CASE AUTH/3197/4/19 ***NO BREACH OF THE CODE***

ANONYMOUS v ETHYPHARM

Sponsored therapy review service

An anonymous contactable group, which described itself as consisting of GPs, NHS leaders, pharmacists, NHS patients and current staff from a named third party service provider, complained about a number of therapy review services provided by that third party on behalf of a number of pharmaceutical companies, including Ethypharm Limited. The Ethypharm service at issue was related to opioid use.

Ethypharm marketed a buprenorphine and naloxone combination as substitution treatment of opioid dependence, Maxitram (tramadol) for moderate to severe pain, and Zomorph (morphine) for severe chronic pain and/or pain resistant to other analgesics, in particular pain associated with cancer.

The complainants stated that a therapy review service sponsored by a pharmaceutical company would, in the majority of cases, lead to an increase in prescribing of that pharmaceutical company's medicines; a fact widely known and accepted within the healthcare industry. It also followed that a therapy review service programme which did not demonstrate an increase in prescribing of the product of the sponsoring company would not lead to ongoing financial investment from the sponsoring company.

In order to remain profitable, the named third party service provider had to retain pharmaceutical companies as clients by providing them with a 'return on investment' when it delivered therapy review services. It did this by coaching its pharmacists on what it called 'client value' which was a guise for 'return on investment'. The complainant stated that the named third party service provider had historically done this verbally, being careful not to put anything in writing. Like most untoward activities however the truth was eventually exposed.

There was now written proof that the named third party service provider linked its therapy review services to the products of the sponsoring pharmaceutical company. This was commercial bias.

The complainants stated that their complaint was based on an internal email sent by a very senior employee at the named third party service provider to the entire clinical team dated 14 August 2018. The complainants alleged that within the email there were several links made between pharmaceutical company product and therapy review service which was totally unacceptable and represented clear breaches of the Code.

The complainants stated that regardless of whether some of the services referred to were currently 'live' or not, the confidence and integrity of the pharmaceutical companies involved, along with the Code had already been breached by the sending of the email.

The complainants referred to a number of companies and used the example of linking some named products to some named companies as implying that other therapy reviews listed where no product was mentioned had a clear and obvious link to client product/therapy priorities. There was a number of cross referrals within the letter of complaint.

The email read as follows with regard to the involvement of Ethypharm:

> **'A new review based on opioid usage which is currently a red-hot topic in primary care that we are launching in the [named region] with a view to expansion across the country when training resource allows.'**

Another extract from the email (final paragraph), provided to Ethypharm was as follows:

> **'As the business evolves a constant challenge will be to transition and integrate client product/therapy priorities into our internal resource and schedules. The addition of new client such as [three named companies-not Ethypharm] also add in the additional challenge of new clinical training. Whilst not every aspect will run exactly to plan the list above illustrates clearly that our reputation as the UK service provider of choice continues to grow and that our objectives of expansion and diversification are on track.'**

The complainants noted the wording of the final paragraph of the email and submitted that it was not Code compliant for an 'independent' clinical service provider to email its pharmacists about integrating client product/therapy priorities into its internal resources and schedules. The complainants alleged that this was an attempt to influence the pharmacists and set the expectation for client product where there should be no link at all. The wording implied that the therapy reviews named in the email had a clear and obvious link to 'client product/therapy priorities'.

As a therapy review from Ethypharm was referred to within the email, a breach of Clause 2 was alleged.

By operating in this way, the sponsored therapy review services were misleading, deceptive and unlawful. The services were not transparent to those who used them or to patients who had their notes accessed and medicines altered without their consent or knowledge of this bias.

The complainants stated that the matter was being reported to the NHS Counter Fraud Authority. The activities would soon be highlighted in the pharmaceutical and mainstream media as it was in the public interest. The public needed to know that GPs were being misled into signing up to 'independent' reviews and that patients had had their treatments changed by the named third party service provider which had a hidden agenda to provide a return on investment to the pharmaceutical companies which paid its wages in order for it to make a profit as a business. The NHS and the public needed protecting from this.

The detailed response from Ethypharm is given below.

