

CSL BEHRING v SWEDISH ORPHAN BIOVITRUM

Charity ball

CSL Behring complained about a charity ball held by Swedish Orphan Biovitrum (Sobi) and an advertisement/invitation for the event placed in the public domain on both Sobi's and a named charity's website. The advertisement stated, *inter alia*, the ticket price which included arrival drinks, a three course meal, table wine and entertainment. Sobi's contact details were provided for tickets and further information. It was stated at the bottom of the advertisement in small font that 'Proceeds will be distributed equally between the following three charities:' followed by their names and logos.

CSL Behring stated that the invitation failed to state who the event was for, health professionals, patients, spouses, patient organisations, families, or other. Without knowing who was invited, who attended and in what capacity and the proportion of the entire group they represented, it was impossible to label the meeting as a corporate event. CSL Behring submitted that the event fell within scope of the Code.

CSL Behring alleged that the event did not give the impression that it was primarily an educational event and that the hospitality was secondary to the purpose of the meeting. The event was wholly social and failed to maintain high standards and was therefore unacceptable. Moreover, the offer of entertainment, music, fun, wine and prizes was excessive. In addition, any hospitality must not be paid or facilitated by the company, and must not form part of the official programme of the meeting. CSL Behring alleged that it was not clear from the invitation exactly what Sobi had funded.

CSL Behring was particularly concerned about the involvement of one of the charities given the ongoing commercialisation and development of two of Sobi's medicines. CSL Behring alleged that Sobi had specifically targeted the audience in a therapy area where it had a vested interest and as the invitation failed to set out a clear agenda or indicate who should attend, the impression was one of disguised promotion.

CSL Behring stated that Sobi did not plan to track or monitor who had attended the event and therefore could not claim that the ball was a corporate event which fell outside the scope of the Code. Breaches of the Code were alleged including a breach of Clause 2.

The detailed response from Sobi is given below.

The Panel noted Sobi's submission that the charity ball was a corporate event that fell outside the scope of the Code as it did not promote any of Sobi's medicines, nor did it target health professionals, other relevant decision makers or patients. The Panel considered that corporate events, including fund raising activities, were a

legitimate activity for a pharmaceutical company to undertake. They were part of normal business practice. Whether a corporate event was covered by the Code would depend on the arrangements. Corporate events covered by the Code had to comply with it.

In the Panel's view, in order to fall outside the scope of the Code corporate events must not otherwise be meetings organised for health professionals, other relevant decision makers or patient organisation representatives and or their members, bearing in mind that meetings organised for such groups which were wholly or mainly of a social or sporting nature were unacceptable. Corporate events could include invited health professionals, other relevant decision makers or patient organisation representatives and/or members but must also include a significant proportion of other invited guests from a different background. Further, the capacity in which health professionals and others were invited to attend such events was an important factor. In the Panel's view inviting health professionals in their capacity as prescribers or as persons who recommended medicines to a corporate event with no educational or scientific input would be in breach of the Code. Such health professionals might be invited to attend in relation to their roles such as senior representatives of professional organisations, hospital trusts, primary care trusts, etc. The Panel noted that the reason that patient organisation representatives and/or their members had been invited might also be relevant. The Panel noted that the event at issue was advertised through a number of channels and those who wanted to attend could purchase tickets. It appeared that no one was invited personally at Sobi's expense.

The Panel noted Sobi's submission that it organised the event with the help of three charities in order to raise funds for them and highlight their important work; Sobi would declare the amount donated to the charities in accordance with the Code. The Panel further noted that Sobi had provided significant administrative support and the confirmation letter sent to those who purchased tickets stated that it had paid part of the costs necessary to hire the venue and provide the catering and the evening's entertainment. This was in contrast to Sobi's submission that the cost of the tickets was more than the value of the hospitality and entertainment so all hospitality was paid for by the attendees. The amount paid by Sobi in that regard was unknown.

The Panel noted that the Code provided that pharmaceutical companies could interact with, *inter alia*, patient organisations to support their work. Taking all the circumstances into account the Panel considered that working with the patient organisations, including those that operated in a field in which Sobi had a commercial interest, to

raise money for those organisations was a matter covered by the Code.

