NUMBER 83 February 2014

CODE OF PRACTICE REVIEW

PMCPA | Prescription Medicines Code of Practice Authority

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

2014 CODE PUBLISHED

The 2014 Code has now been published and is available to download from the PMCPA website or in hardcopy upon request. The Interactive Code on the PMCPA website has also been updated.

Most of the amendments to the Code result from the new EFPIA Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations and changes to the EFPIA Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals.

Full details including a presentation listing all of the changes to the Code are available to download from the PMCPA website.

The guidance and support documents available from the PMCPA website such as the Clause 3 guidance, Guidance on Certification, Digital Communications Guidance and the Quick Guides to the Code have all been updated to reflect the 2014 Code.

IFPMA SIGNS CONSENSUS FRAMEWORK FOR ETHICAL COLLABORATION

Five global healthcare organisations have established a Consensus Framework for Ethical Collaboration to support partnerships that will aim to deliver greater patient benefits and support high quality patient care. The organisations are the International Alliance of Patients' Organizations (IAPO), International Council of Nurses (ICN), International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), International Pharmaceutical Federation (FIP), and the World Medical Association (WMA).

Derived from the individual codes of ethical practice and health policy positions of the five supporting organisations, this framework is based on four overarching principles:

- putting patients first;
- supporting ethical research and innovation;
- ensuring independence and ethical conduct; and
- promoting transparency and accountability.

While individual codes of practice govern the activities of each group, this broad-based consensus framework applies across much of the healthcare community to include interactions involving patients, nurses, pharmacists, doctors, and the healthcare industry.

The Consensus Framework for Ethical Collaboration between Patients' Organisations, Healthcare Professionals and the Pharmaceutical Industry is accessible via the IFPMA website.

For more information, please contact Heather Simmonds, (email: hsimmonds@pmcpa.org.uk).

SIGNATORIES

Companies are required by Clause 14.4 to inform both the PMCPA and the Medicines and Healthcare Products Regulatory Agency (MHRA) (signatories.advertising@mhra.gsi.gov.uk), in advance who their final signatories are and what qualifications they hold. Companies need to advise promptly if this information changes.

The supplementary information to Clause 14.1 states that 'In deciding whether a person can be a nominated signatory, account should be taken of product knowledge, relevant experience both within and outwith the industry, length of service and seniority. In addition signatories must have an up-to-date, detailed knowledge of the Code.'

TRANSFER OF VALUE DISCLOSURE CRIB NOTES

The PMCPA has produced a set of Transfer of Value Disclosure Crib Notes which is available to download from the PMCPA website. The table of notes has been produced to help set out all of the transfer of value disclosure requirement in the 2014 Code.

CODE OF PRACTICE TRAINING

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

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

The next Code of Practice seminar date on which places remain available is:

Friday 28 March 2014

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

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

HOW TO CONTACT THE AUTHORITY

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

www.pmcpa.org.uk

Telephone:	020 7747 8880
Facsimile:	020 7747 8881

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

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

Heather Simmonds:	020 7747 1438
Etta Logan:	020 7747 1405
Jane Landles:	020 7747 1415
Tannyth Cox:	020 7747 8883

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

The Authority rather than the ABPI is the contact point for information on the application of the Code.

ANONYMOUS v LUNDBECK, CHIESI, MENARINI and BAYER

Sponsorship of a meeting

An anonymous, non-contactable complainant was concerned about pharmaceutical company sponsorship of the annual scientific meeting of the Bihar Jharkhand Medical Association (BJMA), UK, held in Bolton in July 2013. The complainant only named Lundbeck and so the complaint was taken up with that company. On receipt of Lundbeck's response, a copy of the scientific agenda provided to Lundbeck by the BJMA listed other companies which had also sponsored the meeting and so the matter was additionally taken up with them.

The complainant alleged that the meeting in question was not a fully educational meeting and was more of a weekend family gathering event, with scientific sessions, children's activities and entertainment etc combined; the meeting programme detailed children's football and variety performances, including BJMA's Got Talent. The BJMA Facebook page stated 'We have arranged a high quality scientific meeting running in two parallel sessions, variety of entertainment programme, finest cuisine from a renowned caterer and various sporting events for the children. Despite the escalating costs involved in organising such a big event, we have managed to keep the delegate fee to a very reasonable level. We hope that you would encourage your family and friends to attend in large numbers and make the programme a big success'.

The complainant was concerned that pharmaceutical companies should not have sponsored such an event and should not have stands promoting their products in front of members of the public.

The detailed responses from Lundbeck, Chiesi, Menarini and Bayer are given below.

It appeared to the Panel that the main purpose of the meeting was the social/cultural aspects, a view reinforced by the documentation for the meeting. The Panel did not consider that the meeting met the requirements of the Code. The two day meeting had a maximum scientific content of just over three hours. The meeting was mainly a social event; the limited scientific programme did not appear to be the main purpose of the event. The Panel had little information about the costs of putting on the exhibition on the Saturday. The organising secretary had stated that the money paid by pharmaceutical companies 'hardly met the cost of the scientific meeting'. This seemed at odds with the activities arranged and that each delegate was to pay £60 to cover everything other than accommodation. The fact that companies had sponsored speakers was also of concern. Lundbeck had paid for two speakers and for an exhibition stand. The company briefed the speakers.

Chiesi had paid for a speaker and for an exhibition stand which it later decided not to use because of lack of clarity regarding the positioning of the stand in relation to the room where the scientific sessions were being held. Chiesi briefed the speaker.

Menarini had paid for two speakers and for an exhibition stand. Menarini had chosen the subject areas and the speakers and the meeting organisers had agreed that they were suitable. Menarini had briefed the speakers.

Bayer had paid for one speaker and for an exhibition stand. The company had briefed the speaker and had provided slides for the speaker to use.

All the companies' involvement with their speakers was at odds with the declaration on the programme that pharmaceutical companies had not influenced the content of the slides.

It appeared that companies had limited information about the meeting before agreeing to support it. They should have ensured that comprehensive copies of documentation had been supplied by the organisers.

In relation to alleged promotion to the public, the Panel noted the companies' submissions including that only registered delegates accessed the exhibition area. Chiesi had not had an exhibition stand and thus there could be no breach in relation to promoting to the public. The complainant had not provided any details regarding this allegation. The complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel considered that this had not been discharged in relation to the alleged promotion to the public and the role of Lundbeck, Menarini and Bayer and no breaches of the Code were ruled.

Taking all the circumstances into account the Panel considered that the arrangements for the meeting did not meet the requirements of the Code such that it was not a meeting for a primarily educational purpose as set out in that clause. Pharmaceutical company involvement in the agenda ie sponsoring speakers and paying for exhibition space and the impression given by pharmaceutical company involvement, particularly in the documents provided by the complainant was unacceptable. The Panel ruled a breach of the Code with regard to Lundbeck's, Chiesi's, Menarini's and Bayer's involvement. Chiesi appealed this ruling. The

Panel considered that high standards had not been maintained and each company was ruled in breach of the Code. These rulings were not appealed.

The Panel noted that Clause 2 was used as a sign of particular censure and reserved for such use. The supplementary information referred to excessive hospitality. The Panel decided the circumstances were such as to bring discredit upon and reduce confidence in the pharmaceutical industry and each company was ruled in breach of Clause 2. Chiesi appealed this ruling.

Upon appeal by Chiesi of the ruling in Case AUTH/2628/8/13 that the meeting did not comply with the Code and the ruling of a breach of Clause 2, the Appeal Board noted that hospitality as defined in the supplementary information to the Code was limited to meals, drinks, accommodation, genuine registration fees and the payment of reasonable travel costs which a company might provide to sponsor a delegate to attend a meeting. It was an established principle of the Code that any meeting held or sponsored by a pharmaceutical company must have a clear educational content. The Appeal Board had some reservations about the educational content at the meeting. The Appeal Board noted that although Chiesi had paid £1,000 which it had subsequently requested be returned, there was no evidence that it had provided any hospitality for the meeting. There was an impression from the agenda that Chiesi had contributed to the catering costs. The email from the organiser stated that whilst other pharmaceutical companies' payments would be used to pay for catering for delegates, Chiesi's would not. On this very narrow ground the Appeal Board ruled no breach of the Code in relation to the hospitality allegation. The appeal on this point was successful.

The Appeal Board noted its comments above and considered that a significant factor in this case was the apparent deliberate lack of key information from the organisers. The Appeal Board noted the Panel's ruling that high standards had not been maintained and considered that Chiesi could have undertaken greater diligence to ensure that its involvement with the meeting complied with the Code but did not consider that in the circumstances it had brought discredit upon, or reduced confidence in the pharmaceutical industry. The Appeal Board ruled no breach of Clause 2. The appeal on this point was successful.

An anonymous, non-contactable complainant was concerned that several pharmaceutical companies had sponsored the 34th Annual Scientific Meeting of the Bihar Jharkhand Medical Association (BJMA), UK, held in 2013. The meeting was held in a Bolton hotel. The complainant only named Lundbeck Ltd and so the complaint was taken up with that company. On receipt of Lundbeck's response, a copy of the scientific agenda provided to Lundbeck by BJMA listed other companies which had also sponsored the meeting and so the matter was additionally taken up with those companies.

The Panel noted that a number of companies had participated by sponsoring at least one speaker and paying for exhibition space. There were differences between the responses including the meeting agendas. The Panel considered each case on the facts of that specific case. The only document considered in all the cases that had been provided by some of the companies but not all, was the list of health professional attendees provided by the BJMA to some of the companies.

COMPLAINT

The complainant was concerned that the meeting in question was not a fully educational meeting and was more of a weekend family gathering event, with scientific sessions, children's activities and entertainment etc combined. The complainant noted that the meeting programme stated that there would be children's football and variety performances, including BJMA's Got Talent. The BJMA Facebook page stated 'We have arranged a high quality scientific meeting running in two parallel sessions, variety of entertainment programme, finest cuisine from a renowned caterer and various sporting events for the children. Despite the escalating costs involved in organising such a big event, we have managed to keep the delegate fee to a very reasonable level. We hope that you would encourage your family and friends to attend in large numbers and make the programme a big success'.

The complainant was concerned that pharmaceutical companies should not have sponsored such an event and should not have stands promoting their products in front of members of the general public. The complainant stated that several pharmaceutical companies sponsored the event but the only company name he/she could recall was Lundbeck.

When writing to the relevant companies, the Authority asked each to respond in relation to Clauses 2, 9.1, 19.1, 22.1 and 22.2 of the Code.

CASE AUTH/2617/7/13 – LUNDBECK

RESPONSE

Lundbeck submitted that it had agreed to provide funding to support the meeting in question. The organisers expected between 200-500 UK health professionals to attend based on previous years' meetings.

Lundbeck paid £2,000 for a promotional stand in the exhibition area associated with the scientific meeting and was told that the funding would be used to support the catering in association with the scientific meeting only. This would comprise tea/coffee outside the scientific meeting rooms on arrival and at breaks and a buffet curry lunch for delegates only. This was considered an appropriate level of hospitality and secondary to the main purpose of the meeting.

Lundbeck considered that this was a reasonable level of financial support for a national scientific meeting

with this number of delegates. The scientific agenda provided to Lundbeck on 11 June stated:

> 'Declaration: The pharmaceutical companies have only paid towards the speaker fees and catering costs for the scientific meeting. They haven't influenced the content of the slides.'

The invoice sent to Lundbeck from the BJMA in June clearly also stated the payment was for 'exhibition space at the conference'.

Lundbeck also agreed with the organisers to support the attendance of two speakers at the scientific meeting: a nurse consultant to speak on 'Reducing alcohol related harm – what steps can we all take to help our patients?' and a consultant psychiatrist, to speak on 'Understanding and managing depression and anxiety: a practical guide'. Both speakers were briefed by Lundbeck regarding their obligations under Lundbeck's Speaker Agreement. These agreements were then signed in accordance with the relevant standard operating procedure (SOP). Each speaker received an honorarium of £500 (plus reasonable travel expenses if required).

Lundbeck knew that a gala dinner would be held in association with the event but this was on the evening of 6 July in a different part of the hotel from the scientific meeting and would have no association with the company's support of the meeting. Lundbeck was not aware of any other activities planned in association with the event.

On the first day of the meeting (6 July 2013) two field-based regional account directors arrived at the hotel around 8.30am to set up the stand and meet the speakers. The scientific meeting and medical exhibition area were on the level 1 mezzanine floor of the hotel which was dedicated to the scientific event. Access to the meeting and exhibition area was via a registration desk for enrolment and badge issue. Registered delegates followed signs to the scientific meeting on the mezzanine floor and accessed the exhibition and scientific meeting rooms through double doors. Only badge wearing, registered delegates accessed the exhibition area and scientific sessions which were not held in a publicly accessible area of the hotel.

Lundbeck submitted that tea and coffee were available in the exhibition area outside the scientific meeting rooms and lunch was provided in a separate room for conference delegates only and not accessible to the general public. There were no 'non-scientific' activities witnessed in proximity to the scientific meeting.

The two Lundbeck attendees packed up the stand and left the meeting around 2.30pm on the afternoon of Saturday, 6 July 2013 whilst the afternoon sessions were in progress; neither went to the gala dinner and no payments were made for the gala dinner. No-one from Lundbeck attended the meeting on 7 July.

The scientific meeting and exhibition took place at a hotel in close proximity to a football stadium. Lundbeck staff checked with the meeting organisers in advance to ensure the meeting was outside the football season; the organisers confirmed that the venue was to be used strictly for its conference facilities only.

With regard to attending delegates, post-meeting the organisers provided Lundbeck with a list of 268 delegates who registered for the event. However, the Lundbeck attendees did not get the impression that all these delegates were present on the morning of Saturday, 6 July.

In addition to Lundbeck, the scientific meeting agenda provided by the meeting organisers documented companies that sponsored the scientific sessions including Chiesi Ltd, Menarini, and Bayer.

Lundbeck stated that the arrangements for this meeting were approved locally by the regional account directors in accordance with the company's SOP for meetings. The approval form for the meeting itself was not archived along with the other meeting documentation and the speaker approval forms and agreements. This would be acted on and further training on this aspect of meetings approval would be undertaken with those responsible for organising and approving such meetings.

Lundbeck stated that it was clear that it had only supported the scientific meeting in association with the annual meeting. The meeting had a strong scientific content and support comprised funding, speaker provision and catering for the scientific meeting delegates only. The scientific content and medical exhibition areas were separate from the general public areas of the hotel and accessible to registered badge wearing delegates only. Similar provision also applied to the hospitality which was provided in association with the meeting. Promotional information for prescription only medicines was not therefore available to the public as alleged.

Lundbeck provided a statement from the organisers which read:

> 'The £2000 Lundbeck paid for a stand went only towards the costs of room hire for the scientific meeting, AV support staff and equipment, signage, delegate packs and modest hospitality for meeting delegates only.
>
> The medical exhibitions and scientific sessions were in a dedicated area of the hotel away from the general public areas and accessed by registered delegates only.'

With respect to the arrangements for supporting this meeting, Lundbeck therefore considered that high standards had been maintained. Hospitality was provided to health professionals only in association with the scientific meeting which was modest and secondary to the main purpose of the meeting. There was no advertising of prescription only medicines to the public. No information was made available about prescription only medicines to the public, directly or indirectly and under no circumstances could Lundbeck's activities be considered to have brought discredit upon, or

reduced confidence in, the pharmaceutical industry. Lundbeck denied breaches of Clauses 2, 9.1, 19.1, 22.1 and 22.2.

FURTHER INFORMATION FROM THE MEETING ORGANISER (relevant to all cases)

The Panel asked the meeting organiser to briefly outline the objectives of BJMA, provide a copy of the final agenda and to confirm which pharmaceutical companies were involved in the meeting be that sponsoring a speaker, paying for exhibition space or advertising in the souvenir. The meeting organiser was asked for a copy of the souvenir and to confirm that the registered delegates would include health professionals and their family members, including children. It was pointed out that the registration form asked for the age of those registered. The meeting organiser was asked what the £60 delegate fee was to cover and whether the refreshments for the meetings were available to all the registered delegates ie the health professionals and those that accompanied them. The meeting organiser was also asked whether any extra fees were charged for the activities such as for the children's football, the talent competition and the dinner on the Saturday evening or did the charge of £60 per registered delegate cover all these costs?

The meeting organiser explained that the BJMA was a 34 year old organisation. It recently celebrated its annual conference in Bolton, next year, as usual, it would be meeting in Birmingham. So far, it had not experienced any concern about the functioning of BJMA. The conference had always been organised very professionally. There were two types of sponsors for the conference. First one was being sponsored by pharmaceutical companies which were exclusively to meet the cost for the scientific meeting attended by doctors only. The meeting was entirely as per ABPI guidelines. It was very well structured and speakers were of a very high quality. Money raised by pharmaceutical companies was not more than 5% – 10% of the total budget, which hardly met the cost of the scientific meeting. The social component of the conference was sponsored by non-pharmaceutical companies and delegate fees. The annual souvenir contained many advertisements but none from pharmaceutical companies.

A copy of the organiser's response was provided to Lundbeck and other companies.

Lundbeck had no additional comment to make.

GENERAL COMMENTS FROM THE PANEL (applicable to all cases)

The Panel noted that the complainant was anonymous and non-contactable. As with any complaint, the complainant had the burden of proving his/her complaint on the balance of probabilities; the matter would be judged on the evidence provided by the parties. Before considering each individual case, the Panel reviewed relevant requirements of the Code in relation to meetings, hospitality and sponsorship.

Clause 19.1 stated that meetings must be held in appropriate venues conducive to the main purpose of the event. Hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting ie subsistence only. The level of subsistence offered must be appropriate and not out of proportion to the occasion. The costs involved must not exceed that level which the recipients would normally adopt when paying for themselves. The supplementary information to Clause 19.1 made it clear that the provision of hospitality was limited to subsistence, accommodation, genuine registration fees and the payment of reasonable travel costs which a company might provide to sponsor a delegate to attend a meeting. The venue must not be lavish, extravagant or deluxe and companies must not sponsor or organise entertainment such as sporting or leisure events. In determining whether a meeting was acceptable or not, consideration needed to be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, subsistence provided and the like. It should be the programme that attracted delegates and not the associated hospitality or venue. The supplementary information also stated that a useful criterion in determining whether the arrangements for any meeting were acceptable was to apply the question 'would you and your company be willing to have these arrangements generally known?' The impression that was created by the arrangements for any meeting must always be kept in mind.

The Panel noted that there were a number of ways that pharmaceutical companies could be involved in meetings organised by third parties. This included general sponsorship of such a meeting, sponsoring a specific part of it, sponsoring delegates to attend or paying to exhibit.

With regard to the implications of a pharmaceutical company paying to exhibit at a third party meeting, the Panel considered that if a company only paid for an exhibition stand then this might not necessarily be in breach of the Code even if certain aspects of the meeting did not meet the requirements of the Code. Companies, however, should undertake due diligence at the outset in relation to compliance and the overall meeting arrangements when deciding whether to pay for an exhibition stand. In the Panel's view certain conditions were relevant. Firstly, the exhibition must be a formal part of a genuine scientific or medical meeting independently organised, for example by a learned society. The meeting overall must not be of a wholly or mainly social or sporting nature. Secondly, the amount paid for the exhibition space must cover the genuine costs of putting on the exhibition and not be used to pay for or subsidise activities that did not meet the requirement of the Code. Thirdly, preferably a number of other companies must also be exhibiting. Fourthly, it should be made clear to all attendees that the pharmaceutical company had only paid for a trade stand. Fifthly, the venue must be appropriate and broadly in line with the requirements of the Code. Finally, apart from paying for an exhibition stand the company must have no other involvement in the meeting or in the arrangements for it. This would

include sponsoring delegates to attend or sponsoring other aspects of the meeting. Each case would be considered on its own merits bearing in mind all the relevant circumstances. The overall impression of the arrangements was an important consideration.

