CASE AUTH/2308/4/10

MEDIA/DIRECTOR v NORGINE

Lack of sponsorship declaration in published letter

On 20 March, the BMJ published an article entitled 'Generic drugs: protest group was not quite what it seemed'. In accordance with the Authority's Constitution and Procedure, the matter was taken up with Norgine as a complaint by the Director.

The article was about an alleged lack of transparency with regard to Norgine's role in the publication of a letter in The Times (24 February). The letter was headed 'Patient wellbeing at risk from substituted generic medicines'. The article claimed that the letter, which had been signed by several doctors and representatives of patient groups, decried generics and pleaded for doctors' choice to prescribe branded drugs to be paramount. The letter was written in response to the Department of Health's (DoH's) consultation on prescribing which proposed automatic generic substitution. The article claimed that Norgine considered that it would be under direct threat as a result of increased use of generics.

The author of the article in the BMJ stated that far from being a spontaneous protest from a group of patients and health professionals, the letter to The Times had been coordinated by a public relations (PR) agency on behalf of Norgine. The article alleged that the agency had searched the published literature for articles written in support of prescribing branded medicines and then invited the authors of those articles to sign a letter protesting against generic substitution. The article stated, however, that the chief operating officer of Norgine did not add his name to the list of signatories. There seemed to be a lack of transparency.

The author further noted that the letter in The Times had been signed on behalf of three patient organisations which received funding from various pharmaceutical companies and some of the doctors who had signed the letter also advised pharmaceutical companies or received research funding from them.

The detailed response from Norgine is given below.

The Panel first had to decide whether or not the matter was subject to the Code. The Code applied to the promotion of medicines to health professionals and to appropriate administrative staff. The Code also applied to certain areas that were non-promotional, including the provision of information to the public about prescription only medicines. The Code defined promotion and stated that the term promotion did not include information relating to human health or diseases provided there was no reference either direct or indirect, to specific medicines.

The Panel noted that the letter in question referred to prescribed medicines, it focussed on differences between branded and generic medicines and the possible adverse effects on patient wellbeing if pharmacists could automatically substitute a generic medicine even if the doctor had written a prescription for a specific brand. The letter was signed by senior figures from several patient organisations, individual health professionals and others including a previous Director General of the ABPI. No medicine was mentioned by name or unique identifying feature. The Panel noted that it might be argued that the removal of automatic generic substitution would benefit companies by increasing/maintaining the use of branded products ie it would promote the prescription, supply, sale or administration of their medicines. However, given the intended audience, the public, and the content of the letter in question, the Panel decided that the letter to The Times was not 'promotion' as defined in the Code. The letter referred a number of times to prescribing and although not explicitly solely about prescription only medicines such medicines would be covered by the letter. Thus, although not promotional, the Panel considered that the letter was subject to the Code as it was information about prescription only medicines aimed at the public.

The Panel noted that the Code required that material relating to medicines and their uses, whether promotional in nature or not, which was sponsored by a pharmaceutical company must clearly indicate that it had been sponsored by that company. The supplementary information required a declaration to reflect the nature of the company's involvement. The Code did not specifically mention lobbying activities but in the Panel's view if such activities resulted in materials relating to medicines and their uses then the Code applied. In the Panel's view the letter to The Times in contrasting branded and generic medicines clearly referred to medicines and their uses. Norgine's role in the development and production of the letter meant that it was responsible for it under the Code and that Norgine had sponsored the letter. The Code required transparency about pharmaceutical company activities so that readers of the material were aware of such involvement.

The Panel noted Norgine's submission that all of the signatories to the letter knew about Norgine's role in the development and production of the letter. In the Panel's view it was equally important that those reading the published letter were also aware of Norgine's role. There was no mention of Norgine either in the published letter itself or as a signatory to the letter. Nor was there any indication of any pharmaceutical company involvement. In the

Panel's view the majority of those reading the letter in The Times would have viewed it differently if they had known that it had been sponsored by a pharmaceutical company with an interest in the views expressed. The Panel considered that by not making its role clear Norgine had failed to comply with the Code and a breach was ruled. The Panel considered that Norgine had therefore failed to maintain high standards and a further breach was ruled.

The Panel noted that every case had to be considered on its own merits. The Code covered pharmaceutical company relationships with patient organisations and applied to patient organisations and the like when such activities were supported by pharmaceutical companies. In this case the campaign in question was initiated and funded by Norgine. The suggestion that a letter be written to The Times, signed by clinicians and patient group representatives, had come from a company-organised roundtable meeting of key journalists to gather their views on how awareness of the issues involved could be raised amongst the general public. Potential signatories to the letter were identified by Norgine or its PR agency; some had been previously identified to sign a consensus document whilst others were contacted only to sign the letter. The Panel noted that where the letter was signed by individuals from patient organisations the organisation was also named and the signatory's position within the organisation stated ie Chair, President, etc. Individuals with no stated involvement with patient organisations had also signed the letter. The Panel queried whether the letter was developed and produced as a result of a formal interaction between Norgine and the patient organisations or as a more personal interaction with individuals operating wholly independently from their patient organisation. However, as patient organisations were named, and the senior position of each signatory within the organisation given, there was an implication that each organisation formally endorsed the letter. This would certainly be the impression given to readers. Readers would not know from the published letter that a pharmaceutical company was also involved. The Panel considered that Norgine had not made its involvement with the patient organisations named in the letter clear. The Panel ruled a breach of the Code. The Code required wording to accurately reflect the nature of a pharmaceutical company's involvement in the declaration of sponsorship and, in the context of relationships with patient organisations, covered all material sponsored by a pharmaceutical company. Norgine's role in the development and production of the published letter was not clear and a breach of the Code was ruled.

Upon appeal by Norgine, the Appeal Board noted that the letter in question referred to prescribed medicines, it focussed on differences between branded and generic medicines and what might happen to patients if pharmacists could automatically substitute a generic medicine even if a specific brand had been prescribed. No medicine was mentioned by name or unique identifying feature. The letter referred a number of times to prescribing and although not explicitly solely about prescription only medicines such medicines would be covered by the letter. Thus, the Appeal Board considered that the letter was subject to the Code as it was information about prescription only medicines aimed at the public.

