conversation with the PV associate or to otherwise help with the collection of data. Overall, the Panel considered that the outcome of the exchange between the superintendent pharmacist and the PV associate was unfortunate – co-operation between the two should have been such that the patient's best interests were uppermost. Nonetheless, the Panel acknowledged that in his/her efforts to collect comprehensive data, the PV associate had asked a third party for the patient's personal details which could not be provided without the patient's consent as acknowledged by Amdipharm Mercury. The Panel noted its comments above and considered that, on the very narrow point of asking for too much personal data without prior consent from the patient, high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that the PV associate had been trained in PV requirements and that training records had been kept. It was unfortunate that in following up one adverse event report the PV associate had asked a third party for more personal information than he/she should have done. Amdipharm Mercury referred to the incident as an isolated case but

acknowledged that the incident had highlighted gaps in explicitly covering patient confidentiality which had led to a deviation by the PV associate. Given Amdipharm Mercury's submission in this regard the Panel considered that the PV associate's mistake meant that, on the balance of probabilities, he/she was not fully conversant with PV requirements in relation to patient confidentiality relevant to his/her work. A breach of Clause 16.2 was ruled.

The Panel noted that Clause 1.9 required companies to comply with all applicable codes, laws and regulations. As breaches of Clauses 9.1 and 16.2 had been ruled, the Panel also ruled a breach of Clause 1.9.

Complaint received **19 December 2014**

Case completed **12 February 2015**

CASE AUTH/2744/12/14

UNIVERSITY PROFESSOR v AEGERION

Promotional emails disguised as educational material

A university professor complained about two emails he received on 16 and 23 December from Aegerion Pharmaceuticals. The first had the subject heading 'New guidance for clinicians on homozygous familial hypercholesterolaemia [HoFH]' and drew attention to, and provided a link to, Cuchel *et al* (2014). The second email was the same text with 'Reminder' added to the subject line and had been sent to those who had not clicked through on the link in the first email. Prescribing information for Lojuxta (lomitapide) was included. Lojuxta was indicated as an adjunct treatment in adults with HoFH.

The complainant stated that both promotional emails were mailed directly to his email address and addressed to him personally. The complainant was uncertain why he needed to be reminded of the information, and queried how Aegerion would know whether he had acted upon the original message. The complainant was concerned because the message was sent with clear promotional intent, masquerading as educational material and also because the Code clearly stated that recipients should have opted-in to such direct mailings and that the nature of the material should align with the recipient's clinical interest. The complainant alleged that neither condition was true in this case. The complainant had not opted-in to such mail, nor did he treat patients with HoFH.

The detailed response from Aegerion is given below.

The Panel noted that the emails discussed HoFH and introduced the consensus paper Cuchel *et al*, which was available via a link, and summarised its key points. The Panel noted that Cuchel *et al* discussed new insights and guidance for clinicians to improve detection and clinical management of HoFH. It discussed treatments and included lomitapide on a suggested algorithm for the management of HoFH. The main text of the email did not refer to a specific product but made a general reference to lipid lowering therapy and a subsequent reference to newer treatments offering the possibility of further LDL-C reduction. The two emails were identical other than the prefix 'Reminder' in the subject heading to the second email. The Panel agreed with the company's submission that the emails were promotional. Cuchel *et al, inter alia*, discussed a product in which the company had a commercial interest and the emails bore prescribing information.

The Panel noted Aegerion's admission that due to an error on its part, the mailing house had wrongly followed the process for emailing educational materials instead of the process for sending promotional materials. This was why the emails had been sent to the complainant without the requisite prior consent. A breach of the Code was ruled.

The Panel noted Aegerion's submission that the email was targeted at health professionals interested in cardiovascular disease and lipid disorders as they might potentially encounter diagnosed and undiagnosed cases of HoFH in their practice. The Panel noted that, according to Aegerion, when the complainant verified his details with the mailing house in April 2014 he indicated that he was a specialist in cardiovascular disease. The Panel also noted the company's submission about his academic profile and research into atherosclerotic plaques of the carotid. Whilst the Panel noted the complainant's submission that he did not treat patients with this condition, it nonetheless considered that given his speciality his need for or interest in the subject matter of the emails could reasonably have been assumed. No breach of the Code was ruled.

The complainant had alleged that the emails were sent with promotional intent but masqueraded as educational material. In that regard the Panel considered that the recipient's initial impression of the emails was important. In the recipient's inbox the emails appeared as from '[name]<information@hofh-management.co.uk'. The subject heading was 'New guidance for clinicians on homozygous familial hypercholesterolaemia'. On opening the email the text of the email did not bear a separate heading and in the Panel's view some recipients might have been left with the initial impression that the emails contained non-promotional information about HoFH as per their subject headings. This impression was compounded by the sender's address which bore no apparent link to a pharmaceutical company or otherwise indicated the emails' promotional content. The corporate logo did not appear at the outset on the hard copy versions of the email provided by the complainant. Those provided by the company bore the corporate logo on the top left hand corner. The Panel noted that the logo might only have appeared when the email was viewed in the web browser. If this was so, the complainant would not even have been aware at the outset that the email was from a pharmaceutical company. The emails were signed by a senior manager. In the Panel's view the length of the email was such that the pharmaceutical company's involvement and that the emails contained prescribing information would not be apparent until the recipient had scrolled down to the bottom of the emails. In such circumstances the Panel considered that despite the presence of prescribing information their primary characterisation at the outset was as a piece of educational material and the emails were disguised in this regard. A breach of the Code was ruled.

The Panel noted its rulings of breaches of the Code above and considered that high standards had not been maintained. A breach of the Code was ruled.

A university professor complained about two emails sent by Aegerion Pharmaceuticals Limited.

The emails (ref HoFK/UK/001) were identical and were sent on 16 and 23 December. The first email was sent with the subject heading 'New guidance for clinicians on homozygous familial hypercholesterolaemia [HoFH]' and drew the reader's attention to, and provided a link to, Cuchel *et al* (2014). The email was resent on 23 December with the subject heading 'Reminder: New guidance for clinicians on homozygous familial hypercholesterolaemia'. Prescribing information for Lojuxta (lomitapide) was included. The second email was only sent to those original recipients who had not clicked through on the link in the first email.

Lojuxta was indicated as an adjunct to a low-fat diet and other lipid lowering medicines with or without low density lipoprotein (LDL) apheresis in adult patients with HoFH. Genetic confirmation of HoFH should be obtained whenever possible. Other forms of primary hyperlipoproteinaemia and secondary causes of hypercholesterolaemia (eg nephrotic syndrome, hypothyroidism) must be excluded.

COMPLAINT

The complainant stated that both promotional emails were mailed directly to his email address and addressed to him in person. The second email was the same text, but with the word 'Reminder' added to the subject line. The complainant was uncertain why he needed to be reminded of the information, and did not know how Aegerion would know if he had acted upon the original message or not. The complainant was concerned firstly because the message was sent with clear promotional intent, masquerading as educational material and secondly, because the Code clearly stated that recipients should have opted-in to such direct mailings and that the nature of the material should align with the recipient's clinical interest. Neither condition was true in this case. The complainant had not opted-in to such mail, nor did he treat patients with this condition.

The Authority asked Aegerion to respond in relation to Clauses 9.1, 9.9, 11.1 and 12.1 of the Code.

RESPONSE

Aegerion submitted that the email was clearly promotional and in that regard it was not disguised as educational material. The recipients were in appropriate categories of health professionals whose need for the information could be assumed.

Aegerion regretfully acknowledged, however, that due to an error recipients, including the complainant, received the email inadvertently without their prior consent as required by Clause 9.9. The email was sent to health professionals with an interest in cardiology, cardiovascular disease, coronary care and paediatric cardiology or those specialties involved in the management of lipid disorders (chemical pathology, pathology, clinical chemistry and biochemistry), whom Aegerion reasonably assumed had an interest in receiving information about Lojuxta which was used to lower low density lipoprotein cholesterol (LDL-C) in patients with HoFH. Based on Aegerion's experience, health professionals with an interest in these specialties were among those who treated HoFH patients. However, the company never intended to email promotional information without obtaining prior consent to do so.

Reflecting common practice, Aegerion exercised diligence and care to ensure that the email distribution complied with the Code and the company's standard operating procedures (SOPs). However, given the error described above, the company had reviewed and updated its SOPs and internal training procedures to help ensure that this type of error did not occur again.

Aegerion submitted that it aspired at all times to uphold high standards and that, other than Clause 9.9, it had not breached Clauses 9.1, 11.1 or 12.1.

1 The email distribution

The email concerned a recent clinical update (Cuchel *et al*) published in the European Heart Journal entitled 'Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholaesterolaemia of the European Atherosclerosis Society'. Lojuxta was approved as an adjunct treatment for adults with HoFH.

HoFH was caused by genetic defects inherited from both parents that affected the function of the LDL receptor, the receptor responsible for removing LDL-C from the body. It typically presented as highly elevated cholesterol levels, severe and progressive atherosclerosis and premature cardiovascular disease. Aegerion considered Cuchel *et al* was a key cardiology publication as it was the first time that a consensus, European or otherwise, had been published on the diagnosis and management of HoFH. All previous publications discussed diagnosis and management guidance either for general dyslipidaemia or familial hypercholesterolaemia rather than its most severe form, HoFH. The publication included a short discussion on a number of potential treatment options for adults with HoFH, including Lojuxta.

The first email was sent to 2,097 health professionals in the UK and the Republic of Ireland with the reminder email being sent to 2,009 who had not clicked through on the first email – a standard approach by the mailing house used. The mailing house recorded health professionals' specialty based on the elections of health professionals. These records were updated on a regular basis. As noted above, the mailing list was comprised of specialties interested in the diagnosis and management of lipid disorders (chemical pathology, pathology, clinical chemistry and biochemistry), and cardiology, cardiovascular disease, coronary care and paediatric cardiology. A full breakdown of the specialties and

numbers was provided. The final number differed as the list of clinicians within the specialties was continuously being updated.

