CASE AUTH/2575/2/13

EX-EMPLOYEE v GEDEON RICHTER

Promotion of Esmya

An ex-employee of Preglem (a wholly owned subsidiary of Gedeon Richter) complained prospectively about the promotion of Esmya (ulipristal acetate) at a meeting to be held in Barcelona, April 2013.

The complainant referred to an invitation to health professionals which was available on a publicly accessible website. The invitation/save the date document referred to Esmya, its generic name, its indication and to Barcelona. The meeting venue was not stated. The complainant alleged that the invitation appeared to promote Barcelona rather than the meeting itself. The registration link and the access code also referred to Barcelona.

The complainant noted that the invitation referred to 'new phase III evaluating the safety and efficacy of ulipristal acetate in the treatment of uterine fibroids'. The complainant submitted that if this was phase III data, then it would amount to promoting off-label as the licence would not be obtained before the meeting. The complainant further noted that the material was approved in January 2013 but there was no medical signatory available then to certify this foreign travel.

The complainant noted that the events company organising the Barcelona meeting had several invitations from Gedeon Richter on the past events section of its website. Some invitations included the name of the medicine and its indication. The complainant alleged that this seemed like a concerted effort to promote a prescription only medicine to the public.

Finally, the complainant noted that Gedeon Richter also held a meeting in Barcelona in March 2012. The invitations were similar to those for the 2013 meeting but were sent before the grant of the licence in February 2012.

The detailed response from Gedeon Richter is given below.

The Panel considered that as the front page of the invitation to the April 2013 meeting featured the Esmya brand imagery, recipients would immediately associate the meeting with the medicine. The invitation stated that the meeting was, *inter alia*, about ulipristal acetate for the treatment of uterine fibroids and referred to 'highly scientific and interactive sessions on new phase III clinical data evaluating the efficacy and safety of ulipristal acetate in the treatment of uterine fibroids'. A footnote stated that Esmya 5mg was indicated for the pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age with a treatment duration limited to 3 months. The Panel considered that although the invitation promoted Esmya it did not do so for an unlicensed indication. The statement about new phase III data only referred to the product's use in the treatment of uterine fibroids and details of the indication were included. The Panel ruled no breach of the Code.

The invitation asked recipients to save the 12, 13 and 14 April. According to the programme the meeting started on Friday, 12 April at 14.15 and finished at 17.30. This was followed by dinner. The agenda for 13 April ran from 09.00-12.00.

The Panel was concerned that the invitation implied that the meeting would finish on 14 April. This was not so. As the meeting referred to on the invitation finished at midday on 13 April, the Panel failed to see why delegates had to keep 14 April free. A symposium for UK delegates was arranged from 14.00-17.00 on 13 April. This was not mentioned on the save the date card. The Panel did not know when the company informed the UK delegates about this additional seminar. The Panel noted Gedeon Richter's submission that it had decided to hold the UK seminar before the save the date card was sent. The Panel thus queried why this was not mentioned on the invitation card.

The Panel noted that 18 of the UK delegates had stayed in Barcelona for the night of 13 April as the finish time of the meeting (17.00) meant that a return flight was either impossible or the timing of such was inconvenient. The Panel noted that the delegates' difficulties in getting back to the UK on the Saturday evening appeared to contradict Gedeon Richter's submission that Barcelona was chosen because of its easy travel links. Dinner was provided for those who stayed in Barcelona on the Saturday night. Some delegates had had three nights' accommodation paid. For a few of the delegates this was so that they could catch early flights out of the UK on 12 April. The Panel did not consider that the content of both meetings justified two or three nights' accommodation.

The Panel noted Gedeon Richter's reasons for choosing Barcelona. Speakers and delegates were mainly from European countries. The Panel accepted that for a European meeting many delegates would have to travel but considered the company should have made better use of the time so that no-one needed to stay for two nights. The Panel was concerned about the arrangements. It queried why the meeting for UK delegates had not started sooner than 2 hours after the end of the morning meeting and when delegates had been informed about this meeting; the afternoon session for UK delegates was referred to in the final

confirmation letter to delegates. The Panel was concerned that the save the date card implied that there would be scientific content on the Sunday.

Overall, the Panel considered the arrangements were unacceptable and a breach was ruled. The Panel ruled a further breach as the invitation to the meeting outside the UK had not been certified as acknowledged by Gedeon Richter.