The letter to The Times, in contrasting branded and generic medicines, clearly referred to medicines and their uses. The letter had been written as a direct result of a campaign orchestrated by Norgine. Norgine had underwritten the costs of the letter being written. The Code required transparency about pharmaceutical company activities so that readers of the material were aware of any such involvement. The letter itself did not refer to Norgine's involvement and no one from Norgine had signed the letter. In the Appeal Board's view those reading the letter in The Times should have been able to do so in the knowledge that a pharmaceutical company with a vested interest had been involved in its creation. Disclosure in this regard would have allowed the reader to form his own fully informed opinion of the views expressed. The Appeal Board considered that by not making its role clear Norgine had failed to comply with the Code and it upheld the Panel's ruling of a breach.

The campaign in question was initiated and funded by Norgine. The suggestion that a letter be written to The Times, signed by clinicians and patient organisation representatives, had come from a company-organised roundtable meeting of key journalists to gather their views on how awareness of the issues involved could be raised amongst the general public. Potential signatories to the letter were identified by Norgine or its PR agency; some had been previously identified to sign a consensus document whilst others were contacted only to sign the letter. The Appeal Board noted from Norgine's representatives at the appeal that each signatory chose which title to use when signing the letter; some chose to refer to their role in a named patient organisation ie Chair, President, etc. Individuals with no stated involvement with patient organisations had also signed the letter. The Appeal Board considered that as patient organisations were named, and the senior position of each signatory within the organisation given, readers would assume that each organisation formally endorsed the letter. The Appeal Board considered that in any event, by deliberately not providing any indication of its involvement with the production of the letter, Norgine had not made its involvement with the patient organisations noted in the letter clear to those reading it. The Appeal Board upheld the Panel's ruling of a breach of the Code.
The Appeal Board considered that the Code required wording to accurately reflect the nature of a pharmaceutical company's involvement in the declaration of sponsorship from the outset. Norgine's role in the development and production of the letter was not made clear to readers of The Times. The Appeal Board upheld the Panel's ruling

of a breach of the Code.

The Appeal Board noted that the letter was directed at the public and thus it was important that the public were fully informed as to who was behind it; Norgine, by not declaring its involvement in the creation of the letter had therefore failed to maintain high standards and the Appeal Board upheld the Panel's ruling of a breach of the Code.

On 20 March, the BMJ published an article entitled 'Generic drugs: protest group was not quite what it seemed'. The author alleged that an apparently spontaneous letter of protest from patients' groups and health professionals which was published in The Times (24 February) was coordinated by a public relations (PR) company, on behalf of Norgine Pharmaceuticals Limited.

In accordance with Paragraph 6.1 of the Authority's Constitution and Procedure, the matter was taken up with Norgine as a complaint by the Director. The author was asked whether she wished to be involved in the case and whether she had any additional information to submit. The author did not submit any more data but asked to be kept informed.

COMPLAINT

The article was about an alleged lack of transparency with regard to Norgine's role in the publication of the letter in The Times. The letter was headed 'Patient wellbeing at risk from substituted generic medicines'. The article claimed that the letter, which had been signed by several doctors and representatives of patient groups, decried generics and pleaded for doctors' choice to prescribe branded drugs to be paramount. The letter was written in response to the Department of Health's (DoH's) consultation on prescribing which proposed automatic generic substitution.

The article stated that far from being a spontaneous protest from a group of patients and health professionals, the letter to The Times had been coordinated by a public relations agency on behalf of Norgine. The article alleged that the agency had searched the published literature for articles written in support of prescribing branded medicines and then invited the authors of those articles to sign a letter protesting against generic substitution. The article stated, however, that the chief operating officer of Norgine did not add his name to the list of signatories. There seemed to be a lack of transparency.

The author of the BMJ article noted that Norgine had organised a paper to be written by its public relations agency last year in response to the DoH's proposals on prescribing. It was this document which was used initially to gather support. The article claimed that Norgine considered that it would be under direct threat as a result of increased use of generics.

The article in the BMJ noted some of the differences in formulation/presentation of branded medicines and generics and stated that while it was important that patients were happy with their medicines it questioned how much the pharmaceutical industry was allowed to press for non-generics. The author noted that the letter in The Times had been signed on behalf of three patient organisations which received funding from various pharmaceutical companies and some of the doctors who had signed the letter also advised pharmaceutical companies or received research funding from them.

When writing to Norgine the Authority asked it to respond in relation to Clauses 9.1, 9.10, 23.2 and 23.8 of the Code.

RESPONSE

Norgine stated that the letter to The Times arose from a campaign to oppose the introduction of generic substitution in primary care in the UK. The campaign was coordinated by its PR agency and funded by Norgine. This project was initiated in March 2009 and involved a public relations and medical communication campaign to raise awareness amongst health professionals, patients and patient groups as to the possible negative implications for all stakeholders arising from the proposals for automatic generic substitution which had arisen from the latest agreement of the Pharmaceutical Price Regulation Scheme (PPRS).

One of the first activities of this campaign was for Norgine and the PR agency to research the clinical issues surrounding generic substitution, particularly looking at what evidence existed relating to the patient level impact that might occur should generic substitution result in branded medicines being substituted for generic versions.

The next step in the campaign was that the agency produced a draft consensus document entitled 'Automatic Generic Substitution – Clinical implications for patients', which involved further research. This sponsorship by Norgine for the production of this document was clearly declared in the document from first draft stage onwards.

A number of individuals who might have an interest in putting their names to the consensus document were identified jointly between Norgine and the agency, and these individuals were contacted by telephone by the agency. The agency's policy was that in any telephone contact with respect to such a campaign, it was always made clear that the campaign was being conducted on behalf of a sponsor company, which was always specifically named.

As part of the campaign, the agency proposed that an advisory board in the form of a consumer roundtable meeting be held to which were invited leading medical correspondents from the lay press. A number of medical correspondents attended this meeting, and the idea of a letter to The Times was

proposed at this meeting by the journalists themselves.

Following the meeting, Norgine agreed to cover the agency's costs for producing this letter as part of the ongoing campaign.

The agency wrote and sent the first draft of the letter to the signatories, a number of whom made revisions to the first draft. These revisions were incorporated in the final draft, which was sent to the signatories for approval, and the letter was then sent to The Times by one of the signatories on behalf of the others.

The letter was published in The Times newspaper on 24 February 2010 and contained the names of nine of the signatories of the letter. The full list of nineteen signatories appeared in the timesonline web site.