The Panel noted that the event was open to anyone who wanted to buy a ticket. The attendee list showed a spread of attendees, primarily Sobi employees, patient organisations and healthcare agencies including partners, family and friends; overall the Panel did not consider that the ball was a meeting organised for health professionals or patient organisation members *per se*. Attendees had to purchase their own tickets. Sobi had not controlled who could buy tickets and in that regard attendees were not guests of the company. The Panel noted Sobi's submission that no health professionals attended the event at Sobi's invitation or expense and as far as Sobi was aware only three or four attendees might qualify as a health professional as defined in the Code and none prescribed Sobi products; they had attended as guests of the charities or other non-pharmaceutical companies that purchased tickets. The Panel considered, on balance that Sobi had organised a charitable event that was open to anyone who wished to purchase a ticket; it was not aimed at health professionals, other relevant decision makers or patient organisations *per se* and no breach of the Code was ruled.

The Panel noted Sobi's submission that the charity ball was a non-promotional event at which there was no direct or indirect promotion of Sobi's medicines. The Panel did not consider that the event was promotional nor were the raffle items offered as an inducement. In the exceptional circumstances of this case the Panel therefore ruled no breach of the Code.

The Panel noted its comments above and Sobi's submission that the event was non-promotional. In that regard, the event could not be disguised promotion and no breach of the Code was ruled.

The Panel did not consider that Sobi had failed to maintain high standards and so no breach of the Code was ruled. The Panel noted its rulings and further ruled no breach of Clause 2.

CSL Behring complained about a charity ball held by Swedish Orphan Biovitrum Limited (Sobi).

COMPLAINT

CSL Behring referred to an advertisement/invitation for the ball placed in the public domain on both Sobi's and a named patient organisation's website. The advertisement depicted part of a tuxedo and was headed 'Sobi Charity Ball'. The date, time and venue were followed by the cost per person which was £65. The cost, according to the advertisement, included arrival drinks, a three course meal, table wine and entertainment. Sobi's contact details were provided for tickets and further information. Black tie was requested. It was stated at the bottom of the advertisement in small font that 'Proceeds will be distributed equally between the following charities:' followed by their names and logos. Although not stated on the invitation, the objective of the ball was

to highlight and raise awareness of the challenges faced by those with rare diseases and the work that was being done to support them.

CSL Behring submitted that in inter-company dialogue it referred to the fact that although it was an established principle of the Code that corporate events were acceptable (Case AUTH/1604/7/04), Sobi needed to be clear who was attending the event and in what capacity. CSL Behring was unable to establish the clear nature and purpose of the charity event without knowing the intended audience; the invitation failed to specify that it was an event for health professionals, patients, spouses, patient organisations, families, or other. Without knowing details of who was invited, who actually attended, in what capacity, and the proportion of the entire group they represented, it was impossible to label the meeting as a corporate event and therefore CSL Behring submitted that it fell within scope of the Code. No programme or agenda was included or referred to in the invitation, nor was there an indication of what the evening would comprise of in terms of content such as presentations, education, etc. Rather, the invitation stated that potential attendees were invited to 'join in the celebrations at this "black tie" event – where you will enjoy welcome drinks, a delicious 3 course meal, table wine, music, fun and entertainment with fabulous prizes to be won and plenty of opportunities to support our charity'.

The overall impression of any meeting must be that it was primarily an educational event and that any hospitality provided was secondary and no more than what was expected to meet the purpose of the meeting. CSL Behring alleged that this charity event did not give that impression. CSL Behring submitted that the event was wholly social and failed to maintain high standards and was therefore unacceptable. Moreover, the offer of entertainment, music, fun, wine and prizes was excessive and in breach of Clause 18.1. In addition, any hospitality must not be paid or facilitated by the company, and must not form part of the official programme of the meeting. CSL Behring acknowledged that third parties were involved but considered that it was ultimately the company's responsibility. It was not clear from the invitation exactly what Sobi had funded.