The Panel noted that the invitation had been available on the events company's website and also Gedeon Richter's submission that it was unlikely that anyone would stumble upon it without being directed by other means. Health professionals would only be directed to the website if they had received a hard copy of the invitation from a representative. The Panel did not consider that in these circumstances the availability of the invitation on an events company's website constituted advertising a prescription only medicine to the public as alleged and no breach was ruled.

The Panel considered that the rulings of breaches above meant that high standards had not been maintained and that the arrangements brought discredit upon and reduced confidence in the pharmaceutical industry. Breaches of the Code were ruled including a breach of Clause 2.

The Panel was concerned that the save the date invitation for a meeting held in Barcelona on 2/3 March 2012 in effect promoted an unlicensed medicine. The invitation, dated December 2011, referred to Esmya by generic name. The preliminary programme which appeared to have been sent with the invitation included the Esmya product logo and presentations 'How is Esmya different'. The agenda included presentations on Esmya and phase III data. The Panel noted that according to its summary of product characteristics (SPC), Esmya was first authorized in February 2012. The Panel considered that both the agenda and the preliminary programme promoted an unlicensed medicine and a breach was ruled. High standards had not been maintained and a breach was ruled.

On balance, the Panel did not consider the circumstances warranted a ruling of a breach of Clause 2 of the Code which was reserved for use as a sign of particular censure.

An ex-employee of Preglem (a wholly owned subsidiary of Gedeon Richter) complained prospectively about the promotion of Esmya (ulipristal acetate) at a meeting to be held in Barcelona, April 2013.

Esmya 5mg was indicated for pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment was limited to 3 months. The summary of product characteristics (SPC) stated that the marketing authorization holder was Gedeon Richter plc Budapest. The Esmya SPC stated that the product was an orally active synthetic selective progesterone receptor modulator (SPRM) and was first licensed in February 2012.

COMPLAINT

The complainant referred to an invitation to health professionals which was available on a publicly accessible website and provided the relevant link. The complainant noted that the invitation/save the date document referred to Esmya, its generic name, its indication and to Barcelona. There was no mention of the venue where the meeting would be held. The complainant alleged that the invitation appeared to promote Barcelona rather than the meeting itself. In that regard the complainant noted that the registration link and the access code also referred to Barcelona.

The complainant noted that the invitation stated that there would be participation on 'new phase III evaluating the safety and efficacy of ulipristal acetate in the treatment of uterine fibroids'. The complainant submitted that if this was phase III data, then it would amount to promoting off-label as the licence would not be obtained before the meeting.

The complainant further noted that the material was approved in January 2013 but there was no medical signatory available then to certify this foreign travel as the medical signatory had left the company in December 2012.

The complainant noted that the events company organising the meeting in Barcelona had several invitations from Gedeon Richter on its website. Some invitations had the name of the medicine and its indication. The complainant referred in this regard to the 'past events' section of the website. The complainant alleged that this seemed like a concerted effort to promote a prescription only medicine to the public.

The complainant further noted that Gedeon Richter also held a meeting in Barcelona in March 2012. The invitations were similar to those for the 2013 meeting but were sent in January before the grant of the licence in February 2012.

When writing to Gedeon Richter, the Authority asked it to consider the requirements of Clauses 2, 3.1, 3.2, 9.1, 14.2, 14.3, 19.1 and 22.1.

RESPONSE

Gedeon Richter explained that the invitation to the meeting in Barcelona April 2013, sent out to certain health professionals requesting that they save the date in advance of the symposium, clearly informed the recipient of the title and therefore the nature of the meeting before informing them of where the meeting was to be held. The font size was no larger than the font size used for the title of the symposium and the colour of the text was not particularly eye-catching.

Gedeon Richter submitted that it was reasonable to inform clinicians that the meeting would be held overseas as this would provide some idea as to the logistics and domestic impact in terms of absence from home that attendance would be likely to have. It was an international meeting with attendees from many European countries. UK attendees were likely to be a significant minority and so it was reasonable

for them to travel overseas to attend this sort of a meeting.

Given the above, Gedeon Richter refuted the allegation that it had promoted the venue rather than the meeting itself and it thus denied a breach of Clause 19.1.