Potential signatories first approached were those individuals who had already signed the consensus document 'Automatic Generic Substitution – Clinical implications for patients'. These signatories were approached by the agency and asked if they were prepared to put their names to a letter to The Times.

Other potential signatories were suggested both by Norgine and the agency and these additional signatories were also telephoned by the agency, when Norgine's involvement was disclosed as per the agency's policy as above.

The agency coordinated the project with oversight and direction from Norgine as described in the contract.

No honoraria or payments or benefits in kind of any description were made to the signatories of the letter, either directly or indirectly.

The letter was not certified under the Code. The letter was the result of discussions and opinions of those involved who freely became signatories. As the letter was not within the scope of the Code, certification was not required.

Before focusing upon the specific clauses of the Code which it had been requested to address, Norgine maintained that the publication of the letter to The Times which was the basis of the complaint, including all of the related interactions, was not within the scope of the Code. Norgine however recognised the importance of transparency and its continued support of both the letter and the spirit of the Code. Thus, in the interests of facilitating the prompt resolution of this matter, and without prejudice, it had provided the information requested. Norgine stated that all its dealings were conducted in a professional and transparent manner, consistent with the Code and Norgine's ethical principles.

With regard to Clause 9.10, Norgine submitted that the letter in The Times was outside the scope of the Code and did not constitute a breach of this clause.

The letter and the allied activities described above were outside the scope of the Code as described in Clauses 1.1 and 1.2. This was not a promotional activity and no specific medicine or groups of medicines had been referred to, other than a range of examples from various therapeutic areas directed at demonstrating the potential impact of generic substitution.

The closest reference to this type of activity within Clause 1 was the exclusion contained within Clause 1.2 which stated that promotion did not include 'information relating to human health or diseases provided there is no reference, either direct or indirect, to specific medicines'.

As described above, the letter arose from the consensus document 'Automatic Generic Substitution – Clinical implications for patients', the preparation of which was sponsored by Norgine. This sponsorship was clearly declared in that document. All parties involved would have been made aware of Norgine's role.

The letter in The Times was about proposed changes to the arrangements for the prescription and dispensing of medicines in the UK. It arose as part of a political lobbying campaign and as such could not be considered as material specifically related to a specific medicine or medicines and their uses, which was the normal interpretation of Clause 9.10. The type of material usually covered under this clause were sponsored journal supplements and the like which referred to specific medicines or diseases.

Clause 9.10 did not cover, and there was no precedent for the use of this clause to cover, political lobbying campaigns undertaken by the pharmaceutical industry.

Norgine recognised that companies had a responsibility to ensure that any such material was factually accurate and not misleading. Given that the Code was not constituted to regulate pharmaceutical companies' political lobbying campaigns which were unrelated to any particular medicine or medicines, for the reasons above Norgine did not believe that these activities and the letter specifically were within the scope of the Code. Any material produced as part of such a non product-related lobbying campaign must therefore be outside the scope of Clause 9.10 of the Code, and therefore it refuted any allegation of a possible breach of Clause 9.10.

Norgine submitted that with regard to Clause 23.2 irrespective of the fact that its lobbying activities, and the letter itself were outside the scope of the Code, Norgine was very aware that particular care needed to be taken in any interaction with patient organisations and individuals representing such organisations. Norgine stated that, since its relationship was not in support of their work and no financial or other 'in kind' sponsorship occurred, Norgine's activities did not come within the scope of Clause 23. Nonetheless, Norgine acted in

accordance with the spirit of the Code, ensuring that its involvement in the lobbying activities was clear from the initial contact and throughout the period.

Therefore in this campaign, the PR agency acting on behalf of Norgine and consistent with its own written ethical policies, made sure that Norgine's involvement was transparent and made clear from the very first contact.

The agency's relationship with the patient organisations was two fold. Firstly supplying them with background information to enable the patient organisations to respond to the generic substitution proposals and the subsequent DoH public consultation, and secondly to see which patient organisations would support and put their name to the consensus document.

A number of individuals and patient organisations who might have an interest in putting their names to the consensus document were identified jointly by Norgine and the agency, and the agency contacted these individuals and individuals representing patient organisations by telephone. It was important to note that it was the policy of the agency that in any telephone contact made to an individual with respect to such a campaign, it was made clear that the campaign was being conducted on behalf of a sponsor company, which was always specifically named.

The information provided by Norgine and/or the agency was not product or medicines related and had been reviewed internally by Norgine to ensure that this was so.

Notwithstanding its contention that these activities did not come within the purview of the Code, Norgine nonetheless submitted that its involvement was made clear, and therefore, in any event, there was no breach of Clause 23.2.

With regard to Clause 23.8 all representatives of patient organisations who were contacted were told about Norgine's involvement from the outset as stated above both in the initial communication by the agency and in the consensus document itself. As a lobbying initiative unrelated to particular medicines or groups of medicines this activity was outside the scope of the Code. It was however important to recognise that neither Norgine nor the agency sponsored any of the patient organisations or signatories to the letter.

The declaration of Norgine's involvement in the consensus document stated: 'The document was researched using interviews with healthcare providers, patient associations and published literature, and drafted by a medical writer [named] funded by Norgine'. Norgine submitted that this declaration accurately reflected the nature of Norgine's involvement as required by Clause 23.8.

Norgine therefore submitted that given that there was no sponsorship of any signatories to the letter and the involvement of Norgine was made clear and acknowledged from the outset, were the Code to apply, which it contended was not the case, there was no breach of Clause 23.8.

With regard to Clause 9.1 Norgine reiterated its assertion that this activity was outside the scope of the Code, but nevertheless and without prejudice, maintained that both Norgine and the agency, had consistently maintained the highest standards with respect to this whole campaign and in particular the circumstances which led up to the letter in question being published in The Times. Norgine's compliance procedures were rigorously applied, and as described above, Norgine ensured that a responsible level of internal review was conducted even in circumstances where such scrutiny was not required. As such it refuted any breach of Clause 9.1.

In summary Norgine stated that it was outside the scope of the Code to regulate how pharmaceutical companies worked with medical communications and public relations companies in political lobbying campaigns which were completely unrelated to any particular medicine or medicines. In particular any material produced as part of a non product-related lobbying campaign was outside the scope of Clause 9.10. This 'material' in the broadest sense might include letters to the lay press.

