CASE AUTH/2643/10/13

ANONYMOUS CONTACTABLE v PHARMAXIS

Approval of material and provision of training

An anonymous complainant, who described his/her relationship to Pharmaxis as one of contractor to client, referred to a number of matters broadly covering the approval and certification of material and training. The complainant submitted that the company knew about these matters but had failed to act over a period of time.

The detailed response from Pharmaxis is given below.

Pharmaxis marketed two medicines in the UK: Bronchitol (mannitol), indicated as add-on therapy for the treatment of cystic fibrosis (CF) in adults aged 18 years and above (launched 1 June 2012) and Osmohale (mannitol), a diagnostic product indicated for identifying bronchial hyper-responsiveness in subjects with a baseline FEV1 ≥ 70% of predicted (launched December 2007).

The complainant alleged that the company's first standard operating procedure (SOP) or system for approval of non-promotional items was in development in the summer of 2013. Assuming an SOP was now in place, the company had thus operated without a process to approve non-promotional materials for some time during the launch and pre-launch phases of Bronchitol and Osmohale. The complainant alleged that for a number of years non-promotional materials were not subject to any medical check or approval.

The complainant alleged that one of a number of materials which Pharmaxis deemed as non-promotional, and so not subject to medical check, review or sign off, was a journal called Current Medical Literature (CML). CML was an update of the latest information in cystic fibrosis, for which Bronchitol was indicated, and as it was circulated by the representatives it was, contrary to the company's view, promotional. CML included advertisements for Pharmaxis in the pre-launch phase and for Bronchitol after the medicine was licensed. The complainant alleged that CML might have also been promotional in the pre-launch phase given that it was in the cystic fibrosis disease area and included company advertisements.

The complainant stated that the Pharmaxis SOP for the approval of promotional materials included certification of final documents and/or certification of a short print run before the bulk was printed as suggested by the PMCPA. The complainant alleged that if certification was now happening it was a recent change and that it had not happened for some years with regard to Bronchitol or Osmohale. Final versions of materials were not retained until recently (if they were now, which was unclear).

In response to a request for further information, the complainant submitted that he/she did not have copies of the CML journal. The complainant alleged that Pharmaxis representatives had circulated a number of issues over the years. Regardless of whether the latest issue was approved, there would be a number of issues that had not been approved as they did not go through any job bag process. The complainant did not have copies of the promotional SOP which was updated in 2013 and approved by management. The previous version included the certification element which the complainant alleged was never followed. Pharmaxis kept central copies of all SOPs including historical ones. The complainant submitted that he/she did not have a copy of the non-promotional material SOP; his/her complaint was that one did not exist and he/she was not clear if one had been completed and signed off.

The Panel noted that the complainant had firstly made a very general allegation that, contrary to the requirements of the Code, Pharmaxis did not have an SOP or process in place for the approval of non-promotional items for a significant period of time and as such those items were not subject to any medical review or approval. Secondly, the complainant alleged that the CML journals had incorrectly been deemed non-promotional and thus not certified.

The Panel noted that the Code required that certain non-promotional material be certified in a manner similar to that required for promotional items and the supplementary information required that other material issued by companies which related to medicines but which were not intended as promotional material for those medicines *per se*, be examined to ensure that it did not contravene the Code or the relevant statutory requirements.

The Panel noted that the complainant bore the burden of establishing his/her case on the balance of probabilities. The Panel noted Pharmaxis's submission that although it had an SOP, effective from April 2012, which covered the certification of promotional items, both promotional and non-promotional materials were subject to the same rigorous review by two registered final signatories. The Panel further noted Pharmaxis's submission that although at that time there was no certification of non-promotional materials the company did not produce any such materials which required certification. A separate written procedure had been introduced in mid October 2013 to specifically cover proactive approval of non-promotional material. The Panel noted that a judgement had to be made on the available evidence. The Panel did not consider that the complainant had shown, on the balance of probabilities, that in relation to the very general allegation about non-promotional materials, and excluding the CML journal which was dealt with separately below, Pharmaxis had failed to approve

or certify certain non-promotional items and no breach was ruled.

The Panel noted the complainant's second allegation that Pharmaxis had incorrectly characterized, *inter alia*, the CML journal as non-promotional despite it being circulated by representatives and it was thus not subject to medical review or sign off.

The Panel noted Pharmaxis's submission that CML was an educational update prepared and reviewed by an independent editorial board and produced by an independent publisher to provide an abstracting service of major medical journals based around specific therapeutic areas for health professionals. The cystic fibrosis CML was supported by an educational grant from Pharmaxis.

The Panel noted Pharmaxis's submission that it had no input into the editorial content of the journal and was therefore unable to formally approve the content prior to publication. The Panel considered that whilst this might be true for the content of the individual articles, Pharmaxis had placed a single page advertisement in each edition of the journal and had agreed to be the sole sponsor and distributor. The Panel considered that Pharmaxis was inextricably linked to the production of the journal and the company was thus responsible under the Code for the content.