Gedeon Richter noted that the supplementary information to Clause 3 that 'The legitimate exchange of medical and scientific information during the development of a medicine is not prohibited provided that any such information or activity does not constitute promotion which is prohibited under this or any other clause'. The Barcelona meeting was to act as a forum to allow interested clinicians to discuss SPRMs, of which ulipristal acetate was one, in the overall treatment of uterine fibroids. As the PEARL III study would have completed by the time the meeting was held, it seemed appropriate to include this data in the discussion; this was the 'new phase III clinical data' mentioned in the invitation. Given the position of this information and its relative lack of prominence in the invitation (it only featured mid-way down the invitation, was in black text whereas the programme title was in an eye-catching blue text, and was of a smaller font than the other elements of the invitation) this was clearly not the main focus of the event.

Gedeon Richter further noted that it would be reasonable to expect that the invited clinicians would understand that phase III data by definition represented data that was outside the current licensed indication which was clearly stated in the prescribing information on the back of the invitation. In order to add yet more clarity as to the precise licence of Esmya an asterisk to the title of the symposium drew the reader's attention to the text at the bottom of the page where the therapeutic indication was stated in full. These elements should help to make it clear to clinicians that this was interesting and relevant scientific information but as it was outside the licensed indication, Gedeon Richter did not recommend its use in this manner.

Gedeon Richter considered that the meeting was an opportunity to discuss SPRMs and for interested health professionals to discuss the status quo and data that would be available when the meeting was held and it did not consider that this represented a breach of Clause 3.2.

Gedeon Richter stated that due to a change in company personnel, including the departure of the company's only medical signatory when the invitation was in the final stages of development, it was not possible to demonstrate that the invitation had undergone the complete review and approval process. Gedeon Richter was a small organisation and the departure of the medical signatory clearly had a significant impact on its ability to function though it strove to adhere to the relevant codes of practice. The UK operating company consisted of a medical practitioner, a head of marketing, a financial controller, a team assistant and the managing director, so clearly the departure of even one member of the team introduced potential challenges. In order to allow clinicians enough time to arrange either study leave or annual leave to attend the meeting, it was decided to send out the invitation. A previous version of it had been reviewed by the medical final signatory and non-medical final signatory and amendments were proposed and subsequently made in order to make the piece comply with the Code. Additionally the first version of the invitation was reviewed by two separate reviewers, both of whom either were then or were now registered with the PMCPA as non-medical final signatories. While this did not represent a complete defence to the alleged breach of Clause 14.3, Gedeon Richter stressed that all possible steps were taken in order to comply with the Code.

Gedeon Richter noted that the events company had acted on its behalf to passively facilitate the registration of attendees to a meeting. There were no promotional activities carried out by the events company and as there were no Internet search engine optimisation techniques applied to the company's website, it was extraordinarily unlikely that a health professional or member of the public would stumble upon the invitations without being directed there by other means. Health professionals would only be directed to the events company's website by receipt of a hard copy of the invitation from a Gedeon Richter representative. Further, Gedeon Richter did not consider that the invitation promoted Esmya. While it was mentioned in the invitation as being a treatment for uterine fibroids, there were no specific promotional claims made or elements of the therapeutic indication mentioned. Mention of a medicine and the disease area in which it could be used should not constitute promotion *per se*. Gedeon Richter stated that the complainant was naturally able to access the events management agency website to highlight the presence of the invitation as he/she had prior knowledge of the website that a member of the public simply would not have.

Given the entirely passive nature of the presence of the invitations on the website, the lack of any promotional activity by the events company and the fact that Gedeon Richter did not consider that the mention of ulipristal acetate in the domain of uterine fibroids constituted promotion, the company denied the alleged breach of Clause 22.1.

With regard to the meeting held in Barcelona in 2012, Gedeon Richter reiterated the supplementary information to Clause 3 with regard to the legitimate exchange of medical and scientific information during the development of a medicine.

The March 2012 symposium in Barcelona was planned as an overview of the management of SPRMs and an opportunity to review the profile of ulipristal acetate which was then in the final stages of regulatory approval. The 'Save the date' card mentioned ulipristal acetate but this was in the context of the management of the disease with SPRMs. The preliminary agenda included in the invitation mentioned ulipristal acetate (Esmya) in only 4 of the 10 meeting sessions and the total time dedicated to ulipristal acetate was no more than 50%. The marketing authorization for ulipristal

acetate was granted by the European Medicines Agency (EMA) after the 'Save the date' card and invitation had been sent but before the meeting took place.

Given that Gedeon Richter did not consider that the 'Save the date' card and the meeting invitation were promotional, it denied a breach of Clause 3.1.

