NOVO NORDISK v BRISTOL-MYERS SQUIBB and ASTRAZENECA

Arrangements for a symposium

Novo Nordisk alleged that a symposium, 'The Kidney in Type 2 Diabetes: Victim or Target?' which was jointly sponsored by Bristol-Myers Squibb and AstraZeneca, promoted dapagliflozin (an SGLT-2 [sodium–glucose transporter-2] inhibitor) before the grant of a marketing authorization. The symposium took place at the Primary Care Diabetes Society (PCDS) conference. In particular, Novo Nordisk alleged that the attendance at the symposium of representatives from Bristol-Myers Squibb implied that the event was promotional. Novo Nordisk submitted that allowing the representatives to be there demonstrated that the sponsors did not intend to control who attended.

Novo Nordisk submitted that it had been given a summary of the topics discussed but without a copy of the slides, which the sponsors had refused to provide, it was difficult to know whether the symposium was fair and balanced or whether there was undue emphasis on dapagliflozin.

Novo Nordisk noted that it had similarly not been given a copy of the speakers' briefs and although an extract had been provided which referred to an 'educational meeting' and 'fair and balanced interpretation and analysis of the data' it was difficult to know if the speakers had been adequately briefed on a topic where pre-licence data was to be discussed.

Novo Nordisk considered that as the approval of a marketing authorization for dapagliflozin was imminent then it was more difficult to argue that the symposium was the legitimate exchange of medical and scientific information and not promotion.

The detailed response from Bristol-Myers Squibb on behalf of both companies is given below.

The Panel noted Bristol-Myers Squibb and AstraZeneca's submission that the annual national PCDS meeting was a legitimate site for appropriate scientific exchange. Supplementary information to the Code stated that the legitimate exchange of medical and scientific information during the development of a medicine was not prohibited provided that any such information or activity did not constitute promotion. The Panel noted that it had been alleged that dapagliflozin, an unlicensed medicine, had been promoted at the symposium. That the symposium might elicit interest in the medicines discussed was not necessarily unacceptable if the arrangements for the symposium and its content complied with the Code.

The Panel noted that a complainant had the burden of proving the complaint on the balance of probabilities.

With regard to the alleged presence of the sponsors' sales representatives at the symposium, the Panel noted a difference of opinion. Bristol-Myers Squibb was clear that neither its nor AstraZeneca's representatives had attended. Briefing material clearly stated, *et al*, that the sales team could not attend.

The Panel considered that there was no evidence to show that the sponsors' representatives attended the meeting; conversely the briefing material clearly showed that they were instructed not to attend. The Panel ruled no breach of the Code. The fact that there was not a list of attendees did not in itself mean the meeting was promotional and on this narrow point no breach of the Code was ruled.

The Panel noted that the Chairman and both speakers at the symposium were independent health professionals. The first presentation discussed, *et al*, currently available medicines. The title slide of the second presentation clearly stated 'This presentation contains information relating to drugs which are in clinical development and do not have marketing authorisation'. The first 4 slides referred to the kidney's role in hyperglycaemia. The next slide referred to SGLT-2 inhibition and its effect in reducing renal glucose reabsorption. Details of the developmental phase of five SGLT-2 inhibitors were provided; four in phase 3 development and the fifth was described as phase 2/3. The next 4 slides showed phase 2 data for canagliflozin. This was followed by 6 slides detailing the design and outcome of a phase 3 double-blind study for dapagliflozin vs glipizide in patients taking open-label metformin. The Panel noted that the style of the slides was low key and scientific. Dapagliflozin was not emboldened and there was no use of a product or company logo. The only reference to SGLT-2 inhibitors on the summary slide was the statement 'SGLT-2 inhibitors are in clinical development'.

The Panel was concerned about a number of aspects particularly the amount of data presented and the nature of that data albeit this was the only clinical data available at the time. The Panel did not accept Bristol-Myers Squibb and AstraZeneca's submission that there was no focus on any of the medicines in development. Phase 2 outcome data had been given for one of the medicines, no data for three others and positive phase 3 data for the Bristol-Myers

Squibb/AstraZeneca product which was expected to receive its marketing authorization later in 2012.