The Panel noted that before considering each individual case, there were general points relevant to the therapy review services and the email in question which in its view were relevant to all of the cases and these are given below. Each individual case would be considered on its own merits.

In the Panel's view, the overall impression of the email was such that in the view of the author the therapy services carried out by the third party service provider were inextricably linked to the products of the sponsoring companies. It was extremely concerning that in places the email linked the service to particular products or only offered the service in practices where the formulary did not preclude the company's product. This and the reminder regarding developing the business including the phrase 'integrate client product/therapy priorities' could link company products to a therapy review service. Even where a particular product was not mentioned by name it was extremely likely that the company's product would be linked to the relevant therapy review, as understandably many of the recipients might see integrating client product/therapy priorities as increased prescribing of the company's medicines. The important consideration for the Panel was the effect and influence of the email in question in relation to all the other arrangements for each therapy review.

The Panel noted Ethypharm's submission that it had had some engagement with the named third party service provider, however, such work remained at the design phase and there were no materials, instructions, briefings or training plans that had been approved as part of the medical sign off and as such were not available for circulation.

The Panel did not have before it the clinical commissioning group recommended prescribing guidelines as referred to by Ethypharm so it was unclear how Ethypharm's medicines were included within these guidelines.

The Panel noted the impression of the entire email but noted that it did not refer to a specific Ethypharm medicine nor link the Ethypharm therapy review service to a specific medicine.

The Panel did not consider that the complainants had provided evidence that the email demonstrated that the arrangements for the review with regard to opioid usage which was in the development stage and was due to be supported by Ethypharm were such that they failed to meet the requirements for medical and educational goods and services in the Code. Nor had the complainants provided evidence that the therapy review constituted disguised promotion. The Panel therefore ruled no breaches of the Code.

In the Panel's view Ethypharm had been let down by the third party service provider. The Panel had serious concerns about the impression given by the entire email. However, it did not consider that in the particular circumstances of this case the complainants had provided evidence to show that Ethypharm had failed to maintain high standards and no breach of the Code was ruled. This ruling was upheld following an appeal from the complainant.

Given its rulings of no breach of the Code the Panel consequently ruled that there was no breach of Clause 2.

An anonymous contactable group, which described itself as consisting of GPs, NHS leaders, pharmacists, NHS patients and current staff from a named third party service provider, complained about a number of therapy review services provided by the third party service provider on behalf of a number of pharmaceutical companies, including Ethypharm Limited. The Ethypharm service at issue was related to opioid use.

Ethypharm marketed a buprenorphine and naloxone combination as substitution treatment of opioid dependence, Maxitram (tramadol) for moderate to severe pain, and Zomorph (morphine) for severe chronic pain and/or pain resistant to other analgesics, in particular pain associated with cancer.

COMPLAINT

By way of background, the complainants stated that the named third party service provider claimed to be an 'independent' clinical service provider. The third party service provider received the vast majority of its income from pharmaceutical companies which paid it to deliver sponsored therapy review services.

The complainants stated that a therapy review service sponsored by a pharmaceutical company would, in the majority of cases, lead to an increase in prescribing of that pharmaceutical company's medicines; a fact widely known and accepted within the healthcare industry. It also followed that a therapy review service programme which did not demonstrate an increase in prescribing of the product of the sponsoring company would not lead to ongoing financial investment from the sponsoring company.

In order to remain profitable, the named third party service provider had to retain pharmaceutical companies as clients by providing them with a 'return on investment' when it delivered therapy review services. The third party did this by coaching its pharmacists on what it called 'client value' which was a guise for 'return on investment'. The third party had historically done this verbally, being careful not to put anything in writing. Like most untoward activities however the truth was eventually exposed.

The complainants stated that they now had written proof that the named third party service provider linked its therapy review services to the products of the sponsoring pharmaceutical company. This was commercial bias.

The third party service provider pharmacists were recruited under the façade of delivering 'independent' therapy reviews, improving outcomes for patients. Generally speaking, there was an industry-wide reluctance for employees to complain for fear of repercussion and damage to future career prospects. Uncomfortable with this commercial bias and having been misled during recruitment, most looked for another job and resigned after a short time instead of complaining to the PMCPA. The complainants alleged that the named third party service provider had very high staff turnover and this untoward activity had gone largely unreported until now.