The Panel noted that this matter was further complicated as it appeared that Pharmaxis had not categorized the journal, at the outset, under the Code. Some editions had been certified as promotional whilst others were treated as non-promotional. In the Panel's view it was difficult in such circumstances to maintain compliance. In the absence of any submission on this point the Panel decided on balance that provision of the CML journal should be regarded as a medical and educational good and service (MEGS). The supplementary information to the Code which stated that medical and educational goods must not bear the name of any medicine did not apply to independently produced text books or journals which included, as part of their texts, the names of medicines. MEGS could bear a corporate name.

The Panel examined two volumes of CML; Volume 3, Number 1, with a Bronchitol advertisement after its marketing authorization was granted and before the updated company certification process was implemented, and Volume 3, Number 2, with the same Bronchitol advertisement after the implementation of the updated company certification process. The Panel noted that MEGS were a non-promotional activity. In the Panel's view, the inclusion of the Bronchitol advertisements in CML rendered the journals promotional. They did not satisfy the requirements for MEGS set out in the Code. CML Volume 3, Number 1 had not been certified and thus a breach of the Code was ruled. CML Volume 3, Number 2 had been certified. However, it had not been certified as a non-promotional MEGS and a breach of the Code was thus ruled.

The complainant alleged that CML might be promotional in the pre-launch phase given it was in the disease area and included company advertisements. The Panel examined Volume 1, Number 1, 2011 of CML which was produced before the launch of Bronchitol. It contained an advertisement on the back page that had the company logo at the top with the strapline 'innovation for life' followed by 'Innovation in Respiratory Medicine'. The Panel considered that it was a corporate advertisement and the journal did not directly or indirectly promote Bronchitol before the grant of its marketing authorization as alleged. No breach of the Code was ruled on this narrow point. The Panel noted that whilst MEGS could contain a company name it queried whether they could contain a corporate advertisement which went beyond a mere reference to the company name. The Panel noted that whilst the journal did not promote Bronchitol, it nonetheless required certification as a MEGS. The journal had not been so certified and a breach of the Code was thus ruled.

The Panel noted that representatives had not distributed the journal to health professionals as alleged but had provided them with a card via which a health professional could request a copy of CF CML to be sent directly from head office with a letter giving them the option to unsubscribe from the journal circulation. The Panel noted that the representatives were not provided with any written instructions regarding the circulation of the card. The Panel considered that it would have been helpful if they had been briefed on how the card could be distributed given that they were, in effect, facilitating the distribution of a MEGS. The Panel noted that whilst the complainant had incorrectly referred to distribution of the journals by representatives, he/she had not made any allegations regarding their instruction and in this regard no breach of the Code was ruled.

The Panel noted that the complainant's allegation that certification of final promotional materials had not happened for years and final versions of materials were not retained until recently if they now were which was unclear. The Panel noted that an audit carried out by an external consultant at the request of Pharmaxis revealed that before August 2013 items were not certified in their final form. The Panel ruled a breach of the Code as acknowledged by Pharmaxis.

The Panel noted Pharmaxis's submission that all materials submitted for review were retained and archived for a minimum of 7 years in line with its SOP. The Panel did not consider that the complainant had shown that, on the balance of probabilities, Pharmaxis had failed to preserve all certificates as required and no breach was ruled.

The Panel noted its rulings and considered that high standards had not been maintained. A breach of the Code was ruled. The Panel considered that Pharmaxis's failure to correctly categorize the cystic fibrosis CML as either promotional or non-promotional at the outset, and to thus correctly certify it, displayed a poor understanding of the

Code and that, together with the company's failure to certify the final form of its material, reduced confidence in, and brought discredit upon, the industry. A breach of Clause 2 was ruled.

The complainant further alleged that no Code training was given to staff to keep them up-to-date and many were out of touch. A junior product manager, who was previously a marketing officer, did not have the ABPI examination accreditation despite being in marketing for over two years.

The Panel noted the marketing support officer's role as described in the job description and considered that it failed to satisfy the definition and role of a representative, as defined in the Code, and so the post holder was not required under the Code to take and pass an appropriate ABPI examination. No breach of the Code was ruled which the Appeal Board upheld on the narrow grounds that the complainant had failed to provide any specific evidence to prove his/her complaint.

The Panel noted the complainant's allegation that no Code training was given to keep Pharmaxis staff up-to-date. The Panel noted Pharmaxis's submission that it ensured all staff undertook training on the Code relevant to their particular role via an online learning management system and the UK sales and marketing team members were additionally required to complete Code of Practice courses on an e-learning website. The Panel noted the list of courses completed by Pharmaxis UK sales and marketing team members in the last 18 months which included a course on the scope of the ABPI Code and various SOPs covering aspects of the Code. The Panel further noted Pharmaxis's submission that representatives were provided with current copies of the Code as soon as they became available. The Panel did not consider that Pharmaxis had provided staff with no Code training as alleged and ruled no breach of the Code.

With regard to staff training the Panel noted its rulings above and ruled no breach of the Code including Clause 2.

An anonymous complainant, who described his/her relationship to Pharmaxis as one of contractor to client, complained about a number of matters broadly covering the approval and certification of material and training. The complainant submitted that Pharmaxis was aware of these matters but had failed to act over a period of time.