As noted above, due to an error on Aegerion's part, the mailing house incorrectly followed the process for emailing educational materials to physicians rather than the process for emailing promotional materials, which would have involved the mailing house sending a non-promotional email inviting recipients to click on a link to a landing page with an opt-in to view the promotional message. This error resulted in the email being sent without the consent required under Clause 9.9.

2 The email was not disguised promotion (Clause 12.1)

Aegerion submitted that it did not disguise the email as educational material, nor did it intend to do so.

The justification for sending the email to interested recipients was to provide information on HoFH and to invite the recipient to contact Aegerion if they were interested in receiving information about Lojuxta as a potential treatment for adults with HoFH. The email was purposely targeted to health professionals with an interest in cardiovascular disease and lipid disorders as they could potentially encounter diagnosed or undiagnosed cases of HoFH in their practice.

The email thus had a promotional purpose. Nowhere in the email or the subject matter was it mentioned that it was intended to be educational material. Nor could it be inferred that the email was intended to be promotional material disguised as educational.

It was clear from the information in the email, which included Aegerion's name and the signature of a senior manager that the promotional communication came from Aegerion. The statements at the end of the email made clear that Aegerion marketed Lojuxta as a treatment for HoFH. The email stated:

> 'If you would like to be contacted to discuss options for the management of HoFH, please contact [name] on [name]@aegerion.com.
>
> Please see the end of this mail for prescribing information on Lojuxta (lomitapide) hard capsules.'

The inclusion of both statements in the email clearly drew attention to the use of Lojuxta as a treatment for HoFH. Further, the email also included a summarised version of the information in the journal and stated that:

> 'Newer treatments offer the possibility of further LDL-C reduction on top of current standard of care.'

The promotional intent of the email was underlined by the fact that, in accordance with the requirement in the supplementary information to Clause 10.1, it was certified as promotional material and included the prescribing information for Lojuxta.

Aegerion had the utmost respect for the knowledge and experience of all health professionals with whom it might, from time to time, contact in accordance with applicable rules. Aegerion never intended to deliberately disguise the nature of any promotional material provided to health professionals. Aegerion regretted that the promotional email was sent to recipients who did not opt-in to receiving such information.

3 The complainant's assumed interest in the email

Aegerion understood that Clause 11.1 meant that a reasonable assumption must be evidenced to demonstrate that a recipient of promotional information required, or was interested in, receiving such material. Such a presumption was, arguably, subjective in nature and should be considered in light of the particular facts of each case.

Given the area of their expertise, Aegerion concluded that it was reasonable to assume that the complainant and other recipients of the email would have an interest in receiving emails of this nature. The recipients were listed in the database of the mailing house as having an interest in, among other things, cardiovascular disease and the management of lipid disorders. The mailing house made the categorisation of specialties based on the self-selection of the health professionals. Aegerion submitted that the complainant last verified his contact information with the mailing house in April 2014 as part of its annual cycle of revalidation. Following this revalidation, the complainant indicated that he was a specialist in cardiovascular disease.

As noted above, since the publication concerned HoFH, which typically presented as highly elevated cholesterol levels, severe and progressive atherosclerosis and premature cardiovascular disease, the email was purposely targeted to health professionals with an interest in these topics as they could potentially encounter diagnosed or undiagnosed cases of HoFH in their practice. In particular, the complainant's profile on a university website stated that he was a member of the Institute of Cardiovascular and Medical Sciences and had a particular interest in clinical trials relating to strokes. Aegerion also understood that one of his areas of research was atherosclerotic plaques of the carotid. The complainant had also co-authored a number of articles concerning cardiovascular diseases. Aegerion further understood that the complainant was involved with a national policy making group and was present during an advisory discussion about the use of Lojuxta within one of the UK regions.

Based on the above, Aegerion submitted that the complainant possessed knowledge of, and, presumably an interest in, HoFH and that there was a reasonable assumption that he would be interested in emails of this nature.

4 High standards

The email was promotional and not disguised as educational material. Aegerion regretfully acknowledged that the company's error resulted in the mailing house using its email distribution process for educational materials rather than for promotional materials. This meant that the email was sent to the complainant and the others in breach of Clause 9.9.

Aegerion was committed to maintaining the high standards for which the Code provided at all times during the course of its operations, including in relation to interactions with health professionals. As noted above, Aegerion was also committed to ensuring that this type of error did not occur again.

PANEL RULING

The Panel noted that the emails discussed HoFH and introduced the consensus paper Cuchel *et al*, which was available via a link, and summarised its key points. The Panel noted that Cuchel *et al* discussed new insights and guidance for clinicians to improve detection and clinical management of HoFH. It discussed a range of treatments including lomitapide which it included on a suggested algorithm for the management of HoFH. The main text of the email did not refer to a specific product but made a general reference to lipid lowering therapy and a subsequent reference to newer treatments offering the possibility of further LDL-C reduction. The two emails were identical other than the prefix 'Reminder' in the subject heading to the second email. The Panel agreed with the company's submission that the emails were promotional. Cuchel *et al*, *inter alia*, discussed a product in which the company had a commercial interest and the emails bore prescribing information.

The Panel noted that the Code prohibited the use of emails to promote medicines, except with the prior permission of the recipient. Previous cases had established that text or dialogue requesting permission to send promotional material had to make it abundantly clear that the intention was to send promotional material from pharmaceutical companies about medicines. The Panel noted Aegerion's admission that due to an error on its part, the mailing house had acted incorrectly in that it followed the process for emailing educational materials to physicians instead of the process for sending promotional materials. This error had resulted in the promotional emails being sent, *inter alia*, to the complainant without his requisite prior consent. A breach of Clause 9.9 was ruled.

The Panel noted Aegerion's submission that the email was purposely targeted at health professionals with an interest in cardiovascular disease and lipid disorders as they might potentially encounter diagnosed and undiagnosed cases of HoFH in their practice. The Panel noted that, according to Aegerion, when the complainant verified his details with the mailing house in April 2014 he indicated that he was a specialist in cardiovascular disease. The Panel also noted the company's submission about his academic profile and research into atherosclerotic plaques of the carotid. Whilst the Panel noted the complainant's submission that he did not treat patients with this condition, it nonetheless considered that given his speciality his need for or interest in the subject matter of the emails could reasonably have been assumed. No breach of Clause 11.1 was ruled.

The complainant had alleged that the emails were sent with promotional intent but masqueraded as educational material. In that regard the Panel considered that the recipient's initial impression of the emails was important. In the recipient's inbox the emails appeared as from '[name]<information@hofh-management.co.uk'. The subject heading was 'New guidance for clinicians on homozygous familial hypercholesterolaemia'. On opening the email the text of the email did not bear a separate heading and in the Panel's view some recipients might have been left with the initial impression that the emails contained non-promotional information about HoFH as per the subject heading of the emails. This impression was compounded by the sender's address which bore no apparent link to a pharmaceutical company or otherwise indicated the emails' promotional content. The corporate logo did not appear at the outset on the hard copy versions of the email provided by the complainant. Those provided by the company bore the corporate logo on the top left hand corner. The Panel noted that the logo might only have appeared when the email was viewed in the web browser. If this was so, the complainant would not even have been aware at the outset that the email was from a pharmaceutical company. The emails were signed by a senior manager. In the Panel's view the length of the email was such that the pharmaceutical company's involvement and that the emails contained prescribing information would not be apparent until the recipient had scrolled down to the bottom of the emails. In such circumstances the Panel considered that despite the presence of prescribing information their primary characterisation at the outset was as a piece of educational material and the emails were disguised in this regard. A breach of Clause 12.1 was ruled.

The Panel noted its rulings of breaches of the Code above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

Complaint received **23 December 2014**

Case completed **13 February 2015**

CASE AUTH/2745/1/15

CHIEF PHARMACIST v SHIRE

Lack of transparency of role in commissioning materials

A chief pharmacist/director of pharmacy services at an NHS foundation trust alleged that Shire had commissioned an agency to develop materials in a way which failed to reveal the company's involvement and that it would use them for promotional purposes.

The complainant explained that a consultant colleague had been approached by the agency to discuss her work with ADHD (attention deficit hyperactivity disorder) Services. Whilst the emails from Shire's agent referred to its work 'receiving sponsorship' from Shire, it did not disclose that Shire would use the material promotionally before it gained consent to speak to the colleague. As the extent of Shire's involvement was not made clear in advance and only emerged at the interview stage, this process was alleged to be unacceptable and did not meet the transparency requirements of the Code.

The detailed response from Shire is given below.

The Panel noted that the complaint concerned the transparency of Shire's role in relation to its initiation and funding of the activity and intended use of the material when its agency invited the health professional to act as a consultant. The health professional was concerned that she had not been fully informed at the outset of the extent of Shire's role in relation to the material. The health professional had raised the matter with a senior pharmacist colleague who in turn had submitted the complaint.

The Panel noted Shire's submission that it had intended to interview the health professional to assist in the compilation of a new module for its existing ADHD Service toolkit. The new module would include case studies and tools relating to patients transitioning from child/adolescent services to adult mental health services. According to Shire the toolkit was used as a service to medicine and would not refer to or promote Shire products or any other medicines. It was used by Shire's health development managers. The Panel had no detail about their role nor did it have a copy of the current toolkit.

The Panel noted that the initial email sent by Shire's agency to the health professional was headed 'Invitation – share your example of good local practice in ADHD Transition Services' and stated that 'We are collecting examples of good practice in transition services …' but did not state who 'We' referred to. At the end of the second paragraph the email stated that the initiative had 'been supported by funding from Shire Pharmaceuticals' and that the health professional would be reimbursed for her time. During a subsequent telephone conversation with the agency the health professional declined further involvement when Shire's role was made clear.

The Panel noted that on instructing the agency Shire had discussed disclosure of its role at a meeting and subsequently by email. The project was described in these communications as 'an initiative by Shire,' a service 'supported by Shire' and 'non-promotional, sponsored/funded by Shire'. The Panel was concerned that contrary to Shire's email instruction to its agency it appeared that the health professional had not been sent a contract by Shire on receipt of a positive response to the initial invitation.