The overall meeting objectives were: to provide a non-promotional forum for scientific and medical exchange on the kidney both as an organ affected during type 2 diabetes and as a potential target in the management of type 2 diabetes; to discuss the various glycaemic treatment options for type 2 diabetes patients with chronic kidney disease (stages 3 - 5) and to explore emerging anti-diabetes therapies that target the kidney for the management of type 2 diabetes. The speaker briefs included suggested topics to be covered and stated that they could provide input to shape their presentation as deemed appropriate. The speakers were requested to provide their slides for examination by Bristol-Myers Squibb and AstraZeneca. The speakers' briefs mentioned the need to highlight any discussion that was off licence or not licensed but there was no advice that promotion of an unlicensed indication or medicine would be a breach of the Code. The suggested topics for the first speaker included issues with current treatment options in certain patients and what did newer agents offer. Similarly the second speaker was asked to cover current unmet needs in the management of type 2 diabetes and molecules in development that targeted the kidneys.

The Panel noted that some of the comments provided as feedback on the symposium referred favourably to the level of interaction and discussion.

The Panel reviewed the DVD of the symposium and noted that one speaker stated that dapagliflozin was 'probably going to be the first of this class of agents [SGLT-2 inhibitors] to hit the market' although no further details were given.

The Panel noted its comments above; its main concern was whether the arrangements met the requirements for the legitimate exchange of medical and scientific information. The event was held in November 2011, at least 7 months before the marketing authorization for dapagliflozin was expected.

The Panel considered that Novo Nordisk had not, on the balance of probabilities, proven its complaint that the symposium promoted an unlicensed medicine. Thus the Panel ruled no breach of the Code including no breach of Clause 2.

Novo Nordisk Limited complained about a symposium jointly sponsored by Bristol-Myers Squibb Pharmaceuticals Limited and AstraZeneca UK Limited, entitled 'The Kidney in Type 2 Diabetes: Victim or Target?', which took place at the Primary Care Diabetes Society (PCDS) conference in November 2011. The flyer for the symposium clearly stated 'This is a medical education symposium organised and funded by Bristol-Myers Squibb and AstraZeneca'. Novo Nordisk alleged that the symposium promoted dapagliflozin (a SGLT-2 [sodium-glucose transporter-2] inhibitor), which had yet to receive a marketing authorization, in breach of Clauses 3, 9.1 and 2 of the Code.

COMPLAINT

Novo Nordisk submitted that several sales representatives from Bristol-Myers Squibb were present at the event which implied that the symposium was promotional. During inter-company dialogue, Bristol-Myers Squibb and AstraZeneca denied that any sales representatives attended. Novo Nordisk stated that it twice requested a copy of the representatives' briefing document but this was not provided by Bristol-Myers Squibb or AstraZeneca. The companies instead confirmed the existence of a briefing document and provided the following quotation from it: 'the sales team cannot attend the symposium, should not proactively invite HCPs [health professionals] to the symposium and should not access or distribute material relating to the symposium'. Novo Nordisk considered that without seeing the entire content of this briefing document, it was difficult to assess whether the instructions provided to the representatives were adequate.

Novo Nordisk stated that a member of its sales force had seen representatives from Bristol-Myers Squibb at the symposium which indicated that there was no intention by Bristol-Myers Squibb and AstraZeneca to control who could enter the symposium. In Novo Nordisk's view, a medical educational event should have a proper registration process with personalised invitations sent out beforehand to ensure that only a relevant audience could enter.

During inter-company dialogue, Bristol-Myers Squibb gave Novo Nordisk a summary of the topics that were discussed during the symposium, but Bristol-Myers Squibb and AstraZeneca had refused to provide copies of the slides presented. Without this information Novo Nordisk considered it difficult to gain a clear understanding as to whether the content of the symposium was fair and balanced and provided focus on all SGLT-2 inhibitors in development, or whether there was an undue emphasis placed on dapagliflozin.

Novo Nordisk submitted that Bristol-Myers Squibb and AstraZeneca had also refused to provide copies of the speaker briefing documents and had only provided the following quotation from them: 'the meeting is non-promotional and the aim is to provide an educational meeting that will facilitate the exchange of scientific and medical information, which the audience may find interesting and relevant. It is also hoped that this meeting will enhance the current state of scientific knowledge and we ask that speakers give a fair and balanced interpretation and analysis of data, describing competitor products where applicable'. Novo Nordisk submitted that without viewing the speaker briefing document in its entirety it was challenging to appreciate whether the speakers were briefed adequately on a topic where pre-licence data regarding a medicine was to be discussed.