The Panel examined the material provided by the complainant. This included a letter from BJMA dated 26 January 2013. The first paragraph referred to the '34th Annual Scientific' meeting and the second paragraph stated that 'the reunion is expected to be attended by nearly 500 delegates from across the country'. The letter listed the costs of an exhibition stall, banners and the rates for 'advert in the Souvenir'. Membership details of the 'Reception', 'Finance', 'Cultural', 'Food', 'Decoration', Scientific', Youth' and 'Children' committees were given.

Another document dated 24 February but which also bore the date 26 January announced the 'Scientific meeting' and that the 'entire team was working hard to make the weekend a memorable event. We have arranged a high quality scientific meeting running in two parallel sessions, variety of entertainment programme, finest cuisine from a renowned caterer and various sporting events for the children'. The letter also stated that the delegate fee had been kept 'to a very reasonable level' and the organisers hoped 'you would encourage your family and friends to attend in large numbers and make the programme a big success'. Delegates were responsible for their own hotel bookings. A document describing the event was provided which referred to the scientific presentations from 10am to 12 noon in the listing of the events for each day and 'Presentations' (1.30-3.45pm) in the afternoon of 6 July. The programme for 6 July stated 'Variety Performances' which included BJMA's Got Talent, a children's football event and, after the presentations referred to above, a gala dinner and dance. 7 July included a cultural programme. The special highlights section referred to a live performance by a dance troupe, world class catering by a named organisation, exhibition stalls including clothing, jewellery, hair salon and spa and various activities for children, including a football camp, disco, bouncy castle, face painting, sumo wrestling, etc and the first ever BJMA's Got Talent. Two further pages were provided by the complainant, the first promoting the children's football camp. The second promoted BJMA's Got Talent beneath a heading '34th Annual Scientific meeting …'. BJMA's Got Talent ran from 2-4pm on 6 July in the Lion of Vienna Suite.

The Panel examined the agenda provided to Lundbeck by the meeting organisers. This version of the agenda named six pharmaceutical companies in addition to Lundbeck. The complaint had been taken up with each of these by the case preparation manager. The version of the agenda provided to Lundbeck by the meeting organisers differed to the agenda provided by the complainant.

PANEL RULING IN CASE AUTH/2617/7/13

According to the agenda provided by Lundbeck, the meeting commenced on Saturday, 6 July with registration at 9am. Four talks of 30 minutes each were held in Hall A. Lundbeck was described as sponsor for the first talk 'Reducing Alcohol related harm – what steps can well (sic) all take to help our patients'. The second talk 'New concepts in asthma management' listed Chiesi as the sponsor. The third talk 'Management of chronic stable angina: an update' listed Menarini as sponsor and the final talk 'Gout: same old, same old?' listed another named company as sponsor. In parallel, four talks each of 30 minutes were listed for Hall B. These being 'Management of chronic dermatitis', Understanding and managing depression and anxiety: a practical guide, 'Type 2 Diabetes – New therapies' and 'New concepts in the management of heart failure'. The listed sponsors were Lundbeck and two other named companies; there was no named sponsor for the one talk. The post lunch session ran in Hall A and none of the five non-clinical talks were sponsored by pharmaceutical companies. At 4-5pm the agenda stated 'ARM/ AGM BJMA'. On Sunday, 7 July the first talk at 10.30am was 'GMC Update'. This was followed by 'Management of Actinic keratosis' and 'The changing face of Anticoagulation in Primary Care: new solutions to old problems' sponsored by a named company and Bayer respectively. This was followed by the declaration 'The pharmaceutical companies have only paid towards the speaker fees and catering cost for the scientific meeting. They haven't influenced the content of the slides'. The final page of the agenda included two photographs, one of a flag and the other of a man playing a drum and what appeared to be women dancing.

The Panel noted that the case preparation manager had written to the secretary of the local organising committee to ask for the details of the pharmaceutical companies sponsoring the event. The response reiterated that the event was the 34th reunion of the BJMA Scientific Conference. The secretary confirmed that there was a mixture of '… reputable sponsors, including various banks, reputable solicitors, specific accountant, GMC and pharmaceutical companies. The secretary confirmed that the money raised from pharmaceutical companies, which took part in the exhibition, was only to fund the scientific section of the conference. The organisers stated that they took care to make sure that the scientific sections and exhibition halls were in an area of the hotel which was away and separate from any public areas which were accessed only by the registered delegates attending the scientific meeting.

The Panel noted that the meeting in question was organised by the BJMA. The BJMA was of course free to organise whatever meetings it wanted to for its own members. If there had been no involvement from pharmaceutical companies then the meeting would not have been covered by the Code. The involvement of the pharmaceutical companies meant the matter was covered by the Code. According to the agenda provided by Lundbeck seven pharmaceutical companies had provided sponsorship in the form of paying speakers. The agenda referred to 'Exhibits Open'. It was not clear from the agenda provided by Lundbeck which companies had exhibition space. This agenda included the declaration 'The

pharmaceutical companies have only paid towards the speaker fees and catering costs for the scientific meeting. They have not influenced the content of the slides'. This declaration also appeared in the agenda provided by the complainant although no pharmaceutical companies were listed. In addition, the documents provided by the complainant did not mention pharmaceutical company sponsorship on the documents sent to announce the meeting nor on the more detailed documents which described all the activities.

The Panel was also mindful of the established principle that a pharmaceutical company could not support a third party activity if that activity was itself in breach of the Code.

The list of health professional attendees had been provided by BJMA to Lundbeck after the meeting. The majority of attendees were general practitioners and hospital doctors. The vast majority were listed as from the UK, a few of those listed were from India, some were listed as retired. Attendees had a very wide range of specialities including consultant anaesthetists, urologists, gynaecologists, paediatricians, cardiologists, orthopaedics, sexual health and geriatricians. The Panel noted that the professional link among the disparate groups listed and the basis of BJMA membership was that they were graduates from certain Indian medical colleges.

The Panel noted that a wide range of groups existed within the medical and scientific communities. Membership of certain groups might be based on medical speciality or professional status or on different criteria such as cultural or, as with the BJMA, academic heritage. In the Panel's view, when membership was based on matters other than medical speciality and professional status, companies should be especially vigilant to ensure the relevant requirements of the Code were satisfied. In addition, given the wide range of clinical roles held by attendees, it was difficult to see how the limited educational agenda could be of sufficient professional relevance to all attendees.

The Panel queried whether the scientific content was reasonable in relation to the requirements of the Code. According to the agenda provided by Lundbeck, scientific sessions ran from 10am -12 noon on the Saturday and from 10.50am - 12 noon on the Sunday. This gave a maximum scientific content of just over three hours bearing in mind the parallel nature of the Saturday sessions. In addition, on Saturday afternoon there were talks from 1.30pm until 3.45pm, only one of which, 'Dealing with partnership disputes in general practice', might possibly be considered as relevant given the requirements of Clause 19. The four other talks related to financial matters including investment in Indian real estate. The BJMA ARM/AGM ran for an hour. The 20 minute GMC update on Sunday (10.30 – 10.50am) might possibly be considered as relevant to Clause 19. The refreshments listed were lunch on both days and refreshments after the Saturday afternoon session. The Panel noted that a number of companies paid for exhibition space and queried whether the amount charged was reasonable.

It appeared to the Panel that the main purpose of the meeting was the social/cultural aspects and in its view this was reinforced by the documentation for the meeting. The Panel did not consider that the meeting met the requirements of the Code. The two day meeting had a maximum scientific content of just over three hours. The meeting was mainly a social event and it appeared to the Panel that the limited scientific programme was not the main purpose of the event. The Panel had little information about the costs of putting on the exhibition on the Saturday. The organising secretary had stated that the money paid by pharmaceutical companies 'hardly met the cost of the scientific meeting'. This seemed at odds with the activities arranged and that each delegate was to pay £60 to cover everything other than accommodation. The fact that companies had sponsored speakers was also of concern. Lundbeck had paid for two speakers and for an exhibition stand. The company briefed the speakers which appeared to be at odds with the declaration on the programme that pharmaceutical companies had not influenced the content of the slides. It appeared that companies had limited information about the meeting before agreeing to support it. Lundbeck should have ensured that comprehensive copies of documentation had been supplied by the organisers.

The Panel noted that Lundbeck representatives had left the meeting early on the Saturday afternoon.

In relation to alleged promotion to the public, the Panel noted Lundbeck's submission that only registered delegates accessed the exhibition area. The complainant had not provided any details regarding this aspect of his/her allegation. The complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel considered that this had not been discharged in relation to the alleged promotion to the public and no breaches of Clauses 22.1 and 22.2 were ruled.

Taking all the circumstances into account the Panel considered that the arrangements for the meeting did not meet the requirements of Clause 19 such that it was not a meeting for a primarily educational purpose as set out in that clause. Pharmaceutical company involvement in the agenda ie sponsoring speakers and paying for exhibition space and the impression given by pharmaceutical company involvement, particularly in the documents provided by the complainant was unacceptable. The Panel ruled a breach of Clause 19.1 with regard to Lundbeck's involvement. The Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel noted that Clause 2 was used as a sign of particular censure and reserved for such use. The supplementary information referred to excessive hospitality. The Panel decided the circumstances were such as to bring discredit upon and reduce confidence in the pharmaceutical industry and a breach of Clause 2 was ruled.

* * * * *

CASE AUTH/2628/8/13 – CHIESI

RESPONSE

Chiesi explained that it purchased a space in which to place a promotional stand and provided a speaker for the meeting. Chiesi paid £1,000 which was invoiced in April 2013 by the meeting organisers. Based on information from the meeting organisers prior to receiving the invoice, this payment was for 'stand space' over a planned two day event in July where an educational meeting was going to take place.

The payment was transferred to BJMA in June to support, in good faith, the funding of a *bona fide*, scientific meeting. Nevertheless, Chiesi performed additional due diligence in seeking and receiving written reassurance from the meeting organisers in July that the funding was for appropriate purposes namely, '… hiring the Lion of Vienna Suite on Sunday, PA system, projection system, catering for delegates attending scientific session on Sunday'. From the BJMA response Chiesi was satisfied that the funding was not being used for anything other than the above and was entirely acceptable.

A few days prior to the meeting and on receipt of the final agenda, Chiesi decided not to place the stand at the two day meeting. Firstly because of a lack of clarity regarding the locality of the pharmaceutical company stands in relation to the room where the scientific sessions were being held, and secondly, because the declarations that were inserted on the final meeting programme at Chiesi's request, did not refer to the provision of a stand specifically. The organisers were given notice of Chiesi's wish not to erect a stand and steps were taken to recoup monies associated with the stand space purchase in that the organising Chiesi representative spoke directly to the meeting organiser regarding potential repayment of the fees.

The meeting was attended by just one Chiesi sales representative on Sunday, 7 July 2013 purely to accompany the Chiesi sponsored speaker. The Chiesi sales representative met the speaker on Sunday morning prior to the session and immediately after the presentation; both the speaker and the sales representative left the meeting and venue, prior to lunch.

No Chiesi staff attended the meeting on Saturday and there was no attendance made, or paid for, regarding the dinner on Saturday evening.

Chiesi submitted that the speaker was a renowned international opinion leader and was assessed by Chiesi as being an appropriate speaker at this large scale educational meeting. In addition, the speaker was ideally located for attendance.

Chiesi submitted that it took proactive steps to ensure that the programme was explicit regarding the fact that Chiesi had provided and reimbursed a speaker. As a result, on Day 2 of the finalised programme, agreed with the meeting organisers, adjacent to the speaker's name the following statement was inserted, 'This speaker has been provided and paid for by CHIESI Limited'. Additionally, in a yellow highlighted box the following underlined statement in bold font appeared, 'Chiesi Limited have also provided and paid for a speaker on the agenda'. This additional declaration was made at the request of Chiesi to ensure transparency. Chiesi confirmed that this amended agenda was used during the meeting as verified by the representative accompanying the Chiesi provided speaker. This agenda was not the version that was provided in the original complaint. Chiesi submitted that the version used during the meeting was that provided by Chiesi.

Chiesi stated that it briefed the speaker during face-to-face and telephone discussions taking place in the six months prior to the meeting. As the speaker had previously spoken on numerous occasions in similar circumstances under a Chiesi agreement, he was already familiar with the high standards and expectations set out in the speaker meeting agreement form having signed the form on each occasion. The signed speaker agreement form was provided. This form outlined the legal obligations that both parties must uphold but also reminded the speaker that he/she must comply with specific guidance in relation to the content and delivery of the presentation to ensure that the high standards expected under the Code were upheld. The speaker signed an agreement and presented a slide deck approved specifically for this meeting, which was reviewed and approved through Chiesi's formal process.

The meeting organiser first discussed the potential of an educational meeting with Chiesi representatives as early as April 2012. More discussions between the meeting organisers and Chiesi sales representatives regarding the potential for Chiesi to support the two day meeting took place from mid-January 2013 leading to a formal written request from the meeting organisers on 21 March 2013. At this point no agenda was available but confirmation was provided that approximately 350 doctors were expected at the event. Throughout the interaction with the meeting organisers the meeting was considered a *bona fide*, educational meeting where Chiesi was purchasing floor space to position a stand, and arrange for a speaker to present at the scientific session. The meeting organisers were not able to send Chiesi a draft outline of the programme until mid June 2013 and the impression from this programme remained that this was an educational meeting of high scientific content. The draft needed subsequent amendments to correct basic inaccuracies regarding both the speaker session that Chiesi was sponsoring and also the correct date of the session. A corrected programme was provided almost immediately.

The draft programme was reviewed at head office, when made available, as part of due diligence and as a result, Chiesi took proactive steps to ensure that the programme was explicit about Chiesi's sponsorship and speaker provision. Subsequently, as agreed with the meeting organisers, adjacent to the speaker's name the statements set out above were inserted.

As already stated, prior to the meeting, Chiesi made a decision not to have a stand at the meeting. It

was therefore attended by just one Chiesi sales representative on the Sunday to accompany the Chiesi sponsored speaker.

The Chiesi sales representative who attended the meeting venue on Sunday morning clearly recalled the amended programme containing the Chiesi declarations on the large meeting programme board outside the plenary sessions. He also confirmed that approximately 100 to 120 delegates were in the plenary session when the speaker delivered his presentation to the scientific audience. At no point was it evident that either lay members of the public or inappropriate delegates were present either in the plenary session or directly outside the meeting room. A delegate list provided by the meeting organisers confirming that the two day event was attended by health professionals and academics was provided.

Additionally, Chiesi confirmed that the layout of the meeting facilities were such that anybody approaching the meeting area was immediately greeted by persons managing a registration desk. The risk of lay persons knowingly or unknowingly entering the scientific areas/sessions restricted to health professionals was therefore controlled.

Chiesi submitted that the document submitted by the complainant and the statements made on the BJMA Facebook page were never received by, or viewed by, anyone from the company. The publicly available website of the BJMA was reviewed in order for approval to attend and support the meeting and no evidence at the time of viewing, led Chiesi to believe that this meeting was not a genuine scientific interaction. Certainly at no time was it made aware of additional non-scientific activities.

With regard to the statement that 'The Pharmaceutical companies have only paid towards the speaker fees and catering costs for the scientific meeting. They haven't influenced the content of the slides'. Chiesi submitted that it ensured that the programme explicitly stated adjacent to the speaker's name the following 'This speaker has been provided and paid for by CHIESI Limited'. Additionally, in the yellow highlighted box the following underlined statement in bold font appeared, 'Chiesi Limited have also provided and paid for a speaker on the agenda'.

Chiesi paid the speaker directly for preparation and delivery of his presentation. No monies were provided directly in reference to catering costs and a sum of £1,000 was paid to the BJMA to allow the placement of a promotional stand.

A formal written request from the meeting organisers, on 21 March stated that approximately 350 doctors were expected. Approximately 100 to 120 delegates were in the plenary session for the presentation according to the Chiesi sales representative that attended.

The sales representative observed only tea, coffee and biscuits being made available to delegates.

Chiesi did not provide funding dedicated to catering and thus it did not obtain a breakdown of catering costs per head however, Chiesi obtained written reassurance from the meeting organisers on 3 July 2013 that the stand related charge was to be used for appropriate purposes.

Chiesi apologised that its response might appear repetitive, however it was vital that the full extent of the control that Chiesi demonstrated throughout this meeting development was clarified and to demonstrate that all decisions were made with the best intent and in no way lowered standards expected by the Code.

Having conducted a thorough investigation and interviewed all parties involved, Chiesi submitted that all staff involved in the discussion and support of this meeting followed all appropriate standard operating procedures (SOPs) and were compliant with the Code in all their activities. Every step was taken to ensure that there was absolute transparency of Chiesi's appropriate involvement. As such, Chiesi refuted any assertion that its involvement represented a breach of Clauses 9.1, 19.1 or 2.

Since Chiesi did not place a stand at the meeting, nor undertook any promotional activity, and could confirm that the delegates only were present during the scientific session similarly it was not in breach of Clauses 22.1 or 22.2.

FURTHER COMMENT FROM CHIESI

The further information from the meeting organiser was provided to Chiesi which pointed out that the meeting organiser clearly stated that the conference had two types of sponsors, and that pharmaceutical companies had provided support exclusively to meet the costs of the scientific meeting only. This reaffirmed its perspective and in fact it gained reassurances from the organiser that this was the case. Chiesi submitted that as it had gone beyond just purchasing stand space, in providing a speaker, it took additional steps to ensure that the final declaration on the agenda clearly stated that Chiesi had provided a speaker in order for attendees to have clear transparency of the company's involvement. Chiesi submitted that both actions were compliant with its SOPs.

Chiesi submitted that the meeting organiser provided additional reassuring clarity by confirming that the scientific element of the conference was attended by 'doctors only' and not by members of the public. Chiesi was not involved in any social aspects of the conference. Pharmaceutical companies did not advertise in the annual souvenir and Chiesi confirmed that it did not, nor was it ever asked, to sponsor or advertise in the annual souvenir.

Finally, Chiesi stated that the response from the meeting organiser provided the PMCPA with evidence that its involvement was with the scientific meeting only. Also the company hoped this demonstrated that its involvement was in accordance with the Code and as such did not represent a breach of Clauses 9.1, 19.1, 2 and similarly Clauses 22.1 or 22.2.

PANEL RULING IN CASE AUTH/2628/8/13

The general comments by the Panel above apply here.

The Panel examined the agenda provided to the pharmaceutical company named in the complaint by the meeting organisers. This version of the agenda named a total of seven pharmaceutical companies. The complaint had been taken up with each of the additional six companies, (one of which was Chiesi) by the case preparation manager. The version of the agenda provided to the pharmaceutical company named in the complaint by the meeting organisers differed to the agenda provided by the complainant. The agenda provided by Chiesi was, again, different. It was unclear which version of the agenda had been provided to delegates. Nonetheless, Chiesi was adamant that its representative had seen the final Chiesi version of the agenda on a large meeting programme board on 7 July.

The Panel noted that Chiesi had proactively sought to have changes made to the agenda provided to it by the meeting organisers regarding declarations of sponsorship. In this regard the Panel noted an email from Chiesi to the meeting organiser dated 3 July. The response from the meeting organiser to this email stated that an agenda had been sent to Chiesi on 13 June. This was a revised version of the agenda sent to Chiesi on 11 June following comments it had received from Chiesi about the date and time of one of the presentations.

According to the final agenda provided by Chiesi, the meeting commenced on Saturday, 6 July with registration at 9am. Four talks of 30 minutes each were held in Hall A. Lundbeck was described as sponsor for the first talk 'Reducing Alcohol related harm – what steps can we all take to help our patients'. The second talk 'Understanding Neuropathic Pain' had no named sponsor. The third talk 'Management of chronic stable angina: an update' listed Menarini as sponsor and the final talk 'Gout: Current concepts and management' also listed Menarini as sponsor. In parallel, three talks each of 25 or 30 minutes were listed for Hall B. These being 'Management of chronic dermatitis', Understanding and managing depression and anxiety: a practical guide, 'New concepts in the management of heart failure'. The listed sponsors Lundbeck and a named company with no named sponsor for the third talk. The agenda showed a break between 10.50 and 11.20am. The post lunch session ran in Hall A and none of the three non-clinical talks were sponsored by pharmaceutical companies. At 4–5pm the agenda stated 'ARM/AGM BJMA'. On Sunday, 7 July the first talk at 10.00 was 'GMC Update'. This was followed by 'New concepts in asthma management', sponsored by Chiesi, 'Management of Actinic keratosis' and 'The changing face of Anticoagulation in Primary Care: new solutions to old problems' sponsored by a named company and Bayer respectively. This was followed by the declaration 'The pharmaceutical companies have only paid towards the speaker fees and catering cost for the scientific meeting. They haven't influenced the content of the slides. Chiesi Limited have also provided and paid for a speaker on the agenda'. The previous versions of the agenda provided to Chiesi on 11 and 13 June included the final page of the agenda which included two photographs, one of a flag and the other of a man playing a drum and what appeared to be women dancing. This appeared to have been removed from the final agenda provided by Chiesi. The talks on property investment opportunities in London and investment in Indian real estate were only on the previous version of the agenda provided to Chiesi by the organisers on 11 June.