The Panel considered that the company's explanation of its role including the intended use of the material should have been unambiguous such that the health professional would fully understand the extent of Shire's involvement and influence on the material at the outset. In the Panel's view, given that the initial email from a third party began with '*We* are collecting together examples …' (emphasis added) and stated that the initiative had been 'supported by funding from Shire Pharmaceuticals', it was not unreasonable that the recipient would assume that the activity in question was an independently run project which had received some finance from Shire. The description of Shire's role was not clear. The Panel considered that high standards had not been maintained and it ruled a breach of the Code. In addition, and on balance, the Panel considered that the failure to make the company's role clear at the outset when contacting the consultant was such that the health professional could not make a fully informed decision about whether to accept the invitation to become a consultant. Shire had failed to recognise the professional standing of the health professional concerned. A breach of the Code was ruled.

Shire had been asked to respond in relation to sponsorship of material relating to medicines and their uses and information relating to human health and diseases. The Panel noted that the complaint did not relate to a declaration of sponsorship on the toolkit but rather transparency of the company's role in relation to initiation, funding and use of the material when the health professional was first contacted ie the nature and terms of the consultancy. The Panel therefore ruled no breach of the Code.

The Panel noted its comments above on the nature of the complaint and also the company's submission that the material was non-promotional. In that regard the material could not be disguised promotion and the Panel ruled no breach of the Code.

Shire had also been asked to respond in relation to joint working and the Panel noted Shire's submission that the project was not 'joint working' as defined in the Code. No breach of the Code was ruled.

The Panel noted its rulings above and did not consider that the circumstances were such as to warrant a ruling of a breach of Clause 2 which was reserved as a sign of particular censure. No breach of Clause 2 was ruled.

A chief pharmacist complained that Shire Pharmaceuticals Limited had commissioned a communications agency to develop materials on its behalf in a manner which failed to reveal that Shire had commissioned the materials and would use them for promotional purposes.

COMPLAINT

The complainant alleged that Shire and it's communications agency had failed to act openly and transparently when they contacted a local clinician in order to produce materials for Shire as part of its promotional activities. Further, Shire and its agent failed to follow the Code in relation to the development of a joint initiative namely the production of a good practice guide in the management of transition services.

The complainant explained that in December 2014 a consultant colleague had contacted him concerned that she had been approached by the communications agency to discuss her work with ADHD [attention deficit hyperactivity disorder] Services. Whilst the emails from Shire's agent referred to its work 'receiving sponsorship' from Shire, it did not disclose that Shire would use this material promotionally before it gained consent to speak to the colleague. As the extent of Shire's involvement was not made clear in advance and only emerged during the interview stage, this process was unacceptable and not in line with the Code in relation to transparency. Copies of various materials were supplied.

In writing to Shire attention was drawn to Clauses 2, 9.1, 9.2, 9.10 and 12.1 of the 2014 Code. The company was also asked to consider the requirements of Clause 18.5 if the project at issue was 'joint working' as defined the supplementary information to that Clause. The 2015 Constitution and Procedure applied to this complaint.

RESPONSE

Shire stated that it was disappointed to receive this complaint and set out its response below.

1 The development of the 'ADHD Service toolkit'

Shire submitted that it had initiated and funded the ADHD Service toolkit with no other pharmaceutical company involvement. It was developed as a service to medicine for use by its healthcare development managers (HDMs) with health service commissioners and health professionals involved in the development of ADHD services. The current iPad version was first certified for use as a digital non-promotional tool in October 2014. The HDMs demonstrated the toolkit to health professionals and then emailed specific toolkit content requested by the health professional for use within their own organisation.

The toolkit did not refer to or promote Shire products, or indeed any other medicines. It contained a wide range of tools intended to help NHS health professionals identify gaps in local ADHD service delivery, as well as proposing and implementing improvements to enhance patient care.

2 Shire's relationship with its communications agency

Shire commissioned a marketing and communications agency to develop an additional module for the ADHD Service toolkit. This additional module was to contain case studies and tools relating to ADHD patients transitioning from child/adolescent to adult mental health services (the Transition Service update). This project was performed under a Master Services Agreement with an agreed Statement of Work for the Transition Service update (copies provided).

The project required the agency to research and compile an update for the ADHD Service toolkit on the subject of Transition Services relating to children and adults with ADHD. This included using public domain information to identify key centres and individuals who could be approached to act as consultants in completing the update.

This update was still in development and the Transition Service update had not yet been approved or used as part of the ADHD Service toolkit or otherwise. There were therefore no certified materials relating to it. The existing, approved ADHD Service toolkit was not shared with health professionals as part of this engagement.

3 The engagement of the health professionals in regard to the 'ADHD Service toolkit update'

a) Meeting and communications between Shire and its communications agency regarding transparency and declarations

Staff from the marketing and communications agency and Shire met in November 2014 to discuss the Transition Service update. The meeting minutes recorded the requirement for full transparency in relation to engaging health professionals to work on the project.

> '[agency] to make an initial approach to these options. Explain how we will want to work with them to write something up and it's an initiative by Shire. An official letter then needs to be written to outline what we are asking them to sign up to, it needs to state it is non-promotional activity; it's a service which is supported by Shire. We will need to make sure to get permissions that it can be put in the tool, that it can be printable; we can use their names, etc.'

A subsequent email sent between agency colleagues in November 2014 reinforced the commitment to be fully transparent with health professionals engaged in the development of this ADHD Service toolkit update.

'Thoughts on what we need to cover in the email:

- About the initiative / service
- Non-promotional, sponsored / funded by Shire
- What we would need them to do – have a telephone call and then review documents / tools (the plan is that these would ultimately be made available and be printable) and agree for us to use their name
- Next steps – a contract would be sent by Shire, and once this is agreed, we'd like to set up a call w/c 8 December.'

b) Identification of the health professional as a potential provider of consultancy services in relation to the Transition Service update

The agency identified the health professional as a potential contact through two key publicly available documents. Shire submitted that had the health professional decided to proceed, a written agreement in accordance with Clause 20 would have been used.

c) Initial communication with the health professional by the agency

The agency emailed the health professional in December 2014 to outline the project and reason for contact. This included the following statement:

> 'This initiative has been supported by funding from Shire Pharmaceuticals and we will be able to re-imburse you for your time.'

The email explained the need for a telephone discussion to discuss details of the engagement further:

> 'We are keen to carry out the telephone discussions before the Christmas break so would be very grateful if you could advise if you would be interested in participating and we can arrange a convenient time to speak to provide more details.'

d) Subsequent communications led to a telephone call to discuss the proposed engagement in more depth

Following the initial email, the health professional agreed to a follow up telephone discussion with the agency. During this telephone call the health professional declined further involvement when Shire's involvement was highlighted. The call was then brought to a close by the agency. A narrative of the telephone call was provided. Shire submitted that there had been no further contact with the health professional. All other emails were provided.

e) Shire's review of the correspondence regarding engagement of the health professional

Shire recognised that the health professional did not appear to know that the engagement proposed by the agency was for a project commissioned solely by Shire. However, Shire's involvement was clearly stated in the initial email from the agency and subsequently during the telephone call to explain the nature of the engagement before any consultant contract was agreed and work initiated. Shire submitted that it had sought to comply with Clause 9.10.

4 Matters concerning the allegation of disguised promotion

In consideration of Clause 12.1 and the allegation of disguised promotion by the complainant that:

> '[The agency] did not disclose that this material would be used for promotional purposes by Shire Pharmaceuticals prior to gaining consent to speak to my colleague.'

As stated above, the material was not intended for promotional use as the ADHD Service toolkit was a non-promotional item for use by health professionals. Shire submitted that no evidence of disguised promotion has been provided. There had been no circulation of materials or activities mentioning Shire products to the health professional. Both the engagement with the health professional and the development of the ADHD Service toolkit were non-promotional in nature and intent. Shire therefore submitted that there was no evidence to support a breach of Clause 12.1.

On the matter of the visibility of Shire's role in this engagement, Shire noted that it had discussed the declaration of its funding via email and verbally during a telephone call to discuss the proposed engagement above.

5 The alleged engagement in the conduct of joint working

Shire noted that the complainant had stated:

> 'Shire pharmaceuticals and its agent failed to follow the Code in relation to the development of a 'joint initiative' namely the production of a good practice guide in the management of transition services.'

Shire submitted that the complainant's phrase 'joint initiative' should be interpreted as meaning Joint Working as defined in the supplementary information of Clause 18.5 of the 2014 Code.

Shire submitted that the ADHD Service toolkit was a non-promotional tool provided by Shire for use by health professionals as a 'Service to Medicine' item intended to enhance patient care and benefit the NHS (Clause 18.4). There was no element of pooled resources and it did not represent joint development/ implementation of an agreed project. This was not joint working as defined by the Code and in this regard, Shire considered that there had been no breach of Clause 18.5.

Conclusion

Shire's submitted that there was no evidence that the agency intended to gain advice by subterfuge. The evidence provided showed the intent for full transparency in working with the health professional concerned. There was no evidence (or intent) of disguised promotion. The project did not meet the criteria for joint working.

Shire believed that it and the agency had upheld high standards as demonstrated within all communications by being courteous and respectful of the health professional's time and expertise, there was no intention to cause offence in any written or verbal communications. Shire denied a breach of Clause 9.1 or 9.2.

In addition, there was no evidence that Shire employees/agents fell short of competent care or conducted other activities as listed in the supplementary information to Clause 2 that brought discredit upon, or reduced confidence in, the pharmaceutical industry. Therefore Shire denied a breach of Clause 2.

PANEL RULING

The Panel noted that the complaint concerned the transparency of Shire's role in relation to its initiation and funding of the activity and intended use of the material when its agency invited the health professional to act as a consultant. The health professional was concerned that she had not been fully informed at the outset of the extent of Shire's role in relation to the material. The health professional had raised the matter with a senior pharmacist colleague who in turn had submitted the complaint.

The Panel noted Shire's submission that it had intended to interview the health professional to assist in the compilation of an update for its existing ADHD Service toolkit. The additional module for the toolkit would include case studies and tools relating to ADHD patients transitioning from child/adolescent services to adult mental health services. According to Shire the toolkit was used as a service to medicine and would not refer to or promote Shire products or any other medicines. It was used by Shire's health development managers. The Panel had no detail about their role nor did it have a copy of the current toolkit.