CSL Behring stated that the event was clearly supported by three named charities and it was particularly concerned about the involvement of one of them given the ongoing commercialisation and development of two of Sobi's medicines. CSL Behring therefore alleged that Sobi had specifically targeted the audience in a therapy area where it had a vested interest and as the invitation failed to set out a clear agenda or indicate who should attend, the impression was one of disguised promotion in breach of Clause 12.

CSL Behring requested immediate withdrawal of all materials relating to the event and cancellation of the event with written communication to all relevant internal and external stakeholders. This did not take place and on 24 March 2016, CSL Behring received written acknowledgement from Sobi that its charity ball would raise funds for three charities,

with which it had long-standing relationships and highlight the important work done by them. Sobi stated that the event was not intended to promote its medicines, or to target health professionals; the event was open to anyone who wished to purchase a ticket. Sobi itself would not pay for anyone to attend; even its personnel who planned to attend had to purchase their own tickets. Sobi stated that it publicised the event by word of mouth to family, friends and business partners, as well as trade and industry media. The charities for which the event would raise money also publicised the event through their networks and membership and Sobi gave them posters to place in their offices. Finally, members of the steering committee used social media to publicise the event to their individual networks. Sobi claimed that because they did not target the event specifically at health professionals or other relevant decision makers, it fell outside the scope of the Code and thus could not be in breach of Clauses 9.1, 18.1 or 22.1 of the Code and since there was no breach of those clauses, there could be no breach of Clause 2. Therefore, Sobi refused to cancel the ball or withdraw any materials relating to the event.

CSL Behring did not consider that Sobi's response adequately addressed its concerns. Although Sobi stated that the event was open to anyone who wished to purchase a ticket, this was not apparent from the posters and other publicity. In addition, it was not clear who developed these posters and other publicity and what involvement, if any, Sobi had in that. This was confounded by the fact that Sobi admitted publicising the event by word of mouth to family, friends and business partners, as well as trade and industry media. Reference to 'business partners' and 'trade media' was ambiguous and could include health professionals. Also, as the charities advertised the event through their own networks and membership, this could have included health professionals and definitely failed to exclude this group. If health professionals were to attend, no statement or disclaimer was made on the advertisement indicating that they should do so in a non-prescribing capacity.

CSL Behring noted that the charity ball took place and Sobi had failed to supply a list of attendees and the capacity within which they attended. In essence, it was clear that Sobi made no plans to track or monitor who had attended the event and therefore could not claim the event was a corporate one that fell outside the scope of the Code.

CSL Behring alleged breaches of Clause 2, discredit to, and reduction of confidence in, the industry through provision of excessive hospitality, Clause 9.1, failing to maintain high standards, Clause 18.1, gifts, rewards or hospitality, the use of competitions, quizzes and Clause 22.1, meetings, hospitality and sponsorship.

RESPONSE

Sobi explained that the charity ball was designed to raise funds for three charities with which Sobi had long-standing relationships and to highlight the important work done by them. Sobi submitted that it organised the event with the full knowledge

and assistance of the three charities. The event was not intended to and did not promote any of Sobi's medicines, nor did it target health professionals or patients and as a non-promotional event that did not target or involve health professionals Sobi considered that it fell outside the scope of the Code.

Sobi submitted that it had the initial idea for the charity ball which was conceived as a non-promotional, corporate event to raise money for the three charities. This was apparent from the posters and other publicity materials which made no reference to any of Sobi's products. In the confirmation letter sent to those who purchased tickets it was made clear that it was a non-promotional charitable event that Sobi employees voluntarily supported by purchasing tickets at the purchase price and attended in their own time and not in a promotional capacity. Those points were reiterated at the event itself. Sobi did not give any presentations about its products or any other topic which could be construed as being promotional in nature. Sobi did not have any booths or displays at the event, nor did it distribute any promotional or non-promotional materials at the event.

The event was organised with help from the three charities. A steering committee of four Sobi employees and a representative from each of the three charities volunteered to plan and implement the event.