When these sorts of activities involved contact with patient organisations, either directly by a pharmaceutical company or by a medical communications company working on behalf of a pharmaceutical company, then Norgine recognised that working with patient organisations needed to comply with the requirements of Clause 23 of the Code, if applicable. In all circumstances, whether or not Norgine's contact with the patient organisation was within the scope of the Code, Norgine as a matter of principle and policy ensured that this relationship was conducted in a transparent, professional and ethical manner.

The signatories to the letter were all individuals of the highest probity, who were made fully aware of Norgine's involvement in this campaign and the letter. No sponsorship of any of the signatories to the letter occurred, and all signatories signed the letter of their own free will.

Norgine believed that the evidence demonstrated that in the interactions between the PR agency and patient organisations the involvement of Norgine was fully transparent and made clear from the outset, and that Norgine had demonstrated that there was no sponsorship to the signatories. Therefore if the Code were to apply, which it contended was not the case, there would in such event be no breach of either Clause 23.2 or Clause 23.8.

Norgine stated that it responded to this complaint as a matter of process and its willingness to comply with the Code, but strongly restated its contention that this was not a matter for the Code and was

therefore outside the jurisdiction of the PMCPA.

In the event that the PMCPA concluded that this matter was within the scope of the Code and that further enquiry was necessary, Norgine challenged the ability of PMCPA normal procedures to address the resolution of this complaint because of a conflict of interest. The topic of this complaint, ie the negative implications of the proposals for generic substitution, was one in which the ABPI had a vested interest given its support for this proposal. The contrary views of Norgine and the ABPI on the subject of generic substitution were well known, and the participation of ABPI employees on the Panel would be prejudicial to Norgine's right to a fair hearing on the determination of whether there had been a breach of the Code.

PANEL RULING

The Panel noted Norgine's comments about a potential conflict of interest. The PMCPA operated independently of the ABPI itself. The Director of the Authority was employed by the ABPI but reported to the Appeal Board in relation to all matters concerning the interpretation of the Code and its operation, and to the President of the ABPI solely for administrative purposes. This was made clear in Paragraph 1.3 of the Constitution and Procedure. There was no reporting line to the Director General of the ABPI. No PMCPA staff, including the Panel, was in any way concerned or involved with ABPI policy on any subject other than matters relating in general to the Code and its operation. The Panel's role was to consider the matter in relation to the Code bearing in mind the material provided by the parties and in accordance with the Constitution and Procedure.

The first decision was whether or not the matter was subject to the Code. Clause 1.1 made it clear that the Code applied to the promotion of medicines to health professionals and to appropriate administrative staff. The Code also applied to certain areas that were non-promotional, including the provision of information to the public about prescription only medicines. Clause 1.2 of the Code defined promotion and that the term promotion did not include information relating to human health or diseases provided there was no reference either direct or indirect, to specific medicines.

The Panel noted that the letter in question referred to prescribed medicines, it focused on differences between branded and generic medicines and the possible adverse effects on patient wellbeing if pharmacists could automatically substitute a generic medicine even if the doctor had written a prescription for a specific brand. The letter was signed by senior figures from several patient organisations, individual health professionals and others including a previous Director General of the ABPI. No medicine was mentioned by name or unique identifying feature. The Panel noted that it might be argued that the removal of automatic generic substitution would benefit companies by increasing/maintaining the use of branded products ie it would promote the prescription, supply, sale or administration of their medicines. However, given the intended audience, the public, and the content of the letter in question, the Panel decided that the letter to The Times was not 'promotion' as defined in Clause 1.2 of the Code. The letter referred a number of times to prescribing and although not explicitly solely about prescription only medicines such medicines would be covered by the letter. Thus, although not promotional, the Panel considered that the letter was subject to the Code as it was information about prescription only medicines aimed at the public.

The Panel noted that Clause 9.10 required that material relating to medicines and their uses, whether promotional in nature or not, which was sponsored by a pharmaceutical company must clearly indicate that it had been sponsored by that company. The supplementary information required a declaration to reflect the nature of the company's involvement. Clause 9.10 did not specifically mention lobbying activities but in the Panel's view if such activities resulted in materials relating to medicines and their uses then Clause 9.10 applied. In the Panel's view the letter to The Times in contrasting branded and generic medicines clearly referred to medicines and their uses. Norgine's role in the development and production of the letter meant that it was responsible for it under the Code and that Norgine had sponsored the letter. The purpose of Clause 9.10 was to require transparency about pharmaceutical company activities so that readers of the material were aware of such involvement.

The Panel noted Norgine's submission that all of the signatories to the letter knew about Norgine's role in the development and production of the letter. In the Panel's view it was equally important that those reading the published letter were also aware of Norgine's role. There was no mention of Norgine either in the published letter itself or as a signatory to the letter. Nor was there any indication of any pharmaceutical company involvement. In the Panel's view the majority of those reading the letter in The Times would have viewed it differently if they had known that it had been sponsored by a pharmaceutical company with an interest in the views expressed. The Panel considered that by not making its role clear Norgine had failed to comply with Clause 9.10. A breach of that clause was ruled. The Panel considered that Norgine had therefore failed to maintain high standards and a breach of Clause 9.1 was also ruled.

The Panel noted that every case had to be considered on its own merits. Clause 23 of the Code covered pharmaceutical company relationships with patient organisations and applied to patient organisations and the like when such activities were supported by pharmaceutical companies. In this case the campaign in question was initiated and funded by Norgine. The suggestion that a letter be written to The Times, signed by clinicians and

patient group representatives, had come from a company-organised roundtable meeting of key journalists to gather their views on how awareness of the issues involved could be raised amongst the general public. Potential signatories to the letter were identified by Norgine or its agency; some had been previously identified to sign a consensus document whilst others were contacted only to sign the letter. The Panel noted that where the letter was signed by individuals from patient organisations the organisation was also named and the signatory's position within the organisation stated ie Chair, President, etc. Individuals with no stated involvement with patient organisations had also signed the letter. The Panel queried whether the letter was developed and produced as a result of a formal interaction between Norgine and the patient organisations or as a more personal interaction with individuals operating wholly independently from their patient organisation. However, as patient organisations were named, and the senior position of each signatory within the organisation given, there was an implication that each organisation formally endorsed the letter. This would certainly be the impression given to readers. Readers would not know from the published letter that a pharmaceutical company was also involved. The Panel considered that Norgine had not made its involvement with the patient organisations named in the letter clear. The Panel ruled a breach of Clause 23.2. Clause 23.8, like Clause 9.10, required wording to accurately reflect the nature of a pharmaceutical company's involvement in the declaration of sponsorship but was not similarly limited to material about medicines and their uses but, in the context of relationships with patient organisations, covered all material sponsored by a pharmaceutical company. Norgine's role in the development and production of the published letter was not clear. A breach of Clause 23.8 was ruled.