The Panel noted that the case preparation manager had written to the secretary of the local organising committee to ask for the details of the pharmaceutical companies sponsoring the event. The response reiterated that the event was the 34th reunion of the BJMA Scientific Conference. The secretary confirmed that there was a mixture of '… reputable sponsors, including various banks, reputable solicitors, specific accountant, GMC and pharmaceutical companies. The secretary confirmed that the money raised from pharmaceutical companies, which took part in the exhibition, was only to fund the scientific section of the conference. The organisers stated that they took care to make sure that the scientific sections and exhibition halls were in an area of the hotel which was away and separate from any public areas which were accessed only by the registered delegates attending the scientific meeting.

The Panel noted that the meeting in question was organised by the BJMA. The BJMA was of course free to organise whatever meetings it wanted to for its own members. If there had been no involvement from pharmaceutical companies then the meeting would not have been covered by the Code. The involvement of the pharmaceutical companies meant the matter was covered by the Code. According to the agenda provided by the company named in the complaint (Lundbeck) seven pharmaceutical companies had provided sponsorship in the form of paying speakers. The final agenda provided by Chiesi named five pharmaceutical companies in total. The agenda referred to 'Exhibits Open'. It was not clear from this which companies had exhibition space. This agenda included the declaration 'The pharmaceutical companies have only paid towards the speaker fees and catering costs for the scientific meeting. They have not influenced the content of the slides'. In addition, it stated that 'Chiesi Limited have also provided and paid for a speaker on the agenda'. The statement 'This speaker has been provided and paid for by CHIESI Limited' appeared next to the details of the speaker. The documents provided by the complainant did not mention pharmaceutical company sponsorship on the documents sent to announce the meeting nor on the more detailed documents which described all the activities. The conference agenda stated 'The Pharmaceutical companies have only paid towards the speaker fees and catering costs for the scientific content they haven't influenced the content of the slides' although no pharmaceutical companies were listed.

The Panel was also mindful of the established principle that a pharmaceutical company could not support a third party activity if that activity was itself in breach of the Code.

The list of health professional attendees had been provided by BJMA to Chiesi after the meeting. The majority of attendees were general practitioners and hospital doctors. The vast majority were listed as from the UK a few of those listed were from India, some were listed as retired. Attendees had a very wide range of specialities including consultant anaesthetists, urologists, gynaecologists, paediatricians, cardiologists, orthopaedics, sexual health and geriatricians. The Panel noted that the professional link among the disparate groups listed and the basis of BJMA membership was that they were graduates from certain Indian medical colleges.

The Panel noted that a wide range of groups existed within the medical and scientific communities. Membership of certain groups might be based on medical speciality or professional status or on different criteria such as cultural or, as with the BJMA, academic heritage. In the Panel's view, when membership was based on matters other than medical speciality and professional status, companies should be especially vigilant to ensure the relevant requirements of the Code were satisfied. In addition, given the wide range of clinical roles held by attendees, it was difficult to see how the limited educational agenda could be of sufficient professional relevance to all attendees.

The Panel queried whether the scientific content was reasonable in relation to the requirements of the Code. According to the final agenda provided by Chiesi, scientific sessions ran from 10am -12 noon on the Saturday and from 10.20am–12 noon on the Sunday. This gave a maximum scientific content of just over three and a half hours bearing in mind the parallel nature of the Saturday sessions. In addition, on Saturday afternoon there were talks from 1.30 until 3.30, only one of which 'Dealing with partnership disputes in general practice' might possibly be considered as relevant given the requirements of Clause 19. The two other talks related to financial matters including 'managing your pensions'. The BJMA ARM/AGM ran for an hour. The 20 minute GMC update on Sunday which started at 10.00 – 10.20am might possibly be considered as relevant to Clause 19. The refreshments listed were lunch on both days and refreshments after the Saturday afternoon session. A previous version of the agenda submitted to Chiesi included talks on 'Property Investment Opportunities in London' and 'Investment in Indian Real Estate'. The Panel noted that a number of companies paid for exhibition space and queried whether the amount charged was reasonable.

It appeared to the Panel that the main purpose of the meeting was the social/cultural aspects and in its view this was reinforced by the documentation for the meeting. The Panel did not consider that the meeting met the requirements of the Code. The two day meeting had a maximum scientific content of just over three and a half hours. The meeting was mainly a social event and it appeared to the Panel that the limited scientific programme was not the main purpose of the event. The Panel had little information about the costs of putting on the exhibition on the Saturday. The organising secretary had stated that the money paid by pharmaceutical companies 'hardly met the cost of the scientific meeting'. This seemed at odds with the activities arranged and that each delegate was to pay £60 to cover everything other than accommodation. The fact that companies had sponsored speakers was also of concern. The Panel noted that Chiesi had paid for a speaker and for an exhibition stand which it later decided not to use because of lack of clarity regarding the positioning of the stand in relation to the room where the scientific sessions were being held. Chiesi had taken steps to try to recoup the money. The Chiesi representative had only attended on the Sunday. Chiesi had briefed the speaker which appeared to be at odds with the declaration on the programme that pharmaceutical companies had not influenced the content of the slides albeit that Chiesi had asked for the additional statement that it had provided and paid for a speaker on the agenda. It appeared that companies had limited information about the meeting before agreeing to support it. Chiesi should have ensured that comprehensive copies of documentation had been supplied by the organisers.

In relation to alleged promotion to the public, the Panel noted Chiesi's submission and considered that as the company had not had an exhibition stand there could be no breach of Clauses 22.1 and 22.2 and ruled accordingly.

Taking all the circumstances into account the Panel considered that the arrangements for the meeting did not meet the requirements of Clause 19 such that it was not a meeting for a primarily educational purpose as set out in that clause. Pharmaceutical company involvement in the agenda ie sponsoring speakers and paying for exhibition space and the impression given by pharmaceutical company involvement was unacceptable. The Panel ruled a breach of Clause 19.1 with regard to Chiesi's involvement. The Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel noted that Clause 2 was used as a sign of particular censure and reserved for such use. The supplementary information referred to excessive hospitality. Chiesi had made some efforts to amend the agenda and had decided not to have an exhibition stand. Nonetheless, its efforts were not sufficient. On balance the Panel decided the circumstances were such as to bring discredit upon and reduce confidence in the pharmaceutical industry and a breach of Clause 2 was ruled.

APPEAL FROM CHIESI

Chiesi noted the Panel's view that it appeared that the main purpose of the meeting was the social aspects and that these had been sponsored by pharmaceutical companies. Chiesi submitted that it only knew about the educational aspects and tried to ensure that Code requirements were met in sponsoring the educational meeting. Chiesi denied a breach of Clause 19.1 and submitted that its actions did not bring the industry into disrepute.

Chiesi further noted the Panel's comment that Chiesi should have ensured that comprehensive copies of documentation had been supplied by the organisers.

Chiesi submitted that it was badly let down by the meeting organisers. Chiesi conducted due diligence in ensuring the meeting was appropriate, the agenda had a clear declaration of involvement, the stand was compliant and the slides were approved.

Chiesi stated that it was asked by the third party to sponsor the meeting and accordingly wanted to ensure the meeting was appropriate to sponsor. Chiesi noted the general inconsistency within the Code and amongst the industry as to what 'sponsorship' was. The term was used for very different activities:

- sponsoring delegates to attend third party meetings implied support
- sponsorship of promotional meetings implied organisation
- declarations of sponsorships implied arm's length arrangements.

Chiesi understood that this sponsorship request would mean that it was responsible for ensuring that the aspects of the meeting which it sponsored complied with the Code, and this included the catering costs and speaker arrangements and slides, and importantly, in terms of the overall educational content of the meeting. Chiesi did not consider that it was responsible for aspects such as the selection of delegates, choice of venue etc.

Chiesi noted that in Case AUTH/2471/1/12, the Appeal Board suggested there should always be written documentation with respect to assessing sponsorship of third party meetings. Chiesi fully appreciated that the agenda was essential to check whether the quantity and quality of education was sufficient to be the main attraction to the meeting, the subsistence was in proportion to the education and the topics were relevant to the audience.

Chiesi submitted that the agenda provided by the meeting organiser indicated this was an educational meeting. In particular:

- the meeting lasted all day Saturday and Sunday morning with no indication of a gala dinner or social agenda
- Saturday afternoon sessions were related to topics that would help delegates in their professional lives and were deemed to be educational and of value
- sufficient education, delivered by respected experts on varied topics, was considered of value to the varied background of delegates.

Chiesi submitted that it also checked that the meeting met the following criteria:

- organised by an independent learned society
- educational in nature and not mainly social, with clear benefits to the NHS
- national delegates from a variety of disciplines attracted to a varied agenda
- catering costs in line with subsistence limits and in proportion to education
- stand material fully approved beforehand
- other companies exhibiting
- speaker highly respected and well-regarded as an expert on asthma
- speaker engagement in compliance with Clause 20 and slides fully approved beforehand.

Therefore, Chiesi submitted that the educational meeting it sponsored complied with the Code.

Chiesi stated that it had asked those who had attended the meeting what their impression of the meeting was, specifically in relation to company sponsorship.

A consultant thought the meeting was both social and educational. 'For the Doctors there was a separate educational meeting and there was a social section where there [sic] other family members could integrate with each other'. He went on to state that, 'The letter I received showed the social side but the separate invitation I had to the Doctor meeting was educational'. In his opinion, the role of the pharmaceutical companies was to 'support the educational side only' and company sponsorship was 'completely for educational support only'. He thought the educational sessions were very good.

A GP also thought the meeting was both social and educational, stating that there were 'two different meetings at once'. He gleaned this from the agenda. In his view, the role of the pharmaceutical companies was 'to support the educational stands only at the meeting'. He was not sure if company sponsorship had paid towards the social aspects of the meeting and also thought the educational sessions were very good.

A Chiesi sponsored speaker and professor who was present on the Sunday stated 'The components that I attended were primarily educational. All medical meetings clearly have an element of networking, and some time during breaks for socialising: that was, as expected, also the case for this meeting'. He also went on to state that 'The meeting agenda had strong educational facets that led to thought provoking conversations about improving patient care'. In his opinion when asked about whether he thought pharmaceutical companies had paid for any social aspects he stated 'No, not from what aspects I saw' and further stated about the sessions 'Excellent varied topics, covering areas that actually provide medical education in areas that the company does not have products'. Again, he thought sessions were very good.

A GP thought there were two separate meetings, a social event and an educational scientific meeting. 'For the Doctors there was a separate educational scientific meeting'. He went on to state that, 'I thought the Pharma companies had only supported the scientific sessions and had also paid for a stand at the meeting'. In his opinion the role of the pharmaceutical companies was to support and sponsor the educational scientific elements only. 'There was a clear distinction between the social side and the scientific meeting. The meeting I attended was purely scientific'. He also thought the educational sessions were very good.

Chiesi noted that delegates mentioned separate meetings and agreed that the educational sessions

were very good. In Case AUTH/2471/1/12, the Appeal Board noted the educational content and ruled no breach of Clause 2.

Chiesi submitted that the Panel made contradictory statements in its ruling: 'Chiesi should have ensured that comprehensive copies of documentation had been supplied by the organisers' and 'The version of the agenda provided to the pharmaceutical company named in the complaint by the meeting organisers differed to the agenda provided by the complainant. The agenda provided by Chiesi was, again, different. It was unclear which version of the agenda had been provided to delegates'. In Chiesi's view, the meeting organiser was accountable for ensuring that when requested, accurate copies of documentation were supplied to all the sponsoring pharmaceutical companies. This should have been the single final copy in use, on the website and distributed to delegates (including the complainant).

Chiesi noted that in fairness to all third parties, it considered each request for sponsorship under its own merits according to strict criteria. Chiesi conducted due diligence in ensuring compliance relating to the following areas:

- the meeting was appropriate in terms of the organizing body, attendees, education, venue and subsistence
- the agenda was checked for a clear declaration of involvement
- the stand was questioned in terms of compliance
- the slides were approved together with a speaker agreement.

Chiesi was disappointed that even after questioning the meeting organiser it was not informed about the social agenda that the Panel considered formed the attraction to this meeting. As a demonstration of how seriously it took its commitment to compliance with the Code, Chiesi noted that at the last minute it decided not to have a stand at the meeting because it did not know where the stand was to be placed and the omission of a stand in the declaration of involvement.

Given the level of due diligence applied and the strong belief in meeting compliance requirements, Chiesi submitted that it would not have sponsored any social meeting (had it known that this meeting was a social event). Chiesi reiterated its view that the sponsored educational meeting complied with the Code.

Chiesi summarised its efforts in requesting documentation, clarity and compliance from the meeting organiser:

January	Representative asked relationship manager for speaker for Sunday 7 July and contribution towards stand costs.
March	Relationship manager asked representative for further information on the meeting including the programme.
2 April	Representative advised that there was currently no formal programme.
11 April	Relationship manager requested information on the audience and representative advised that 200 doctors across the UK attending.
13 June	Representative provided agenda.
30 June	Speaker sent his slides to relationship manager for approval.
1 July	Relationship manager noted inaccuracy in agenda – speaker presenting on asthma and not GMC and requested speaker's slides be approved in Zinc.
3 July	Email from another representative that he had requested the final agenda from the organisers. Meeting organiser emailed that no room for declaration other than next to speaker's name. Meeting agenda forwarded for Zinc approval. After discussion with medical and compliance, relationship manager asked meeting organiser to clarify nature of dinner on Saturday night. Relationship manager emailed meeting organiser to explain the importance of including the required declarations and to gain further information about what Chiesi's sponsorship was being used for and what was happening on the Saturday evening. Meeting organiser confirmed that the main declaration could be changed and the agenda reformatted and explained what Chiesi sponsorship was being used for, PDF of new programme. Medical and compliance happier with agenda.
4 July	Meeting organiser confirmed stand positions. Medical alerted that stands might be in the main plenary room. Medical confirmed that as no mention in the disclaimer about the stand, Chiesi could not erect a stand.
5 July	Speaker alerted as to meeting logistics, speaker agreement and final approved slides.

Chiesi submitted that in terms of the declaration of involvement on the agenda, the ruling in Cases AUTH/2546/11/12, AUTH/2547/11/12, AUTH/2548/11/12, AUTH/2552/11/12, AUTH/2554/11/12, AUTH/2556/11/12, AUTH/2559/11/12, AUTH/2560/11/12, AUTH/2561/11/12 and AUTH/2563/11/12 was borne in mind. Chiesi was therefore mindful of third party meeting agendas and insisted that its involvement was explicitly declared on such materials.

The final agenda provided therefore stated:

- 'The pharmaceutical companies have only paid towards the speaker fees and catering costs for the scientific meeting. They have not influenced the content of the slides'
- 'Chiesi Limited have also provided and paid for a speaker on the agenda'
- 'This speaker has been provided and paid for by CHIESI Limited'.

Chiesi submitted that one of the reasons the stand was not erected was because the declaration of involvement did not mention it.

Chiesi submitted that it was clear from this chronology that it went to a great deal of effort to apply due diligence and take corrective action. It was not clear from the ruling what more Chiesi could have done with respect to this matter, as it submitted that it was badly let down by the meeting organiser.

Chiesi submitted that it would be helpful if the Panel and Appeal Board could address the lack of clarity in the ruling:

- should companies exert complete control over third party meetings they sponsor?
- should companies question and be suspicious of third party documentation provided and communications?
- as compliance could never be guaranteed at third party meetings, should pharmaceutical companies be encouraged not to sponsor them at all?

Chiesi submitted that if a breach of Clause 2 was upheld, it would effectively prevent pharmaceutical companies sponsoring any third party meetings in the future.

Chiesi submitted that the rulings from Cases AUTH/2546/11/12, AUTH/2547/11/12, AUTH/2548/11/12, AUTH/2552/11/12, AUTH/2554/11/12, AUTH/2556/11/12, AUTH/2559/11/12, AUTH/2560/11/12, AUTH/2561/11/12 and AUTH/2563/11/12 stated if a company had a stand only at a third party meeting then it would not be held responsible for the rest of the meeting (if other criteria were met).

Chiesi submitted that since companies commonly provided a stand and sponsored other aspects of a third party meeting, it was not entirely clear in this case, whether the Panel considered Chiesi was fully responsible for the entire meeting. If this was the case, Chiesi was concerned that this represented an untenable situation for pharmaceutical companies sponsoring third party meetings. Chiesi submitted that third parties would not welcome the independence of their meetings being jeopardised by pharmaceutical companies exerting control. Yet this seemed the only way for companies to avoid similar breaches.

Chiesi submitted that upholding a breach of Clause 2 would not be consistent with recent rulings. A recent successful appeal (Case AUTH/2611/6/13) demonstrated that the Appeal Board considered it fair for a pharmaceutical company to make assumptions about the actions of a third party. A breach of the Code was not upheld. In addition, the ruling in Cases AUTH/2546/11/12, AUTH/2547/11/12, AUTH/2548/11/12, AUTH/2552/11/12, AUTH/2554/11/12, AUTH/2556/11/12, AUTH/2559/11/12, AUTH/2560/11/12, AUTH/2561/11/12 and AUTH/2563/11/12 suggested that there was an impression that pharmaceutical companies were linked to the sponsorship of social events. No company was found in breach of Clause 2 even though the educational agenda listed golf and gala dinner.

In summary, Chiesi submitted that the meeting in question was educational and it had applied due diligence to ensure the educational meeting it sponsored complied with the Code. In Chiesi's opinion, the meeting organiser was accountable for ensuring that when requested, accurate copies of documentation were supplied to all the sponsoring pharmaceutical companies.

Chiesi stated that it would welcome support in sending this as a clear message to third party meeting organisers. Chiesi hoped that it was evident that, given the level of due diligence applied and strong belief in meeting compliance requirements, it would not have sponsored any social meeting.

Chiesi accepted that internal procedures were not followed in the initial communication between the field and head office and it therefore it had already accepted that high standards were not maintained in breach of Clause 9.1.

Chiesi submitted that delegates were attracted to the meeting by its educational content. Further, delegates thought the education was very good. Chiesi denied a breach of Clause 19.1.

Chiesi submitted its specific actions did not bring the industry into disrepute and therefore it was not in breach of Clause 2.

APPEAL BOARD RULING

The Appeal Board noted that the Panel's ruling of a breach of Clause 9.1 related to its view that the meeting was not primarily for an educational purpose. In addition, pharmaceutical company involvement in the agenda ie sponsoring speakers and paying for exhibition space, and the impression given by pharmaceutical company involvement was unacceptable. The Panel had considered that high standards had not been met. The Appeal Board noted that Chiesi had accepted this ruling on a different basis this being that Chiesi's internal procedures were not followed in the initial communication between the field and head office.