Pharmaxis marketed Bronchitol (manitol) and Osmohale (manitol). Bronchitol was indicated for the treatment of cystic fibrosis (CF) in adults aged 18 years and above as add-on therapy to best standard of care. Bronchitol was an orphan-designated medicine which was approved through the European centralised procedure on 13 April 2012 and launched in the UK on 1 June 2012. Osmohale was a diagnostic product indicated for identifying bronchial hyper-responsiveness in subjects with a baseline FEV1 ≥ 70% of predicted. It was registered and launched in the UK in December 2007.

1 Approval and certification of material

COMPLAINT

The complainant alleged that contrary to the Code, Pharmaxis did not have a standard operating procedure (SOP) or system for approval of non-promotional items. One was in development in the summer of 2013 and, if it had come into practice, would be signed off by management making the date of its introduction clear. It did not supersede a previous version. The complainant alleged that, assuming an SOP was now in place, the company had operated without one and therefore without a process to approve non-promotional materials for a significant period of time during both the launch and pre-launch phase of Bronchitol. This also applied to Osmohale. The complainant alleged that for a number of years non-promotional materials were not subject to any medical check or approval.

The complainant alleged that Pharmaxis deemed a number of materials as non-promotional and so they were not subject to medical checking or sign off. This included a journal called Current Medical Literature (CML). The complainant explained that CML was an update of the latest information in cystic fibrosis, for which Bronchitol was indicated, and as it was circulated by the representatives it was thus promotional. CML included advertisements for Pharmaxis in the pre-launch phase and Bronchitol advertisements after the medicine had gained a marketing authorization. The complainant alleged that as there was a misunderstanding and no process in place for materials deemed to be non-promotional, CML was exempt from any review. Further, CML was incorrectly assumed to be non-promotional despite being circulated by representatives. The complainant alleged that CML might have also been promotional in the pre-launch phase given that it was in the cystic fibrosis disease area and included company advertisements.

The complainant stated that the Pharmaxis SOP for the approval of promotional materials included certification of final documents and/or certification of a short print run before the bulk was printed as suggested by the PMCPA. The complainant alleged that if certification was now happening it was a recent change and that it had not happened for some years with regard to Bronchitol and Osmohale. Final versions of materials were not retained until recently (if they were now, which was unclear).

In response to a request for further information, the complainant submitted that he/she did not have copies of the CML journal. The complainant alleged that Pharmaxis representatives had circulated a number of issues over the years. Regardless of whether the latest issue was approved, there would be a number of issues that had not been approved as they did not go through a non-promotional or promotional materials job bag, the former of which did not exist at the time. Pharmaxis kept copies of the journal in its literature stores. The complainant did not have copies of the promotional SOP which was updated in 2013 and approved by management. The previous version included the certification element which the

complainant alleged was never followed. Pharmaxis kept central copies of all SOPs including historical ones. The complainant submitted that he/she did not have a copy of the non-promotional material SOP; his/her complaint was that one did not exist. The complainant submitted that one was in development but he/she was not clear if it had been completed and signed off. The complainant submitted that Pharmaxis would be able to provide a copy of this SOP which would detail its inception date and the company could confirm that it was the first SOP for that type of approval.

When writing to Pharmaxis, the Authority asked it to respond in relation to Clauses 3.1, 9.1, 14.1, 14.3, 14.6, 15.9 and 2.

RESPONSE

Pharmaxis was disappointed to receive the complaint. It was committed to complying with both the letter and spirit of the Code and using the Code as a benchmark for its compliance procedures. The company had investigated the aspects of this complaint in detail.

Pharmaxis submitted that it was entirely incorrect to state that there was no medical check of non-promotional items. Before April 2013, when an external consultant was brought in to review all procedures, the approval and certification procedure (SOP/UK/012; effective date 1 April 2012 which replaced SOP/UK/011; effective date 9 November 2007) covered the certification of promotional items only but non-promotional items were subject to the same rigorous review process whilst being created and were reviewed by two final signatories registered with the Medicines and Healthcare Products Regulatory Agency (MHRA) and the PMCPA (one of whom was a medical signatory) before. Pharmaxis submitted that the process was robust and ensured that all materials were thoroughly reviewed in terms of medical accuracy, product licence, form and suitability whether deemed to be promotional or non-promotional. During their review the signatories would determine whether material was promotional or non-promotional and promotional material was certified. Pharmaxis submitted that although at that time there was no certification of non-promotional materials, it did not produce any material listed in Clause 14.3 that required certification. Pharmaxis denied a breach of Clause 14.3.

Pharmaxis embraced the opportunity to continue to improve its processes and in April 2013 an audit of its written procedures relating to all aspects of the Code was undertaken by an external consultant. It was identified that in addition to a written process for the approval of promotional materials (which was in place) a separate written process should be introduced to specifically cover proactive approval of non-promotional material. The new procedure had been approved and was now in place. A copy of the current procedures for the approval of promotional and non-promotional materials was provided.