Novo Nordisk was aware that the approval of a marketing authorization for dapagliflozin was imminent. Bristol-Myers Squibb had submitted

during inter-company dialogue that 'in the context of scientific exchange, information on drugs in development can be discussed legitimately, and timing of launch should bear no relevance on this…'. Novo Nordisk considered that the closer the granting of a marketing authorization, the more difficult it was to argue that activities such as this symposium were the legitimate exchange of medical and scientific information and not promotion. The Panel highlighted this point with Novo Nordisk in Case AUTH/2234/05/09.

In summary, without being able to review all the evidence surrounding the arrangements for the symposium, Novo Nordisk was concerned that the event promoted a product prior to the grant of a marketing authorization.

RESPONSE

Bristol-Myers Squibb responded on behalf of both companies.

Bristol-Myers Squibb and AstraZeneca were concerned that because Novo Nordisk had not presented any objective evidence to them in its initial inter-company dialogue, and no evidence to the Authority in its subsequent formal complaint, they were being asked to defend unclear and unsubstantiated allegations. While a complaint might be raised if information was put forward which suggested the Code might have been contravened, the burden of proving the complaint, on the balance of probabilities, rested with the complainant and not the respondent. Given that no such evidence was presented by Novo Nordisk during inter-company dialogue, it was impossible for the companies to either defend, accept or concede any point raised in the complaint.

Bristol-Myers Squibb and AstraZeneca submitted that no member of either sales force was present at this medically-led and organised satellite symposium. Novo Nordisk had provided no evidence to support its allegation and Bristol-Myers Squibb and AstraZeneca were able to provide evidence to the contrary. All sales force who were present at the wider PCDS meeting were explicitly briefed in writing not to attend the symposium (copy provided). An on-site verbal briefing to the same effect was also delivered by the medical team. Neither was either sales force involved in the invitation process – the only invitation was solely distributed via a 'bag drop', ie in the delegate bags of registered attendees of the PCDS conference.

Bristol-Myers Squibb and AstraZeneca submitted that the Code did not require a proper registration process for a medical educational event with personalised invitations sent out beforehand to ensure that only a relevant audience could enter. Indeed, the approach suggested by Novo Nordisk seemed more appropriate to a specifically tailored and targeted commercial meeting, as opposed to the open, transparent and legitimate exchange of scientific information as permitted and outlined in the Code.

Membership of the PCDS was only open to health professionals working in primary care and it focused on those with a specialist interest in diabetes. The society aimed 'to support primary care professionals to deliver high quality clinically effective care, in order to improve the lives of people living with diabetes'. Bristol-Myers Squibb and AstraZeneca had taken the view, with reference and aligned to Case AUTH/2310/4/10, that this was an appropriate setting for such exchange of scientific information.

Bristol-Myers Squibb and AstraZeneca stated that the vast majority of diabetics were managed day-to-day in primary care, with members of the PCDS taking an active and leading role. This was reflected in the breakdown of attendees at the congress: GPs 35%, GPs with special interest 3%, diabetes specialist nurses 21%, practice nurses 24% and consultants or specialist registrars 2%. Novo Nordisk had agreed during inter-company dialogue that the annual national PCDS meeting was a legitimate site for appropriate scientific exchange.

Bristol-Myers Squibb and AstraZeneca submitted that the topic chosen was broad and clinically relevant to the PCDS attendees. The invitation was in the delegate bag which attendees received on their arrival and registration at the conference. The satellite symposium followed a keynote lecture and a clear announcement was made about the start of a sponsored satellite symposium. At that point, around half of the audience left, leaving only those interested in the symposium topic. Bristol-Myers Squibb and AstraZeneca therefore considered that the symposium was relevant to the audience and that there was no real risk of accidental attendance at the meeting by members of the public or others who were not health professionals.

Bristol-Myers Squibb and AstraZeneca considered that this approach was open, transparent, non-promotional and therefore appropriate in the context of the PCDS national conference. Pursuing the Novo Nordisk approach of a closed satellite symposium with a targeted, profiled and proactive approach would be against the spirit of such open, transparent and legitimate scientific exchange. It seemed to Bristol-Myers Squibb and AstraZeneca that the use of personalised invitations could imply that individuals had been specifically targeted and selected according to some hidden agenda.

Bristol-Myers Squibb and AstraZeneca explained that the symposium at issue examined the effect of diabetes on the kidney and the effect of the kidney on diabetes, and explored possible therapeutic options. The topic for the symposium was chosen to be relevant to an audience at the forefront of diabetes management. Chronic kidney disease (CKD) affected almost a third of all type 2 diabetics in the UK and was likely to be an eventual complication in most patients given the progressive nature of the disease. These patients could be challenging to manage given the limited treatment options available and the high risk of complications. There was also a growing body of evidence of the role of the kidney in compounding hyperglycaemia,

contributing to the so called 'ominous octet' of pathophysiologies of type 2 diabetes.

