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**