The Panel considered that it was important that when companies engaged health professionals as consultants they were, *inter alia*, transparent about the arrangements and the extent of their role. The Panel noted that the initial email sent in December 2014 by an account director from Shire's agency to the health professional was headed 'Invitation – share your example of good local practice in ADHD Transition Services' and stated that 'We are collecting examples of good practice in transition services …' but did not state who 'We' referred to. The email referred to the health professional's local model on which 'We' would like to compile a short case study to guide her colleagues. The email further explained that the examples would sit within an ADHD Service toolkit which would help local areas assess their services, identify gaps and implement plans for local improvement. At the end of the second paragraph the email stated that the initiative had 'been supported by funding from Shire Pharmaceuticals' and that the health professional would be reimbursed for his/her time. During a subsequent telephone conversation with the agency's medical writer, the health professional declined further involvement when Shire's role was made clear.

The Panel noted that on instructing the agency Shire had discussed disclosure of its role at a meeting and subsequently by email. The project was described in these communications as 'an initiative by Shire,' a service 'supported by Shire' and 'non-promotional, sponsored/funded by Shire'. The Panel was concerned that contrary to Shire's email instruction to its agency in November, it appeared that the health professional had not been sent a contract by Shire on receipt of a positive response to the initial invitation.

The Panel considered that the company's explanation of its role including the intended use of the material should have been unambiguous such that the health professional would fully understand the extent of Shire's involvement and influence on the material at the outset. In the Panel's view, given that the initial email was sent from a third party and began with '*We* are collecting together examples …' (emphasis added) and stated that the initiative had been 'supported by funding from Shire Pharmaceuticals', it was not unreasonable that the recipient would assume that the activity in question was an independently run project which had received some finance from Shire. The description of Shire's role in the initial invitation email was not clear. The Panel considered that high standards had not been maintained in this regard and ruled a breach of Clause 9.1. In addition, and on balance, the Panel considered that the failure to make the company's role clear at the outset when contacting the consultant was such that the health professional could not make a fully informed decision about whether to accept the invitation to become a consultant. Shire had failed to recognise the professional standing of the health professional concerned. A breach of Clause 9.2 was ruled.

Shire had been asked to respond to Clause 9.10 of the Code which referred to sponsorship of material relating to medicines and their uses and information relating to human health and diseases. The Panel noted that the complaint did not relate to a declaration of sponsorship on the toolkit but rather transparency of the company's role in relation to initiation, funding and use of the material when the health professional was first contacted ie the nature and terms of the consultancy. The Panel therefore considered that Clause 9.10 did not apply. No breach of Clause 9.10 was ruled.

The Panel noted its comments above on the nature of the complaint and also the company's submission about the non-promotional nature of the material.

The Panel thus considered that Clause 12.1 which related to disguised promotion did not apply. No breach of Clause 12.1 was ruled.

The Panel noted that Shire had been asked to respond to Clause 18.5 in relation to joint working only if the activity was a joint working project as defined in the supplementary information to that clause. The Panel noted Shire's submission that the project was not 'joint working' as defined in the Code. No breach of Clause 18.5 was ruled.

The Panel noted its rulings above and did not consider that the circumstances were such that they warranted a ruling of a breach of Clause 2 which indicated particular censure and was reserved for such use. No breach of Clause 2 was ruled.

Complaint received **9 January 2015**

Case completed **13 March 2015**

DIRECTOR OF RESEARCH v ASTRAZENECA

Tweet about the incidence of a disease

A director of research, based in the US, complained about the following tweet posted by AstraZeneca on 11 December 2014 from the San Antonio Breast Cancer Symposium: 'Approximately 30% of women with early breast cancer will develop advanced or metastatic breast cancer'. The complainant explained that he was both a medical professional with a UK licence and the husband of a breast cancer survivor. He understood that survival rates were above 98% for early breast cancer.

The complainant queried the evidence upon which the tweeted statement was made, the; target audience and whether AstraZeneca had considered the negative effect that the tweet could have on a woman recently diagnosed with early breast cancer. The complainant noted that AstraZeneca had cited O'Shaughnessy (2005) on a fact sheet in support of the statement however the figure of 30% was an unreferenced comment from the author and not based on any data. Despite contacting the company several times, the complainant noted that he had not received a formal reply and that the tweet was still posted on the company's twitter page on 9 January 2015.

The complainant asked that his complaint be considered with regard to the lack of evidence for the statement, the distress caused to those impacted by breast cancer and the company's lack of a formal response.

The detailed response from AstraZeneca is given below.

The Panel noted that the tweet was sent from AstraZeneca's global twitter account. The global headquarters was based in the UK thus the twitter account had to comply with the UK Code.

The Panel noted that the complainant was concerned that the tweeted statement 'Approximately 30% of women with early breast cancer will develop advanced or metastatic breast cancer' could not be substantiated. It was referenced to O'Shaughnessy (2005); the statement in the paper was unreferenced and appeared in the introduction section. In 2009 an 'Advanced breast cancer: diagnosis and treatment' guideline from the National Institute for Health and Care Excellence (NICE) stated that data generated in the West Midlands in 2012 indicated that in addition to the 5% of patients with metastases when they were diagnosed with breast cancer, a further 35% of all those with a primary diagnoses went on the develop metastases in the 10 years after diagnosis with little data to quantify the number of cases of advanced breast cancer developing after 10 years. It was stated that in summary there was little information available regarding advanced breast cancer; up to 40% of those diagnosed with breast cancer would develop advanced disease within 10 years. The 2012 pilot report from the West Midlands noted that although the outcomes of breast cancer had improved greatly over the past 20 years, dealing with recurrent and metastatic disease remained a significant and challenging problem, particularly given the high prevalence of the disease. It was further noted that the data at issue was not a suitable basis for estimating the full extent and nature of recurrent and metastatic breast cancer nationally.

The Panel noted that the complainant referred to a survival rate of more than 98% for early breast cancer but considered that this referred to 5 year survival – Cancer Research UK had produced data to show that for stage 1 cancer at diagnosis, 5 year relative survival was 99.1% and for stage 2 breast cancer at diagnosis it was 87.6%. As stated above, however, a proportion of women with breast cancer would go on to develop metastatic disease within 10 years or longer.

The Panel considered that the situation was difficult. Precisely quantifying the percentage of women diagnosed with early breast cancer who would then go on, perhaps many years later, to develop metastatic breast cancer was extremely difficult and at any time point would encompass women who had been first diagnosed years apart and who thus might have received very different treatment regimens. Thus when figures for metastatic disease were calculated, they were retrospective in terms of the initial diagnosis and might not reflect what newly diagnosed patients could expect in the future given advances in treatment. Nonetheless it was important that health professionals and patients with early breast cancer knew of the possibility of metastatic disease developing even if the original diagnosis had been made some years ago; any figure so used must reflect the requirements of the Code and be capable of substantiation. The Panel noted the limitations of the data and that the complainant bore the burden of proof. AstraZeneca had some data to support its position. Whilst it might have been helpful to provide more information about the data, on balance the Panel considered that given the difficulty in determining a precise figure, the reference to 'approximately 30% of women' in the tweet was not unreasonable. No breach of the Code was ruled. The Panel considered, on balance, that the statement could be substantiated by O'Shaughnessy and data taken from the West Midlands. No breach of the Code was ruled.

The Panel noted that the complainant had asked that his complaint be considered with regard to the distress cause to those impacted by breast cancer.

The Panel sympathised with the complainant's position but nonetheless considered that this aspect of the complaint was not covered by any of the clauses raised and thus it made no ruling in that regard. The complainant had also asked that the complaint be considered on the basis of the lack of response from AstraZeneca. The Panel noted that AstraZeneca had responded, albeit not within the time frame specified by the complainant. The company, however, had not been asked to consider the relevant clause of the Code and so in that regard the Panel could not make a ruling.

A director of research based in the US, complained about a tweet posted by AstraZeneca. The tweet stated 'Approximately 30% of women with early breast cancer will develop advanced or metastatic breast cancer'. The tweet carried the hashtags #breastcancer and #SABCS14 (San Antonio Breast Cancer Symposium 2014) and included a graphic to illustrate the statement.

COMPLAINT

The complainant stated he was both a medical professional with a UK licence and the husband of a cancer survivor – his wife had had the misfortune to be diagnosed with breast cancer on two separate occasions – both distinct tumours which required gruelling and unpleasant treatments but based on good evidence of long-term survival with therapies including surgery, chemotherapy, radiotherapy and hormonal therapies. The complainant understood that the survival rates were above 98% for early breast cancer.

On 11 December 2014, AstraZeneca posted a tweet and an image which stated that '30% of women with early breast cancer will develop advanced or metastatic breast cancer'.

The complainant responded to the company via twitter and email to query the evidence upon which the statement was made, the target audience and whether it had considered the negative effect that the tweet could have on a woman recently diagnosed with early breast cancer. The complainant noted that he had not had a formal written response from AstraZeneca so far and the tweet was still posted on the company's twitter page on 9 January 2015.

The complainant also emailed the American Cancer Society to ask if it was aware of the evidence behind this statement; it stated that it could not find the evidence to support the statement. Although AstraZeneca provided a reference (O'Shaughnessy 2005) on its fact sheet, the statistic was an unreferenced comment from the author and not based on any data.

The complainant asked that his complaint be considered based on the lack of evidence for the statement, the distress caused to him, his family and others impacted by breast cancer and the lack of a formal response from AstraZeneca. Obviously, if the statement was true for women with early breast cancer treated in 2014 then the complainant would apologise but he suspected that this was not so.

When writing to AstraZeneca, the Authority asked it to respond in relation to Clauses 7.2 and 7.4 of the 2014 Code and to note the supplementary information to Clause 23.2 Information to the Public, and Clause 25.