The complainants stated that their complaint was based on an internal email sent by a very senior employee of the named third party service provider to the entire clinical team dated 14 August 2018 . The complainants alleged that within the email there were several links made between pharmaceutical company product and therapy review service which was totally unacceptable and represented clear breaches of the Code.

The complainants stated that regardless of whether some of the services referred to were currently 'live' or not, the confidence and integrity of the pharmaceutical companies involved, along with the Code had already been breached by the sending of the email.

The complainants referred to a number of companies and used the example of linking some named products to some named companies as implying that other therapy reviews listed where no product was mentioned had a clear and obvious link to client product/therapy priorities. There was a number of cross referrals within the letter of complaint.

The email read as follows with regard to the involvement of Ethypharm:

> 'Dear All
>
> As most of you will be aware we are currently in the midst of several adjustments to the business as we introduce and train-in new services and align our activities to client priorities.
>
> The phasing of these changes will of course raise a few short term challenges but will also deliver the increase in client and therapy mix we have been working towards throughout 2018. To clarify these changes I list below the client plan for the remained [sic] of 2018
>
> …
>
> **Ethypharm**
>
> A new review based on opioid usage which is currently a red-hot topic in primary care that we are launching in the […] region with a view to expansion across the country when training resource allows.'

Another extract from the email (final two paragraphs), provided to Ethypharm was as follows:

> 'In addition to the range above we continue to hold large advance payments for our BGTS and PN clients who are all looking to us to do more between now and the end of the year to generate bookings against the many practice opportunities listed in [named database]. These reviews should not be devalued as simple cost cutting as when done well, they offer a range of great clinical outcomes for practices and patients alike.
>
> As the business evolves a constant challenge will be to transition and integrate client product/therapy priorities into our internal resource and schedules. The addition of new client such as [three named companies-not Ethypharm] also add in the additional challenge of new clinical training. Whilst not every aspect will run exactly to plan the list above illustrates clearly that our reputation […] continues to grow and that our objectives of expansion and diversification are on track.'

The complainants noted the wording of the final paragraph of the email and submitted that it was not Code compliant for an 'independent' clinical service provider to email its pharmacists about integrating client product/therapy priorities into its internal resources and schedules. The complainants alleged that this was an attempt to influence the pharmacists and set the

expectation for client product where there should be no link at all. The wording implied that the therapy reviews named in the email had a clear and obvious link to 'client product/therapy priorities'.

As a therapy review from Ethypharm was referred to within the email, a breach of Clause 2 was alleged.

The complainants noted that under the PMCPA guidance for digital communications, a pharmaceutical company was responsible under the Code for any activities carried out on its behalf by a third party even if that third-party acted beyond the scope of its contract.

In summary the complainants submitted that in their view, the case for sponsoring company product linked to therapy review service (commercial bias) had been conclusively proven.

By operating in this way, the sponsored therapy review services were misleading, deceptive and unlawful. The services were not transparent to those who used them or to patients who had their notes accessed and medicines altered without their consent or knowledge of this bias.

Based on the above, the named third party service provider should not be permitted to operate as a clinical service provider to the NHS where it received funds from pharmaceutical companies to deliver 'independent' services. It was inconceivable for the third party to be allowed to continue based on the information supplied.

The complainants stated that the matter was being reported to the NHS Counter Fraud Authority. The activities would soon be highlighted in the pharmaceutical and mainstream media as it was in the public interest. The public needed to know that GPs were being misled into signing up to 'independent' reviews and that patients had had their treatments changed by the third party service provider which had a hidden agenda to provide a return on investment to the pharmaceutical companies which paid its wages in order for it to make a profit as a business. The NHS and the public needed protecting from this.

When writing to Ethypharm, the Authority asked it to consider the requirements of Clauses 2, 9.1, 12.1 and 19.2 of the Code. Relevant extracts of the email were provided to the company and not the complete email.

On receipt of the initial response from Ethypharm the case preparation manager ruled no *prima facie* case to answer in relation to the review based on opioid usage. The parties were so advised. The complainants did not accept the case preparation manager's view. The matter was therefore referred to the Panel as required by Paragraph 5.5 of the PMCPA Constitution and Procedure.