Sobi publicised the event by word of mouth to family, friends and business partners, such as recruitment, advertising and communications agencies. Sobi understood that the charities also publicised the event through their networks and membership. Sobi gave them some posters to place in their offices and Sobi employees and charity members used social media to publicise the event to their personal networks.

Sobi submitted that the intended audience included its employees, business partners such as agencies that provided services to Sobi, and their respective guests. The charities involved were able to generate ticket sales through their own networks. Sobi submitted that it did not target health professionals or other relevant decision makers. No health professionals attended the event at Sobi's invitation or expense and as far as Sobi was aware, of the approximately 150 individuals that attended, only three or four might qualify as a health professional as defined in the Code and none were prescribers of Sobi products; they had attended as guests of the charities or other non-pharmaceutical companies that purchased tickets. Sobi submitted that those health professionals were academic and therefore unlikely to be active prescribers or did not operate in the specialist therapeutic areas for which Sobi marketed products. Sobi did not pay for any attendees; even its own employees, with the exception of two steering committee members, had to buy their own tickets.

Sobi submitted that the cost of each ticket was £65 which was more than the value of the hospitality and entertainment provided. The combination of

ticket sales and fundraising on the night more than covered the entire cost of the event so Sobi did not subsidise the event in any way. The profits of the night were shared equally by the three charities. In addition, Sobi pledged to donate an amount equivalent to 50% of the total costs of the event and donated £5,224.16 to be shared equally between the three charities which would be publicly disclosed in due course in accordance with the requirements of Clause 27.7.

Sobi submitted that hospitality comprised a three course meal accompanied by wine and soft drinks. Music was provided by a local band and there was a raffle with prizes donated by Sobi employees, Sobi business partners, local business or people connected with the three charities (a list of prizes was provided). In addition, one of the charities arranged for four children, whom it supported, to give a short demonstration of a dance that they have developed. The children used dance as a form of exercise and to help them express themselves which had proven very valuable as part of their disease management. The children and their parents or carers were provided with a light buffet in a separate room at the venue before leaving.

Sobi stated that the Code applied to the promotion of medicines to health professionals and other relevant decision makers as well as to non-promotional information about prescription only medicines made available to the public. It also applied to hospitality provided to health professionals and other relevant decision makers, whether or not in a promotional context. The Sobi charity ball did not involve the promotion of any Sobi's products or the dissemination of non-promotional information about Sobi's products. This event was not targeted at health professionals or other relevant decision makers and Sobi did not provide any hospitality to such persons and as a result submitted that the event fell outside of the scope of the Code.

Sobi noted that Case AUTH/1604/7/04 confirmed that corporate events were in general acceptable under the Code. That case concerned three separate corporate events which had been attended by health professionals as guests and at the expense of a pharmaceutical company. In that case, the Panel explained that corporate events were a legitimate activity for pharmaceutical companies to undertake and whether the event came within the scope of the Code would depend on the arrangements. In particular, to be exempt from the Code, events must not otherwise be meetings organised for health professionals or appropriate administrative staff. The Panel ruling for Case AUTH/1604/7/04 also confirmed that the corporate events that included health professionals could be exempt from the Code, provided that a significant proportion of other guests were from a different background and health professionals were invited to attend in a capacity other than mere prescribers or persons who could recommend medicines.

Sobi reiterated that the charity ball was not targeted at health professionals or other relevant decision makers and, while a small number of the guests

invited by the charities or other organisations present might meet the definition of health professionals under the Code, none were there as guests of or at the invitation of Sobi or in a capacity as a prescriber of one of Sobi's medicines. Applying the principles set out in Case AUTH/1604/7/04, the event fell outside the scope of the Code.

Clause 14.1 of the Code required companies to certify the compliance of promotional materials with the Code, while certain other educational, patient support and similar materials required certification under Clause 14.3. Since the event was non-promotional and no materials relating to diseases, therapy areas or Sobi's medicines were disseminated before or during the event, all materials relating to the event, such as the posters, tickets and confirmation letters fell outside the scope of the certification requirements under the Code. Nonetheless, applying the principle described in the supplementary information to Clause 14.3, Sobi sought to examine and approve all items planned for public dissemination to ensure they did not contravene the Code. Those materials were reviewed and approved through the electronic approval system. All other items not planned for wide public dissemination (ie tickets and confirmation letter to guests) were not approved electronically but were examined before use.