APPEAL BY NORGINE

Norgine explained that the background to this complaint was the perceived benefits and potential risks of generic substitution and a potential change in UK health policy on this issue. Compulsory or automatic generic substitution was the practice by which a pharmacist would dispense a generic version of a medicine despite the fact that the prescriber had prescribed the medicine by brand name.

Generic substitution was proposed by the ABPI at the last renegotiation of the PPRS. This proposal was initially rejected by the DoH, but later accepted. The alternative proposal from the DoH to reduce expenditure on medicines in 2010 was an across the board price cut for all medicines that would, unlike the generic substitution proposal, affect all member companies roughly in equal measure. The ABPI's proposal was in direct conflict with ABPI policy at the time.

Norgine submitted that differing views on the implications of generic substitution (which could come in many forms) were honestly held by various interested parties, but it was without doubt an important matter of health policy and principle that was not directly concerned with specific medicines and their uses. It needed careful consideration because in some cases it had the potential to have a serious negative impact on patient wellbeing.

Norgine submitted that it had, therefore, in the consultation being conducted by the DoH, taken an entirely different position to the ABPI and its members. As this complaint originated from the PMCPA itself and concerned Norgine's lobbying against the ABPI's interests on the generic substitution proposals, the ABPI and its member companies and affiliated organisations had a potential conflict of interest that undermined their ability to be seen to act without bias. As with all conflicts of interest this applied regardless of whether there was evidence of bias. This issue, therefore, affected the Panel's role in relation to its initial decision to deal with the article in the BMJ as a complaint and in relation to its initial ruling, and affected the appeal being heard by any members of the Appeal Board who were employees of ABPI member companies.

As a preliminary point, therefore, Norgine sought a determination by the Chairman of the Appeal Board on the issue of conflict of interest and how the Appeal Board might be constituted to avoid any perception of possible bias.

Grounds for appeal

Norgine submitted that the core of its appeal was that the Panel was incorrect to conclude that the letter fell within the scope of Clause 1.1. The focus of the Code was the promotion of medicines. However, it also covered certain non-promotional activities. Norgine noted that non-promotional materials were treated as outside the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice and whilst that code encouraged member associations to consider where it might be appropriate to have provisions relating to non-promotional information, Norgine submitted that exceptions to the general rule that the Code was about promotion of medicines should be clearly stated and restrictively construed.

Norgine submitted that the relevant paragraph of Clause 1.1 stated 'The Code also applies to a number of areas which are non-promotional, including information made available to the public about prescription only medicines'.

Norgine submitted that because 'information' was not defined in the Code, the term should be given its natural meaning. A typical thesaurus entry for 'information' gave the following synonyms: info, data, statistics, facts, figures, gen, material, evidence. It was helpful in understanding the intended meaning of 'information' in respect to Clause 1.1 if one or two synonyms were substituted, for example: 'The Code also applies to … data made

available to the public about prescription only medicines,' or 'The Code also applies to … facts made available to the public about prescription only medicines.'

Norgine submitted that this exercise clarified the intention of Clause 1.1, which was, quite reasonably, to bring into the scope of the Code the provision to the public of information, data or facts about prescription only medicines. On this basis it was completely appropriate, for instance, that press releases about particular medicines, and the progress made in research of their uses or their authorization and launch should be covered by the Code. In contrast it was inappropriate to stretch the Code to cover this type of lobbying activity on health policy.

Norgine submitted that examined from this perspective, the letter to The Times had nothing to do with the provision of information, data or facts about any prescription medicine or medicines. Health policy in this industry necessarily referred to medicines as the background field of activity, but health policy in relation to pricing or generic substitution and similar topics transcended issues and facts concerning particular medicines or their uses or health information that discussed treatment options for particular conditions. Therefore, the current debate concerned itself solely with the proposed changes to the way in which prescribed medicines were dispensed. Whilst prescribing was mentioned in the letter, the explicit references to prescribing did not provide any information (data or facts) about medicines. These references merely highlighted the fact that the prescribing decision could be impacted by separate decisions upon dispensing that might have an unintended impact upon the patient.

Norgine suggested that indirect references to medicines in this way were not intended to be covered by Clause 1.1 and should be deemed to be outside the scope of the Code.

Norgine submitted that such legitimate comment by interested parties about general issues of health policy, unconnected with specific medicines, groups of medicines or disease awareness, was not, and should not, be regulated by the Code. The letter in question referred to none of these areas and as such it was outside the scope of the Code.

Clause 9.10

Regarding the alleged breach of Clause 9.10, consistent with its argument above, Norgine submitted that the letter at issue was outside the scope of the Code and did not constitute a breach of this clause. Clause 9.10 only related to 'material relating to medicines and their uses' (whether promotional or not). A restriction of the scope of Clause 9.10 to 'medicines and their uses' was consistent with the limited extension of the Code, as described in Clause 1.1, to matters such as 'information made available to the public about prescription only medicines'. The letter in The Times was about proposed changes to the arrangements for the prescription and dispensing of medicines in the UK. It arose out of a political lobbying campaign and as such could not be considered as material specifically related to a specific medicine or medicines and their uses, which was the concern of Clause 9.10.

Norgine submitted that lobbying activities must be treated as outside the Code unless they related to specific medicines. It was a potentially dangerous extension of the Code to conclude that lobbying activities, which resulted in materials relating to dispensing principles or other health policy issues, came within the scope of Clause 9.10. The letter was not about the use of medicines, but dispensing principles. There was no precedent for the use of this clause to cover political lobbying campaigns undertaken by the pharmaceutical industry.