RESPONSE

AstraZeneca noted that complaint was about a non-promotional tweet which was sent at 5.50pm (GMT) on 11 December 2014, by its global corporate affairs team who had attended the 2014 San Antonio Breast Cancer Symposium. The tweet was sent from the AstraZeneca global twitter account - @AstraZeneca. The global corporate affairs team was part of the global organisation and did not report into the UK marketing company, although its offices were based in the UK.

The tweet was produced and then peer-reviewed by corporate affairs. As the tweet was non-promotional it was not certified. The entire content of the tweet was taken from an infographic approved by AstraZeneca global nominated signatories according to their procedures. The infographic was created by global as a background information fact sheet for use with media communications during the San Antonio Breast Cancer Symposium and made available to other functions and affiliates to use subject to their own procedures.

The tweet would have been received by all followers of the AstraZeneca global twitter account and it contained the text 'Approximately 30% of women with early breast cancer will develop advanced or metastatic breast cancer'. The tweet also contained a graphic which depicted 30 out of 100 symbols, representing the female body, emboldened and coloured differently, to represent the 30% described in the statement. This non-promotional tweet was sent to communicate the current unmet need in breast cancer despite the many advances made over the last few decades and to stimulate thought and debate during the San Antonio Breast Cancer Symposium. The target audience was anyone interested in, attending or following the San Antonio Breast Cancer Symposium, which was why the official hash tag of the symposium (#SABCS14) was included, as well as (#breastcancer). The audience could include health professionals, patients, non-government organisations and media etc. AstraZeneca understood that twitter was an open-source social network, accessible to the public, however the content of the tweet was suitable for that audience and in line with relevant provisions of the Code. The tweet did not receive any other complaints or replies besides those of the complainant; however, AstraZeneca regretted if even one person was upset by the tweet and it sincerely apologised to the complainant for not replying to his last email more promptly.

The complainant cited an early breast cancer survival statistic in relation to his concerns about the factual accuracy of the tweet. Early breast cancer was defined as that which had not spread beyond the breast or the lymph nodes in the armpit on the same side of the body and with a tumour diameter of less

than 5cm. According to the widely accepted staging classification of breast cancer, early breast cancer met the criteria of stages 0-3A. The complainant cited that survival rates were above 98% for early breast cancer. According to data published on the Cancer Research UK website, 5 year survival rates in the UK for the most commonly diagnosed stages of early breast cancer, ie stages 1 and 2, were 99% and 88% respectively. Whilst this was so, AstraZeneca submitted that the statement in relation to the risk of progression, which was different to survival, was substantiated by a number of referenced articles, papers and national and European guidelines. These referenced papers, articles and guidelines supported the statement that approximately 30% of women diagnosed with early breast cancer would develop advanced or metastatic breast cancer in their lifetime (despite the high 5 year survival rates). Furthermore, the time from original breast cancer diagnosis to recurrence could vary widely and this was demonstrated in the Recurrent and Metastatic Breast Cancer Data Collection Project Pilot report where 19% of the patients were originally diagnosed more than 10 years before recurrence.

AstraZeneca submitted that the statement in the tweet was clear and unambiguous and there was no intention to mislead. As the statement was accurate and could be substantiated it complied with Clauses 7.2 and 7.4. AstraZeneca also submitted that the statement, issued to the public, complied with the supplementary information to Clause 23.2 and was in accordance with the provisions of the PMCPA guidance on digital communications and Clause 25.

AstraZeneca had corresponded with the complainant and provided the O'Shaughnessy reference to substantiate the tweeted statement. This initial correspondence was via twitter, first publicly and then latterly privately. The complainant who was based in the US subsequently telephoned the local AstraZeneca US offices on 16 December and then also emailed the office. These were dealt with according to the US company's medical information procedures. On 18 December the complainant emailed the US company again and demanded a reply by 9 January. The US personnel knew that the complainant's email related to the tweet sent by corporate affairs so they forwarded it to two colleagues in corporate affairs on 23 December 2014. Unfortunately, corporate affairs did not respond to the email before the deadline set by the complainant. However, AstraZeneca had since replied to his email and, given the sensitivity of the matter and his circumstances, had given him the opportunity to discuss his concerns with its global medical affairs leader for oncology.

In summary, AstraZeneca submitted that it had thoroughly investigated this matter and that it treated all such complaints seriously and responsibly. Whilst it had not received any other complaints it sincerely regretted that the complainant had apparently been upset by the tweet and this was clearly unintended. AstraZeneca submitted that the tweet was non-promotional and did not contain any information about medicines, was accurate and capable of substantiation. The tweet was not misleading and complied with the Code with regard to communication with the public and on the Internet. AstraZeneca also considered the PMCPA guidance on digital communications. AstraZeneca therefore believed it had fully met all the relevant requirements of the Code regarding the communication.

FURTHER INFORMATION FROM THE COMPLAINANT

Before the response was received from AstraZeneca, the complainant provided a copy of an email from AstraZeneca and his comments upon it. These were sent to AstraZeneca.

The email, dated 23 January 2015, provided links to O'Shaughnessy and to a meta analysis of long-term outcome for early breast cancer published in the Lancet, 2012.

The complainant stated that O'Shaughnessy contained an unreferenced statement from the author in what he suspected was not a particularly influential journal; he was surprised that AstraZeneca chose this as its primary reference. With regard to the article from the Lancet, the complainant noted that it contained data from old studies some of which had control arms which would not be appropriate today. The tweet did not contain any qualification about whether or not modern treatment would reduce the 30% risk which was what the complainant suspected patients with new onset early breast cancer would find the most alarming. The complainant still did not understand who the target audience was for the tweet. Twitter was not just read by those attending medical conferences. The complainant noted the delay in receiving a formal, written, response; in his view he had still not received one unless AstraZeneca counted its email. The complainant further noted that the American Cancer Society could not find evidence to support AstraZeneca's statement in its tweet.

The complainant noted that the tweet at issue had now been removed which suggested that, on reflection, AstraZeneca's confidence in the data was not 100%.

FURTHER RESPONSE FROM ASTRAZENECA

AstraZeneca stated that it had addressed the issue of substantiation of the statement in the tweet above and it had no further comments except to add that The Oncologist, the journal in which O'Shaughnessy was published, had been established for more than twenty years; it had an extensive editorial board and its articles were peer-reviewed.

AstraZeneca submitted that it had referred to the Lancet paper in the email to the complainant in the anticipation that it would have dialogue with him and that this paper, when placed in proper context, would be part of the discussion in highlighting recurrence rates in breast cancer.

AstraZeneca had acknowledged that regrettably the email from the complainant which requested a reply by the 9 January was not responded to by

this deadline. This was at least in part because AstraZeneca closed its offices from 24 December until 2 January. The local US office handled the original contact from the complainant according to its procedures and forwarded the email to corporate affairs on the 23 December. AstraZeneca had offered the complainant the opportunity to discuss this matter directly to no avail, with the exception of his email of 26 January which was copied to the PMCPA.

AstraZeneca could not comment on the private correspondence the complainant had had with the American Cancer Society.

With regard to the complainant's allegation that the tweet had been removed because AstraZeneca accepted that the information was incorrect, AstraZeneca stated that although it did not consider the statement was incorrect, the fact that it had upset someone was sufficient grounds for its removal to avoid any risk of repetition and further upset.

FURTHER INFORMATION FROM ASTRAZENECA

In response to a request from the Panel for more information such that it could understand the context in which the tweet at issue was sent, AstraZeneca provided copies of other tweets about the San Antonio Breast Cancer Symposium sent from the global corporate affairs twitter account. The company noted that this included retweets of tweets originally sent from the US AstraZeneca twitter account '@AstraZenecaUS'. AstraZeneca reiterated that the tweet at issue had already been deleted and so was not included in the material now provided.

AstraZeneca noted that the tweet at issue was part of a much larger narrative about breast cancer. The strapline on the tweet, 'View more photos and videos' was a standard hyperlink on any tweet image or video posted on twitter; it linked to a tab on the twitter page that contained all of that user's photographs and videos. In the case of AstraZeneca, it linked to content on twitter (the relevant web address was given). Copies of the four photographs and video tweet features sent during and related to the breast cancer symposium were provided. AstraZeneca also provided a hard copy of relevant web pages and a link to a YouTube video from the San Antonio Breast Cancer Symposium 2013.

PANEL RULING

The Panel noted that the tweet was sent from AstraZeneca's global twitter account. The global headquarters was based in the UK thus the twitter account had to comply with the UK Code.

The Panel noted that the complainant was concerned that the tweeted statement 'Approximately 30% of women with early breast cancer will develop advanced or metastatic breast cancer' could not be substantiated. It was referenced to a 2005 paper by O'Shaughnessy; the statement in the paper was unreferenced and appeared in the introduction section. In 2009 an 'Advanced breast cancer: diagnosis and treatment' guideline from the National Institute for Health and Care Excellence (NICE) stated that data taken from the West Midlands Cancer Intelligence Unit indicated that in addition to the 5% of patients with metastases at the time of diagnosis of breast cancer, a further 35% of all those with a primary diagnoses went on the develop metastases in the 10 years following diagnosis with little data to quantify the number of cases of advanced breast cancer developing after the 10-year time period. The guideline stated that in summary there was little information available regarding advanced breast cancer; up to 40% of those diagnosed with breast cancer would develop advanced disease within 10 years. The report from the West Midlands Cancer Intelligence Unit (2012) noted that although the outcomes of breast cancer had improved greatly over the past 20 years, dealing with recurrent and metastatic disease remained a significant and challenging medical problem, particularly in view of the high prevalence of the disease. It was further noted that data from the pilot was not a suitable basis for estimating the full extent and nature of recurrent and metastatic breast cancer nationally.

The Panel noted that the complainant referred to a survival rate of more than 98% for early breast cancer but considered that this referred to 5 year survival – Cancer Research UK had produced data to show that for stage 1 cancer at diagnosis, 5 year relative survival was 99.1% and for stage 2 breast cancer at diagnosis it was 87.6%. As stated above, however, a proportion of women with breast cancer would go on to develop metastatic disease within 10 years or longer.