The Appeal Board noted that, based on the material provided to Chiesi by the meeting organiser, Chiesi had agreed to have a promotional stand at the meeting and to sponsor a speaker to talk on asthma at a cost of £1,000 which was half the normal fee for a stand and a speaker. In reply to an email from Chiesi, the organiser stated that the Chiesi sponsorship would be used for organising the scientific session only. The organiser referred to a dinner on the Saturday evening and a cultural event for the delegates but provided no further details of any social aspects. It appeared that Chiesi had not asked for further information and while noting that there was a limit to what investigation a company should have to undertake to establish the nature of any third party meeting it wished to sponsor, the Appeal Board queried whether Chiesi could have done more. Companies needed to be certain that meeting arrangements complied with the Code. If meeting organisers were not prepared to provide full details of events then pharmaceutical companies should very carefully consider whether they should be involved. The Appeal Board, however, noted the difficulty that Chiesi had experienced in obtaining comprehensive and accurate information from the organiser and in that regard noted the organiser had not informed

the company about the social arrangements which ran alongside the scientific meeting. In the Appeal Board's view, Chiesi had been badly let down by the organiser.

The Appeal Board noted that Chiesi had agreed to have a stand at the meeting and sponsor a speaker. It was concerned that the sponsorship declaration on the final programme, 'Declaration The Pharmaceutical companies have only paid towards the speaker fees and catering costs for the scientific meetings. They have not influenced the content of the slides. Chiesi Limited have also provided and paid for a speaker on the agenda' did not accurately reflect Chiesi's involvement. Chiesi had done more than 'provided and paid for a speaker', it had briefed the speaker and formally reviewed and approved the presentation. When Chiesi reviewed the final agenda a few days before the meeting it decided not to have a stand at the meeting because of associated compliance issues (although it was unable to recoup the cost of its sponsorship in this regard) and so its involvement was limited to a representative attending the Sunday morning session to accompany the Chiesi sponsored speaker. The Appeal Board noted the educational content of the meeting and that the delegates included GPs and hospital doctors from a range of medical and surgical specialties. In that regard the Appeal Board noted the difficulty in making one agenda relevant to all attendees. The Appeal Board noted an email from the organiser to Chiesi dated 3 July which stated that '…the Chiesi sponsorship is being used for the scientific session only (of course other pharmaceuticals like Bayer, Eli Lilly and GMC are also contributing to the Sunday morning session – the cost of hiring the Lion of Vienna Suite on Sunday, PA system Projection system, catering for delegates attending the scientific session on Sunday)'. This email also stated that on the Saturday there was a dinner and cultural event for delegates attending the conference. The sponsorship from pharmaceutical companies would not be used to fund these – non pharmaceuticals were sponsoring this event. The Appeal Board noted that Chiesi had not agreed to pay for any social aspect of the meeting and had been told that its sponsorship would be used for organising the scientific session only. The invoice from the BJMA included a handwritten noted signed by the organiser that the £1,000 invoice was for stand space. This invoice was authorized by Chiesi on 20 June 2013. The Appeal Board noted that hospitality as defined in the supplementary information of Clause 19.1 was limited to refreshments/subsistence (meals and drinks), accommodation, genuine registration fees and the payment of reasonable travel costs which a company might provide to sponsor a delegate to attend a meeting. It was an established principle of the Code that any meeting held or sponsored by a pharmaceutical company must have a clear educational content (Clause 19.1 supplementary information). The Appeal Board had some reservations about the educational content at the meeting. The Appeal Board noted that although Chiesi had paid £1,000 which it had subsequently requested be returned, there was no evidence that Chiesi had provided any hospitality for the meeting. There was an impression from the agenda that Chiesi had contributed to the catering costs. The email from the organiser stated that whilst other pharmaceutical companies' payments would be used to pay for catering for delegates, Chiesi's would not. On this very narrow ground the Appeal Board ruled no breach of Clause 19.1. The appeal on this point was successful.

The Appeal Board noted its comments above and considered that a significant factor in this case was the apparent deliberate lack of key information from the organisers. The Appeal Board noted the Panel's ruling of a breach of Clause 9.1 and considered that Chiesi could have undertaken greater diligence to ensure that its involvement with the meeting complied with the Code but did not consider that in the circumstances it had brought discredit upon, or reduced confidence in the pharmaceutical industry. The Appeal Board ruled no breach of Clause 2. The appeal on this point was successful.

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CASE AUTH/2629/8/13 – MENARINI

RESPONSE

Menarini submitted that it did not directly provide hospitality for this event; it agreed to a payment of £1,500 for an exhibition stand plus two sessions within the scientific meeting. The company understood that this money was used by the organisers to contribute to the cost of room hire and catering for the scientific meeting. The venue, a hotel at a football stadium was appropriate and conducive to the main purpose of the event ie medical education. The hospitality provided to health professionals within the scientific meeting was secondary to the purpose of the meeting ie subsistence only, and did not exceed the level which the recipients would normally adopt when paying for themselves. The hospitality provided within the scientific meeting also did not extend beyond the members of the health professions and appropriate administrative staff.

Prior to the meeting Menarini was unaware of any activities or hospitality arranged for the partners and families of health professionals alongside the scientific meeting. It now understood that such activities took place separately to the scientific meeting but submitted that this was entirely segregated and that it did not provide hospitality or support for it in any way.

Menarini submitted therefore that it did not breach Clause 19.1.

Menarini submitted that it did not promote or advertise medicines to the public in any way at this event. The scientific meeting sponsored by Menarini was accessible only to health professionals and supportive administrative staff. A system of registration and name badges was in place at the event and members of the organising committee were at the doors of the scientific meeting ensuring that non-health professionals did not enter.

Menarini therefore submitted that it did not breach Clauses 22.1 or 22.2.

Accordingly, Menarini was confident not to have breached Clauses 19.1, 22.1 or 22.2 in this matter and had acted at all times to maintain the high standards of the pharmaceutical industry and committed no breach of Clauses 9.1 or 2.

Menarini provided a floor plan of the layout of the Premier Suite where registration and the buffet lunch for the scientific meeting both took place. It understood that the medical exhibition and scientific presentations took place in the Lion of Vienna Suite, below the Premier Suite, but had not been able to obtain a floor plan for this. Name badges were worn by delegates for the scientific programme and members of the organising committee were present on the entrances to the Lion of Vienna and Premier Suites to prevent non-health professionals from entering.

Menarini now understood that activities were taking place for the partners and families of the health professionals elsewhere. However, it was not aware of this before the meeting and at the event, it appeared to Menarini staff to be appropriately segregated from the scientific meeting and thus did not arouse their concern.

Menarini had committed to a payment of £1,500 for an exhibition stand plus two sessions on the scientific programme 'Management of chronic stable angina: an update' 11am to 11.30am and 'Gout: Same old, same old?' 11.30am to 12 noon.

It did not specifically ask for or receive a detailed breakdown of what the organisers used the money for, but understood it to contribute to the costs of providing the scientific meeting ie room hire and catering.

The only other payments committed in relation to this meeting were to be made directly to the two speakers in relation to the above sessions.

The Menarini attendees at the meeting were a key account specialist and three account managers. All arrived between 8am and 8.30am and estimated that they left between 1.30pm and 2pm ie after the medical exhibition and presentations had finished and once they had taken down the exhibition stand and materials. None of them knew of, attended or were invited to the gala dinner. No payment was asked for or made for the gala dinner.

Having agreed to sponsor two sessions on the scientific programme, Menarini agreed the subject areas with the meeting organisers and the speakers it suggested were recognised opinion leaders who had previously delivered high quality medical education for GP audiences on the subjects of stable angina and gout. The conference organisers agreed that these subjects and speakers were suitable. Menarini then ascertained that they were available to speak on the day and to the subject in question, discussed with them the name and purpose of the meeting with an expected attendance of between 200-300 health professionals, most of whom would be GPs. A suitable speaker fee was agreed in line with Menarini's standard operating procedure (SOP) and a standard consultancy agreement form was signed by each.

One of the meeting organisers emailed a draft copy of the scientific meeting programme to one of the account managers who, on the same day, asked the organisers to correct this draft which showed another pharmaceutical company as sponsors of the gout session rather than Menarini. Menarini had since discovered that there were a number of different versions of the agenda circulated by the BJMA.

At no time had anyone at Menarini seen a programme for any element of the meeting other than the scientific meeting, nor had it any knowledge prior to the event of any element to the meeting other than the scientific meeting. Furthermore Menarini was not aware of any registration form with different age groups, nor was it aware of the BJMA website prior to the meeting.

The £1,500 committed for an exhibition stand and two sessions on the scientific programme provided a suitable level of subsistence-type hospitality within the scientific programme only. Tea and coffee was available in the Lion of Vienna Suite, and a buffet lunch of chicken curry (or vegetarian option) with two choices of starters was served on plastic plates in the Premier Suite and was available for delegates at the scientific meeting only ie not family members of health professionals or the general public.

No payment was agreed or made specific to catering costs other than the £1,500 detailed above which was for the exhibition stand plus two sessions on the scientific programme.

Menarini staff estimated that 200 delegates attended the scientific session (the exhibition space and the presentations made in Hall A and Hall B) (estimated by the individuals varied from 150-250). The number of delegates who were in Hall A during the presentations by the Menarini sponsored speakers was 44.

Non-health professionals did not have access to the lunch and refreshment breaks of the scientific meeting. A system of registration and name badges was in place at the event and members of the organising committee were at the doors of the scientific meeting ensuring that non-health professionals did not enter.

Menarini did not know the catering costs paid by the conference organisers. The £1,500 fee paid was for an exhibition stand plus two sessions on the scientific programme, which it understood the conference organisers used to pay, or part-pay, for the room hire and catering. If the £1,500 was the full catering amount across 200 delegates, the catering cost per head would be £7.50. A theoretical calculation was made of the estimated catering cost per head were Menarini's full payment of £1,500 used to cater for the anticipated audience of 69 delegates attending the stable angina and gout speaker sessions – this gave an anticipated theoretical cost per head of £21.74 and

dividing the £1,500 by the actual number attending the stable angina and gout speaker sessions gives an actual cost per head of £34.09.

However, Menarini stressed that its support of the meeting was a £1,500 payment for an exhibition stand and two sessions on the scientific programme, not specifically sponsorship of the catering thus making this calculation a theoretical one only.

A copy of the meeting organiser's comments was provided to Menarini which had no further comments.

PANEL RULING IN CASE AUTH/2629/8/13

The Panel's general comments above apply here.

The Panel examined the agenda provided to the pharmaceutical company named in the complaint by the meeting organisers. This version of the agenda named a total of seven pharmaceutical companies. The complaint had been taken up with each of the additional six companies (one of which was Menarini) by the case preparation manager. The version of the agenda provided to the company named in the complaint by the meeting organisers differed to the agenda provided by the complainant. The agenda provided by Menarini was again different.

According to the agenda provided by Menarini, the meeting commenced on Saturday, 6 July with registration at 9am. Four talks of 30 minutes each were held in Hall A. Lundbeck was described as sponsor for the first talk 'Reducing Alcohol related harm – what steps can well (sic) all take to help our patients'. The second talk 'GMC update' listed Chiesi as the sponsor. The third talk 'Management of chronic stable angina: an update' listed Menarini as sponsor and the final talk 'Gout: same old, same old?' also listed Menarini as sponsor. In parallel, four talks each of 30 minutes were listed for Hall B. These being 'Management of chronic dermatitis', Understanding and managing depression and anxiety: a practical guide, 'Type 2 Diabetes – New therapies' and 'New concepts in the management of heart failure'. The listed sponsors were Lundbeck and two named pharmaceutical companies. There was no named sponsor for one of the talks. The post lunch session ran in Hall A and none of the five non-clinical talks were sponsored by pharmaceutical companies. At 4–5pm the agenda stated 'ARM/ AGM BJMA'. On Sunday, 7 July the first talk at 10.30am was 'New concepts in asthma management' which did not list a sponsor. This was followed by 'Management of Actinic keratosis' and 'The changing face of Anticoagulation in Primary Care: new solutions to old problems' sponsored by a named company and Bayer respectively. This was followed by the declaration 'The Pharmaceutical companies have only paid towards the speaker fees and catering cost for the scientific meeting. They haven't influenced the content of the slides'. The final two pages of the agenda included two photographs, one of a flag and the other of a man playing a drum and what appeared to be women dancing.

The Panel noted that the case preparation manager had written to the secretary of the local organising committee to ask for the details of the pharmaceutical companies sponsoring the event. The response reiterated that the event was the 34th reunion of the BJMA Scientific Conference. The secretary confirmed that there was a mixture of '… reputable sponsors, including various banks, reputable solicitors, specific accountant, GMC and pharmaceutical companies. The secretary confirmed that the money raised from pharmaceutical companies, which took part in the exhibition, was only to fund the scientific section of the conference. The organisers stated that they took care to make sure that the scientific sections and exhibition halls were in an area of the hotel which was away and separate from any public areas which were accessed only by the registered delegates attending the scientific meeting.

The Panel noted that the meeting in question was organised by the BJMA. The BJMA was of course free to organise whatever meetings it wanted to for its own members. If there had been no involvement from pharmaceutical companies then the meeting would not have been covered by the Code. The involvement of the pharmaceutical companies meant the matter was covered by the Code. According to the agenda provided by Menarini six pharmaceutical companies had provided sponsorship in the form of paying speakers. The agenda referred to 'Exhibits Open'. It was not clear from the agenda provided by Menarini which companies had exhibition space. This agenda included the declaration 'The pharmaceutical companies have only paid towards the speaker fees and catering costs for the scientific meeting. They have not influenced the content of the slides'. This declaration also appeared in the agenda provided by the complainant although no pharmaceutical companies were listed. In addition, the documents provided by the complainant did not mention pharmaceutical company sponsorship on the documents sent to announce the meeting nor on the more detailed documents which described all the activities.

The Panel was also mindful of the established principle that a pharmaceutical company could not support a third party activity if that activity was itself in breach of the Code.

Menarini provided their own attendance list which stated twenty-two GPs, fourteen other GPs, one primary care trust manager, six consultants and one specialist registrar were in attendance. The company did not appear to have a full list of attendees to the meeting. A post meeting list had been provided by BJMA to some of the companies. The majority of attendees were general practitioners and hospital doctors. The vast majority were listed as from the UK a few of those listed were from India, some were listed as retired. Attendees had a very wide range of specialities including consultant anaesthetists, urologists, gynaecologists, paediatricians, cardiologists, orthopaedics, sexual health and geriatricians. The Panel noted that the professional link among the disparate groups listed and the basis of BJMA membership was that they were graduates from certain Indian medical colleges.

The Panel noted that a wide range of groups existed within the medical and scientific communities. Membership of certain groups might be based

on medical speciality or professional status or on different criteria such as cultural or, as with the BJMA, academic heritage. In the Panel's view, when membership was based on matters other than medical speciality and professional status, companies should be especially vigilant to ensure the relevant requirements of the Code were satisfied. In addition, given the wide range of clinical roles held by attendees, it was difficult to see how the limited educational agenda could be of sufficient professional relevance to all attendees.

The Panel queried whether the scientific content was reasonable in relation to the requirements of the Code. According to the agenda provided by Menarini, scientific sessions ran from 10am to 12 noon on the Saturday (including a 30 minute GMC update) and from 10.30 – 12 on the Sunday. This gave a maximum scientific content of around three hours bearing in mind the parallel nature of the Saturday sessions. In addition, on Saturday afternoon there were talks from 1.30 until 3.45pm, only one of which 'Dealing with partnership disputes in general practice' might possibly be considered as relevant given the requirements of Clause 19. The four other talks related to financial matters including investment in Indian real estate. The BJMA ARM/AGM ran for an hour. The 30 minute GMC update on Saturday might possibly be considered as relevant to Clause 19. The refreshments listed were lunch on both days and refreshments after the Saturday afternoon session. The Panel noted that a number of companies paid for exhibition space and queried whether the amount charged was reasonable.

It appeared to the Panel that the main purpose of the meeting was the social/cultural aspects and in its view this was reinforced by the documentation for the meeting. The Panel did not consider that the meeting met the requirements of the Code. The two day meeting had a maximum scientific content of around three hours. The meeting was mainly a social event and it appeared to the Panel that the limited scientific programme was not the main purpose of the event. The Panel had little information about the costs of putting on the exhibition on the Saturday. The organising secretary had stated that the money paid by pharmaceutical companies 'hardly met the cost of the scientific meeting'. This seemed at odds with the activities arranged and that each delegate was to pay £60 to cover everything other than accommodation. Menarini had paid for two speakers and for an exhibition stand. Menarini had chosen the subject areas and speakers and the meeting organisers had agreed that they were suitable. The fact that companies had sponsored speakers was also of concern. Menarini had briefed the speakers which appeared to be at odds with the declaration on the programme that pharmaceutical companies had not influenced the content of the slides. It appeared that companies had limited information about the meeting before agreeing to support it. Menarini should have ensured that comprehensive copies of documentation had been supplied by the organisers.

The Panel noted that Menarini representatives had left the meeting early on the Saturday afternoon.

In relation to alleged promotion to the public, the Panel noted Menarini's submission that only health professionals and supportive (sic) administrative staff accessed the exhibition area. The complainant had not provided any details regarding this aspect of his/her allegation. The complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel considered that this had not been discharged in relation to the alleged promotion to the public and no breaches of Clauses 22.1 and 22.2 were ruled.

Taking all the circumstances into account the Panel considered that the arrangements for the meeting did not meet the requirements of Clause 19 such that it was not a meeting for a primarily educational purpose as set out in that clause. Pharmaceutical company involvement in the agenda ie sponsoring speakers and paying for exhibition space and the impression given by pharmaceutical company involvement was unacceptable. The Panel ruled a breach of Clause 19.1 with regard to Menarini's involvement. The Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel noted that Clause 2 was used as a sign of particular censure and reserved for such use. The supplementary information referred to excessive hospitality. The Panel decided the circumstances were such as to bring discredit upon and reduce confidence in the pharmaceutical industry and a breach of Clause 2 was ruled.

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CASE AUTH/2631/8/13 – BAYER

RESPONSE

Bayer stated that it sponsored what it believed to be a scientific meeting organised by an independent third party. All approval procedures were followed according to Bayer's standard operating procedure (SOP).

The meeting sponsorship was agreed by the Bayer key account manager (KAM) and approved by the regional business manager (RBM). The speaker was arranged by the professional relations team (PRT) and the speaker agreement approved by the general medicine business unit in head office.

Bayer made only one payment to the BJMA and this was £1,000 for an exhibition stand. The Bayer KAM and RBM had an initial meeting in November 2012 with a BJMA representative to discuss sponsorship of the 34th annual scientific meeting. During this meeting many questions were raised with regard to the arrangements with the need to comply with the Code in mind. Copies of the email correspondence dated 30 January 2013 in which further questions, raised by head office, were posed and an email, letter and invoice from BJMA were provided. The letter of 26 January 2013 clearly referred to a scientific meeting on both days with over 500 delegates. Bayer was not aware of any arrangement other than the scientific programme until the lunch time on the first day of the meeting 6 of July 2013 and consequently

the Bayer representatives, having been faced with a *fait accompli*, expressed their concerns. Despite the lunch arrangements it must be emphasised that at no time was the scientific programme or exhibition accessible to the general public. A GP with special interest in cardiology was contacted by the head office professional relations manager and agreed to speak at the meeting. He was briefed about the meeting arrangements.

The Bayer KAM's provided a detailed account of the meeting arrangements.

Copies of the floor plans for Saturday 6 July and Sunday, 7 July document were provided.

Bayer paid £1,000 for the exhibition stand which was to be used to hire the meeting rooms for the BJMA scientific meeting and for catering for health professionals on Saturday lunchtime and coffee/tea.

On Saturday: two Bayer staff attended (8am-4.30pm) and (8am-3.30pm) and on Sunday: three (10am-1.30pm as meeting over-ran by approximately one hour) from Bayer attended. No Bayer staff were invited to attend or attended the Gala dinner; the Gala dinner had no connection to the scientific programme and was not part of its sponsorship agreement.

Bayer was asked to provide a speaker to talk on 'Anticoagulation in Primary Care' in April 2013. The Bayer KAM asked the PRT team to suggest a suitable speaker for this event, providing them with the BJMA 2013 letter dated 26 January 2013, draft conference agenda, and any other information during telephone conversations. After contacting a number of potential candidates a speaker was agreed. Speaker honorarium discussion was between the PRT team and the speaker, neither the KAM nor the BJMA had any involvement in the sum agreed. Bayer briefed the speaker for the meeting, adapting an existing speaker briefing document which was approved before discussion with the speaker. The speaker briefing was undertaken by a Bayer representative, prior to the meeting. The speaker used an approved slide set which was provided by Bayer on the day of the meeting by the representative.