Bristol-Myers Squibb and AstraZeneca submitted that the first half of the slide deck was about the relationship of diabetes and CKD; the second half was about the effect of the kidney on glucose reabsorption. Copies of the slides were provided. Bristol-Myers Squibb and AstraZeneca stated that the 'ominous octet' of pathologies was explained by the second speaker at the symposium who detailed the role of the various organs in contributing to hyperglycaemia. The physiology of renal handling of glucose was then explored. Finally, the possibility of using the kidney as a therapeutic target was addressed. The unlicensed and exploratory nature of these medicines was made clear at the start of the presentation, both verbally and on the slides. The class of medicines explored was the SGLT-2 inhibitors. All current compounds in phase 3 development were shown (canagliflozin, dapagliflozin, empagliflozin, ipragliflozin and tofogliflozin).

Bristol-Myers Squibb and AstraZeneca submitted that the only compounds that had clinical data available at the time of the presentation were canagliflozin and dapagliflozin, both of which were in phase 3 development. Only dapagliflozin had reported phase 3 data at the time of the symposium. A fair and accurate balance was addressed by presenting the most contemporaneous data from the latest international diabetes conferences (American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD)) and in the spirit of legitimate scientific exchange.

Bristol-Myers Squibb and AstraZeneca stated that of the 40 slides presented, one referred to all SGLT-2 inhibitors and their current phase of development. Six slides (one trial design, two efficacy and three safety slides) discussed dapagliflozin, while four slides discussed canagliflozin. There was no focus on any of the medicines in development; any discussion of dapagliflozin was therefore appropriate in the context of an accurate and balanced scientific discussion of such future therapies.

Bristol-Myers Squibb and AstraZeneca considered that the discussion of the relevant topic was fair, accurate, balanced and non-promotional. The audience was appropriate as was the amount of time spent on molecules under development proportionate to the pathophysiology of diabetes, based on the latest available information. Finally, the agenda allowed time for a proper question and answer session, to facilitate scientific exchange. This was a very animated session, with the majority of questions about the management of CKD in type 2 diabetics. The audience even elected to extend the question and answer session by ten minutes which further emphasised the educational nature of the event. Independent feedback collected by the congress organizers voted the symposium very highly with a score of 91%, the highest of all the symposia at the PCDS conference.

Bristol-Myers Squibb and AstraZeneca did not have a copy of the summary of product characteristics (SPC) for dapagliflozin and the marketing authorization application was filed with European Medicines Agency (EMA) in December 2010.

Bristol-Myers Squibb and AstraZeneca considered that the symposium was conducted within the spirit of legitimate exchange of medical and scientific information and to the letter of the Code, with no disguised or pre-licence promotion of dapagliflozin, either intentionally or inadvertently. The symposium was organized, funded and developed by the medical team, with no involvement of the marketing or sales teams from either company. The topic chosen was broad, appropriate and highly relevant to those registered to attend the PCDS conference; they were dedicated to managing patients with diabetes and had a genuine interest in relevant medicines in clinical development.

Bristol-Myers Squibb and AstraZeneca submitted that the chair and speakers were carefully briefed to deliver non-promotional, fair, balanced, up-to-date and clinically relevant presentations for the symposium with the intention of enhancing scientific knowledge of the audience. There should be an unbiased view of the topics discussed. Copies of the speaker briefs were provided.

To keep true with the spirit of scientific exchange and Code requirements, speakers were asked to ensure all data presented was accurate, balanced, fair, objective, unambiguous, based on an up-to-date evaluation of all the evidence, not misleading, capable of substantiation and not disparaging or disrespectful to competitor companies or products.

To ensure that the presentations were non-promotional, speakers were asked to use non-proprietary names where appropriate and not to present product logos and to highlight both verbally and with a statement on the slides if products referred to were discussed in an off-licence manner or were not yet licensed.

Bristol-Myers Squibb and AstraZeneca reiterated their view that this was a high quality and fully compliant, non-promotional educational meeting to support the legitimate exchange of scientific information. The companies therefore refuted the alleged breaches of Clauses 2, 3 and 9.1.