Despite the formal lack of medical final certification of the invitation to the symposium to be held in Barcelona in April 2013, Gedeon Richter considered that the steps that were taken to ensure that the invitation complied with the Code demonstrated that it had not failed to maintain high standards.

The company also absolutely refuted the allegation that it had breached Clause 2 as it did not consider, particularly given the nature and origin of the complaint, that it had brought discredit upon, or reduced confidence in, the pharmaceutical industry.

In response to a request for further information, Gedeon Richter submitted that the meeting invitations were offered to consultant gynaecologists interested in the treatment of uterine fibroids as it was considered that they would get the greatest benefit from participating in a scientific meeting with speakers who were considered to be thought leaders in this field. There were no requirements set out to determine eligibility to receive an invitation to attend the meeting and registration was on a 'first come, first served' basis. The invitations were distributed through the field-based team of key account managers either as a hard copy or by email. A similar system was in pace for the 2012 meeting; the target audience was the same group of health professionals and registration was again operated on a 'first come, first served' basis.

Gedeon Richter provided the agendas for the 2012 and the 2013 meetings. The company submitted that there had been few recent developments in the treatment of uterine fibroids so these international scientific symposia were developed to support ongoing scientific discussions and education in this field. They gave interested gynaecologists an opportunity to hear international thought leaders speak about the most up-to-date information on the disease and its treatment. As the vast majority of speakers for both the 2012 and 2013 meetings were not from the UK (as was evident from the agendas for both meetings) it was considered that it would be reasonable to invite UK health professionals to attend the meeting and to facilitate their travel.

Barcelona was chosen as the venue for the two meetings as it had easy travel links to the rest of Europe and a number of venues that could accommodate meetings such as those at issue. The number of UK attendees (53 out of 295 in 2012 and 40 out of 378 in 2013 (attendance figures by country were also provided)) also represented a significant minority so based on this it was considered reasonable to invite UK health professionals to the meeting. While uterine fibroids was an area of unmet clinical need in the UK and the rest of the world, the relative lack of therapies meant that the topic was often under-represented at gynaecology conferences. By bringing together the thought leaders in this branch of gynaecology the 2012 and 2013 meetings offered an opportunity for gynaecologists to expand their knowledge and understanding of the treatment of uterine fibroids. Given that these meetings allowed gynaecologists to gain education in this area it was considered appropriate to invite UK health professionals and indeed, some of those who had attended the 2012 meeting expressed an early interest in attending the 2013 meeting as they considered that it was a valuable learning resource.

In response to a second request for further information Gedeon Richter submitted that following discussion between clinicians and the key account managers about what information the clinicians would find useful, it was decided to hold an additional session for the UK delegates following the closure of the main part of the meeting. The agenda for this was only recently confirmed and a copy was provided. As the decision to include an extra session had been made before the flights were booked it was appropriate to arrange the delegates' return flights so that airport transfers could begin after the close of this additional session. If it was possible for a delegate to catch a return flight that evening (Saturday, 13 April) the arrangements were made. If, however, there were no return flights to their airport of choice or logistical issues dictated that they would be travelling particularly late (such as if they would have a significant onward journey following arrival in the UK) then it was reasonable to offer an additional night's accommodation in Barcelona and arrange return travel for the next day (Sunday, 14 April). Details of the travel arrangements of each of the delegates were provided.

The decision to hold an additional UK session was made before the 'Save the date' card was sent and so it was decided to give a degree of warning that return travel from the meeting might therefore include Sunday, 14 April. Gedeon Richter offered and paid for only the minimum number of nights' accommodation in the hotel that would be required to facilitate attendance at the meeting.

Gedeon Richter provided several screenshots of the website that delegates would visit to register for the meeting and to indicate their travel plans.

Gedeon Richter stated that Esmya 5mg was currently indicated '…for pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The duration of treatment is limited to 3 months'. This indication was obtained as part of the marketing authorization which was granted largely as a result of the PEARL I and PEARL II studies. These studies used doses of 5mg and 10mg once daily and the data was referred to in the Esmya SPC. PEARL III was a placebo-controlled study to assess the benefit of a short course of progestin (or placebo) following Esmya 10mg for 12 weeks for the treatment of fibroids. These treatments were then repeated three further times. The use of repeated courses of Esmya was described in the Esmya Risk Management Plan as an

area of 'missing information' and so one key aim of PEARL III was to help to provide this information.