Bayer's understanding of the meeting programme was that this was a purely scientific conference for health professionals, who were members of the BJMA medical association, from across the UK. The Bayer KAM and RBM met the local organising secretary in November 2012 (an account of the meeting discussion was provided). The meeting organiser outlined the meeting and invited Bayer to support it. At no time was there any reference to the meeting being anything other than a scientific meeting. The emails and conversations with the meeting organiser were all with regard to BJMA's scientific meeting and this was what Bayer agreed to be involved with. Approximately 45 to 50 delegates attended the Bayer scientific session.

Bayer submitted that the food was of ordinary Indian restaurant cooking standard, it was served from two tables to people who queued. The food was prepared by an off-site caterer, who set up two large white vans in the car park with a large awning, preparing and cooked the food on site. Bayer was not involved in the catering arrangements and did not know the costs.

The catering arrangements for the Saturday were as follows: On the mezzanine floor, designated for the scientific meeting, a coffee station was available throughout most of the day. These refreshments were for health professionals moving between the two meeting rooms and also for exhibition stand staff. The route to the meeting area clearly stated the way for health professionals. Health professionals were served lunch in a communal dining hall on a different floor and no pharmaceutical company activity was present in this area. Whilst the two separate events were served lunch in the same area, Bayer was assured that the two activities were funded via separate sources. On the Sunday coffee/tea was available in the meeting room. This was the only refreshment on offer and was only available to the health professionals in the meeting room. Bayer did not know catering costs per head.

In conclusion, Bayer sponsored a scientific meeting in good faith on the information provided by BJMA, it was not aware of any other arrangements or activities associated with the 34th Annual Scientific Meeting of the Bihar Jharkhand Medical Association. All approvals were in accordance with Bayer SOPs and consequently Bayer submitted that it had not breached Clauses 2, 9.1, 19.1, 22.1 or 22.2.

Bayer was provided with a copy of the further comments from the meeting organiser and had no further submission to make.

PANEL RULING IN CASE AUTH/2631/8/13

The Panel's general comments above apply here.

The Panel examined the agenda provided to the pharmaceutical company named in the complaint by the meeting organisers. This version of the agenda named a total of seven pharmaceutical companies. The complaint had been taken up with each of the additional six companies (one of which was Bayer) by the case preparation manager. The version of the agenda provided to the company named in the complaint by the meeting organisers differed to the agenda provided by the complainant. The Panel referred to the agenda provided by the pharmaceutical company named by the complainant. Bayer did not provide a copy of the agenda but stated that it was displayed at the meeting.

According to the agenda provided by the pharmaceutical company named by the complainant the meeting commenced on Saturday, 6 July with registration at 9am. Four talks of 30 minutes each were held in Hall A. Lundbeck was described as sponsor for the first talk 'Reducing Alcohol related harm – what steps can well (sic) all take to help our patients'. The second talk 'New concepts in asthma management' listed Chiesi as the sponsor. The third talk 'Management of chronic stable angina: an update' listed Menarini as sponsor and the final talk 'Gout: same old, same old?' listed another named company as sponsor. In parallel, four talks each of 30 minutes were listed for Hall B. These being 'Management of

chronic dermatitis', Understanding and managing depression and anxiety: a practical guide, 'Type 2 Diabetes – New therapies' and 'New concepts in the management of heart failure'. The listed sponsors were Lundbeck, two named companies and there was no named sponsor for one third talk. The post lunch session ran in Hall A and none of the five non-clinical talks were sponsored by pharmaceutical companies. At 4–5pm the agenda stated 'ARM/ AGM BJMA'. On Sunday, 7 July the first talk at 10.30am was 'GMC Update'. This was followed by 'Management of Actinic keratosis' and 'The changing face of Anticoagulation in Primary Care: new solutions to old problems' sponsored by a named company and Bayer. This was followed by the declaration 'The pharmaceutical companies have only paid towards the speaker fees and catering cost for the scientific meeting. They haven't influenced the content of the slides'. The final page of the agenda included two photographs, one of a flag and the other of a man playing a drum and what appeared to be women dancing.

The Panel noted that the case preparation manager had written to the secretary of the local organising committee to ask for the details of the pharmaceutical companies sponsoring the event. The response reiterated that the event was the 34th reunion of the BJMA Scientific Conference. The secretary confirmed that there was a mixture of '… reputable sponsors, including various banks, reputable solicitors, specific accountant, GMC and pharmaceutical companies. The secretary confirmed that the money raised from pharmaceutical companies, which took part in the exhibition, was only to fund the scientific section of the conference. The organisers stated that they took care to make sure that the scientific sections and exhibition halls were in an area of the hotel which was away and separate from any public areas which were accessed only by the registered delegates attending the scientific meeting.

The Panel noted that the meeting in question was organised by the BJMA. The BJMA was of course free to organise whatever meetings it wanted to for its own members. If there had been no involvement from pharmaceutical companies then the meeting would not have been covered by the Code. The involvement of the pharmaceutical companies meant the matter was covered by the Code. According to the agenda provided by Lundbeck seven pharmaceutical companies had provided sponsorship in the form of paying speakers. The agenda referred to 'Exhibits Open'. It was not clear from the agenda provided by Lundbeck which companies had exhibition space. This agenda included the declaration 'The pharmaceutical companies have only paid towards the speaker fees and catering costs for the scientific meeting. They have not influenced the content of the slides'. This declaration also appeared in the agenda provided by the complainant although no pharmaceutical companies were listed. In addition, the documents provided by the complainant did not mention pharmaceutical company sponsorship on the documents sent to announce the meeting nor on the more detailed documents which described all the activities.

The Panel was also mindful of the established principle that a pharmaceutical company could not support a third party activity if that activity was itself in breach of the Code.

Bayer had not provided a list of health professional attendees. Bayer provided a copy of the meeting request form which listed, as meeting contacts, six GPs and eight hospital doctors by name. In addition, another 253 unnamed attendees were listed as present. Bayer stated that around 45 – 50 delegates attended the Bayer scientific session. Bayer did not appear to have a full list of attendees to the meeting. A post meeting list had been provided by BJMA to some of the companies. The majority of attendees were general practitioners and hospital doctors. The vast majority were listed as from the UK a few of those listed were from India, some were listed as retired. Attendees had a very wide range of specialities including consultant anaesthetists, urologists, gynaecologists, paediatricians, cardiologists, orthopaedics, sexual health and geriatricians. The Panel noted that the professional link among the disparate groups listed and the basis of BJMA membership was that they were graduates from certain Indian medical colleges.

The Panel noted that a wide range of groups existed within the medical and scientific communities. Membership of certain groups might be based on medical speciality or professional status or on different criteria such as cultural or, as with the BJMA, academic heritage. In the Panel's view, when membership was based on matters other than medical speciality and professional status, companies should be especially vigilant to ensure the relevant requirements of the Code were satisfied. In addition, given the wide range of clinical roles held by attendees, it was difficult to see how the limited educational agenda could be of sufficient professional relevance to all attendees.

The Panel queried whether the scientific content was reasonable in relation to the requirements of the Code. According to the agenda provided by Lundbeck, scientific sessions ran from 10am to 12 noon on the Saturday and from 10.50 – 12 noon on the Sunday. This gave a maximum scientific content of just over three hours bearing in mind the parallel nature of the Saturday sessions. In addition, on Saturday afternoon there were talks from 1.30pm until 3.45, only one of which 'Dealing with partnership disputes in general practice' might possibly be considered as relevant given the requirements of Clause 19. The four other talks related to financial matters including investment in Indian real estate. The BJMA ARM/AGM ran for an hour. The 20 minute GMC update on Sunday (10.30–10.50am) might possibly be considered as relevant to Clause 19. The refreshments listed were lunch on both days and refreshments after the Saturday afternoon session. The Panel noted that a number of companies paid for exhibition space and queried whether the amount charged was reasonable. The Panel noted that Bayer stated that lunch was served to all attendees not just those health professionals attending the meeting. It appeared to the Panel that the main purpose of

the meeting was the social/cultural aspects and in its view this was reinforced by the documentation for the meeting. The Panel did not consider that the meeting met the requirements of the Code. The two day meeting had a maximum scientific content of just over three hours. The meeting was mainly a social event and it appeared to the Panel that the limited scientific programme was not the main purpose of the event. The Panel had little information about the costs of putting on the exhibition on the Saturday. The organising secretary had stated that the money paid by pharmaceutical companies 'hardly met the cost of the scientific meeting'. This seemed at odds with the activities arranged and that each delegate was to pay £60 to cover everything other than accommodation. The fact that companies had sponsored speakers was also of concern. Bayer had paid for one speaker and for an exhibition stand. The company briefed the speaker and had provided slides for the speaker to use which was at odds with the declaration on the programme that pharmaceutical companies had not influenced the content of the slides. It appeared that companies had limited information about the meeting before agreeing to support it. Bayer should have ensured that comprehensive copies of documentation had been supplied by the organisers. It appeared that Bayer had not seen a copy of the agenda prior to the meeting.

In relation to alleged promotion to the public, the Panel noted Bayer's submission that only registered delegates accessed the exhibition area. The complainant had not provided any details regarding this aspect of his/her allegation. The complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel considered that this had not been discharged in relation to the alleged promotion to the public and no breaches of Clauses 22.1 and 22.2 were ruled.

Taking all the circumstances into account the Panel considered that the arrangements for the meeting did not meet the requirements of Clause 19 such that it was not a meeting for a primarily educational purpose as set out in that clause. Pharmaceutical company involvement in the agenda ie sponsoring speakers and paying for exhibition space and the impression given by pharmaceutical company involvement was unacceptable. The Panel ruled a breach of Clause 19.1 with regard to Bayer's involvement. The Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel noted that Clause 2 was used as a sign of particular censure and reserved for such use. The supplementary information referred to excessive hospitality. The Panel decided the circumstances were such as to bring discredit upon and reduce confidence in the pharmaceutical industry and a breach of Clause 2 was ruled.

Case AUTH/2617/7/13:

Complaint received **22 July 2013**
Case completed **25 October 2013**

Case AUTH/2628/8/13:

Complaint received **7 August 2013**
Case completed **27 November 2013**

Case AUTH/2629/8/13:

Complaint received **7 August 2013**
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Case AUTH/2631/8/13:

Complaint received **7 August 2013**
Case completed **25 October 2013**

CASE AUTH/2624/8/13

SENIOR PUBLIC HEALTH SPECIALIST v HRA PHARMA

Conduct of representative

A senior public health specialist alleged that the way in which a representative from HRA Pharma had communicated with her and one of her public health colleagues about the quality of the sexual health services provided in the local area and the training provided to pharmacists across the wider geographical area, breached the Code. The representative was concerned that ellaOne (ulipristal acetate), which was indicated for use in emergency contraception (EC), was not available locally through the pharmacy scheme for EC. An email from the representative to the complainant included:

> **'I appreciate there will be valid reasons for this decision, but it concerns me that because of the very active, and well promoted, pharmacy scheme for EC in … that women are actually receiving a poorer service than in other areas with a less well used pharmacy scheme. That may sound strange, but having spoken to GPs at meetings in ... most of them say they use very little emergency contraception as they refer girls to the pharmacy, where they can only get [a named product] unless they present after 72 hours (which very few do). … So, of the 3 options for women to receive emergency contraception, the 2 options (GPs and [contraception and sexual health services]) where they *could* be offered emergency contraception in line with Faculty guidance – ie to be offered all 3 choices – are being accessed less and less in favour of the one option – the pharmacy – where they can only be offered one choice. So what I am trying to point out, is that because [the local area] has been so good at promoting its pharmacy scheme, that is now the most chosen option to access EC, to the detriment of [contraception and sexual health services] and GPs, but it only offers the least effective method.**
>
> **Having read the [Health and Wellbeing] Board draft strategy, I see there are plans to increase access to EC, but surely if there is such inequity of service, that should be improved as well. I have been discussing the possibility of including ellaOne in the pharmacy scheme for use before 72 hours with yourself and [a named person] before you for over 2 years now. In that time there have been potentially over 60 pregnancies each year that could have been prevented. …'**

In a written response to the representative, the complainant stated that she found the email concerning and offensive and considered that it made unsubstantiated claims about the quality of the service offered in the local area and the number of the unintended pregnancies in the city. The complainant acknowledged the apology she had received from the representative and her manager, and went on to state:

> **' … We take great offence regarding your allegations of a poorer service, working out with faculty guidance and increasing unintended pregnancies. Evidence from service providers demonstrates that the majority of women who attend for EC are offered a copper coil and data shows an increase of women choosing this method. For those who choose oral hormonal contraception the majority present within 72 hours and if for any reason they are unable to have [a named product] are referred on appropriately. Commissioned services are underpinned by specifications and [patient group directions] that are evidence based and meet with [National Institute for Health and Care Excellence] and Faculty guidance in addition we have demonstrable evidence that they are efficient and cost effective.**
>
> **Assessment of need is on-going as is assessment of service provision. I am assured that women continue to have appropriate choice in where they go to receive emergency contraception as well as the contraceptive they receive.'**

In response to a request for further information by the Authority, the complainant noted that the representative had referred to discussing the matter with the head of service for the sexual health services in the provider trust. Although the complainant did not know the detail of that conversation or the content of the conversation with GPs, her interpretation from the email was that the representative had directed information on policy decisions to prescribers rather than commissioners. The representative had inferred that providers were concerned about EC provision, but this had never been raised directly with the complainant by any providers.

The complainant alleged that the claim about the prevention of over 60 unintended pregnancies if ellaOne had been used was over exaggerated and lacked objectively as there was no evidence. The complainant acknowledged that company trials and research had demonstrated that potential but it was potential rather than fact.

The complainant also complained about an email sent by the representative to a colleague which stated in relation to proposed meetings about pharmacy training:

> **'Although I have supported these meetings in the past, I don't think I can justify continuing to support them as national guidance came out around 18 months ago, and this training isn't in line with that guidance. Other areas around the country provide training which is in line with the guidance so it's not really ethical for me to support anything else.'**

The detailed response from HRA Pharma is given below.

The Panel noted that the representative had sent two emails to people involved in contraception and sexual health service provision. The first email was in response to a request for support for two EC training sessions for pharmacists. The representative declined and stated that it would not be ethical for her to support the proposed training as it was not in line with national guidance. In her second email which was to the complainant, the representative criticised local EC service provision and noted that because, locally, women were more likely to access EC via a pharmacy rather than from a GP or a contraception and sexual health service, they were only offered one named product rather than having the choice of three methods (including ellaOne). The representative was thus concerned that women in the area were 'actually receiving a poorer service than in other areas with a less well used pharmacy scheme'. The representative implied that by visiting a pharmacy, women were not being offered EC in line with Faculty [of Sexual & Reproductive Healthcare] guidance. The representative referred to a named product as 'the least effective medicine' and noted that in the two years she had unsuccessfully discussed the possibility of including ellaOne in the local pharmacy scheme, there had potentially been over 120 pregnancies which could have been prevented. Finally the representative stated that she would be happy to provide further information or a business case to help bring the local EC service provision in line with faculty guidance.

The Panel noted that in alleging a breach of the Code, the complainant had referred to a clause which dealt with advance notification of new products or product changes. The Panel noted that ellaOne was a licensed medicine. The email had not promoted the medicine outwith its marketing authorization or in a manner inconsistent with the particulars listed in the SPC. No breach of the Code was ruled in that regard.

The Panel noted that by sending the email to the complainant, the representative had, in effect, created and distributed her own promotional material which had not been certified prior to use; the representative had thus failed to maintain high standards. A breach of the Code was ruled as acknowledged by HRA Pharma.

The Panel noted that the email to the complainant promoted ellaOne and included, *inter alia*, a claim that, had it been more widely used locally, potentially more than 120 pregnancies could have been prevented over a 2 year period. The Panel noted HRA's submission that that claim was not inconsistent with the differences in relative risk contained in the SPC when applied to the local population in question. Nonetheless, it was not clear how the number of potentially preventable pregnancies had been calculated; there was no reference to the differences in absolute risk and there was no reference to the potential failure rate with ellaOne. Overall, the Panel considered that in the context in which it had been presented, the claim was misleading and exaggerated. Breaches of the Code were ruled as acknowledged by HRA Pharma.

The Panel considered that both emails disparaged local EC service provision. A breach of the Code was ruled as acknowledged by HRA Pharma.

The Panel noted its rulings above and considered that sending the emails at issue was a serious breach of professionalism and that in doing so the representative had failed to maintain a high standard of ethical conduct. The representative had also failed to comply with all the relevant requirements of the Code. A breach of the Code was ruled as acknowledged by HRA Pharma.

The Panel noted that a ruling of a breach of Clause 2 of the Code denoted particular censure. The Panel noted HRA Pharma's submission that the representative's email to the complainant had been an 'uncharacteristic lapse in professional judgement'. In the Panel's view both emails were unprofessional and disparaging and were such as to bring discredit upon, and reduce confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

Upon appeal by HRA Pharma, the Appeal Board noted that the company had taken swift, positive action in response to the complaint and had acknowledged that what the representative had written was wholly unacceptable. In an unreserved email apology to the complainant, the representative acknowledged that her earlier email was 'inappropriate and unprofessional'. In his unreserved apology to the complainant, the general manager described the representative's email as 'inappropriate and appalling'. The national sales manager had also written to the complainant stating that the episode had clearly fallen below company standards. The Appeal Board considered that despite the fulsome and sincere apologies from the company and clear acknowledgement all round that the emails to the complainant and her colleague should never have been sent, the fact that they had, in itself, brought discredit upon, and reduced confidence in, the pharmaceutical Industry. The Appeal Board thus upheld the Panel's ruling of a breach of Clause 2. The appeal on this point was unsuccessful.

A senior public health specialist complained about the conduct of a HRA Pharma UK & Ireland Ltd key account manager in the course of promoting ellaOne (ulipristal acetate) for emergency contraception (EC).

COMPLAINT

The complainant alleged that the way in which the representative in question had communicated with her and one of her public health colleagues about the quality of the sexual health services and the training provided to pharmacists across the geographical area, breached Clauses 3.2, 7.2, 7.10, 8.2 and 15.2 of the Code.

The complainant stated that the representative had sent her the following email on 26 July 2013:

'We met earlier this year to discuss including ellaOne (ulipristal acetate) in the pharmacy scheme, but I understand that since then it has been decided not [to] move forward on this yet.

I appreciate there will be valid reasons for this decision, but it concerns me that because of the very active, and well promoted, pharmacy scheme for EC in … that women are actually receiving a poorer service than in other areas with a less well used pharmacy scheme. That may sound strange, but having spoken to GPs at meetings in …, most of them say they use very little emergency contraception as they refer girls to the pharmacy, where they can only get [a named product] unless they present after 72 hours (which *very* few do). They could also go to … , but again, …, their use of emergency contraception is falling as girls just go the pharmacist, and indeed [a named pharmacy] give out around 250 units [of] emergency contraception each month, which is way in excess of what the C&SH [contraception and sexual health services] service give out. So, of the 3 options for women to receive emergency contraception, the 2 options (GPs and C&SH) where they *could* be offered emergency contraception in line with Faculty guidance – ie to be offered all 3 choices – are being accessed less and less in favour of the one option – the pharmacy – where they can only be offered one choice. So what I am trying to point out, is that because … has been so good at promoting its pharmacy scheme, that is now the most chosen option to access EC, to the detriment of C&SH and GPs, but it only offers the least effective method.

I looked at what proportion of all EC is given out as ellaOne in primary care across my territory, and as you can see … gives out one of the lowest proportions, with just over 1 out of every 50 women getting ellaOne. That is because the vast majority of women use pharmacy as their source of EC … .