Sobi noted that whilst in its view the charity ball fell outside the scope of the Code, for completeness it responded to each of the alleged breaches.

Clause 12

Sobi noted that CSL Behring argued that as the event involved a charity which was active in a therapy area for which Sobi marketed and developed prescription only medicines, the event was somehow disguised promotion in breach of Clause 12. Clause 12 concerned materials and activities that were disguised so that while appearing to be non-promotional they were in fact promotional. Sobi reiterated that the ball did not involve the promotion of any of its products, nor did it involve the dissemination of non-promotional information about its products. Further, Sobi did not provide any hospitality to health professionals, either free of charge or as an inducement to prescribe or recommend Sobi's products. Rather, this was a non-promotional, corporate event, which did not target health professionals or other relevant decision makers. Given that no promotion of, or even reference to, any Sobi's products had occurred in connection with the charity ball, the event could not constitute disguised promotion and be in breach of Clause 12.

Clause 18.1

Sobi noted that Clause 18.1 prohibited the supply, offer or promise of gifts, pecuniary advantages or benefits to health professionals or other relevant decision makers in connection with the promotion of medicine or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. In the context of Clause 18.1, CSL Behring had referred to the use of competitions

and quizzes. The supplementary information to Clause 18.1 provided that use of competitions, quizzes and such like, and the giving of prizes, were unacceptable methods of promotion.

Sobi submitted that the charity ball was a non-promotional, corporate event at which there was no direct or indirect promotion of Sobi's medicines. The event did not target health professionals and as far as Sobi was aware none of the small number of health professionals who attended prescribed Sobi's medicines. Consequently there could not have been any inducement for such health professionals to prescribe, supply, administer, recommend, buy or sell any medicine. In any event, since all attendees other than the steering committee were required to purchase a ticket which cost more than the value of the hospitality and Sobi did not pay for anyone to attend, Sobi had not given any benefit to any person, let alone to a health professional or other relevant decision maker. Further, since the event fell outside the scope of both Clause 18.1 and the Code in general, there could not have been a breach of Clause 18.1 or any of the guidance contained in the supplementary information to Clause 18.1.

Clause 22.1

Sobi noted Clause 22.1 provided that (i) companies must not provide hospitality to health professionals and other relevant decision makers except in connection with appropriate meetings, (ii) meetings must be held at an appropriate venue, (iii) hospitality must be strictly limited to the main purpose of the event, (iv) the level of subsistence must be appropriate and proportionate, (v) the costs involved must not extend beyond health professionals and other relevant decision makers.

Sobi reiterated that the charity ball was a non-promotional corporate event that did not target health professionals or other relevant decision makers. The very few health professionals that attended the ball did not do so in their capacity as prescribers and, as far as Sobi was aware, they did not prescribe Sobi's medicines. Applying the principles from Case AUTH/1604/7/04 discussed above, it was clear that this corporate event fell outside the scope of Clause 22.1 and the Code more generally so there could not have been a breach of Clause 22.1.

Further, Sobi did not provide hospitality to anyone let alone a health professional. Clause 22.1 made it clear that the costs involved in an event covered by Clause 22.1 must not exceed the level which recipients would normally adopt when paying for themselves. In this case, admission to the event was by ticket only and Sobi did not pay for anyone to attend. The cost of the ticket was more than the value of the hospitality and entertainment, so all hospitality was paid for by the attendees.

Clause 9.1

Sobi noted that Clause 9.1 required that high standards be maintained at all times. It was, however, unclear from the complainant exactly

in which regard Sobi had failed to maintain high standards. Sobi noted that the supplementary information to Clause 9.1 stated that the special nature of medicines and the professional audience to which the material was directed required that standards for the promotion of medicine were higher than those which might be acceptable for general advertising. That suggested that the high standards referred to in Clause 9.1 related to the promotion of prescription medicines.