Pharmaxis submitted that it had an SOP for the approval of promotional materials since the first product was introduced in 2007. Pharmaxis submitted that although a small company, it had developed rapidly since the approval of Bronchitol, its first therapeutic medicine, in 2012. The company realised that it needed external support to ensure that all of its practices complied with the Code and in April 2013 an experienced consultant was employed to review its practices and provide a list of any findings to be addressed by the company. One of the areas identified was certification.

Pharmaxis submitted that it had always had two employees (including a physician) appropriately nominated to the MHRA and PMCPA as 'final' signatories for materials within the job bag process. The audit, however, revealed that certification was taking place at the final artwork stage rather than certification of the final form. Once this omission had been recognised, a revised process was created and the appropriate signatories and support staff trained. Pharmaxis submitted that since August 2013, all materials had followed the revised process through to certification. The certificates and the equivalent job bags would be retained by the company for at least three years after the withdrawal date of the material in compliance with the requirements of Clause 14.6. In addition, a new medical signatory joined the company in July 2013. Pharmaxis submitted that although it now certified the final form of all material, it recognised that pre August 2013 it had not complied with Clause 14.1 and was at that time in breach of that clause.

Pharmaxis submitted that CML was an independent, peer-reviewed, educational publication that had existed for many years. Various editions covered a variety of disease areas and provided an abstracting service of major medical journals based around specific therapeutic areas for health professionals.

The cystic fibrosis CML (CF CML) was prepared and reviewed by an independent editorial board of 8-10 clinical experts from around the world. It was produced by an independent medical education and publishing company. This CML was supported by a grant from Pharmaxis which was the sole sponsor. The publishers approached Pharmaxis with that proposal and a copy of the statement from the publisher confirming that Pharmaxis had no input into the editorial content of CF CML was provided.

Sponsorship opportunities were provided to pharmaceutical companies who could provide the journal to health professionals and place a single page advertisement in each edition. The sponsoring company had no involvement at any stage in the choice of editorial board members, nor did it have any input into the educational content of any volume, including choosing authors of any article within it. In order to maintain the independence of this educational material, no employee of Pharmaxis saw any volume before it was published.

As Pharmaxis had no involvement in developing the content of each CML volume, the company

was unable to formally approve the content prior to publication. The advertisements placed in the journal were all approved via the company approval process and a statement was included in the journal clearly indicating that the company provided financial support. Pharmaxis submitted therefore that the statement from the complainant that 'the material was not subject to any medical checking or sign off' was incorrect.

Pharmaxis submitted that before Bronchitol was launched, it placed a corporate advertisement in CF CML to highlight Pharmaxis' engagement with respiratory medicine. As the corporate advertisement was non-promotional it was not certified, however, it was subject to the medical review process as described above.

During the review process, the medical certifier determined that the initial advertisement proposed for journal inclusion was promotional and therefore inappropriate as it referred to cystic fibrosis. The advertisement was therefore amended during the review process which illustrated that a robust review process was in place as required by the Code. A copy of the rejected advertisement and the comments from the medical certifier were provided.

Pharmaxis considered that it was acceptable to include a corporate advertisement in non-promotional material. There was no mention of Bronchitol, either in the CF CML itself or in the corporate advertisement. Pharmaxis therefore refuted the allegation that the CF CMLs produced pre-launch promoted Bronchitol before the grant of its marketing authorization in breach of Clause 3.1. A copy of the CF CML pre-launch was provided.

Post product launch, CF CML contained a Bronchitol advertisement. Until August 2013, the product advertisement was approved as promotional but as acknowledged above, before August 2013, the company did not complete the final stage of certification of materials as required by the Code. Pharmaxis submitted that the process had since been updated and all materials were now appropriately certified in line with Clause 14.1 including the latest volume of CF CML (Volume 3, Number 2).

Copies of Volume 3, Number 1, with a product advertisement after marketing authorization was granted and before the updated company certification process was implemented, and Volume 3, Number 2, with a product advertisement after marketing authorization was granted and after the updated company certification process was implemented, were provided. For the latter, a copy of the certification document was also enclosed. Pharmaxis volunteered to provide copies of all volumes of the CML if the Authority wanted them.

Pharmaxis submitted that it was the sole distributer of CML. Representatives did not distribute it to health professionals but were provided with a card via which a health professional could request a copy from Pharmaxis head office. The journals were sent directly to the relevant health professional once received by Pharmaxis with a letter giving the health professional an option to unsubscribe from the journal circulation. Pharmaxis submitted that as the request card did not relate to the technical aspects of a medicine which the representatives promoted, no briefing was provided on how the card could be distributed and there was no briefing that advocated, either directly or indirectly, any course of action by a representative which was likely to lead to a breach of the Code. Pharmaxis therefore refuted a breach of Clause 15.9.

Pharmaxis submitted that pre August 2013, although it had thoroughly reviewed and approved promotional material it had not certified the final form and at that time was in breach of Clause 14.1. An internally commissioned review identified this issue and it was addressed as part of a process of continual improvement. Pharmaxis therefore did not consider that it had failed to maintain high standards and was thus not in breach of Clause 9.1. Subsequently Pharmaxis denied that it brought discredit upon, or reduced confidence in the industry and was therefore not in breach of Clause 2.