Having read the [Health and Wellbeing] Board draft strategy, I see there are plans to increase access to EC, but surely if there is such inequity of service, that should be improved as well. I have been discussing the possibility of including ellaOne in the pharmacy scheme for use before 72 hours with yourself and … for over 2 years now. In that time there have been potentially over 60 pregnancies *each year* that could have been prevented. I appreciate it has been a time of huge change, but teenage conceptions remain a problem, and other areas are now reviewing their pharmacy schemes as part of the overall NHS structural change and bringing them in line with Faculty guidance. If I can be of any assistance in helping that happen in …, I'd be happy to provide further information, or a business case.'

In a written response to the representative, the complainant stated that she found the email concerning and offensive and considered that it made unsubstantiated claims about the quality of the service offered in … and the number of the unintended pregnancies. The complainant acknowledged the apology she had received from the representative and her manager, and went on to state:

'As the lead commissioner for sexual health services in … I believe that we currently provide an excellent service to all who present for services, although I accept that there is always room for improvement. As you know I work closely with the provider service leads in … as well as my public health colleagues across [the area] and I have shared your email with them. We take great offence regarding your allegations of a poorer service, working out with faculty guidance and increasing unintended pregnancies. Evidence from service providers demonstrates that the majority of women who attend for EC are offered a copper coil and data shows an increase of women choosing this method. For those who choose oral hormonal contraception the majority present within 72 hours and if for any reason they are unable to have [a named product] are referred on appropriately. Commissioned services are underpinned by specifications and [patient group directions] that are evidence based and meet with [National Institute for Health and Care Excellence] and Faculty guidance in addition we have demonstrable evidence that they are efficient and cost effective.

Assessment of need is on-going as is assessment of service provision. I am assured that women continue to have appropriate choice in where they go to receive emergency contraception as well as the contraceptive they receive.'

In response to a request for further information by the Authority, the complainant noted, with regard to Clause 3.1, that the representative had referred to discussing the matter with the head of service for the sexual health services in the provider trust. Although the complainant did not know the detail of that conversation or the content of the conversation with GPs, her interpretation from the email was that the representative had directed information on policy decisions to prescribers rather than commissioners. The representative had inferred that providers were concerned about EC provision, but this had never been raised directly with the complainant by any providers.

With regard to Clause 7.10, the complainant alleged that the claim about the prevention of over 60 unintended pregnancies if ellaOne had been used was over exaggerated and lacked objectively as there was no evidence of that being the case. The complainant acknowledged that company trials and research had demonstrated that potential but it was potential rather than actual fact.

The complainant also complained about an email sent by the representative to a colleague which stated in relation to proposed meetings about pharmacy training:

'Although I have supported these meetings in the past, I don't think I can justify continuing to support them as national guidance came out around 18 months ago, and this training isn't in

line with that guidance. Other areas around the country provide training which is in line with the guidance so it's not really ethical for me to support anything else.'

When writing to HRA Pharma, the Authority asked that, in addition to the clauses cited by the complainant, it also respond in relation to Clauses 2 and 9.1.

RESPONSE

HRA Pharma noted that the representative concerned was a contract sales representative. In responding to this complaint, HRA Pharma had liaised closely with the contract sales company.

The email sent by the representative and the cause of this complaint contravened both HRA Pharma's and the contract sales company's internal procedures and training pertaining to the Code and specifically instructions about communications with health professionals. In the light of this contravention, the representative was immediately suspended pending an investigation by the contract sales company, which had resulted in formal disciplinary action.

Both HRA Pharma and the contract sales company treated adherence to the Code with high importance, and both had taken immediate corrective and augmentative measures. Both companies deeply regretted that despite full training and clearly defined operating procedures the representative had acted such that a health professional had complained.

With regard to Clause 3.2, HRA Pharma stated that whilst it did not seek to minimise the breaches of the Code inherent in the email, the claims made were not out of line with the marketing authorization and summary of product characteristics (SPC), which specifically contained a table of odds ratios demonstrating that ellaOne was significantly more effective than a named product over the period 0 – 72 hours. Additionally the claims solely pertained to the use of the medicine as an emergency contraceptive which was clearly within the scope of the SPC.

In her letter, the complainant referred to elements of the supplementary information to Clause 3.1 which concerned advance notification of new products. EllaOne had been available and licensed since 2009, so there was no reason why discussions with clinical leads could not be conducted.

In conclusion HRA Pharma denied a breach of Clause 3.2.

HRA Pharma noted that the email sent by the representative contained promotional claims, did not contain prescribing information and had not been through the company's approval and certification process and therefore was not certified for release. Claims had been made without providing references (and proper context) to substantiate them. The claim of a possible additional 60 pregnancies prevented was not inconsistent with the differences in relative risk contained in the SPC when applied to the local population, but this calculation was not adequately explained in the email and there was also no reference to the differences in absolute risk, thus the potential benefit was presented without proper contextual balance. Additionally there was no mention of the potential failure rate of ellaOne ie number of pregnancies that would still occur, hence HRA Pharma accepted that the email had breached Clauses 7.2 and 7.10.

The email contravened the internal HRA Pharma Field Briefing document, 'Communication with [health professionals] via e mail' and also was in breach of the contract sales company's standard operating procedure (SOP), 'COM 008 – Use of e-mail and other methods of communication by field force'. Copies of these procedures were provided. HRA Pharma and the contract sales company believed that these procedures represented good practice in relation to the management of communications between sales people and health professionals.

HRA Pharma acknowledged that the email, at best, was clumsily worded and at worst was plainly pejorative in its description of the emergency contraceptive services available in Newcastle. HRA Pharma accepted breaches of Clauses 8.2 and 15.2.

HRA Pharma noted that the representative had spent many years in the pharmaceutical industry, mostly as a sales representative. She passed her ABPI examination with distinction and had, until now, enjoyed an unblemished record. Given this, her maturity and also the training she had received as well as the understanding demonstrated during that training, it was hard to understand why she wrote the email at all. HRA Pharma was certain that it was a momentary lapse of professional judgment which was entirely out of character. HRA Pharma accepted a breach of Clause 9.1 in that the representative failed to maintain high standards at all times. HRA Pharma referred to its comments with regard to Clause 15.2 and held up her previous unblemished record as mitigation.

Given the overriding importance of Clause 2, HRA Pharma had outlined the most pertinent points so that this incident, which appeared to be an uncharacteristic lapse in professional judgment by one of its most experienced and trusted representatives, could be placed in its proper context.

Both HRA Pharma and the contract sales company treated adherence to the Code with high importance, and both had extensive training and robust procedures in place to ensure that their representatives complied with the Code. On becoming aware of this complaint, both companies took immediate corrective actions and instigated further measures. Details were provided.

Contract Sales Company

Investigation:

- The representative was suspended whilst it undertook an internal investigation. This involved undertaking an investigation with the representative, the analysis of training records and validations on the company's internal SOPs (including – Use of email and other methods of communication by field force), other internal SOPs and the Code. The representative was up-to-date with training on the Code as part of the company-wide refresher training.

Corrective action:

- A disciplinary procedure was completed
- The representative would undergo further refresher training on both the Code and relevant SOP

Augmentative actions:

- Within the next month the company would review its SOP to ensure it remained fit for purpose and all directions were being adhered to by the relevant employees
- Within the next month remote training would be provided to the entire field force to highlight the importance of adhering to the SOP and clearly outline the implications of not doing so
- Managers would be required to discuss the SOP with each of their reports during the next scheduled field visit and this would be documented in the field visit database.

HRA Pharma

- The representative and her HRA Pharma line manager had formally apologised in writing to the complainant
- A letter had been sent to the complainant to apologise on behalf of HRA Pharma, and also to let her know that it had taken appropriate corrective actions
- HRA Pharma's internal training records clearly showed the training given regarding the Code and specifically recorded the team's, and specifically the representative's, acceptance and understanding of the email protocol
- HRA Pharma had re-issued and strengthened its guidance for representatives on email communication and would implement further Code training at the cycle briefing in early September.

Whilst HRA Pharma and the contract sales company were deeply disappointed that this had happened they were confident, having reviewed procedures and the training provided to representatives by both companies, that they had the appropriate controls in place to avoid, as far as was possible, such occurrences in the future.

In conclusion, an experienced and trusted representative had flagrantly ignored clear written instructions and acted in contravention of her documented training on the Code, received from both companies. This action was completely out of character for her and therefore completely arbitrary and unforeseeable. Both companies had acted decisively and urgently to manage the situation and HRA Pharma had provided a timely and unreserved apology to the complainant. Given the circumstances as set out, HRA Pharma did not accept that a ruling of a breach of Clause 2 was warranted.

PANEL RULING

The Panel noted that the representative had sent two emails to people involved in contraception and sexual health service provision. The first email was in response to a request for support for two emergency contraception (EC) training sessions for pharmacists. The representative declined and stated that it would not be ethical for her to support the proposed training as it was not in line with national guidance. In her second email which was to the complainant, a public health specialist, the representative criticised local EC service provision and noted that because, locally, women were more likely to access EC via a pharmacy rather than from a GP or a contraception and sexual health service, they were only offered one product rather than having the choice of three methods (including ellaOne). The representative was thus concerned that women in the area were 'actually receiving a poorer service than in other areas with a less well used pharmacy scheme'. The representative implied that by visiting a pharmacy, women were not being offered EC in line with Faculty [of Sexual & Reproductive Healthcare] guidance. The representative referred to a named product as 'the least effective medicine' and noted that in the two years she had unsuccessfully discussed the possibility of including ellaOne in the local pharmacy scheme, there had potentially been over 120 pregnancies which could have been prevented. Finally the representative stated that she would be happy to provide further information or a business case to help bring the local EC service provision in line with faculty guidance.

The Panel noted that in alleging a breach of Clause 3.2, the complainant had referred to part of the supplementary information to Clause 3.1 which dealt with advance notification of new products or product changes. The Panel noted that ellaOne was a licensed medicine. The email to the complainant only referred to ellaOne as an emergency contraceptive and in that regard had not promoted the medicine outwith its marketing authorization or in a manner inconsistent with the particulars listed in the SPC. No breach of Clause 3.2 was ruled.

The Panel noted that by sending the email to the complainant, the representative had, in effect, created and distributed her own promotional material; the email had not been certified prior to use in accordance with Clause 14. The Panel considered that the representative had thus failed to maintain high standards. A breach of Clause 9.1 was ruled as acknowledged by HRA Pharma.

The Panel noted that the email to the complainant promoted ellaOne and included, *inter alia*, a claim that, had it been more widely used locally, potentially more than 120 pregnancies could have been prevented over a 2 year period. The Panel

noted HRA's submission that that claim was not inconsistent with the differences in relative risk contained in the SPC when applied to the local population in question. Nonetheless, it was not clear how the number of potentially preventable pregnancies had been calculated; there was no reference to the differences in absolute risk and there was no reference to the potential failure rate with ellaOne. Overall, the Panel considered that in the context in which it had been presented, the claim was misleading and exaggerated. Breaches of Clauses 7.2 and 7.10 were ruled as acknowledged by HRA Pharma.

The Panel considered that both emails disparaged local EC service provision. A breach of Clause 8.2 was ruled as acknowledged by HRA Pharma.

The Panel noted its rulings above and considered that sending the emails at issue was a serious breach of professionalism and that in doing so the representative had failed to maintain a high standard of ethical conduct. The representative had also failed to comply with all the relevant requirements of the Code. A breach of Clause 15.2 was ruled as acknowledged by HRA.

The Panel noted that a ruling of a breach of Clause 2 of the Code denoted particular censure. The Panel noted HRA Pharma's submission that the representative's email to the complainant had been an 'uncharacteristic lapse in professional judgement'. In the Panel's view both emails were unprofessional and disparaging and were such as to bring discredit upon, and reduce confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

APPEAL FROM HRA PHARMA

HRA Pharma appealed on the grounds that the particular censure inherent in a ruling of a breach of Clause 2 was not appropriate in the circumstances as the events, and its response to them, had neither reduced confidence in the industry nor brought discredit upon it. Indeed, HRA Pharma submitted that the open way in which it had acknowledged the mistakes made by a single representative, and had addressed them, actually enhanced the reputation of the industry.

HRA Pharma submitted that the ruling might set a precedent that if the Panel judged the breaches to be of significant severity then a breach of Clause 2 was ruled regardless of a company's culture and governance frameworks and any actions it took to acknowledge and prevent a repetition or rectify the situation.

In this instance HRA Pharma submitted that it could not conceive of any further action it could reasonably be expected to have taken and it outlined these actions briefly as follows:

- HRA Pharma employed only experienced representatives via industry respected suppliers,
- Representatives received full and regular training on the Code from the contract sales company and HRA Pharma
- Both HRA Pharma and the contract sales company had specific policies and guidance in place about email communication with health professionals when these events took place
- On becoming aware of the emails, an unreserved written apology was issued by the representative in question
- A further written apology was sent by the responsible line manager
- Further to this, a comprehensive written apology was sent by the managing director which emphasised HRA Pharma's values and how this incident had fallen well below them
- These actions were taken because HRA Pharma did not tolerate disrespectful communication with customers, and held adherence to the Code as the highest priority. HRA Pharma decided to take those actions before it knew that a formal complaint had been made, although there was some overlap in implementation. Ongoing follow-up would also have been taken but for the need to go through the due process of the formal complaint. HRA Pharma's commitment to follow-up remained however, and on completion of the appeal process it would contact the complainant again to de-brief as she requested in response to the managing director's letter
- The complainant was also told about the internal actions taken and that the company had treated this matter responsibly and with due priority
- After an initial investigation into the circumstances, the representative was suspended pending a disciplinary investigation
- This investigation resulted in formal disciplinary action and the representative received further training on the Code. The entire HRA Pharma team also received further specific training on the requirements for email communication with health professionals
- On receipt of the complaint HRA Pharma assessed the evidence and conceded that breaches of Clauses 7.2, 7.10, 8.2, 9.1 and 15.2 had occurred and stated the rationale for each, which demonstrated a proper responsibility towards the Code and the complainant.

HRA Pharma thus submitted that it had acted in a responsible and proper manner, fully in keeping with responsible reasonable expectations placed upon the industry and, in doing so, had in fact acted to augment the credibility and confidence in the industry in the face of a justifiable complaint. Surely the best measure of a company's credibility (and the industry's) was how it acted to ensure, as far was possible, compliance with the Code at all times and to identify and rectify any transgressions.

COMMENTS FROM THE COMPLAINANT

The complainant stated that she was happy with the decisions made and although she had not cited a breach of Clause 2 she was reassured that the Panel considered that the representative's behaviour was in breach of that clause.

APPEAL BOARD RULING

The Appeal Board noted that HRA Pharma had taken swift, positive action in response to the complaint and had acknowledged that what the representative

had written was wholly unacceptable. In an unreserved email apology to the complainant, the representative acknowledged that her earlier email was 'inappropriate and unprofessional'. In his unreserved apology to the complainant, the general manager described the representative's email as 'inappropriate and appalling'. The national sales manager had also written to the complainant stating that the episode had clearly fallen below company standards. The Appeal Board considered that despite the fulsome and sincere apologies from the company and clear acknowledgement all round that the emails to the complainant and her colleague should never have been sent, the fact that they had, in itself, brought discredit upon, and reduced confidence in, the pharmaceutical Industry. The Appeal Board thus upheld the Panel's ruling of a breach of Clause 2. The appeal on this point was unsuccessful.

Complaint received **31 July 2013**

Case completed **19 December 2013**

CASE AUTH/2648/10/13

VOLUNTARY ADMISSION BY ROSEMONT

Failure to sit ABPI Medical Representatives Examination

Rosemont Pharmaceuticals voluntarily advised the Authority that five long standing members of its sales team, although previously exempt from having to take the ABPI Medical Representatives Examination, did not sit the examination when the exemption was removed in 2006. The employees involved had all passed the ABPI Generic Representatives Examination.

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

Rosemont explained that it discovered this issue following a compliance review conducted when the company was taken over by Perrigo earlier in the year. All affected staff would now sit the examinations within the next 12 months and must pass both sets of papers within the next 24 months. If they failed to do so, Rosemont would terminate their employment in a sales capacity. Rosemont assured the Authority that it had robust procedures in place for all new sales employees and was confident that this breach could not happen again.

The detailed response from Rosemont is given below.

The Panel noted that Rosemont accepted that the Code required the individuals concerned to take the Medical Representatives Examination. Due to staff turnover it was unclear why in 2006 when the staff concerned could no longer take the benefit of the exemption, the company did not require them to take the ABPI Medical Representatives Examination. The Panel noted that this particular change had been communicated to companies as an intention well ahead of time. The changes were agreed in principle by ABPI members in 2003 before becoming part of the Code in 2006. The Panel was concerned that the matter only came to light during a compliance audit when Rosemont was taken over by another company. The Panel was also very concerned about Rosemont's proposal for the employees concerned to take the examination. The Panel noted that this was contrary to the supplementary information to the Code which referred to extensions from the Director. The Panel considered that the company should ensure that the relevant employees contacted the Director forthwith and that they should not carry out the medical representative's role unless the appropriate extension had been granted.

The Panel noted that five Rosemont representatives had not passed an appropriate Medical Representatives Examination as required by the Code and that the matter was only identified during a compliance audit some seven years after the exemption was removed. High standards had not been maintained. Breaches of the Code were ruled. On balance the Panel did not consider that the circumstances warranted a breach of Clause 2 which was used as a sign of particular censure and was reserved for such circumstances. No breach of Clause 2 was ruled.

Rosemont Pharmaceuticals Ltd voluntarily advised the Authority that five long standing members of its sales team, although previously exempt from having to take the ABPI Medical Representatives Examination, did not sit the examination when the exemption was removed in 2006. The employees involved had all passed the ABPI Generic Representatives Examination.

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

VOLUNTARY ADMISSION

Rosemont explained that following a full review of compliance which was conducted when the company was taken over by Perrigo earlier in the year, it was noted that five long standing members of its sales team who had passed the ABPI Generic Representatives Examination and who were previously exempt from taking the ABPI Medical Representatives Examination as they were nurses prior to entering the pharmaceutical industry, did not take the ABPI Medical Representatives Examination when the exemption was removed in 2006. This was an oversight by the company at that time which had only recently come to light.

Rosemont submitted that it had started to rectify the situation to ensure compliance with the Code. All of the employees in question had been asked to register to take the morning and afternoon papers (as they passed the morning papers more than 3 years ago). In line with the timings set out in the Code, they would sit the examinations within the next 12 months and must pass both sets of papers within the next 24 months. If they failed to do so, Rosemont would terminate their employment in a sales capacity.

Rosemont submitted that the breach of Clause 16.3 only affected a small number of long standing employees. Rosemont assured the Authority that it had robust procedures in place for all new sales employees and was confident that this breach could not happen again. The procedures stated that all personnel employed in sales must produce their original certificates showing that they had passed the morning and afternoon examinations or agree to undertake the examinations within their first two years of employment within the industry in line with the Code. New employees with only the Generic Representatives Examination were required to pass

the Medical Representatives Examination within two years of changing their duties. Their employment contract stated that failure to do so would result in termination of their employment in sales.

When writing to Rosemont, the Authority asked it to respond in relation to Clauses 2, 9.1 and 16.3 of the Code.

RESPONSE

Rosemont submitted that unfortunately no one who was in sales management from 2006 or before was still with the company, so it was difficult to determine exactly what occurred then. However, all the sales employees in question had submitted that they were not asked by anyone within the company to undertake the ABPI Medical Representatives Examination in 2006. At that time they thought that they were exempt from the need to do so (they were all qualified nurses and were sufficiently qualified as they had passed the ABPI Generic Representatives Examination. Rosemont was, and always had been, a generic company as well as a long standing member of the ABPI.

The sales force role had changed and developed over time and representatives now discussed medicines management of patients who were unable to swallow tablets and capsules. This therefore went beyond the scope of the generic representatives qualification. It appeared that in 2006, those in charge of the sales functions either considered that the generics examination was sufficient to cover the job roles or failed to recognise the need for these employees to sit the examinations.

Rosemont submitted that since 2000 it had been a stipulation that all of its new sales people must have passed the ABPI Medical Representatives Examination or would study and pass the examination as part of their employment requirements. Unfortunately the representatives in question were long standing employees and it appeared that they had not been asked to sit the Medical Representatives Examination. This was currently being rectified and all of them had been asked to register immediately to take and pass these examinations.