Sobi submitted that it had maintained high standards at all times, in that the organisation of the event was conducted appropriately, the materials and publicity surrounding such a corporate, non-promotional event (which was therefore outside the scope of the Code) were appropriate and all attendees were made fully aware of its non-promotional nature. Since the event fell outside the scope of the Code and did not involve any direct or indirect promotion of any of Sobi's medicines, it followed that there could not have been a breach of Clause 9.1.

Clause 2

Sobi noted that CSL Behring alleged a breach of Clause 2 'through provision of excessive hospitality'. Sobi submitted that a breach of Clause 2 was a sign of particular censure for events that brought discredit upon, or reduced confidence in, the pharmaceutical industry. Sobi submitted that as the charity ball fell outside the scope of the Code and Sobi had not breached Clause 18.1 or any of the provisions of the Code relating to hospitality, there could be no breach of Clause 2 relating to such hospitality.

PANEL RULING

The Panel noted that the provisions of Clause 22 of the Code applied to meetings organised for health professionals regardless of whether the meetings were promotional or not. Clause 22.1 of the Code permitted companies to provide appropriate hospitality to members of the health professions and other relevant decision makers in association with scientific and promotional meetings. Hospitality must be secondary to the purpose of the meeting and the level of hospitality offered must be appropriate and not out of proportion to the occasion. The costs incurred must not exceed the level which recipients would normally adopt if paying for themselves. It must not extend beyond members of the health professions or other relevant decision makers. The supplementary information stated that the impression created by the arrangements must be borne in mind. Meetings organised for groups of doctors, other health professionals and/or other relevant decision makers etc which were wholly or mainly of a social or sporting nature were unacceptable. The relevant supplementary information also made it clear that the requirements of the Code did not apply to the provision of hospitality other than that referred to in, *inter alia*, Clause 27.2 and the supplementary information to Clause 26.2. The latter made it clear that meetings organised for or attended by members of the public, journalists and patient organisations must comply with Clause 22. Clause 27.2 stated that

Clause 22 applied to pharmaceutical companies supporting patient organisation meetings. The Panel noted that the charity ball was not a patient organisation meeting sponsored by Sobi.

The Panel firstly had to consider whether the charity ball was covered by the Code. The Panel noted Sobi's submission that the charity ball was a corporate event that fell outside the scope of the Code as it did not promote any of Sobi's medicines, nor did it target health professionals, other relevant decision makers or patients. The Panel considered that corporate events, including fund raising activities, were a legitimate activity for a pharmaceutical company to undertake. They were part of normal business practice. Whether a corporate event was covered by the Code would depend on the arrangements. Corporate events covered by the Code had to comply with it.

The Panel noted that both parties had referred to Case AUTH/1604/7/04. Whilst that case provided useful guidance, breaches of the Code were ruled in that case in relation to corporate events to which health professionals had been personally invited and paid for by a pharmaceutical company. This was not the case with the Sobi charity ball.

In the Panel's view, in order to fall outside the scope of the Code corporate events must not otherwise be meetings organised for health professionals, other relevant decision makers or patient organisation representatives and or their members, bearing in mind that meetings organised for such groups which were wholly or mainly of a social or sporting nature were unacceptable. Corporate events could include invited health professionals, other relevant decision makers or patient organisation representatives and/or members but must also include a significant proportion of other invited guests from a different background. Further, the capacity in which health professionals and others were invited to attend such events was an important factor. In the Panel's view inviting health professionals in their capacity as prescribers or as persons who recommended medicines to a corporate event with no educational or scientific input would be in breach of the Code. Such health professionals might be invited to attend in relation to their roles such as senior representatives of professional organisations, hospital trusts, primary care trusts, etc. The Panel noted that the reason that patient organisation representatives and/or their members had been invited might also be relevant. The Panel noted that the event at issue was advertised through a number of channels and those who wanted to attend could purchase tickets. It appeared that no one was invited personally at Sobi's expense.