Norgine recognised that as part of general good corporate governance, companies had a responsibility to ensure that any such material was factually accurate and not misleading. Norgine had been scrupulous in this regard, and where it was the originator of material on the issue of generic substitution, took care about the content of material it sponsored and its role. The Consensus Document 'Automatic Generic Substitution – Clinical implications for patients', was sponsored by Norgine as clearly declared in that document. All parties involved in that document were told of Norgine's role as sponsor.

Norgine noted the Panel's view as expressed in its ruling that the majority of those reading the letter in The Times would have viewed it differently if they had known that it was indirectly associated with Norgine's opposition to generic substitution and, in a limited way, had been facilitated by a pharmaceutical company with an interest in the views expressed.

Norgine submitted that it could not say whether this was true or not. Norgine expected most people to judge the letter by reference to the force of the points it made. Norgine was not alone in having an interest in the views expressed and, therefore, it was not critical that Norgine's interest in the letter was explained in it. The Government was currently considering the outcome of a formal public consultation on these proposals (provided). Significant opposition to generic substitution had been expressed by groups representing patients, doctors and pharmacists who responded to the consultation (provided).

Norgine did not think that readers would look at the content of the letter any differently had they known about the limited involvement of Norgine. Pharmaceutical companies had a degree of expertise in the arrangements for the supply of medicines, so the arguments made in the letter would be seen as equally valid if readers were informed of company involvement.

Norgine observed that if it were necessary for the letter to refer to the alleged 'sponsorship' by Norgine, the Code would require not just the fact of such 'sponsorship' but also the nature of it to appear. The authors would have a legitimate interest in making sure that readers knew that the views they expressed were honestly held and they had not been coerced by Norgine into writing it or paid for their time in writing it. The statement of sponsorship required where the involvement of Norgine was so limited and tangential would have involved text disproportionate to the main text of the letter itself, and might have meant that The Times would not have printed it, which would have been an unfortunate consequence. This was a clear pointer to the fact that, even if - contrary to Norgine's main point - lobbying on health policy fell within the Code, it would be wholly disproportionate to the aims of Clause 9.10 to require a statement of sponsorship in these circumstances. Furthermore, the letter which appeared in The Times was substantially rewritten from the first draft authored by the PR agency (drafts provided).

Norgine reiterated that this type of activity was outside the scope of the Code. There were numerous precedents where pharmaceutical companies would have been involved to a greater or lesser extent in facilitating this sort of letter in reference to health and medicines policy in general, yet no indication of company involvement was treated as required.

In a situation where a letter in the medical or lay press related to a specific medicine and a pharmaceutical company was involved in providing information, disclosure of the role of an individual company or companies was not usual, despite the fact that this sort of activity would on the arguments made by the Panel in this case be within the scope of the Code.

Clause 23.2

Clause 23.2 contained a general statement that 'When working with patient organisations, companies must ensure that the involvement of the company is made clear and that all of the arrangements comply with the Code'. It then went on to refer to the Code requirements that were engaged. Norgine submitted that it did not create a free standing obligation that was not specified elsewhere in that clause or elsewhere in the Code. In that respect it was unlike the original Clause 20.3, which at the time, was the only provision relating to the interaction between industry and patient organisations such that all obligations were encompassed within Clause 20.3. The only breach of requirements alleged by the Panel was the breach of the sponsorship acknowledgement in Clause 23.8. Therefore, Norgine did not consider that the Panel was correct to treat Norgine as separately in breach of Clause 23.2. Norgine, therefore, addressed the substance of the complaint under Clause 23.8 below and denied any separate breach of Clause 23.2.

Clause 23.8

Norgine submitted that its lobbying activities, and the letter at issue, was outside the scope of the Code. Furthermore, it denied that its limited role in helping the authors of the letter agree the text of it, was 'working with patient organisations' in a way that the provision was intended to cover such that a 'sponsorship' of the decision of the patient association representative to sign the letter needed to be declared.

Norgine was not cavalier about such matters. In relation to the production of the Consensus Document, its view of the scope of the Code did not affect the care it exercised in its interactions on this issue with patient organisations and their representatives. This was made clear in Norgine's response to the Panel, and it affirmed its commitment to this principle.

The declaration of sponsorship in respect of that document stated: 'The document was researched using interviews with healthcare providers, patient associations and published literature, and drafted by a medical writer [identified] funded by Norgine'.

Norgine submitted that in this campaign, its PR agency, acting as its agent and consistent with its own written ethical policies, ensured that Norgine's involvement was transparent and made clear from the very first contact and throughout the process. The agency's relationship with patient organisations was two-fold. Firstly, the agency supplied patient organisations with background information to enable them to assess and respond to the generic substitution proposals and the subsequent DoH public consultation. Secondly, the agency assisted in the process of identifying which individual clinicians and patient organisations shared Norgine's concern about the proposed change in policy in relation to the dispensing of prescribed medicines and would support and put their name to the Consensus Document. A number of such individuals and patient organisations were identified jointly by Norgine and the agency. The agency thereafter contacted these individuals and individuals representing patient organisations by telephone.

Norgine submitted that it was important to note that it was the agency's policy that in any telephone contact made to an individual with respect to such a campaign, it was made clear that the campaign was being conducted on behalf of a sponsor company, which was always specifically named. The information provided by Norgine and/or the agency was not product or medicines related and had been reviewed internally by Norgine to ensure that this was the case. The information related to health policy and the dispensing of prescribed medicines generally, and the patient safety risks associated with the proposed changes.

Norgine submitted that in contrast to the production of the Consensus Document, the letter to The Times was not an initiative of Norgine, but was a personal

initiative of attendees at the meeting sponsored by Norgine. Norgine did not ask that the letter be written nor pay signatories for their time in writing it. The only contribution Norgine made to its production was that a medical writer from the agency, who had taken notes at the meeting, agreed to do a first draft for the relevant individuals to help them move the matter forward. The authors then contributed to and agreed the text of the letter that the lead signatory submitted to The Times on behalf of himself and the other signatories.

Neither Norgine nor the agency sponsored any of the patient organisations or signatories to the letter. No honoraria, payments or benefits in kind were made to the individual signatories of the letter or patient organisations either directly or indirectly. This was a situation in which Norgine and the individual signatories shared a profound, but independent, concern that the proposed changes in the dispensing of prescription medicines posed an unacceptable patient safety risk and that the public should be made aware of this issue and provided relevant information relating thereto.