Rosemont provided a copy of the current job descriptions for the three different types of jobs undertaken by the employees in question. All of the job descriptions stated that the employee must have the full ABPI examination. All new employees had to sit the examination or upgrade from the generics examination within the time specified in the Code, if they did not already hold the qualification.

The introduction checklist for new employees stated that the company must see and store on their personnel records a copy of their ABPI examination certificates, which was part of the company's employment policy for sales personnel. Rosemont also provided a copy of the letter sent to all new personnel about the ABPI examination requirement.

Rosemont submitted that this had been an oversight by the company which was being rectified as a matter of urgency; the employees had been asked to sit and pass the full examination. Rosemont accepted that it had breached Clause 16.3, but did not consider that it had brought discredit to the industry or intentionally failed to maintain standards. Rosemont held the Code in extremely high regard and endeavoured to uphold both the spirit and the letter of the Code at all times.

PANEL RULING

The Panel noted that Clause 16.3 stated that representatives must take an appropriate representatives examination within their first year of such employment and pass it within two. The relevant supplementary information stated that prior to passing an appropriate examination, representatives might be engaged in such employment for no more than two years, whether continuous or otherwise and irrespective of whether with one company or with more than one company. The Director had discretion in the event of failure to comply with either time limit to either grant an extension or agree to the continued employment of the relevant employee as a representative past the end of the two year period subject to the representative taking or passing the examination within a reasonable time.

The Panel noted that a representative was defined in Clause 1.6 as someone who called on members of the health professions and administrative staff in relation to the promotion of medicines. In the Panel's view such people would often have job titles other than 'representative'. The term promotion was defined in Clause 1.2 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 16.3 of the Addendum to the Second 2012 Edition of the Code stated that an appropriate examination for medical representatives was one that required a broad understanding of body systems, diseases and treatments, the development of new medicines and the structure and function of the NHS and of the pharmaceutical industry. An appropriate examination for generic sales representatives was one that required a broad understanding of body systems, the structure and function of the NHS and of the pharmaceutical industry. The supplementary information to Clause 16.3 Examinations, stated that the ABPI Medical Representatives Examination was appropriate for and must be taken by representatives whose duties comprised or included one or both of calling upon, *inter alia*, doctors and/or other prescribers; the promotion of medicines on the basis, *inter alia*, of their particular therapeutic properties. The Generic Sales Representatives Examination was appropriate for, and must be taken by, representatives who promoted primarily on the basis of price, quality and availability to those who did not prescribe medicines. The supplementary information to Clause 16.3 Time Allowed to Pass an Examination, stated that service as a representative prior to 1 January 2006 by persons who were exempt from taking the appropriate examination by virtue of Clause 16.4 of the 2003 edition of the Code did not count towards the two year limit on employment as a representative prior to passing the appropriate examination.

The Panel noted that Rosemont accepted that the individuals concerned were required under the Code to take the Medical Representatives Examination. Due to staff turnover it was unclear why in 2006 when the staff concerned could no longer take the benefit of the exemption, the company did not require them to take the ABPI Medical Representatives Examination. The Panel noted that this particular change had been communicated to companies as an intention well ahead of time. The changes were agreed in principle by ABPI members in 2003 before becoming part of the Code in 2006. The Panel was concerned that the matter only came to light during a compliance audit when Rosemont was taken over by another company. The Panel was also very concerned about Rosemont's submission that the employees concerned had registered to take the examination within one year of the date of the company's response to the complaint and must pass the examination within two years of this date. The Panel noted that this was contrary to the supplementary information to Clause 16.3 which referred to extensions from the Director agreeing to their continued employment subject to their passing the examination within a reasonable time. The Panel considered that the company should ensure that the relevant employees contacted the Director forthwith and that they should not carry out the medical representative's role unless the appropriate extension had been granted.

The Panel noted that five Rosemont representatives had not passed an appropriate Medical Representatives Examination as required by the Code. A breach of Clause 16.3 was ruled. The Panel was concerned that the matter was only identified during a compliance audit some seven years after the exemption was removed. High standards had not been maintained. A breach of Clause 9.1 was ruled.

On balance the Panel did not consider that the circumstances warranted a breach of Clause 2 which was used as a sign of particular censure and was reserved for such circumstances. No breach of Clause 2 was ruled.

Voluntary admission received **29 October 2013**

Case completed **28 November 2013**

CASE AUTH/2649/10/13

VOLUNTARY ADMISSION BY GLAXOSMITHKLINE

Retrospective certification of joint working project

GlaxoSmithKline voluntarily admitted that materials relating to a joint working project were certified after the project had started.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with GlaxoSmithKline.

GlaxoSmithKline explained that an ongoing disciplinary process had revealed that material relating to a joint working project, which was due to run from October 2011 to October 2012, was not certified before use. When this oversight was noted in May 2012 corrective action was taken immediately and the materials were certified. GlaxoSmithKline submitted that lack of certification at the proper time was an administrative error by an ex-employee.

The detailed response from GlaxoSmithKline is given below.

The Panel noted that the Code required that material prepared in relation to joint working between the NHS and the pharmaceutical industry be certified before use in its final form, to which no subsequent amendments would be made, by two persons, one of whom must be a registered medical practitioner.

The Panel noted that the joint working project at issue was due to run from October 2011 to October 2012. Relevant materials, however, were not certified until May/June 2012, 7-8 months in to the 12 month project. The joint working project had commenced and the material had been used before it had been certified. A breach of the Code was ruled as acknowledged by GlaxoSmithKline. The Panel considered that the material was not covered by the certification requirements for promotional material and no breach of the Code was ruled in that regard.

The Panel noted the importance of certification and its role in underpinning the self-regulatory compliance system. The Panel considered that as material which should have been certified had been used before final sign-off, high standards had not been maintained. A breach of the Code was ruled.

The Panel noted GlaxoSmithKline's submission that the lack of sign-off was an isolated incident, due to one person's action rather than due to lack of process. The Panel noted, however, that although the individual in question had inexplicably cancelled the job within Zinc, the joint working project had nonetheless gone ahead. In the Panel's view this should not have been possible. The Panel noted GlaxoSmithKline's submission that because the job had been cancelled in Zinc, the executive summary had not been made publicly available before the project started. In the Panel's view, the requirement to publish the executive summary before the arrangements were implemented, as required by the Code, should have prompted an investigation into the matter at the outset. The lack of certification however, was not noted until May 2012 and although materials were certified retrospectively, senior managers were not informed that company process had not been followed. The matter only came to senior managers' attention in connection with another matter.

The Panel noted that the joint working project at issue involved one particular NHS area working in partnership with GlaxoSmithKline to improve local chronic obstructive pulmonary disease (COPD) healthcare. That the project went ahead without key documents being certified was unacceptable. Given the direct impact that joint working projects must have on patient care, all parties to a joint working agreement must be sure that the arrangements had been robustly scrutinised and signed off at the highest level before implementation. The Panel noted its comments above about the importance of certification and considered that an approval system which could be circumvented such as to allow a joint working project with the NHS to proceed with uncertified materials brought discredit upon, and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled which was appealed.

The Appeal Board noted that this case had arisen from a voluntary admission and GlaxoSmithKline's submission that since this matter had come to light the company had improved its compliance procedures to ensure that such issues could not arise in future. The Appeal Board also noted GlaxoSmithKline's submission that a review of all of its other joint working projects had not revealed any problems similar to those that had occurred with the project at issue in this case.

The Appeal Board noted from the Zinc route map that the head office employee responsible for ensuring that the joint working project at issue was certified, had not completed the certification process. The employee had received the job bag in Zinc, after it had been initially reviewed by a number of people, in September 2011 but did nothing with it until February 2012 when the employee cancelled it for reasons unknown. This individual had left GlaxoSmithKline. In the meantime, the project started in October 2011. The procedure within GlaxoSmithKline at the time, which allowed such projects to start, was that the responsible head office employee would inform the responsible field based employee that the project was certified; no documentation of this exchange was required. (The field based employee had no access to Zinc to check that certification was indeed complete).

Once informed by his/her head office colleague that certification was complete, the field based employee could draw down funds to start the project, which he/she was able to do, albeit in the absence of certification, in this case.

The Appeal Board noted from GlaxoSmithKline at the appeal that as a result of a company reorganisation, an internal audit had discovered that the joint working project had not been certified; materials were thus retrospectively certified in May and June 2012. The Appeal Board was very concerned that, given their key role in compliance, none of the three signatories involved immediately reported the retrospective approval to senior colleagues. In the Appeal Board's view, this lack of action by the signatories compounded the original error. The Appeal Board noted that only when the lack of prior certification of the project arose in mid October 2013 as a result of another matter, did GlaxoSmithKline make a voluntary admission to the PMCPA.

The Appeal Board considered that joint working arrangements with the NHS and pharmaceutical companies were complex and would directly affect patient care. Companies must have robust processes to ensure that such arrangements complied with the Code and were certified before projects started. The Appeal Board did not consider the appropriateness *per se* of the project at issue which appeared to benefit COPD patients. That this project went ahead without prior certification of the arrangements was completely unsatisfactory. The Appeal Board considered that, at the time, GlaxoSmithKline's compliance procedures, financial controls and structural relationships between head office and the field regarding joint working projects were wholly inadequate.

The Appeal Board considered that by not certifying the joint working project before it started, and its subsequent failings in its compliance procedures, GlaxoSmithKline had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Appeal Board thus upheld the Panel's ruling of a breach of Clause 2. The appeal on this point was unsuccessful.

GlaxoSmithKline voluntarily admitted that materials relating to a joint working project were certified after the project had started.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with GlaxoSmithKline.

VOLUNTARY ADMISSION

GlaxoSmithKline explained that as a result of an ongoing disciplinary process it was noted that a joint working project between GlaxoSmithKline and the NHS in a named area had been certified after the project had started. The job bag retrieved from the Zinc system showed that it had been certified retrospectively, including the 'child' job which contained the executive summary. An associated file note indicated that the retrospective certification was due to a 'colleague misunderstanding'.

GlaxoSmithKline explained that the Zinc route map showed that the job was initiated by the business owner on 4 August 2011, reviewed by a number of colleagues and passed back to the business owner in August 2011. A certification cycle was started on 22 September 2011 by the business owner and the job was back with him (uncertified) on 27 September. The job then remained with the business owner with no further action until 29 February 2012 when he cancelled it. The job was reactivated by a Zinc administrator on 3 May 2012 and delegated to another member of the team who initiated the certification round and the job was certified by the medical advisor and business unit director on 15 May 2012.

GlaxoSmithKline explained that the certification oversight was noticed during a mini-audit of joint working projects during the final stages of a major reorganisation of GlaxoSmithKline in the UK. Corrective action was applied immediately. This was supported by the audit trail which showed that the new business owner took control of the job in Zinc and progressed it to certification and ensured that an executive summary was posted on the company's external-facing website.

GlaxoSmithKline stated that because the original business owner was no longer employed by the company, it was unable to further investigate the circumstances which led him to act in a way that was inconsistent with company expectations.

GlaxoSmithKline submitted that independent of this issue and as part of the reorganisation referred to above, a revised joint working project had been developed and had been in place since September 2012 based primarily on the ABPI joint working roadmap. All active joint working projects were now reviewed for compliance with mandatory reporting requirements on a monthly basis.

GlaxoSmithKline submitted that this was an administrative error on the behalf of an ex-employee. Whilst this was no excuse for the error, the company was confident that this was an isolated incident. GlaxoSmithKline took its obligations for compliance with the Code seriously and was committed to ensuring that all staff were appropriately trained and acted in compliance with the Code.

When writing to GlaxoSmithKline, the Authority asked it to respond to Clauses 2, 9.1, 14.1 and 14.3 of the Code.

RESPONSE

GlaxoSmithKline accepted that the joint working project in question was not certified in advance as required by Clause 14.3. However, as soon as the omission was noticed, the material was certified by senior medical and commercial personnel as required by Clause 14.1.

Since the executive summary of a joint working project was a dependent document of the main project it was therefore also impossible for this to have been certified in accordance with Clause 14.3 and the executive summary itself was not publicly available before the arrangements of the project

were implemented. The executive summary was certified on 29 June 2012.

The audit map of the project in Zinc clearly showed that the individual in question took the irregular step of cancelling the certification process for the project on 29 February. Importantly, it was an internal audit that identified that the project had not been certified before it started. Immediate steps were taken to rectify the issue; certification responsibility for the business case was delegated to another employee on 3 May 2012 and certification was completed 12 days later. At this stage the matter and the remedial actions taken should have been notified to senior management as being out of process. GlaxoSmithKline regretted that this did not occur and it was only early in October 2013 that this shortcoming was noticed in connection with another matter and immediately brought to the attention of senior management. The individual had since left the company.

GlaxoSmithKline expected its employees to comply with the Code, laws and regulations, the GlaxoSmithKline code of practice and policies and maintain high standards at all times. It appeared that the individual in question had deliberately acted in a way that was inconsistent with the company's expectations for reasons unknown.

However, once the problem was identified corrective action was immediately taken to ensure that the required standards were met.

Subsequent to, and independent of, the post-hoc certification of the joint working activity, GlaxoSmithKline had substantially reorganised its UK structure which required the development and training of a revised joint working process. This process, based on the ABPI joint working roadmap, had been in place since September 2012. All active joint working projects were reviewed for compliance with mandatory reporting requirements on a monthly basis.

GlaxoSmithKline considered that the process it currently operated, which was different to that which was in operation at the time of this event, greatly reduced the likelihood of any further such event occurring.

GlaxoSmithKline always strove to maintain high standards as required by Clause 9.1 and in this instance the company considered that the root cause of the problem was not a lack of process but a breach by an individual. GlaxoSmithKline did not consider that a breach of Clause 9.1 was warranted as the company took relevant action to correct the issue as soon as it became apparent.

GlaxoSmithKline stated that it was committed to open and transparent behaviour.

As set out above, the company had identified that the cause of this event was an individual whose actions were inconsistent with the company's expectations. A senior manager was made aware of the issue and took immediate and appropriate action to ensure it was investigated which resulted in the voluntary admission.

GlaxoSmithKline regretted that a breach of the Code had occurred, however it strongly considered that it had acted quickly and transparently to bring this to the attention of the PMCPA. As such, the company did not believe that it had brought the industry into disrepute.

PANEL RULING

The Panel noted that Clause 14.1 required that promotional material must not be issued unless its final form, to which no subsequent amendments would be made, had been certified by two persons on behalf of the company. One of the two persons must be a registered medical practitioner or a UK registered pharmacist. Clause 14.3 required other material to be similarly certified, including material prepared in relation to joint working between the NHS and the pharmaceutical industry. Material referred to in Clause 14.3 must be certified by two persons, one of whom must be a registered medical practitioner.

The Panel noted that the joint working project at issue was due to run from October 2011 to October 2012. The business case and the executive summary, however, were not certified until May and June 2012 respectively, 7-8 months in to the 12 month project. The joint working project had commenced and the material had been used before it had been certified. A breach of Clause 14.3 was ruled as acknowledged by GlaxoSmithKline. The Panel considered that as the material at issue was not promotional, it was not covered by the certification requirements of Clause 14.1. No breach of that clause was ruled.

The Panel noted the importance of certification and its role in underpinning the self-regulatory compliance system. The Panel considered that as material which should have been certified had been used before final sign-off, high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted GlaxoSmithKline's submission that the lack of sign-off was an isolated incident, due to one person's action rather than due to lack of process. The Panel noted, however, that although the individual in question had inexplicably cancelled the job within Zinc, the joint working project had nonetheless gone ahead. In the Panel's view this should not have been possible. The Panel noted GlaxoSmithKline's submission that because the job had been cancelled in Zinc, the executive summary had not been made publicly available before the project started. In the Panel's view, the requirement to publish the executive summary before the arrangements were implemented, as required by Clause 18.5, should have prompted an investigation into the matter at the outset. The lack of certification however, was not noted until May 2012 and although materials were certified retrospectively, senior managers were not informed that company process had not been followed. The matter only came to senior managers' attention in connection with another matter.

The Panel noted that the joint working project at issue involved NHS organisations in one particular area working in partnership with GlaxoSmithKline to improve local chronic obstructive pulmonary disease (COPD) healthcare. The project had an overall goal of reducing hospital admissions and outpatient referrals. The business case for the project stated that GlaxoSmithKline would fund and implement the delivery of automated patient audit tools in 27 practices. That the project went ahead without key documents being certified was unacceptable. Given the direct impact that joint working projects must have on patient care, all parties to a joint working agreement must be sure that the arrangements had been robustly scrutinised and signed off at the highest level before implementation. The Panel noted its comments above about the importance of certification to the self-regulatory system and considered that an approval system which could be circumvented such as to allow a joint working project with the NHS to proceed with uncertified materials brought discredit upon, and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

APPEAL FROM GLAXOSMITHKLINE

GlaxoSmithKline strongly submitted that a breach of Clause 2 was a disproportionate sanction given that this was a voluntary admission about an administrative error discovered via internal processes and checks. The importance of good governance and high standards had been acknowledged from the outset and GlaxoSmithKline had outlined steps for continually improving its systems. Finally, the joint working project itself was considered appropriate and had been reviewed by appropriate GlaxoSmithKline and NHS staff before it started.

GlaxoSmithKline submitted that it took its responsibilities under the Code extremely seriously and in order to maintain confidence in the industry from patients, the NHS and the general public it considered voluntary admission to be a key aspect of self-regulation.

GlaxoSmithKline submitted that in this case it was a gross oversimplification to equate failure to certify the activity in advance with circumvention of the approval process. The project had been reviewed through the Zinc system which meant that its components had been scrutinised and commented on. The project had not been marked as rejected which indicated that the reviewers were satisfied that it was fit to proceed towards certification with minor amends. The comments from the reviewers at this stage did not materially affect the nature of the proposed work.

GlaxoSmithKline submitted that the last step of certification clearly did not happen although, as stated above, this was for reasons unknown as the business owner responsible no longer worked for the company.

GlaxoSmithKline submitted that it had identified the problem internally and immediately rectified the situation. Subsequently, and before it made its voluntary admission, GlaxoSmithKline had implemented a revised approach to joint working which followed the ABPI joint working roadmap published at around the time that this issue occurred.

In addition, as a result of its ongoing review of this matter, GlaxoSmithKline had introduced a further safeguard to the physical joint working agreement template such that it had to be countersigned by one of the certifying signatories before it could be signed by the NHS to initiate the project.

In conclusion, GlaxoSmithKline submitted that the Panel's ruling of a breach of Clause 2 was disproportionate given that the company's response should have retained or improved confidence in the pharmaceutical industry, and the robustness of voluntary admission within a self regulatory framework.

APPEAL BOARD RULING

The Appeal Board noted the Panel's comments regarding the importance of certification to the self-regulatory system and its subsequent rulings of breaches of Clauses 14.3 and 9.1 of the Code which GlaxoSmithKline had accepted.

The Appeal Board noted that this case had arisen from a voluntary admission and GlaxoSmithKline's submission that since this matter had come to light the company had improved its compliance procedures to ensure that such issues could not arise in future. The Appeal Board also noted from the GlaxoSmithKline representatives at the appeal that a review of all of its other joint working projects had not revealed any problems similar to those that had occurred with the project at issue in this case.

The Appeal Board noted that it had to consider the actions of GlaxoSmithKline employees between August 2011 and May 2012. Although noting the passage of time and that a key individual had left the company, the Appeal Board was very concerned that the GlaxoSmithKline representatives at the appeal were unable to answer a number of questions. One of the representatives had only assumed responsibility for the matter after the event and the field-based employee who signed the contract between GlaxoSmithKline and the NHS, and who should have known a lot about how the project had evolved, was not present.