The Panel considered that the situation was difficult. Precisely quantifying the percentage of women diagnosed with early breast cancer who would then go on, perhaps many years later, to develop metastatic breast cancer was extremely difficult and at any time point would encompass women who had been first diagnosed years apart and who thus might have received very different treatment regimens. In that sense when any figures for metastatic disease were calculated, they were by definition retrospective in terms of the initial diagnosis and might not reflect what newly diagnosed patients could expect in the future given advances in treatment. Nonetheless it was important that health professionals and patients with early breast cancer were aware of the possibility of metastatic disease developing even if the original diagnosis had been made some years ago and any figure so used must reflect the requirements of the Code and be capable of substantiation. The Panel noted the limitations of the data and that the complainant bore the burden of proof. AstraZeneca had some data to support its position. Whilst it might have been helpful to provide more information about the data, on balance the Panel considered that given the difficulty in determining a precise figure, the reference to 'approximately 30% of women' in AstraZeneca's tweet was not unreasonable. No breach of Clause 7.2 was ruled. The Panel considered on balance that the statement could be substantiated by O'Shaughnessy and data taken from the West Midlands indicating that 35% of patients would go on to develop metastatic breast cancer within 10 years. No breach of Clause 7.4 was ruled.

The Panel noted that the complainant had asked that his complaint be considered based on the distress cause to him, his family and others impacted by breast cancer. The Panel sympathised with the complainant's position but nonetheless considered that this aspect of the complaint was not covered by any of the clauses raised and thus it made no ruling in that regard. The Panel queried whether the complainants concerns in this regard were covered by the Code. The company had been asked to note but not respond to Clause 25 and the supplementary information to Clause 23.2 and so the Panel did not make a ruling under either clause but it noted its comments above that the tweet came within the scope and the Code and based on the data available, the tweet was not unreasonable. The complainant had also asked that the complaint be considered on the basis of the lack of response from AstraZeneca. The Panel noted that AstraZeneca had responded to the complainant, albeit not within the time frame specified by the complainant – some of the delay was due to intervening Christmas holidays. The company, however, had not been asked to consider Clause 7.5 and so in that regard the Panel could not make any ruling with regard to the requirements of that clause.

During its consideration of this case, the Panel noted that the tweet at issue had not been certified. The Panel queried whether in that regard the requirement of Clause 14.3 had been met. Clause 14.3 stated that educational material for the public or patients which related to diseases or medicines had to be certified in advance. The Panel requested that AstraZeneca be advised of its concerns in this regard.

Complaint received **12 January 2015**

Case completed **27 March 2015**

CASE AUTH/2752/3/15

ANONYMOUS v OTSUKA

Conduct of an employee

An anonymous, non-contactable complainant alleged that a male employee of Otsuka Pharmaceuticals (UK) behaved inappropriately and provided inappropriate hospitality following a dinner at a meeting partly funded by the pharmaceutical industry. The complainant stated that he/she went from the private function area at a hotel where dinner had been held to the public hotel bar and noticed three Otsuka employees. Descriptions were provided. A female health professional, who the complainant remembered as being very drunk at the dinner, subsequently entered the bar and started talking to the Otsuka employees. Although she was obviously intoxicated a male Otsuka employee continued to ply her with drinks; his two female colleagues seemed unhappy with this.

A fourth Otsuka employee joined the female employees and this group seemed concerned about the conduct of their male colleague. The body language between the male Otsuka employee and the health professional became more intimate and flirtatious and after a number of drinks being bought by the male in question for the female health professional the two left the bar.

The complainant alleged that the conduct of the male Otsuka employee breached Clause 2; the health professional was obviously intoxicated and by continuing to buy her more drink he put her at risk and potentially brought the industry into disrepute.

The detailed response from Otsuka is given below.

The Panel noted that the Code set out detailed requirements in relation to meetings and in particular the provision of subsistence and made it clear that it should be the programme that attracted delegates and not the associated hospitality or venue. The supplementary information also stated that a useful criterion in determining whether the arrangements for any meeting were acceptable was to apply the question 'would you and your company be willing to have these arrangements generally known?'. The impression created by the arrangements for any meeting must always be kept in mind.

The Panel noted that the identity and professional status of the woman in question was unknown although according to Otsuka she had described herself as a researcher. Overall it appeared that the woman was a delegate at the meeting. The Panel disagreed with Otsuka's submission that a researcher was neither a health professional, nor a relevant decision maker and thus the relevant provisions in the Code about meetings would not apply. In the Panel's view, irrespective of whether a researcher was a health professional, relevant decision maker (2015 Code), appropriate administrative staff (2014 Code) or member of the public, subsistence should meet the requirements of the Code in relation to meetings. This was particularly relevant as from the company's submission it was clear that it did not know the woman in question and she could have been a health professional.

The Panel accepted that company employees would want to wind down at the end of a full day at a meeting. The employees were at the conference venue as representatives of their company and as such they should continue to be mindful of the impression created by behaviour beyond the formal meeting and any associated meetings/subsistence. This was particularly important when interacting with UK health professionals and especially so in a late-night social environment.

The Panel noted that whilst there were some differences between the complaint and the company's response, including between the statements of relevant staff, there was overall much agreement. All staff present at the bar agreed that the woman had approached the senior male Otsuka employee, that she appeared intoxicated and that the senior employee required two colleagues to each buy her a drink during the evening. According to Otsuka this was contrary to company procedures which required subsistence to be purchased by the senior member of staff present which would be the man in question. One of the employees purchased two small glasses of wine at the woman's request; the other employee, contrary to the senior employee's instruction, bought her a glass of water. In addition, one member of staff referred to the woman and male employee each holding a drink prior to the aforementioned purchases. It was unclear who had purchased these. One employee said that when she came to the bar from her bedroom the senior employee bought her a drink. The account of the fourth Otsuka employee, who subsequently joined the group, was consistent.

The Panel considered that the Otsuka employees would have known that delegates from the adjoining dinner, including UK health professionals, would have been in the hotel bar and should have been mindful of the impression created by any interaction with them and aware of the public nature of their behaviour. A number of employees referred to talking to customers in the bar. The drinks were purchased by a pharmaceutical company for someone who had attended the meeting's dinner. The Panel queried whether a shared late night social environment could ever be appropriate and in particular did not consider that it was an appropriate environment for the senior employee, who was relatively new to the

therapy area, to be introduced to relevant health professionals.

In the Panel's view, the purchase of drinks for the woman in question in such circumstances was contrary to the requirements of the Code and a breach was ruled. It could not be argued that the purchase was part of the subsistence provided at the meeting. High standards had not been maintained; a further breach was ruled.

The Panel noted its rulings above and was particularly concerned about the impression given by the senior Otsuka employee organising the purchase of drinks for a delegate who was by all accounts intoxicated. The Panel noted the descriptions of the behaviour of both the senior employee and the delegate in question whilst in the public bar. The Panel considered that overall the matter brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

An anonymous, non-contactable complainant was concerned about the conduct of an Otsuka Pharmaceuticals (UK) Ltd employee following the dinner at a British clinical group meeting which took place in Ireland in January 2015.

COMPLAINT

The complainant stated that he attended the gala dinner held on the Thursday evening. The meeting was held in a private area, away from the general public and was funded by health professionals and the pharmaceutical industry.

During the evening the complainant stated that he/she left the private function area and went to the hotel bar which was open to all including the public. At the bar the complainant stated that he/she noticed three individuals, two of whom he/she knew worked for Otsuka and the third the complainant found out later also worked for Otsuka. Descriptions were provided. During the evening a health professional entered the bar; the complainant named the hospital where he/she believed the health professional worked. The complainant particularly remembered the individual as she was very drunk at the dinner. Whilst at the bar she struck up a conversation with the Otsuka employees. Despite the fact that she was obviously intoxicated a male Otsuka employee continued to ply her with drinks. The two female employees seemed unhappy with this and comments were exchanged.

The complainant stated that a fourth Otsuka employee joined the two females. This group of three seemed concerned and a number of looks and comments were made regarding the conduct of the male in question. During the evening the body language between the male and the health professional became more intimate and flirtatious. Eventually after a number of drinks having being bought by the male in question for the female health professional they left the bar within minutes of each other.

The complainant stated that it was not for him/her to comment on the action of two individuals and what might or might not have transpired at the end of the evening. However he/she alleged that the Otsuka employee made a clear breach of Clause 2. The health professional was obviously intoxicated when entering the public bar, yet Otsuka continued to provide her with more drink, putting her at risk and potentially bringing the industry into disrepute.

When writing to Otsuka the Authority asked it to bear in mind the requirements of Clauses 2, 9.1 and 22.1 of the 2015 Code. Although the alleged incident took place during the transition period between the 2014 Code and 2015 Code, the relevant requirements of both Codes were the same. This case would thus be considered under the 2015 Code.

RESPONSE

Otsuka submitted that it set high ethical standards for all employees and expected them to be maintained at all times so it was disappointed to receive such a complaint, particularly from an anonymous complainant.

Otsuka investigated the events of the night of the alleged incident and the level of hospitality offered to health professionals attending the dinner.

There were five Otsuka UK personnel at the meeting, a senior employee and four managers. The senior employee was at the meeting throughout and was responsible for managing the UK team, managing the promotional stand, ensuring that the Otsuka symposium was delivered to plan and, as he was relatively new to the area, meeting some of the health professionals at the meeting.

Otsuka UK had also sponsored two health professionals, one from the UK and another from Italy to attend the meeting and to present at the Otsuka symposium. The sponsorship included economy flights, accommodation, registration and subsistence in line with Clause 22.1. Otsuka stated that it had no involvement in the arrangements for, or the sponsorship of, the gala dinner although it did purchase two tickets for it.

On the night of the alleged incident two managers attended the dinner whilst the senior employee and the two other managers took the two sponsored health professionals for a meal as part of subsistence. On return to the hotel the health professionals and one manager went to their rooms. The other four Otsuka UK employees met in the public bar. Otsuka noted the complainant's description and stated it was clear that the complainant was referring to this group.