Norgine submitted that, therefore, in relation to the letter it did not 'work with' the patient association to further its objectives, and there was no sponsorship of the associations or their representatives. The Panel seemed to recognise the probable lack of any material 'working with' patient associations. In its ruling the Panel had stated: 'The Panel queried whether the letter was developed and produced as a result of a formal interaction between Norgine and the patient organisations or a more personal interaction with individuals operating wholly independently from their patient organisation. However, as patient organisations were named and the senior position of each signatory within the organisation given, there was an implication that each organisation formally endorsed the letter. This would certainly be the impression given to readers'.

Norgine submitted that the Panel was correct as to the first element of this analysis, and it respectfully suggested was wrong to treat the fact that certain individuals decided to sign as representatives of their associations rather than in their purely personal capacity, changed the reality and meant Norgine was 'working with' the patient association. Norgine and the PR agency interacted both with individual health professionals and individuals who were associated with patient organisations. It was not possible to interact with an abstract concept like a 'patient organisation'; one had to interact with individual people.

Norgine submitted that it had no way of knowing at the time, nor would it have been proper for it to enquire, about what involvement these individuals had with their patient organisations. That was wholly a matter for these individuals and their organisations. The signatories determined how their affiliation should appear. This was not a matter for Norgine or the agency given that the content of the letter was outside of its control.

Patient organisations no doubt had their own policies about internal interactions in this sort of situation, and Norgine was very unhappy about the clear suggestion in the Panel ruling that individuals representing patient groups might have improperly taken it upon themselves to represent their patient group.

Norgine noted that the Panel had ruled a breach of Clause 23.8 because Norgine's role was not clear. Notwithstanding its previous arguments as to why this letter was outside the scope of the Code; Norgine submitted that its role was not to work with the patient associations in question in the production of the letter or to 'sponsor' it, and as such on both these counts it rejected the ruling of a breach of Clause 23.8.

Clause 9.1

From the points made above, Norgine reiterated its assertion that this activity was outside the scope of the Code, but nevertheless and, without prejudice, it submitted that both Norgine and its agent had consistently maintained the highest standards with respect to this campaign and in particular the circumstances which led up to the letter in question being published in The Times. Norgine's compliance procedures were rigorously applied, and as described above, Norgine ensured that a responsible level of internal review was conducted even in circumstances where such scrutiny was not required. As such Norgine rejected any breach of Clause 9.1.

Moreover, even if the Appeal Board found that the letter was within the scope of the Code, which Norgine firmly believed was not the case for the reasons outlined above, to stretch the normal understanding of the Code to find a breach of Clause 9.1 seemed unfair.

Norgine noted that Clause 9.1 stated that 'High standards must be maintained at all times'. This broad wording was interpreted by the Code through connection to Clause 9.2, which read: 'All material and activities must recognise the special nature of medicines and the professional standing of the audience to which they are directed and must not be likely to cause offence'. In fact the Code provided combined supplementary information to both Clauses 9.1 and 9.2 under the heading 'Suitability and Taste'. The supplementary information to Clauses 9.1 and 9.2 stated that:

'The special nature of medicines and the professional audience to which the material is directed require that the standards set for the **promotion of medicines** are higher than those which might be acceptable for general commodity **advertising.**

It follows therefore that certain types, styles and methods of **promotion,** even where they might be

acceptable for the **promotion** of products other than medicines, are unacceptable' (emphasis added).

Norgine submitted that it appeared from the wording of the supplementary information set out above that Clauses 9.1 and 9.2 applied to the inappropriate promotion of medicines and not to non-promotional activities or materials. Moreover, it also followed from the supplementary information to these two clauses that in principle, the term 'high standards' was interlinked to the concepts of 'good taste' and 'what was likely to cause offence'. The examples given in this supplementary information reinforced this interpretation as they all related to activities that, in the context of the promotion of medicines, would be considered in poor taste and/or could cause offence to the recipients.

Norgine accepted, however, that Clause 9.1 had been applied to non-promotional activities governing statements about specific medicines and that on occasions, this might be reasonable, particularly where company procedures were seen to be so lax that they resulted in obvious breaches of the Code.

However, Norgine submitted that this was not the case in this instance. Norgine had not issued information in poor taste or likely to cause offence. Nor had it issued inconsistent or incomplete information indicative of poorly executed procedures. This letter was agreed not to concern an issue of promotion or even a non-promotional piece about a specific identified medicine. It concerned health policy and it could not be said that the decision of the Panel involved a straightforward application of the sponsorship provisions.

If, contrary to Norgine's primary contention that these activities were outside the Code and the Appeal Board considered the letter in question and Norgine's involvement in it being issued was within the Code, the case raised a discrete issue not clearly addressed in the Code or supplementary information to it. Where the standard was not clearly established in relation to an activity, it was difficult to see how a finding of failure to meet high standards was fair. Clause 9.1 was seemingly intended to address serious breaches, particularly involving the use of promotional pieces in poor taste or likely to cause offence and which, therefore, did not adequately reflect the special responsibility imposed upon pharmaceutical companies when issuing material relating to their products. This was not such a case and a breach of Clause 9.1 was not appropriate.

Summary

Norgine submitted that if the Appeal Board ruled, that the letter to The Times was outside the scope of the Code, then the Panel's rulings could not stand.

Whilst the Panel and the complainant might consider that the public would like to know more about the background to such a letter, the reality was that the Code did not require any further disclosure. Whilst some might like/want to know certain information or find it of interest, that was not the question before the Appeal Board. The question was whether the letter came within the scope of the Code, and the answer, was 'no'. To find otherwise, no matter how seemingly attractive that proposition, would stifle political lobbying activities on issues of general health policy and patient safety.

Moreover, even if the Appeal Board was to find a breach of Clause 9.10, it would be an unacceptable stretch to find a breach of Clause 9.1. Similarly, Norgine contended that there was no separate breach of Clause 23.2 and no breach on the facts of Clause 23.8. Clauses 23.2 and 23.8 did not give rise to independent breaches and a multiplication of complaints arising out of the same alleged breach would be an unacceptable extension.

Finally, Norgine had grave concerns about the ability of the Panel in the first instance, and ABPI members generally, to impartially rule upon alleged breaches of the Code arising out of a letter critical of a policy of which the ABPI was the proponent. This was not an aspect of the Code that reflected laws relating to promotion, but reflected the separate policy of ABPI members. The inherent conflict of interest was manifest and transparent to Norgine, yet the vested interests of the adjudicating bodies was not transparent to the public. The Panel itself, in rendering its decision, should have been transparent to the public, by disclosing the interests of its affiliated members in promulgating the policy of automatic generic substitution, of which the letter was disparaging and which policy, Norgine had vociferously condemned.