The Appeal Board noted from the Zinc route map that the head office employee responsible for ensuring that the joint working project at issue was certified, had not completed the certification process. The employee had received the job bag in Zinc, after it had been initially reviewed by a number of people, in September 2011 and instead of submitting it for final certification, had done nothing with it until February 2012 when he cancelled it. The reasons for the employee's actions were unknown. This individual had left GlaxoSmithKline. In the meantime, the project started in October 2011. The procedure within GlaxoSmithKline at the time, which allowed such projects to start, was that the responsible head office employee would inform the responsible field based employee that the project was certified; no documentation of this exchange was required. (The field based employee had no access to Zinc to check that certification was indeed complete). Once informed by his/her head office colleague that certification was complete, the field based employee could draw down funds against a field based budget to start the project,

which he/she was able to do, albeit in the absence of certification, in this case.

The Appeal Board noted from GlaxoSmithKline at the appeal that as a result of a company reorganisation, an internal audit had discovered that the joint working project had not been certified; the business case was thus retrospectively certified in May 2012 and the executive summary in June 2012. The Appeal Board was very concerned that, given their key role in compliance, none of the three signatories involved immediately reported the retrospective approval to senior colleagues. In the Appeal Board's view, this lack of action by the signatories compounded the original error. The Appeal Board noted that only when the lack of prior certification of the project arose in mid October 2013 as a result of another matter, did GlaxoSmithKline make a voluntary admission to the PMCPA in late October 2013.

The Appeal Board considered that joint working arrangements with the NHS and pharmaceutical companies were complex and would directly affect patient care. Companies must have robust processes to ensure that such arrangements complied with the Code and were certified before projects started. The Appeal Board did not consider the appropriateness *per se* of the project at issue which appeared to be beneficial to patients with an overall goal of reducing hospital admissions and outpatient referrals for COPD. That this project went ahead without prior certification of the arrangements was completely unsatisfactory. The Appeal Board considered that, at the time, GlaxoSmithKline's compliance procedures, financial controls and structural relationships between head office and the field regarding joint working projects were wholly inadequate.

The Appeal Board considered that by not certifying the joint working project before it started, and its subsequent failings in its compliance procedures, GlaxoSmithKline had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Appeal Board thus upheld the Panel's ruling of a breach of Clause 2. The appeal on this point was unsuccessful.

Voluntary admission made	**31 October 2013**
Case completed	**8 January 2014**

CASE AUTH/2652/11/13

ANONYMOUS EMPLOYEE v GRÜNENTHAL

Failure to distinguish between call rates and contact rates

An anonymous and non-contactable employee of Grünenthal complained about an email sent by a senior employee to remind the sales force to enter data into a customer relationship management (CRM) system [Advance] daily.

The complainant noted that the email only referred to interactions and thus failed to reflect the Code which stated 'When briefing representatives, companies should distinguish clearly between expected call rates and expected contact rates'. In that regard the complainant highlighted the statement 'I would therefore have expected to see the data for the 2+ target interactions per day and 5-7 total interactions per day that is our role activity standard in ….'.

The detailed response from Grünenthal is given below.

The Panel noted that the email was headed 'Advance interactions entry and your personal responsibility for the Advance System – PLEASE READ ASAP'. It reminded recipients that they should enter data daily and submit interactions for 1:1 contacts and meeting contacts. In five bullet points it detailed 'big chunks of data missing'. Representatives were reminded that data entry was not optional and given two days to complete the required data entry.

The Panel did not accept Grünenthal's submission that the email was not a briefing on call rates but was sent with reference to the entry of interactions into the CRM system. The email referred to 2+ target interactions per day and 5-7 total interactions per day as Grünenthal's role activity standard. One bullet point read 'I am not seeing the total activity that relates to our role capacity in the system for many people – 1-2 total interactions a day maximum are appearing in many territories'. A subsequent paragraph read 'Our structure is in place to see a level of target and accessible customers within a priority account plan framework – if we can't see the customers then we need different resourcing. We just aren't seeing enough key people if this advance data is analysed. When we had the old coverage…..back in 2012 we were above 7 interactions a day average across the UK. I am keen to keep our current account plan bottom up targeting of customers as part of the cycle plan, but not if it results in this huge reduction in customer activity. Your new [quarter] 4 cycle plan should give the framework to meet our activity expectations'. The Panel considered that the email went beyond data entry and clearly instructed representatives on expected call rates and in this regard had to comply with the Code.

The Panel noted Grünenthal's submission that in quarter 4, 2012 it had moved to a bottom up cycle approach to sales activity planning. Representatives were expected to see two target customers and 5-7 customers per day. These were not incentivised and Grünenthal submitted that the representatives' cycle plans did not stipulate expected call rates or expected contact rate targets. The Panel noted Grünenthal's submission that interactions as stated in the email referred to any contact representatives had with health professionals, whether in 1:1 calls or at group meetings. The Panel further noted Grünenthal's submission that it was specifically open about what form these interactions might take as the value of the interaction was more important than the nature of it. The Panel noted that Grünenthal could organize its sales force as it saw fit but, nonetheless, had to ensure that interactions with health professionals and instructions to representatives in this regard complied with the Code.

The Panel noted Grünenthal's submission that it provided reminders that the Code only permitted a maximum of 3 unsolicited calls in any one year but queried whether these were adequate. An internal presentation in January 2013 referred to 'at least 5 high quality interactions* as permitted, and call back opportunities solicited by health professional'. The relevant Code requirement appeared as a footnote at the bottom of the slide '* = three unsolicited calls per year are permitted' and on the next slide. It appeared that the representatives had not been provided with the definitions of 'contact rate' and 'call rate' as referred to in the Code and how they sat with the term 'interaction'. The Panel noted that the email, however, had to stand alone. The Panel was concerned that the representatives had not been provided with details of the requirements of the Code in relation to call rates.

The Panel considered that taking all of the circumstances into account the email in question was not sufficiently clear about the differences between call rates and contact rates as referred to in the relevant supplementary information. The Panel ruled a breach of the Code on the narrow ground alleged.

An anonymous, non-contactable complainant who described themselves as an employee of Grünenthal Ltd, complained about an email sent to the sales force from a senior employee. The complainant provided a copy of the email which reminded recipients of the need to enter data into a customer relationship management (CRM) system on a daily basis. The email referred to missing data and that completion to the timeline of the CRM system was not optional.

COMPLAINT

The complainant noted that Clause 15.4 of the Code stated 'When briefing representatives, companies should distinguish clearly between expected call rates

and expected contact rates'. The complainant stated that the author of the email in question had failed to do this as the email only referred to interactions.

The complainant highlighted the statement 'I would therefore have expected to see the data for the 2+ target interactions per day and 5-7 total interactions per day that is our role activity standard in ….'.

RESPONSE

Grünenthal explained that in order to have sufficient oversight of its interactions with health professionals it was important that it maintained records within a CRM system. The company required that all interactions with external customers were entered into the CRM system on a daily basis whether in a 1:1 call setting or interactions at a meeting and the email in question was sent in reference to that requirement.

Grünenthal stated that when it moved to a new CRM system (Advance) in quarter 2, 2013 it made some concessions regarding the requirement to input information on all interactions with external customers on a daily basis whilst some of the bugs in the system were corrected. This transition period was now complete and Grünenthal was able to run reports on the data entered. Bullet points in the email referred to various information from the report that indicated that some representatives had not met the internal requirements to enter data daily. This naturally caused some concern as Grünenthal might not have accurate records of every interaction its staff had with health professionals. The email was sent to highlight and address the requirement to log interactions daily.

Grünenthal noted that Clause 15.4 and its supplementary information addressed the frequency, duration, timing and manner of calls made by representatives on health professionals and associated administrative staff. The supplementary information provided specific guidance that 'the number of calls made on a doctor or other prescriber by a representative each year should not normally exceed three on average'. In addition, as referenced in the complaint, it stated 'when briefing representatives companies should distinguish clearly between expected call rates and expected contact rates'.

Grünenthal submitted that the email in question was not a briefing on call rates; it was sent with reference to the submission of interactions with health professionals into the CRM system. The email referred to expected standard contact rates (2+ target interactions per day and 5-7 total interactions per day). There was an expectation that representatives saw seven health professionals per day including at least two targets. This number depended on location and experience of the representative in individual calls or at meetings. This was not a formal or incentivised target but this number of expected interactions was how the company devised resource allocation within the sales team. The number of targets or total daily interactions was not for example recorded as a core activity or goal for representatives in their objectives. Grünenthal provided a copy of a document which outlined the core activities and goals for promotional staff in 2013.

Grünenthal stated that it did not incentivise its representatives to work to call rates, coverage rates or frequency rates. The company stopped this in quarter 4, 2012 when it moved to a bottom up cycle planning approach to sales activity planning. The commercial teams were sized with reference to the number of target customers on each territory. Each quarter, representatives planned their territory activities for the quarter ahead in the CRM and listed those customers they intended to see from the list of targets. They did this based on their personal knowledge of the local environment and where they believed they should focus their activities for maximum return (product sales) as this was what representatives were bonused on (copies of internal presentation slides were provided).

To achieve their cycle plan, representatives were expected to see two target customers and 5-7 customers per day depending on location and experience, however, this was not incentivised nor were any targets in place regarding 1:1 call interactions vs contacts at meetings. Business activities focused on the cycle plans individual representatives devised and the resultant sales. Given the average number of target customers per territory, and the average number of working days per representative, this contact rate could be compliantly maintained within the limit of three unsolicited calls per year, even if no requests for follow-up or return visits were made. Once completed by representatives, cycle plans were reviewed by line managers for appropriateness and compliance before being approved within the CRM system. This provided the opportunity to ensure the plans were appropriate from all business aspects and they were regularly monitored by line managers during the quarter. These plans did not stipulate targets regarding expected call rates and expected contact rates.

During cycle planning briefings, Grünenthal provided reminders that the Code only permitted a maximum of 3 unsolicited calls in any one year (a slide from a certified internal presentation in January 2013 was provided). In addition, the annual representative refresher training from an external supplier also referred to the Code requirements in that area (a copy of a slide taken from the annual representative refresher training was provided).

Commercial insight had been provided regarding the benefit of multiple interactions with an individual health professional (a slide from a certified presentation delivered on January 2013 was provided), however, the focus was on the representatives to establish a relationship with individual health professionals that allowed them to return at the request and invitation of the health professional. Representatives should provide such value, whether clinical data, educational resources, opportunities to attend educational meetings etc that the health professional would like to see them on repeat occasions.

With regard to the use of the words 'target interactions' and 'interactions' in the email, Grünenthal explained that 'target interactions' were interactions with individual health professionals with a specialization or clinical interest in the management of pain. Interactions referred to any contact a representative had with these specialists whether in 1:1 calls or at group meetings. Grünenthal was specifically open about what form these interactions might take as it considered the value of the interaction was more important than its nature.

Grünenthal reiterated that it did not stipulate call or contact targets for representatives therefore no one had failed to meet call/contact targets. Grünenthal submitted that it did not certify the email in question as it was not promotional and did not constitute a technical briefing. It also did not instruct its representatives about how to interact with health professionals or associated administrative staff. The email was sent to address the failure by some staff to properly maintain internal records. Grünenthal stated that it did not formally approve emails related to administrative duties expected of its staff.

Grünenthal stated that it was completely committed to adhering to the Code in all of its business activities. It was disappointed to have received this complaint as it had multiple internal reporting channels available to employees genuinely concerned about conduct within the business. Training on these channels was provided to all employees in March 2013 and repeated the week the complaint was submitted (relevant training slides were provided). Grünenthal submitted that complaints such as these, especially when anonymous and non-contactable, demoralised the various cross-functional teams involved and Grünenthal questioned the genuine nature and intent of this complaint.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. Like all complaints, anonymous complaints were judged on the evidence provided. The complainant bore the burden of proving his/her complaint on the balance of probabilities.

The Panel noted that Clause 15.4 required representatives to ensure that the frequency, timing and duration of calls on, *inter alia*, health professionals, together with the manner in which they were made, did not cause inconvenience. The supplementary information to that clause stated that companies should arrange that intervals between visits did not cause inconvenience. The number of calls made on a doctor or other prescriber by a representative each year should normally not exceed three on average excluding attendance at group meetings and the like, a visit requested by the doctor or other prescriber or a visit to follow up a report of an adverse reaction. Thus although a representative might speculatively call upon or proactively make an appointment to see a doctor or other prescriber three times on average in a year, the annual number of contacts with that health professional might be more than that. The supplementary information to Clause 15.4 also advised that when briefing representatives companies should distinguish clearly between expected call rates and expected contact rates. Targets must be realistic and not such that representatives breached the Code in order to meet them.

The Panel noted that the email in question from a senior employee bore the subject heading 'Advance interactions entry and your personal responsibility for the Advance System – PLEASE READ ASAP' and was sent to the UK sales force. It reminded recipients that data entry should be on a daily basis and interactions submitted for 1:1 contacts and meeting contacts. In five bullet points it detailed 'big chunks of data missing' and reminded representatives that data entry was not optional. They were given two days to complete the required data entry.

The Panel did not accept Grünenthal's submission that the email in question was not a briefing on call rates but was sent with reference to the entry of interactions with health professionals into the CRM system. Whilst the email clearly discussed administrative matters, it also went beyond such matters and instructed representatives on call rates.

The email referred to 2+ target interactions per day and 5-7 total interactions per day as Grünenthal's role activity standard. One bullet point read 'I am not seeing the total activity that relates to our role capacity in the system for many people – 1-2 total interactions a day maximum are appearing in many territories'. A subsequent paragraph read 'Our structure is in place to see a level of target and accessible customers within a priority account plan framework – if we can't see the customers then we need different resourcing. We just aren't seeing enough key people if this advance data is analysed. When we had the old coverage…..back in 2012 we were above 7 interactions a day average across the UK. I am keen to keep our current account plan bottom up targeting of customers as part of the cycle plan, but not if it results in this huge reduction in customer activity. Your new [quarter] 4 cycle plan should give the framework to meet our activity expectations'. The Panel considered that the email went beyond data entry and clearly instructed representatives on expected call rates and in this regard had to comply with the Code.

The Panel noted Grünenthal's submission that in quarter 4, 2012 it had moved to a bottom up cycle approach to sales activity planning. Representatives were expected to see two target customers and 5-7 customers per day. These were not incentivised and Grünenthal submitted that the representatives' cycle plans did not stipulate expected call rates or expected contact rate targets. The Panel noted Grünenthal's submission that interactions as stated in the email referred to any contact representatives had with health professionals, whether in 1:1 calls or at group meetings. The Panel further noted Grünenthal's submission that it was specifically open about what form these interactions might take as the

value of the interaction was more important than the nature of it. The Panel noted that Grünenthal could organize its sales force as it saw fit but, nonetheless, had to ensure that interactions with health professionals and instructions to representatives in this regard complied with the Code, including Clause 15.4.

The Panel noted that although a representative might call on a doctor or other prescriber three times in a year the number of contacts with that health professional in the year might be more than that provided it was made clear that only three of those contacts could be cold calls. Without this explanation, instructions to representatives regarding interactions might advocate a course of action which was likely to breach the Code. In the Panel's view companies needed to be especially cautious in this regard and therefore be clear and unambiguous about Code requirements when they used a term such as 'interaction' which differed from the language used in the Code and industry practice.

The Panel noted Grünenthal's submission that it provided reminders that the Code only permitted a maximum of 3 unsolicited calls in any one year but queried whether these were adequate. An internal presentation in January 2013 delivered by the general manager referred to 'at least 5 high quality interactions* as permitted, and call back opportunities solicited by health professional'. The relevant Code requirement appeared as a footnote at the bottom of the slide '* = three unsolicited calls per year are permitted' and on the next slide. It appeared that the representatives had not been provided with the definitions of 'contact rate' and 'call rate' as referred to in the Code and how they sat with the term 'interaction'. The Panel noted that the email, however, had to stand alone. The Panel was concerned that the representatives had not been provided with details of the requirements of the Code in relation to call rates.

The Panel considered that taking all of the circumstances into account the email in question was not sufficiently clear about the differences between call rates and contact rates as referred to in the relevant supplementary information. The Panel ruled a breach of Clause 15.4 on the narrow ground alleged.

Complaint received **8 November 2013**

Case completed **7 January 2014**

CODE OF PRACTICE REVIEW – February 2014

Cases in which a breach of the Code was ruled are indexed in **bold type.**

2617/7/13	**Anonymous v Lundbeck**	**Sponsorship of a meeting**	**Breaches Clauses 2, 9.1 and 19.1**	**No appeal**	**Page 3**
2628/8/13	**Anonymous v Chiesi**	**Sponsorship of a meeting**	**Breach Clause 9.1**	**Appeal by respondent**	
2629/8/13	**Anonymous v Menarini**	**Sponsorship of a meeting**	**Breaches Clauses 2, 9.1 and 19.1**	**No appeal**	
2631/8/13	**Anonymous v Bayer**	**Sponsorship of a meeting**	**Breaches Clauses 2, 9.1 an 19.1**	**No appeal**	
2624/8/13	**Senior Public Health Specialist v HRA Pharma**	**Conduct of representative**	**Breaches Clauses 2, 7.2, 7.10, 8.2, 9.1 and 15.2**	**Appeal by respondent**	**Page 23**
2648/10/13	**Voluntary admission by Rosemont**	**Failure to sit ABPI Medical Representatives Examination**	**Breaches Clauses 9.1 and 16.3**	**No appeal**	**Page 30**
2649/10/13	**Voluntary admission by GlaxoSmithKline**	**Retrospective certification of joint working project**	**Breaches Clauses 2, 9.1 and 14.3**	**Appeal by respondent**	**Page 33**
2652/11/13	**Anonymous employee v Grünenthal**	**Failure to distinguish between call rates and contact rates**	**Breach Clause 15.4**	**No appeal**	**Page 38**

PMCPA | Prescription Medicines Code of Practice Authority

The Prescription Medicines Code of Practice Authority was established by the Association of the British Pharmaceutical Industry (ABPI) in 1993 to operate the Code of Practice for the Pharmaceutical Industry at arm's length from the ABPI itself. Compliance with the Code is obligatory for ABPI member companies and, in addition, over sixty non member companies have voluntarily agreed to comply with the Code and to accept the jurisdiction of the Authority.

The Code covers the advertising of medicines to health professionals and administrative staff and also covers information about prescription only medicines made available to the public.

It covers:

- journal and direct mail advertising
- the activities of representatives, including detail aids and other printed or electronic material used by representatives
- the supply of samples
- the provision of inducements to prescribe, supply, administer, recommend, buy or sell medicines by the gift, offer or promise of any benefit or bonus, whether in money or in kind
- the provision of hospitality
- the organisation of promotional meetings
- the sponsorship of scientific and other meetings, including payment of travelling and accommodation expenses
- the sponsorship of attendance at meetings organised by third parties
- all other sales promotion in whatever form, such as participation in exhibitions, the use of audio or video-recordings in any format, broadcast media, non-print media, the Internet, interactive data systems and the like.

It also covers:

- the provision of information on prescription only medicines to the public either directly or indirectly, including by means of the Internet
- relationships with patient organisations
- the use of consultants
- non-interventional studies of marketed medicines
- the provision of items for patients
- the provision of medical and educational goods and services
- grants and donations to institutions.

Complaints submitted under the Code are considered by the Code of Practice Panel which consists of three of the four members of the Code of Practice Authority acting with the assistance of independent expert advisers where appropriate. One member of the Panel acts as case preparation manager for a particular case and that member does not participate and is not present when the Panel considers it.

Both complainants and respondents may appeal to the Code of Practice Appeal Board against rulings made by the Panel. The Code of Practice Appeal Board is chaired by an independent legally qualified Chairman, Mr William Harbage QC, and includes independent members from outside the industry. Independent members, including the Chairman, must be in a majority when matters are considered by the Appeal Board.

In each case where a breach of the Code is ruled, the company concerned must give an undertaking that the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in the future. An undertaking must be accompanied by details of the action taken to implement the ruling. Additional sanctions are imposed in serious cases.

Further information about the Authority and the Code can be found at www.pmcpa.org.uk

Complaints under the Code should be sent to the Director of the Prescription Medicines Code of Practice Authority, 7th Floor, Southside, 105 Victoria St, London SW1E 6QT

telephone 020 7747 8880
facsimile 020 7747 8881
by email to: complaints@pmcpa.org.uk.