PANEL RULING

The Panel noted that Gedeon Richter had organised two meetings in Barcelona, one in April 2013 and the other in March 2012.

The Panel reviewed relevant requirements of the Code in relation to meetings, hospitality and sponsorship and Gedeon Richter UK's responsibility.

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 refreshments/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 also noted the supplementary information to Clause 19.1, Meetings and Hospitality, which stated that meetings organised by pharmaceutical companies which involved UK health professionals at venues outside the UK were not necessarily unacceptable. There had, however, to be valid and cogent reasons for holding meetings at such venues. These were that most of the invitees were from outside the UK or, given the location of the relevant resource or expertise that was the object or subject matter of the meeting, it made greater logistical sense to hold the meeting outside the UK. As with meetings held in the UK, in determining whether such a meeting was acceptable or not, consideration must also be given to the educational programme, overall cost, facilities offered by the venue, nature of the audience, subsistence provided and the like. As with any meeting it should be the programme that attracted delegates and not the associated hospitality or venue.

The Panel noted that Clause 3 prohibited the promotion of a medicine prior to the grant of the marketing authorization and required that promotion was in accordance with the marketing authorization and not inconsistent with the SPC. The supplementary information to Clause 3, Marketing Authorization, stated that the legitimate exchange of medical and scientific information during the development of a medicine was not prohibited provided that any such information or activity did not constitute promotion which was prohibited under this or any other clause.

1 Barcelona meeting April 2013

The Panel noted that the front page of the meeting invitation was headed 'Save the date!' and featured the brand imagery associated with Esmya. In that regard the Panel considered that recipients would immediately associate the meeting with Esmya. The invitation stated that the meeting was about SPRMs and ulipristal acetate for the treatment of uterine fibroids. The invitation referred to 'highly scientific and interactive sessions on new phase III clinical data evaluating the efficacy and safety of ulipristal acetate in the treatment of uterine fibroids'. The indication was included as a footnote which stated that Esmya 5mg was indicated for the pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age with a treatment duration limited to 3 months. The Panel considered that the invitation itself promoted Esmya for the treatment of uterine fibroids. Prescribing information was included on the reverse. The Panel was concerned that Gedeon Richter submitted that the invitation was not promotional. It could not be anything else given that it referred to a product and included an indication.

The Panel did not consider that the invitation promoted Esmya for an unlicensed indication. Although the invitation mentioned new phase III data it only referred to the product's use in the treatment of uterine fibroids and details of the indication were included. The Panel considered that there was no breach of Clause 3.2 and ruled accordingly. The meeting discussed the new phase III data which according to Gedeon Richter's submission included data on the 10mg dose which was not licensed. The Panel noted Gedeon Richter's submission that the SPC included some of the 10mg data. It also noted that there was no complaint in this regard about the meeting.

The invitation asked the recipient to save the 12, 13 and 14 April. According to the programme the meeting started on Friday, 12 April at 14.15 and finished at 17.30. This was followed by dinner. The agenda for 13 April ran from 09.00–12.00. There was no date of preparation on the agenda document.

The Panel was concerned that the invitation implied that the meeting would finish on 14 April. This was not so. The meeting referred to on the invitation 'International Scientific Symposium dedicated to Selective Progesterone Receptor Modulators (SPRMs) and ulipristal acetate for the treatment of uterine fibroids' finished at midday on 13 April. The Panel failed to see why a meeting arranged to finish at midday on 13 April required delegates to keep 14 April free. A symposium for UK delegates was arranged from 14.00-17.00 on 13 April. This was not mentioned

on the save the date card. The Panel did not know when the company informed the UK delegates about this additional seminar. The Panel noted Gedeon Richter's submission that the decision to hold the UK seminar was made before the save the date card had been sent. The Panel queried why the afternoon seminar was not mentioned on the invitation card.

The Panel noted that 18 of the UK delegates had stayed on in Barcelona for the night of 13 April as the finish time of the meeting (17.00) meant that either they could not catch flights back that evening or they considered the time of a possible return flight was inconvenient. One delegate considered that a possible flight at 19.20 (used by other delegates) was too late on the Saturday evening to return home because, *inter alia*, he/she had a long drive from the airport; this delegate returned instead at 20.00 on the Sunday. Two other people also decided against a possible 19.20 flight home on the Saturday and their request to stay an extra night was granted 'due to the time being close'. The Panel noted that the delegates' difficulties in getting back to the UK on the Saturday evening appeared to contradict Gedeon Richter's submission that Barcelona was chosen because of its easy travel links. Dinner was provided for those who stayed in Barcelona on the Saturday night. Sixteen delegates flew back to the UK on the Saturday evening and one delegate paid for his own accommodation for the Saturday evening. Some delegates had had three nights' accommodation paid. For a few of the delegates this was so that they could catch early flights out of the UK on 12 April. The Panel did not consider that the content of both meetings justified two or three nights' accommodation.