The Panel noted Sobi's submission that it organised the event with the help of three charities who were represented on the steering committee in order to raise funds for them and highlight their important work. The profits were shared equally by the three charities. In addition, Sobi pledged to donate an amount equivalent to 50% of the total costs of the event to be shared equally between the three charities; Sobi would declare the amount donated to the charities in accordance with Clause 27.7. In

addition the Panel noted that Sobi had provided non-financial support; its contact details had appeared on all the materials, ticket payments were made via the company's charity account, it issued tickets and corresponded with guests. Significant administrative support had therefore been provided. It was not known who had paid for printing costs. In addition the Panel noted the confirmation letter sent to those who purchased tickets stated that Sobi had provided part of the costs necessary to hire the venue and provide the catering and the evening's musical entertainment. This was in contrast to Sobi's submission that the cost of the tickets was more than the value of the hospitality and entertainment so all hospitality was paid for by the attendees. The amount paid by Sobi in that regard was unknown.

The Panel noted that Clause 27.1 provided that pharmaceutical companies could interact with, *inter alia*, patient organisations to support their work. Taking all the circumstances into account the Panel considered that working with the patient organisations, including those that operated in a field in which Sobi had a commercial interest, to raise money for those organisations was a matter covered by the Code.

The Panel then had to decide whether the charity ball was in breach of the Code as alleged bearing in mind its comment above that corporate events were a legitimate activity. The Panel noted that the event was open to anyone who wanted to buy a ticket although as might be anticipated, given the advertising channels, it appeared to be largely attended by those with a professional connection to the company or therapy area and their friends and colleagues. Overall there were 163 attendees including Sobi staff. According to Sobi three or four might be described as health professionals and were not prescribers of Sobi's products. The Panel did not know whether these individuals could recommend products. The Panel noted that there was a spread of attendees, primarily Sobi employees, patient organisations and healthcare agencies. Those attending under the Sobi or patient organisation banner included partners, family and friends. For instance for one patient organisation 6 attendees had a formal role at the organisation, such as trustees or staff, whilst 10 were family or friends and 3 were connected with its marketing and public relations agency. Overall the Panel reviewed the full attendee list and considered that the charity ball was not a meeting organised for health professionals or patient organisation members *per se*. Attendees even Sobi's own employees with the exception of two steering committee members, were required to purchase their own tickets. Sobi had not controlled who could buy tickets and in that regard attendees were not guests of the company although it had organised the ball and met certain costs. The Panel noted Sobi's submission that no health professionals attended the event at Sobi's invitation or expense and as far as Sobi was aware only three or four attendees might qualify as a health professional as defined in the Code and none prescribed Sobi products; they had attended as guests of the charities or other non-pharmaceutical companies that purchased tickets. The Panel considered, on balance that Sobi had

organised a charitable event that was open to anyone who wished to purchase a ticket; it was not aimed at health professionals, other relevant decision makers or patient organisations *per se* and no breach of Clause 22.1 was ruled.

The Panel noted that Clause 18.1 stated that no gift, pecuniary advantage or benefit might be supplied, offered or promised to members of the health professions or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine, subject to the provisions of Clauses 18.2 and 18.3. The supplementary information to Clause 18.1 provided that use of competitions, quizzes and such like, and the giving of prizes, were unacceptable methods of promotion. The Panel noted Sobi's submission that the charity ball was a non-promotional event at which there was no direct or indirect promotion of Sobi's medicines. The Panel did not consider that the event was promotional nor were the raffle

items offered as an inducement. In the exceptional circumstances of this case the Panel therefore ruled no breach of Clause 18.1.

The Panel noted that CSL Behring had cited Clause 12 although not included it in its list of alleged breaches. Nonetheless, the Panel considered that there was an allegation of disguised promotion and Sobi had responded to it. The Panel noted its comments above and Sobi's submission that the event was non-promotional. In that regard, the event could not be disguised promotion and no breach of the Code was ruled.

The Panel did not consider that Sobi had failed to maintain high standards and so no breach of Clause 9.1 was ruled. The Panel noted its rulings and further ruled no breach of Clause 2.

Complaint received **12 May 2016**

Case completed **18 August 2016**