COMMENTS FROM THE COMPLAINANT

The complainant stated that the bottom line was that the letter to The Times letter would not have existed were it not for the activities of the PR agency, employed by Norgine, and Norgine's instructions to it. This was not transparent in the letter in The Times, which was misleading. This was not a spontaneous out-pouring of concern.

The complainant had emails showing that the initial contact from at least one signatory was via the agency, and verbal confirmation of this from another. As far as the complainant could see, the agency co-ordinated the signatories. This wasn't clear in the published letter. Had Norgine included a signatory from itself at least it would have been clear that there was pharmaceutical company involvement. Norgine did not and the complainant alleged that this brought the status of pharma into disrepute.

The complainant stated that it was a bit silly to use 'facts' as a synonym for 'information'. The point about 'information' was that it was unverified, and was prone to bias. The letter to the Times was information about prescription medicines – information which was alarmist about generic

prescribing and provided many views on prescribing. Of course it should be covered by the Code.

The complainant submitted that there was no evidence at all that people had or had not felt misled by the omission of a signatory from Norgine. The argument that this inclusion would have meant that The Times would not have printed it proved the point that this was not an 'ethical' letter – ie that being 'truthful' would lead to non publication.

The complainant noted that it seemed that the letter was written by an agency employee after discussions, for the approval of signatories, who were also being sought by the agency in tandem and who had not always been involved in meetings organised by the agency at the start of the campaign. This letter would not have been published without the co-ordination of the agency, and thus Norgine. Journalists (whom the complainant presumed were paid to be present) at meetings with the agency – which was organised to suggest ways forward – opined that a letter be written. The letter was then drafted by an agency employee. Then the agency co-ordinated the letter and the signatories. To suggest that this was not an initiative of Norgine seemed rather baseless.

The complainant explained that she became interested in this letter because it appeared to be spontaneous which the complainant thought was unusual, even strange. That was why she had contacted people to see why they had signed the letter. Initially, the complainant thought that she might have missed something – having been very much 'pro' generics – why were so many people in disagreement with her? It became clear, on asking the people who responded (and not all did, stating in the BMJ rapid responses that the complainant should have made it clear she was a writer – as though an ordinary member of the public should expect less response) that the origin of this letter was part of an orchestrated campaign. Of that, the complainant had no real objections – free speech and liberty – except that of transparency. Had Norgine put its name to the letter, the complainant would have known the reason for it, and would have confined the newspaper to the recycling bin. When the complainant spoke to Norgine and asked why its name had been missed off, the response was that it considered that it might have 'sullied' the message. The irony was deep and unpleasant.

APPEAL BOARD RULING

The Appeal Board noted that it had first to decide whether the letter published in The Times came within the scope of the Code. Clause 1.1 made it clear that the Code applied to the promotion of medicines to health professionals and to appropriate administrative staff. The Code also applied to certain areas that were non-promotional, including the provision of information to the public about prescription only medicines.

The Appeal Board noted that the letter in question referred to prescribed medicines, it focused on differences between branded and generic medicines and what might happen to patients if pharmacists could automatically substitute a generic medicine even if a specific brand had been prescribed. No medicine was mentioned by name or unique identifying feature. The letter referred a number of times to prescribing and although not explicitly solely about prescription only medicines such medicines would be covered by the letter. Thus, the Appeal Board considered that the letter was subject to the Code as it was information about prescription only medicines aimed at the public.

The Appeal Board noted that the letter to The Times, in contrasting branded and generic medicines, clearly referred to medicines and their uses. The letter had been written as a direct result of a campaign orchestrated by Norgine. Norgine had underwritten the costs of the letter being written. The purpose of Clause 9.10 was to require transparency about pharmaceutical company activities so that readers of the material were aware of any such involvement. The letter itself did not refer to Norgine's involvement and no one from Norgine had signed the letter. In the Appeal Board's view those reading the letter in The Times should have been able to do so in the knowledge that a pharmaceutical company with a vested interest had been involved in its creation. Disclosure in this regard would have allowed the reader to form his own fully informed opinion of the views expressed. The Appeal Board considered that by not making its role clear Norgine had failed to comply with Clause 9.10 and it upheld the Panel's ruling of a breach of that clause. The appeal on this point was unsuccessful.

The Appeal Board noted that the campaign in question was initiated and funded by Norgine. The suggestion that a letter be written to The Times, signed by clinicians and patient organisation representatives, had come from a company-organised roundtable meeting of key journalists to gather their views on how awareness of the issues involved could be raised amongst the general public. Potential signatories to the letter were identified by Norgine or its PR agency; some had been previously identified to sign a consensus document whilst others were contacted only to sign the letter. The Appeal Board noted from Norgine's representatives at the appeal that each signatory chose which title to use when signing the letter; some chose to refer to their role in a named patient organisation ie Chair, President, etc. Individuals with no stated involvement with patient organisations had also signed the letter. The Appeal Board considered that as patient organisations were named, and the senior position of each signatory within the organisation given, readers would assume that each organisation formally endorsed the letter. The Appeal Board considered that in any event, by deliberately not providing any indication of its involvement with the production of the letter, Norgine had not made its involvement with the

patient organisations noted in the letter clear to those reading it. The Appeal Board upheld the Panel's ruling of a breach of Clause 23.2. The appeal on this point was unsuccessful.

The Appeal Board considered that Clause 23.8 required wording to accurately reflect the nature of a pharmaceutical company's involvement in the declaration of sponsorship from the outset. Norgine's role in the development and production of the letter was not made clear to readers of The Times. The Appeal Board upheld the Panel's ruling a breach of Clause 23.8. The appeal on this point was unsuccessful.

The Appeal Board noted that the letter was directed at the public and thus it was important that the public were fully informed as to who was behind it; Norgine, by not declaring its involvement in the creation of the letter had therefore failed to maintain high standards and the Appeal Board upheld the Panel's ruling of a breach of Clause 9.1. The appeal on this point was unsuccessful.

Proceedings commenced	**6 April 2010**
Case completed	**13 August 2010**