Both before and after dinner, a few drinks were bought at the public bar by the Otsuka UK team for their consumption. There were also two glasses of wine bought for the woman as described; none for the sponsored health professionals or any other health professional. The bar bill for all four employees throughout the evening was £127. Having reviewed the individual bills, as well as the

drinks price list of the hotel, Otsuka submitted that this equated to around four drinks per employee throughout the course of the evening (pre- and post-dinner).

Each of the Otsuka employees who were in the bar was interviewed separately by the company and transcripts of their description of the evening were provided. Otsuka submitted these were generally consistent with each other and with the complainant's version of events. They all referred to the woman who appeared to have been drinking and approached the senior employee in the public bar. She was flirtatious and tactile and the senior Otsuka employee in question spent some time talking to her. He also asked one of the managers to buy drinks for the woman, which the manager did. Lastly, there was consistency in that the woman left the public bar on her own and that the senior employee left the bar to go to his room shortly afterwards. However, Otsuka submitted there were two important factual differences between the interviewees and the complainant's versions of events.

1 The woman who was alleged to be a health professional by the complainant described herself to the Otsuka staff as a researcher at a named UK hospital.

2 The drinks bought for this woman were two small glasses of wine (one red, one white) and a glass of water. These were ordered and paid for by an employee at the request of the senior employee.

Otsuka submitted that the meeting was a multidisciplinary meeting attracting health professionals from many specialties, but also basic scientific researchers in oncology. Such researchers were not all 'health professionals' as defined by Clause 1.4 of the Code as they would not, in the course of their professional activities, administer, prescribe, purchase, recommend or supply a medicine, nor would they all be considered as 'other relevant decision makers' as defined in Clause 1.5.

Otsuka did not deny that the senior employee spoke to a woman in the public bar nor that she was flirtatious and tactile. It was also clear that the senior employee asked a member of his team to purchase alcoholic drinks for this woman, on her own request, and two small glasses of wine were purchased by an employee. These facts (corroborated by all interviewees) were not consistent with the complainant's assertion that 'despite the fact that she was obviously intoxicated the senior male Otsuka employee continued to ply her with drinks'.

Even if the woman were a health professional, which was denied, Otsuka did not believe that this was an unreasonable level of hospitality to provide in the course of an evening associated with a scientific meeting. Thus Otsuka submitted that the senior employee's actions did not constitute a breach of Clause 22.1, were it to apply to this case.

Although there was consistency in the accounts that the woman was flirtatious and tactile, the evidence of how the senior employee behaved towards her was inconclusive and neither the complainant nor the Otsuka employees present heard any of the conversation between the two parties. Accordingly, there was no clear evidence that he acted inappropriately. Therefore, Otsuka submitted that his actions did not constitute a breach of Clause 9.1, were it to apply to this case.

As this was an anonymous complaint and the name of the woman was not provided and she was not known by any of the Otsuka UK employees, there was no way to confirm whether she was a health professional or other relevant decision maker. Since Otsuka UK was of the view that the woman was not a health professional, or other relevant decision maker, the fact that the senior employee asked a direct report to buy her drinks, paid for by Otsuka UK, had resulted in the company commencing an internal disciplinary process.

In the circumstances, Otsuka submitted that the complainant had not established a prima facie case for it to answer.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. As stated in the introduction to the Constitution and Procedure, anonymous complaints were accepted and like all complaints, judged on the evidence provided by the parties. Complainants had the burden of proving their complaint on the balance of probabilities. The Panel noted that it was not possible to ask the complainant for further information.

Clause 22.1 stated that hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting ie subsistence only. The level of subsistence offered must be appropriate and not out of proportion to the occasion. Clause 22.1 applied to scientific meetings, promotional meetings, scientific congresses and other such meetings and training. The supplementary information to Clause 22.1, in addition, referred, *inter alia*, to training and investigator meetings for clinical trials. The supplementary information also made it clear that the provision of hospitality was limited to refreshments/subsistence (meals and drinks), accommodation, genuine registration fees and the payment of reasonable travel costs which a company might provide to sponsor a delegate to attend a meeting. In determining whether a meeting was acceptable or not consideration needed to be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, subsistence provided and the like. It should be the programme that attracted delegates and not the associated hospitality or venue. The supplementary information also stated that a useful criterion in determining whether the arrangements for any meeting were acceptable was to apply the question 'would you and your company be willing to have these arrangements generally known?'. The impression that was created by the arrangements for any meeting must always be kept in mind.

The Panel noted that in addition to the requirements in the Code regarding meetings and the provision of hospitality companies were required to have a written document setting out their policies on meetings and hospitality and associated allowable expenditure. The Panel noted that company policies and procedures had to be in line with the Code. A company's policies might be even more restrictive than the Code.

The Panel noted that there was a discrepancy regarding that date of the gala dinner. The complainant stated it was on a Thursday. Otsuka stated it was on a Wednesday. The Otsuka employees stated it was on a Thursday. The Panel noted the identity of the woman in question was unknown and thus it was not possible to confirm her professional status. According to three of the four unsigned witness statements provided by Otsuka the woman had described herself as a researcher from a named UK hospital. The fourth witness statement referred to the presence of the woman in question at the dinner and subsequently at the bar. Other witness statements also made reference to the woman at the gala dinner and at educational parts of the meeting. It thus appeared that the woman was a delegate at the meeting. The Panel disagreed with Otsuka's submission that a researcher was neither a health professional, nor a relevant decision maker and thus Clause 22 would not apply. The Panel noted that the supplementary information to Clause 22.1 Meetings and Hospitality referred to investigator meetings for clinical trials at which, in the Panel's view, researchers might be present. The Panel noted that the supplementary information to Clause 26.2, Information to the Public stated that meetings organised for or attended by members of the public, journalists and patient organisations must comply with Clause 22. Similar requirements also applied to patient organisation meetings supported by pharmaceutical companies (Clause 27.2). Thus, Clause 22 was of broader application than inferred by Otsuka and applied to meetings irrespective of whether the attendees were health professionals or journalists or other members of the public. Thus, in the Panel's view, irrespective of whether a researcher was a health professional, relevant decision maker (2015 edition of the Code), appropriate administrative staff (2014 Code) or member of the public subsistence should meet the requirements of Clause 22.1. This was particularly relevant as the company's submission was clear that the woman was not known to them and she could of course have been a health professional.

The Panel noted that the provision of hospitality and other interactions between the pharmaceutical industry and health professionals outside the formal meeting proceedings was a subject that attracted much public scrutiny and criticism. Companies should be mindful of the impression given by such interactions and ensure that when applicable such activity complied with the UK Code. The meeting took place in Ireland and thus other codes might also be relevant.

The Panel accepted that company employees would want to wind down and discuss conference matters at the end of a full day at a meeting. The employees were in the conference city as representatives of their company for business reasons and as such they should continue to be mindful of the impression created by behaviour beyond the formal meeting and any associated meetings/subsistence. This was particularly important when interacting with UK health professionals and especially so in a late-night social environment.

The Panel noted that whilst there were some differences between the complaint and the company's response, including between the statements of relevant staff, there was overall much agreement. All staff present at the bar agreed that the woman had approached the senior male Otsuka employee and all agreed that she appeared intoxicated. It was also agreed that the senior male Otsuka employee required two female employees to each buy her a drink at different points in the evening. According to Otsuka this was contrary to its SOP which required subsistence to be purchased by the senior member of staff present which would be the man in question. One of the employees purchased two small glasses of wine at the woman's request; one red and one white. Subsequently, the other employee and contrary to the senior employee's instruction provided the woman in question with a glass of water. In addition, one member of staff referred to the woman and male employee in question each holding a drink prior to the aforementioned purchases. It was unclear who had purchased these. One employee stated that when she came to the bar from her bedroom the senior employee bought her a drink. The account of the fourth Otsuka employee, who subsequently joined the group, was consistent.

The Panel considered that the Otsuka employees would have known that delegates from the adjoining gala dinner including UK health professionals would have been in the hotel bar and should have been mindful of the impression created by any interaction with them and aware of the public nature of their behaviour. A number of employees referred to talking to customers in the bar. The drinks were purchased by a pharmaceutical company for someone who had attended the dinner. The Panel queried whether a shared late night social environment could ever be appropriate and in particular did not consider that it was an appropriate environment for the senior employee who was relatively new to the therapy area to be introduced to relevant health professionals.

In the Panel's view, the purchase of drinks for the woman in question in such circumstances was contrary to the requirements of Clause 22.1 of the Code. It could not be argued that the purchase was part of the subsistence provided at the meeting. A breach of Clause 22.1 was ruled. High standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted its rulings above and was particularly concerned about the impression given by the senior Otsuka employee organising the purchase of drinks for a delegate who was by all accounts

intoxicated. The Panel noted the descriptions of the behaviour of both the senior employee and the delegate in question whilst in the public bar. The Panel considered that overall the matter brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

Complaint received **17 March 2015**

Case completed **28 April 2015**

Case AUTH/2753/3/15

VOLUNTARY ADMISSION FROM ViiV HEALTHCARE

Number of pages of advertising in one journal

ViiV Healthcare UK voluntarily admitted that the International Journal of STD and Aids (February 2015) included a double-page advertisement for Triumeq (dolutegravir/abacavir/lamivudine) plus a belly band wrapper around the outside of the journal. This exceeded the 2 page limit allowed under the Code.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with ViiV Healthcare.

ViiV Healthcare explained that the advertisement and wrapper had appeared together in one issue of the journal due to a scheduling error for which the publisher had taken full responsibility. The publisher had reviewed its internal working processes and would ensure that relevant staff were aware of the Code requirements regarding the frequency of advertisements. ViiV Healthcare recognised that whilst the publisher made the error, it had overall responsibility and it had reviewed its own working practices and implemented changes.

The response from ViiV Healthcare is given below.

The Panel noted that ViiV Healthcare planned to use a Triumeq belly band around the journal at issue only when it otherwise contained a one page advertisement for the medicine. The company had never planned to use a belly band for the February 2015 edition. A belly band originally scheduled for January had been postponed for use until March. A letter from the publisher to the media agency, however, stated that due to human error, the cancellation of the Triumeq belly band in the February issue had not been registered on the publisher's system and thus it had been included. This was confusing as there had never been a belly band scheduled for February. The Panel considered that however the error had occurred, ViiV Healthcare had been let down by the publisher. A breach of the Code was ruled as acknowledged by ViiV Healthcare.