In response to a request for further information, Pharmaxis submitted that its SOP regarding approval of promotional material created by the European regional office clearly stated that 'The Regional Office will ensure that all materials submitted for review are retained and archived. These should be maintained for a minimum of 7 years'. The term 'materials' related to both the job bag and appropriate accompanying certificates. Pharmaxis submitted that all materials were retained appropriately and denied that any materials had breached Clause 14.6 which required materials and certificates to be preserved for at least three years after use. A copy of the card via which a health professional could request a copy of CF CML was provided.

In response to a request for further information Pharmaxis submitted that when Pharmaxis set up its European operations in the UK, it was decided that it was most appropriate for the company to use the UK Code as its benchmark for compliance. All materials produced by its European office, including those for the UK, were prepared in line with Pharmaxis's understanding of the remit of the Code at that time. This was documented initially in SOP/UK/011 (2007) and then updated in SOP/UK/012 in 2012. However, Pharmaxis launched Bronchitol to its first non-UK European market in 2012 and realised that it needed an additional SOP so that its colleagues in Germany and other countries had guidance on how materials they created or adapted locally would be assessed for compliance and SOP/UK/013, Approval of promotional materials created or adapted by the local companies (Europe), was created. Copies of the SOPs were provided. Pharmaxis apologised for creating confusion with use of its terminology. The SOP for approval of promotional material had always included the need for material to be certified in its final form. The internal audit highlighted the fact that two authorised signatories had been certifying the final artwork rather than the final form. The 'process' was updated in the sense that appropriate staff were retrained on the relevant SOPs and the need for certification of the final form

but no changes to the written process was required as the information was already included in the SOP. Pharmaxis submitted that the need to certify the final form of any piece was also included in the non-promotional material SOP (EU/MED/SOP/MA/0015).

Pharmaxis submitted that as stated in its initial response, although it had always had two personnel (including a physician) appropriately nominated to the MHRA and PMCPA as final signatories, it was aware that before August 2013 certification was taking place at the final artwork stage rather than certification of the final form. In addition Pharmaxis was aware that historically it lacked a separate SOP for non-promotional materials. Both of these issues had been corrected. Pharmaxis submitted that the CF CML Volume 1, Number 1 was reviewed by the medical signatories and deemed to be non-promotional but was not certified. The first volume of CML that was published after August 2013 and thus was fully certified was volume 3, number 2. This volume and the relevant certification materials had been provided with Pharmaxis's initial response. Pharmaxis submitted that the most recent volume (Volume 3, Number 3) had just been received at head office and was currently going through the approval process and would be certified in a similar way to Volume 3, Number 2 before distribution.

Pharmaxis confirmed that CML journals were sent directly from head office to those health professionals who had requested them together with a covering letter, a copy of which was provided. The same letter was sent with each volume of the CML so that health professionals were always made aware that they could unsubscribe from receiving future volumes. Pharmaxis submitted that as the letter was an administrative piece it had not been approved as either promotional or non-promotional.

PANEL RULING

The Panel noted that the complainant had firstly made a very general allegation that contrary to the requirements of the Code Pharmaxis did not have an SOP or process in place for the approval of non-promotional items for a significant period of time and as such those items were not subject to any medical review or approval. Secondly, the complainant alleged that the CML journals had incorrectly been deemed non-promotional and thus not certified.

The Panel noted that Clause 14.3 required that certain non-promotional material be certified in a manner similar to that provided for by Clause 14.1 and the supplementary information required that other material issued by companies which related to medicines but which were not intended as promotional material for those medicines *per se*, be examined to ensure that it did not contravene the Code or the relevant statutory requirements. Non-promotional items requiring certification under Clause 14.3 included educational material for the public or patients, material relating to working with patient organisations, materials prepared in relation to joint working, material relating to patient support programmes and material relating to the provision of medical and educational goods and services (MEGS).

The Panel noted that the complainant bore the burden of establishing his/her case on the balance of probabilities. The Panel noted Pharmaxis's submission that although the SOP, effective from April 2012, only covered the certification of promotional items, both promotional and non-promotional materials were subject to the same rigorous review by two registered final signatories. The Panel further noted Pharmaxis's submission that although at that time there was no certification of non-promotional materials the company did not produce any materials requiring certification as listed in Clause 14.3. A separate written procedure had been introduced in mid October 2013 to specifically cover proactive approval of non-promotional material. The Panel noted that a judgement had to be made on the available evidence. The Panel did not consider that the complainant had shown, on the balance of probabilities, that in relation to the very general allegation about non-promotional materials, and excluding the CML journal which was dealt with separately below, Pharmaxis had failed to approve or certify certain non-promotional material listed in Clause 14.3 as alleged and no breach of Clause 14.3 was ruled.

The Panel noted the complainant's second allegation that Pharmaxis had incorrectly deemed a number of materials including the Current Medical Literature (CML) journal to be non-promotional despite it being circulated by representatives and it was thus not subject to medical review or sign off.