The Panel noted Gedeon Richter's reasons for choosing Barcelona. The speakers and delegates were mainly from European countries; the number of UK delegates (40) was the fourth largest group and the Spanish delegates formed the third largest group (42). The Panel accepted that for a European meeting many delegates would have to travel but considered the company should have made better use of the time so that no one needed to stay for two nights. The Panel was concerned about the arrangements. It queried why the meeting for UK health professionals had not started sooner than 2 hours after the end of the morning meeting and when delegates had been informed about this meeting; the afternoon session for UK delegates was referred to in the final confirmation letter to delegates. The Panel was concerned that the save the date card gave the impression that there would be scientific content on the Sunday.

This was the second year that the company had organised a meeting in Spain.

Overall, the Panel considered the arrangements were unacceptable and a breach of Clause 19.1 was ruled.

The Panel noted that Gedeon Richter acknowledged that the invitation to the meeting outside the UK had not been certified by a registered medical practitioner or a UK registered pharmacist as required by Clause 14.2 and a breach of Clause 14.2 was ruled.

The Panel noted that the invitation had been available on the events management agency website. The Panel noted Gedeon Richter's submission that this role had been passive and that there were no Internet search engine optimisation techniques applied to the website. Further it was unlikely that a health professional or a member of the public would stumble upon the invitations without being directed by other means. Health professionals would only be directed to the website if they had received a hard copy of the invitation from a Gedeon Richter representative. The Panel did not consider that in these circumstances the availability of the invitation on an events management website constituted advertising a prescription only medicine to the public as alleged. No breach of Clause 22.1 was ruled.

The Panel considered that the rulings of breaches regarding the arrangements for the meeting including the failure to certify meant that high standards had not been maintained and a breach of Clause 9.1 was ruled. The Panel considered that the arrangements brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

2 Invitation to the Barcelona meeting 2012

The Panel noted that a save the date letter had been sent in December 2011 for a meeting to be held in Barcelona on 2 and 3 March 2012. The meeting invitation was headed 'Scientific symposium dedicated to SPRMs and ulipristal acetate, Barcelona, Spain'. The agenda included presentations on Esmya and phase III data. The meeting ran from 15.15 to 18.30 on 2 March and 9.00 – 12.30 the following day.

The Panel noted that according to the Esmya SPC it was first authorized in February 2012.

The Panel noted Gedeon Richter's reasons for choosing Barcelona.

The Panel was concerned that the save the date invitation in effect promoted an unlicensed medicine. The invitation dated December 2011 referred to the product by generic name and that it was a SPRM. The preliminary programme which appeared to have been sent with the invitation included the brand name Esmya in logo format and presentations 'How is Esmya different'. The Panel considered that the both the agenda and the preliminary programme promoted an unlicensed medicine and a breach of Clause 3.1 was ruled. High standards had not been maintained and a breach of Clause 9.1 was ruled.

On balance, the Panel did not consider the circumstances warranted a ruling of a breach of Clause 2 of the Code which was reserved for use as a sign of particular censure.

During its consideration of the allegation about the invitation to the meeting in Barcelona, 2012 the Panel queried whether the content of the meeting would attract delegates rather than the venue. The programme content was on the limits of acceptability

in that the meeting, which lasted just over 6 hours, was spread over two days. The Panel was also concerned that the invitation and programme did not appear to have been certified prior to distribution. The invitation had a November 2011 date of preparation and was dated December 2011. The programme had a November 2011 date of preparation. The Panel did not accept the submission that the meeting met the supplementary information for Clause 3 in relation to the legitimate exchange of medical and scientific information during the development of a medicine. However, the complaint was about the content of the invitation not about its certification or the meeting itself and by the time of the meeting, Esmya had a marketing authorization. The Panel requested that its concerns were drawn to the company's attention.

Complaint received **6 February 2013**

Case completed **7 May 2013**