ViiV Healthcare UK Ltd voluntarily admitted that the February 2015 printed edition of the International Journal of STD and Aids included advertisements for Triumeq (dolutegravir/abacavir/lamivudine) which exceeded the limit allowed under the Code.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with ViiV Healthcare.

VOLUNTARY ADMISSION

ViiV Healthcare stated that on Thursday, 12 March its media-buying agency advised that it had identified an error in the printed February 2015 edition of the International Journal of STD and Aids in that the journal had a double page spread advertisement for Triumeq (ref UK/TRIM/0022/14a(1)) as well as a Triumeq belly band advertisement (ref UK/TRIM/0022/14b) wrapped around the outside. The approval certificates for both advertisements were provided. ViiV Healthcare submitted that the advertising in the journal thus exceeded the maximum number of two pages for a particular product (Clause 6.3) as it contained two pages and the loose wrap advertisement. The online issue of the journal was not affected as the wrap advertisement was a printed item only. ViiV Healthcare submitted that the publisher had taken full responsibility for this scheduling error and had reviewed its internal working processes and would ensure that relevant staff were aware of the Code requirements regarding the frequency of advertisements.

ViiV Healthcare submitted that it had a longstanding relationship with the media agency which secured advertising space on its behalf and this was the first issue with any placement the agency had made for the company. ViiV Healthcare referred to a detailed UK specific project agreement which outlined the activities the agency was to undertake on behalf of ViiV Healthcare in 2015 and a reminder of the requirement to adhere to all elements of the Code.

On detailed review of the causative factors, it appeared the original documented schedule agreed between ViiV Healthcare and the agency was correct. Artwork delays on the belly band advertisement caused some knock-on changes in scheduling in late December 2014 which the journal publisher did not enter into the system used to manage advertising bookings. This administration error by the publisher caused the two advertisements to appear in the same journal.

ViiV Healthcare recognised that whilst the publisher made the error, it had overall responsibility for promotional activity relating to this incident, and responsibility for actions made by the media-buying agency (liaising with the publisher) on its behalf. As a result of this error, ViiV Healthcare had reviewed its own working practices and those with third party agencies, and had implemented the following actions and controls:

- Immediate review of any current advertisements placed by ViiV Healthcare which were in print and those remaining on the agreed schedule. Schedule to be reconfirmed with the agency and the publishers involved.
- The publisher of the journal at issue had confirmed that it had reviewed its working practices and made a number of changes to avoid any reoccurrence of this event.

ViiV Healthcare stated that it took its responsibilities under the Code very seriously and sincerely regretted the publisher's unfortunate error.

When writing to confirm that the matter would be taken up under the Code, the Authority asked ViiV Healthcare to respond in relation to Clause 6.3.

RESPONSE

ViiV Healthcare provided a copy of the original advertising schedule which showed that the belly band wrapper was only planned for use when a single page advertisement was planned for the inside of the journal. Belly bands had been planned for January and March 2015. The advertising schedule was subsequently updated and the January belly band cancelled; the rescheduled slots for the belly band were March and May 2015. Correspondence between the publisher and the agency showed the original bookings for January and March together with the cancellation order for January and the new booking for May.

PANEL RULING

The Panel noted that the International Journal of STD and Aids was the official journal of the British Association for Sexual Health and HIV and the International Union against Sexually Transmitted Infections. The publisher, editor and deputy editors were based in the UK and it was a Royal Society of Medicine Journal. In the Panel's view, advertisements for medicines placed in the journal came within the scope of the Code.

The Panel noted that ViiV Healthcare had planned to use a Triumeq belly band around the journal at issue only when it otherwise contained a one page advertisement for the medicine. The company had never planned to use a belly band for the February edition of the journal. A belly band originally scheduled for January had been postponed for use until March. A letter from the publisher to the media agency, however, stated that due to human error, the cancellation of the Triumeq belly band in the February issue of the journal had not been registered on the publisher's system and thus it had been included. This was confusing as there had never been a belly band scheduled for February. The Panel considered that however the error had occurred, ViiV Healthcare had been let down by the publisher; advertising schedules clearly showed that it had never intended a belly band to be used with a journal which also contained a double-page spread. Nonetheless, it was an accepted principle under the Code that pharmaceutical companies were responsible for the acts or omissions of those who worked with their authority. That the journal at issue contained a double-page spread and incorporated a belly band for Triumeq, was a clear breach of Clause 6.3 as acknowledged by ViiV Healthcare; the Panel ruled accordingly.

Complaint received **20 March 2015**

Case completed **13 April 201**

CODE OF PRACTICE REVIEW – May 2015

Cases in which a breach of the Code was ruled are indexed in **bold type.**

AUTH/2620/7/13	**Novo Nordisk/ Director v Sanofi**	**Breach of undertaking**	**Breaches Clauses 2, 9.1 and 25** **Audit and re-aduit required by Appeal Board**	**No appeal** **Report from the Panel to the Appeal Board**	**Page 4**
AUTH/2730/9/14	Anonymous health professional v Merck Serono	Sponsorship to attend, and subsistence at an international meeting	No breach	No appeal	Page 12
AUTH/2736/9/14	**Voluntary admission by Sanofi**	**Relationships with patient organisations*** **** This case concerned activities carried out in 2013 and 2014. The clauses cited in this summary therefore variously come from two codes. See case report for details***	**Breaches Clauses 2 and 9.1** **Twenty breaches Clause 14.3** **Twelve breaches Clause 23.3** **Twenty-two breaches 23.7** **Eight breaches Clause 23.8** **Four breaches Clause 24.3** **Audit required by Appeal Board** **Publicly reprimanded by Appeal Board**	**No appeal** **Report from Panel to the Appeal Board**	**Page 19**
AUTH/2739/11/14	**Pfizer/Bristol Myers Squibb v Daiichi-Sankyo**	**Satellite symposium to provide advance notification**	**Breaches Clauses 3.1 and 9.1**	**Appeal by the respondent**	**Page 30**
AUTH/2741/12/14	**Representative v Chiesi**	**SOP training**	**Breach Clause 9.1**	**No appeal**	**Page 46**
AUTH/2743/12/14	**Community pharmacist v Amdipharm Mercury**	**Yellow card follow-up**	**Breaches Clauses 1.9, 9.1 and 16.2**	**No appeal**	**Page 54**
AUTH/2744/12/14	**University professor v Aegerion**	**Promotional emails disguised as educational material**	**Breaches Clauses 9.1, 9.9 and 12.1**	**No appeal**	**Page 58**
AUTH/2745/1/15	**Chief pharmacist v Shire**	**Lack of transparency of role in commissioning materials**	**Breaches Clauses 9.1 and 9.2**	**No appeal**	**Page 62**
AUTH/2746/1/15	Director of research v AstraZeneca	Tweet about the incidence of a disease	No breach	No appeal	Page 67
AUTH/2752/3/15	**Anonymous v Otsuka**	**Conduct of an employee**	**Breaches Clauses 2, 9.1 and 22.1**	**No appeal**	**Page 72**
AUTH/2753/3/15	**Voluntary admission from ViiV Healthcare**	**Number of pages of advertising in one journal**	**Breach Clause 6.3**	**No appeal**	**Page 77**

PMCPA | Prescription Medicines Code of Practice Authority

The Prescription Medicines Code of Practice Authority was established by the Association of the British Pharmaceutical Industry (ABPI) in 1993 to operate the Code of Practice for the Pharmaceutical Industry at arm's length from the ABPI itself. Compliance with the Code is obligatory for ABPI member companies and, in addition, over sixty non member companies have voluntarily agreed to comply with the Code and to accept the jurisdiction of the Authority.

The Code covers the advertising of medicines to health professionals and other relevant decision makers and also covers information about prescription only medicines made available to the public.

It covers:

- journal and direct mail advertising
- the activities of representatives, including any printed or electronic material used by them
- the supply of samples
- the provision of inducements in connection with the promotion of medicines and inducements to prescribe, supply, administer, recommend, buy or sell medicines by the gift, offer or promise of any benefit or bonus, whether in money or in kind
- the provision of hospitality
- the organisation of promotional meetings
- the sponsorship of scientific and other meetings, including payment of travelling and accommodation expenses
- the sponsorship of attendance at meetings organised by third parties
- all other sales promotion in whatever form, such as participation in exhibitions, the use of audio or video-recordings in any format, broadcast media, non-print media, the Internet, interactive data systems, social media and the like.

It also covers:

- the provision of information on prescription only medicines to the public either directly or indirectly, including by means of the Internet
- relationships with patient organisations
- disclosure of tranfers of value to health professionals and organisations
- joint working between the NHS and pharmaceutical companies
- the use of consultants
- non-interventional studies of marketed medicines
- the provision of items for patients
- the provision of medical and educational goods and services
- grants, donations and benefits in kind to institutions.

Complaints submitted under the Code are considered by the Code of Practice Panel which consists of three of the four members of the Code of Practice Authority acting with the assistance of independent expert advisers where appropriate. One member of the Panel acts as case preparation manager for a particular case and that member does not participate and is not present when the Panel considers it.

Both complainants and respondents may appeal to the Code of Practice Appeal Board against rulings made by the Panel. The Code of Practice Appeal Board is chaired by an independent legally qualified Chairman, Mr William Harbage QC, and includes independent members from outside the industry. Independent members, including the Chairman, must be in a majority when matters are considered by the Appeal Board.

In each case where a breach of the Code is ruled, the company concerned must give an undertaking that the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in the future. An undertaking must be accompanied by details of the action taken to implement the ruling. Additional sanctions are imposed in serious cases.

Further information about the Authority and the Code can be found at www.pmcpa.org.uk

Complaints under the Code should be sent to the Director of the Prescription Medicines Code of Practice Authority, 7th Floor, Southside, 105 Victoria St, London SW1E 6QT

telephone 020 7747 8880
facsimile 020 7747 8881
by email to: complaints@pmcpa.org.uk.