The Panel noted Pharmaxis's submission that CML was an educational update prepared and reviewed by an independent editorial board and produced by an independent publishing company to provide an abstracting service of major medical journals based around specific therapeutic areas for health professionals. The cystic fibrosis CML was supported by an educational grant from Pharmaxis.

The Panel noted that it was possible for a company to sponsor material, produced by a third party, which mentioned its own products, and not be liable under the Code for its content, but only if, *inter alia*, there had been a strictly arm's length arrangement between the parties. In practical terms the arrangements must be such that there could be no possibility that the pharmaceutical company has been able to exert any influence or control over the final content of the material.

The Panel noted Pharmaxis's submission that it had no input into the editorial content of the journal and was therefore unable to formally approve the content prior to publication. The Panel considered that whilst this might be true for the content of the individual articles, Pharmaxis had placed a single page advertisement in each edition of the journal and had agreed to be the sole sponsor and distributor. The Panel considered that Pharmaxis was inextricably linked to the production of the journal and the company was thus responsible under the Code for the content.

The Panel noted that this matter was further complicated as it appeared that Pharmaxis had not categorized the journal, at the outset, under the Code. Some editions had been certified as promotional whilst others were treated as non-promotional. In the Panel's

view it was difficult in such circumstances to maintain compliance. In the absence of any submission on this point the Panel, noting the company's comments about the journal's creation and content, decided on balance that provision of the CML journal should be regarded as a medical and educational good and service (MEGS) as set out in Clause 18.4 of the Code. The supplementary information to that clause stated that the requirement in Clause 18.4 that medical and educational goods must not bear the name of any medicine did not apply where the goods involved consisted of independently produced text books or journals which included, as part of their texts, the names of medicines. MEGS could bear a corporate name. The Panel noted that Pharmaxis had not been asked to respond to Clause 18.4 of the Code. The Panel further noted that Clause 14.1 required MEGS to be certified under Clause 14.3.

The Panel examined two volumes of CML; Volume 3, Number 1, with a Bronchitol advertisement after its marketing authorization was granted and before the updated company certification process was implemented, and Volume 3, Number 2, with the same Bronchitol advertisement after its marketing authorization was granted and after the implementation of the updated company certification process. The Panel noted that MEGS were a non-promotional activity. In the Panel's view, the inclusion of the Bronchitol advertisements in CML rendered the journals promotional. They did not satisfy the requirements for MEGS set out in Clause 18.4 and its supplementary information. CML cystic fibrosis, Volume 3, Number 1 had not been certified and thus a breach of Clause 14.3 was ruled. CML cystic fibrosis Volume 3, Number 2 had been certified. However, it had not been certified as a non-promotional MEGS as required by Clause 14.3. A breach of Clause 14.3 was thus ruled.

The complainant alleged that CML might be promotional in the pre-launch phase given it was in the disease area and included company advertisements. The Panel examined Volume 1, Number 1, 2011 of CML which was produced before the launch of Bronchitol. It contained an advertisement on the back page that had the company logo at the top with the strapline 'innovation for life' followed by 'Innovation in Respiratory Medicine'. The Panel considered that it was a corporate advertisement and the journal did not directly or indirectly promote Bronchitol before the grant of its marketing authorization as alleged. No breach of Clause 3.1 was ruled on this narrow point. The Panel noted that whilst MEGS could contain a company name it queried whether they could contain a corporate advertisement which went beyond a mere reference to the company name. The Panel noted that whilst the journal was not promotional for Bronchitol, it nonetheless required certification as a MEGS. The journal had not been so certified and a breach of Clause 14.3 was thus ruled.

The Panel noted that representatives had not distributed the journal to health professionals as alleged but had provided them with a card via which a health professional could request a copy of CF CML to be sent directly from head office with a letter giving them the option to unsubscribe from the journal circulation. The Panel noted that the representatives were not provided with any written instructions regarding the circulation of the card. The Panel considered that it would have been helpful if the representatives had been briefed on how the card could be distributed given that they were, in effect, facilitating the distribution of a MEGS. The Panel noted the supplementary information to Clause 18.4 explained that material relating to MEGS including, *inter alia*, internal instructions must be certified as required by Clause 14.3. The Panel noted that Pharmaxis had been asked to respond to Clause 15.9 which required that representatives' briefing material on the technical aspects of each medicine promoted was produced and certified. The Panel noted that whilst the complainant had incorrectly referred to distribution of the journals by representatives, he/she had not made any allegations regarding their instruction in this regard. Bearing this in mind and noting its comments above about the relevance of the clause, the Panel ruled no breach of Clause 15.9.

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. The Panel noted that the complainant's allegation that certification of final promotional materials had not happened for years with regard to Bronchitol, Osmohale or Aridol and final versions of materials were not retained until recently if they now were which was unclear. The Panel noted that an audit carried out by an external consultant at the request of Pharmaxis revealed that before August 2013 items were not certified in their final form. The Panel ruled a breach of Clause 14.1 as acknowledged by Pharmaxis.

The Panel noted Pharmaxis's submission that all materials submitted for review were retained and archived for a minimum of 7 years in line with its SOP. The Panel did not consider that the complainant had shown that, on the balance of probabilities, Pharmaxis had failed to preserve all certificates as required by Clause 14.6 and no breach of that clause was ruled.