Bristol-Myers Squibb and AstraZeneca submitted that throughout this matter they had complied with the spirit and letter of the Code; the symposium in question was conducted to the highest standards, in line with the Code, and they had been fully transparent and forthright with the Panel to demonstrate this.

Following a request for further information, Bristol-Myers Squibb and AstraZeneca submitted that the marketing authorization application for dapagliflozin was filed with the EMA in December 2010. An opinion from the Committee for Human Medicinal Products (CHMP) was expected in the second quarter

2012, with a decision on marketing authorization expected approximately two months later. Assuming that there were no further steps or aspects to be addressed, the earliest that the marketing authorization was anticipated was the third quarter of 2012.

Bristol-Myers Squibb stated that it had filmed the symposium for potential internal use only (a DVD copy was provided). There were no specific plans to use this material; to date it had not been used in any way either internally or externally.

In summary Bristol-Myers Squibb and AstraZeneca stated that the symposium lasted 62 minutes with the majority of time spent discussing a relevant disease area, pertinent to the audience, allowing almost 25% of the time for discussion and feedback; only a small fraction of time was spent discussing specific medicines. Any discussion clearly signposted these as being unlicensed and this was reinforced verbally on three occasions by the speakers. Of the 10 minutes spent discussing developmental SGLT-2 inhibitors, 3 minutes were spent on the canagliflozin phase 2 data and 7 minutes on the dapagliflozin phase 3 data, reflecting the latest publicly available data at the time of the presentation.

The speaker slides were not made available to the delegates of the symposium although health professionals could request copies through medical information. The potential to provide the slides in this way was not raised or highlighted, either as part of the meeting or in any other materials relating to the meeting. To date, no requests for these slides had been received.

The symposium booklet was given to all delegates of the symposium to aid note taking. The companies did not envisage that there would be any requests for the booklet following the symposium and to date, no requests for copies had been received.

PANEL RULING

The Panel noted Bristol-Myers Squibb and AstraZeneca's submission that the annual national PCDS meeting was a legitimate site for appropriate scientific exchange. The supplementary information to Clause 3, Marketing Authorization, stated that the legitimate exchange of medical and scientific information during the development of a medicine was not prohibited provided that any such information or activity did not constitute promotion which was prohibited under Clause 3 or any other clause. The Panel noted that it had been alleged that dapagliflozin, an as yet unlicensed medicine, had been promoted at the symposium. That the symposium might elicit interest in the medicines discussed was not necessarily unacceptable if the arrangements for the symposium and its content satisfied the supplementary information to Clause 3.1.

The Panel considered that when determining whether a meeting promoted a medicine before the grant of a marketing authorization, or was the legitimate exchange of medical and scientific information, the content and context in which it took place were important as were the general arrangements.

The Panel noted that the symposium had taken place in the context of the PCDS conference. In that regard the Panel considered that such conferences might be an appropriate setting for the legitimate exchange of medical and scientific information. The Panel did not consider, however, that symposia which took place in association with learned society conferences would automatically be regarded as the legitimate exchange of medical and scientific information.

The Panel noted that a complainant had the burden of proving the complaint on the balance of probabilities.

With regard to the alleged presence of Bristol-Myers Squibb and AstraZeneca sales representatives at the satellite symposium, the Panel noted that there was a difference of opinion. One of the Novo Nordisk representatives who had attended the symposium reported seeing sales representatives from Bristol-Myers Squibb at the event. Bristol-Myers Squibb was clear that neither its nor AstraZeneca's representatives had attended the satellite symposium. With regard to the symposium at issue the briefing material clearly stated that the sales team could not attend, it should not proactively invite health professionals and if information was discussed it should refer health professionals to the medical team or to the communications agency for a symposium flyer. The briefing material referred to the symposium flyers as invitations. These would be included in the delegate packs and were not to be distributed from the disease education stands. Symposium booklets would be made available to the delegates during the symposium. The sales team should not access or distribute any material relating to the symposium.

The Panel noted that Bristol-Myers Squibb and AstraZeneca did not know which of the PCDS delegates attended the satellite symposium. There was no requirement in the Code for it to do so. However, for companies to claim that symposia were the legitimate exchange of medical and scientific information the status of the audience was relevant; delegates should be able to participate in debate for it to be an exchange of medical and scientific information.

The Panel considered that there was no evidence to show that Bristol-Myers Squibb or AstraZeneca sales representatives attended the meeting; conversely the briefing material clearly showed that they were instructed not to attend. The Panel ruled no breach of Clauses 9.1, 3.1 and 2 in this regard. Similarly, the fact that there was not a list of attendees did not in itself mean the meeting was promotional. Thus on this narrow point no breach of Clauses 9.1, 3.1 and 2 was ruled.