The Panel noted its rulings and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel considered that Pharmaxis's failure to correctly categorize the cystic fibrosis CML as either promotional or non-promotional at the outset, and to thus correctly certify it, displayed a poor understanding of the Code and that, together with the company's failure to certify the final form of its material, reduced confidence in, and brought discredit upon, the industry. A breach of Clause 2 was ruled.

2 Training

COMPLAINT

The complainant alleged that no Code training was given to staff to keep them up-to-date and many were out of touch. A junior product manager, who was previously a marketing officer, did not have the ABPI examination accreditation despite being in a marketing role for over two years.

When writing to Pharmaxis, the Authority asked it to respond in relation to Clauses 9.1, 16.1, 16.4 and 2 of the Second 2012 Edition of the Code.

RESPONSE

Pharmaxis strongly refuted the complainant's allegation and stated that it had robust systems to ensure all staff were trained on the Code. Pharmaxis had invested significantly to develop an online learning management system (LMS) by which all employees were required to complete training modules relevant to their particular role. The output from the LMS was in the form of a system report which detailed content and date of course completion. A copy of the training record for the employee at issue, a UK marketing support officer, was provided as an example of the training records. Pharmaxis submitted that both field-based and head office staff were set up on the LMS soon after they joined the company.

In addition, all members of the UK sales and marketing team were provided with individual accounts for an e-learning website upon joining Pharmaxis. When new courses on the Code became available, they had to complete them in a timely fashion. Pharmaxis submitted that the e-learning website which it used was well recognised within the pharmaceutical industry as a reputable source of representative training and when a course was completed, the outcome was recorded and a certificate was provided for the individual who had successfully completed the course concerned. Copies of the certificate were added to employees' personal training folders.

A list of courses completed by members of the UK sales and marketing team during the last 18 months was provided. The list had been anonymised to maintain confidentiality but the job role of each individual was marked. In addition, all representatives were provided with hard copies of the Code including updated versions when they became current.

In relation to the representatives' examination, it was a prerequisite that all representatives who joined the company provided documented evidence that they had passed the required ABPI examination; no representative was employed without this qualification. Pharmaxis submitted that whilst it had never been the case, if a representative who had not previously completed the ABPI examination joined the company, it would seek to ensure that they completed it within the timeline specified in Clause 16.4.

Pharmaxis submitted that its four representatives who called on health professionals in relation to the promotion of medicines were experienced and had completed the examination for representatives as outlined in Clause 16.4 before joining the company. Before any job offer was made, candidates had to provide the recruitment agency with documented proof that they had completed the representative's examination.

Pharmaxis submitted that while it was clearly necessary for all representatives to complete the ABPI qualification within the two year time limit, there was no requirement under the Code for employees in a job role outside that of a representative as defined in Clause 1.6 to complete the representatives' examination. It was, however, important that any individual involved in the preparation of marketing materials had some background training on the expectations concerning the Code, even one in a junior role. The individual named by the complainant was not a representative, he/she had completed all the relevant e-learning Code training modules as documented in his/her training record and a copy of his/her job description was provided. The individual also had the most recent Code at his/her workstation for reference.

PANEL RULING

Clause 16.4 of the 2012 Second Edition of the Code stated that the ABPI Medical Representatives Examination must be taken by representatives whose duties comprised or included one or both of calling upon, *inter alia*, doctors and/or other prescribers; and/or the promotion of medicines on the basis of their particular therapeutic properties. The Panel noted that a representative was defined in Clause 1.6 of the Code 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, some employees would not have representative in their job titles but would nonetheless fulfil the role of a representative and would then need to sit and pass an appropriate ABPI examination. The Panel noted the marketing support officer's role as described in the job description and considered that it failed to satisfy the definition and role of a representative, as set out above, and so the post holder was not required under the Code to take and pass an appropriate ABPI examination. No breach of Clause 16.4 was ruled. This ruling was appealed by the complainant.

The Panel noted that Clause 16.1 required all relevant personnel including representatives and members of staff (including persons retained by way of contract with third parties) concerned in any way with the preparation or approval of promotional material, or of information to be provided to members of the UK health professions and to appropriate administrative staff, or of information to be provided to the public and recognised patient organisations to be fully conversant with the requirements of the Code and the relevant laws and regulations. The Panel noted the complainant's allegation that no Code training was given to Pharmaxis staff to keep them up-to-date. The Panel noted Pharmaxis's submission that it ensured all staff undertook training on the Code relevant to their particular role via an online learning management system and the UK sales and marketing team members were additionally required to complete Code of Practice courses on an e-learning website. The Panel noted the list of courses completed by Pharmaxis UK sales and marketing team members in the last 18 months which included a course on the scope of the ABPI Code and various SOPs covering aspects of the Code. The Panel further noted Pharmaxis's submission that representatives were provided with current copies of the Code as soon as they became available. The Panel did not consider that Pharmaxis had provided staff with no Code training as alleged and ruled no breach of Clause 16.1 in that regard.

The Panel noted its rulings above and ruled no breach of Clauses 9.1 and 2.