The Panel noted that the Chairman and both speakers at the symposium were independent health professionals. The meeting agenda detailed in the speaker briefing documents showed that after a 5 minute introduction there were two 15 minute presentations, 'Renal impairment and type 2 diabetes' and 'Can the kidney provide a new solution to old problems?' This was followed by ten minutes of questions and answers. The meeting was scheduled to last 45 minutes. In total 40 slides were presented. The first presentation discussed, *et al*, currently available medicines. The title slide of the second presentation clearly stated 'This presentation contains information relating to drugs which are in clinical development and do not have marketing authorisation'. The first 4 slides referred to the kidney's role in hyperglycaemia. The next slide referred to SGLT-2 inhibition and its effect in reducing renal glucose reabsorption. Details of the developmental phase of five SGLT-2 inhibitors were provided; four in phase 3 development and the fifth was described as phase 2/3. The next 4 slides showed phase 2 data for canagliflozin. This was followed by 6 slides detailing the design and outcome of a phase 3 double-blind study for dapagliflozin vs glipizide in patients taking open-label metformin. Results were shown for HbA1c, weight, hypoglycaemia and adverse events over two years. The Panel noted that the style of the slides was low key and scientific. Dapagliflozin was not emboldened and there was no use of a product or company logo. The only reference to SGLT-2 inhibitors on the summary slide was the statement 'SGLT-2 inhibitors are in clinical development'.

The Panel was concerned about a number of aspects particularly the amount of data presented and the nature of that data albeit this was the only clinical data available at the time. The Panel did not accept Bristol-Myers Squibb and AstraZeneca's submission that there was no focus on any of the medicines in development. Phase 2 outcome data had been given for one of the medicines, no data for three others and positive phase 3 data for the Bristol-Myers Squibb/ AstraZeneca product which was expected to receive its marketing authorization later in 2012.

The overall meeting objectives according to the Chairman's brief were threefold: to provide a non-promotional forum for scientific and medical exchange on the kidney both as an organ affected during type 2 diabetes and as a potential target in the management of type 2 diabetes; to discuss the various glycaemic treatment options for type 2 diabetes patients with chronic kidney disease (stages 3 - 5) and to explore emerging anti-diabetes therapies that target the kidney for the management of type 2 diabetes.

The speaker briefs included suggested topics to be covered and stated 'The scope of your presentation is in italics and we are happy for you to provide input to shape your presentation as deemed appropriate'. The speakers were requested to provide their slides for examination by Bristol-Myers Squibb and AstraZeneca.

The speakers' brief referred to the meeting as non-promotional with the aim being to provide an educational meeting that would facilitate the exchange of scientific and medical information. There was mention of the need to highlight any discussion that was off licence or not licensed. Further the speaker brief stated 'It is also hoped that this meeting will enhance the current state of scientific knowledge and we ask that speakers give a fair and balanced interpretation and analysis of data, describing competitor products where applicable'. There was no advice that promotion of an unlicensed indication or medicine would be a breach of the Code.

The six suggested topics for the first speaker included issues with current treatment options in certain patients and what newer agents offered. Similarly the second speaker was asked to speak about current unmet needs in the management of type 2 diabetes and molecules in development that targeted the kidneys.

The Panel noted that some of the comments provided as feedback on the symposium referred to the interesting information on new medicines; other comments were complimentary about the speakers and some delegates referred favourably to the level of interaction and discussion.

The symposium booklet gave the CVs of the speakers and reproduced four of each speakers' slides. None of these slides referred to any medicine.

The Panel reviewed the DVD of the symposium and noted that the second speaker, when presenting data on dapagliflozin, stated that the medicine was 'probably going to be the first of this class of agents [SGLT-2 inhibitors] to hit the market' although no further details were given.

The Panel noted all its comments above. Its main concern was whether the arrangements met the requirements for the legitimate exchange of medical and scientific information. The event was held in November 2011 and the earliest that the marketing authorization was expected was the third quarter of 2012, ie at least 7 months after the symposium had taken place.

The Panel considered that Novo Nordisk had not, on the balance of probabilities, proven its complaint that the symposium promoted an unlicensed medicine. Thus the Panel ruled no breach of Clause 3.1 of the Code and consequently no breach of Clauses 9.1 and 2.

Complaint received **8 February 2012**

Case completed **28 May 2012**