During the consideration of this case, the Panel considered that Pharmaxis should review its procedures to ensure that any information as to changes to the Code etc, including reports of decided cases, were circulated to relevant personnel as detailed in the guidelines on company procedures relating to the Code of Practice.

APPEAL FROM THE COMPLAINANT

The complainant appealed the Panel's ruling of no breach of Clause 16.4 and noted that Pharmaxis had referred to its employee at issue as a UK marketing support officer and provided a job description for that role. The complainant alleged that this was disingenuous and was disappointed that Pharmaxis had not been transparent. The complainant submitted that the Pharmaxis employee was promoted to junior product manager EU and UK some months ago and no job description was created at the time. The Panel stated that the ABPI examination was only relevant to those who performed the duties of a representative. The Pharmaxis employee attended local meetings and other more major events such as meetings of the British Thoracic Society, the European Cystic Fibrosis Society etc where he/she interacted with UK health professionals in a selling role. His/her role was to book and plan the meetings, stands and materials and be present on the stands where he/she interacted with customers in a sales scenario. He/she also booked and attended evening events such as dinners where he/she would interact with customers in a sales situation. Whilst not a representative, he/she performed the same duties as a representative, as expected of any product manager. The complainant appealed the ruling that the Pharmaxis employee did not require the ABPI examination on the basis of his/her role. The complainant urged the Appeal Board to raise the provision of incorrect facts with Pharmaxis.

The complainant alleged that the Pharmaxis employee's objectives for his/her current role, that he/she had been for some months, included a sales focus. This further backed the sales element of his/her role. The objectives were agreed with his/her then manager, who had now left Pharmaxis but the complainant was sure he/she could be contacted if necessary.

The complainant alleged that the Pharmaxis employee performed the duty of a representative not infrequently yet did not have the ABPI examination expected of someone in that position. The complainant alleged that Pharmaxis had incorrectly stated that its employee was a UK marketing support officer; the complainant was disappointed that Pharmaxis had told the Panel incorrect facts. The Pharmaxis employee moved from a UK to a European role and from an administrative officer role to product manager function and with that his/her responsibilities and goals changed to involve direct promotion to customers at exhibitions and congresses where he/she spent significant amounts of time. Regardless of title, the Pharmaxis employee had, and still performed, the duties expected of a representative and given that he/she did not have that background, unlike the majority of junior product managers, then the ABPI examination was a gap that needed to be filled. Pharmaxis had not ensured that this had happened and it had given an incorrect job title to the Panel.

COMMENTS FROM PHARMAXIS

Pharmaxis refuted the allegations that its response had been dishonest.

Pharmaxis submitted that as stated in Clause 1.6, 'The term "representative" means a representative calling on members of the health professions and administrative staff in relation to the promotion of medicines'. As noted by the complainant, its employee attended UK and European congresses, but this was in an organisational capacity, to liaise with stand builders, organise material provision and manage other logistical arrangements. The employee was not responsible for calling on members of the health professions in relation to the promotion of medicines. Pharmaxis acknowledged that its employee would interact with health professionals while on stands at congresses but only for the duration of the congress. However, within his/her current and previous roles its employee had never 'called on' health professionals to promote medicines. As such its employee had been trained on the Code but had not taken the ABPI representatives examination.

Pharmaxis submitted that it had checked previously, and re-checked again recently in light of the complainant's insistence, with two ABPI medical certifiers, both of whom had confirmed that its understanding of the Code in this respect was the same as theirs, and in line with the Panel's ruling of no breach of Clause 16.4.

FINAL COMMENTS FROM THE COMPLAINANT

The complainant noted that Pharmaxis had refuted that it was dishonest. Pharmaxis had not denied, however, that its employee's role changed from an administrative marketing officer to product manager which was the case in point. The complainant submitted that the word dishonest might be incorrect but noted that the point at issue was that Pharmaxis had provided incorrect information to the PMCPA. The role change was relevant to the case and the company's provision of inaccurate information should be kept in mind when any other claims that Pharmaxis had made were assessed.

The complainant noted that Pharmaxis had acknowledged that its employee had interacted with doctors on product promotional exhibition stands. The complainant alleged that product discussions would inevitably take place on the stands by anyone who interacted with those health professionals. Furthermore they also took place at evening events/meals at such congresses and the Pharmaxis employee organised and attended these. The Pharmaxis employee's logistical and organisational function was not in question however the appeal was that he/she interacted with doctors as a representative did whilst at these events. Product discussions would also occur at personal visits to clinicians which were inevitably required in a marketing function.

APPEAL BOARD RULING

The Appeal Board noted that as in all cases, the complainant had the burden of proving his/her complaint on the balance of probabilities. The Appeal

Board considered that the complainant had failed to provide any specific evidence to show that the role of the employee at issue satisfied the definition of a representative given in Clause 1.6 of the Code and that he/she was hence required to take and pass the appropriate ABPI representatives examination. The Appeal Board upheld the Panel's ruling of no breach of Clause 16.4 on this narrow point. The appeal was unsuccessful.

Complaint received **1 October 2013**

Case completed **19 February 2014**