* * * * *

Complaint – additional information

The complainants disagreed with the case preparation manager's consideration that there was a difference between a service, the terms of which had been agreed or largely agreed but was not live, and a service or proposed service, the terms and detail of which had not been agreed, and for which there was little or no documentation.

RESPONSE

Ethypharm confirmed that it had had some engagement with the named third party service provider, however, such work remained at the design phase and there were no materials, instructions, briefings or training plans that had been approved as part of the medical sign off and as such were not available for circulation.

Ethypharm stated that any therapy review service that it might consider introducing in the future would be designed and delivered to be fully compliant with the Code. Until the complaint had been considered by the Panel, Ethypharm had taken the precautionary decision to delay the launch of any such service so that relevant learnings and guidance could be incorporated.

Ethypharm reiterated that the service was at the development stage and that any materials, protocols and services would be fully compliant with the Code.

Ethypharm recommended that the Authority review its processes as it was unacceptable that an 'anonymous' organisation purporting to represent patients, healthcare professionals, the industry and taxpayers could make claims which potentially damaged companies and the industry. Ethypharm noted that as they were anonymous, it was unable to take legal action against them or understand their motives for such accusations.

Ethypharm further submitted that rather than the review being seen as 'unacceptable conduct', it should be upheld as responsible activity demonstrated by the industry. Ethypharm submitted that as a company which marketed strong opioids, it took the decision to review all aspects of how it marketed these products to ensure that it was doing all it could to reduce any patient risk. Ethypharm submitted that its objectives for the third party service provider project were: with GP practice permission to review all patients on strong opioids to ensure they were obtaining the appropriate dose; to review whether these patients should be on opioids at all; and to identify where the practice was not adhering to the clinical commissioning group (CCG) recommended prescribing guidelines designed to ensure the most cost-effective medicine was prescribed. If any patients were identified as per the above, then the practice was informed so it could take whatever action it saw fit for the patient.

PANEL RULING

General comments

The Panel noted that before considering each individual case, there were general points relevant to the therapy review services and the email in question which in its view were relevant to all of the cases. Each individual case would be considered on its own merits.

The Panel noted that under Clause 19 of the Code medical and educational goods and services which enhanced patient care or benefited the NHS and maintained patient care could be provided subject to the provisions of Clause 18.1. They must not be provided to individuals for their personal benefit. The supplementary information to Clause 19.1 gave further details. Pharmaceutical companies could promote a simple switch from one product to another but must not assist a health professional in implementing that switch. A therapeutic review which aimed to ensure that patients received optimal treatment following a clinical assessment was a legitimate activity for a pharmaceutical company to support and/or assist. The result of such clinical assessments might require, among other things, possible changes of treatment including

changes of dose or medicine or cessation of treatment. It was not necessarily a breach of the Code for products from the company providing the service to be prescribed. However, a genuine therapeutic review should include a comprehensive range of relevant treatment choices including non–medicinal choices for the health professional and should not be limited to the medicines of the sponsoring pharmaceutical company. The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual patient's treatment must be documented with evidence that it was made on rational grounds.

The Panel noted that Clause 19.2 stated that medical and educational goods and services in the form of donations, grants and benefits in kind to institutions, organisations and associations that were comprised of health professionals and/or, *inter alia*, provided healthcare were only allowed if they complied with Clause 19.1, were documented and kept on record by the company and did not constitute an inducement to, *inter alia*, prescribe.

The Panel noted that the supplementary information to Clause 19.1 stated, *inter alia*, that service providers must operate to detailed written instructions provided by the company. These should be similar to the briefing material for representatives as referred to in Clause 15.9. The written instructions should set out the role of the service provider and should cover patient confidentiality issues. Instructions on how the recipients are to be informed etc should be included. The written instructions must not advocate, either directly or indirectly, any course of action which would be likely to lead to a breach of the Code.

The Panel noted that pharmaceutical companies investing in therapy review services were very likely to have commercial interests in the area. One of the questions to be considered was whether the therapy review service would likely lead to the use of a particular medicine and whether such an outcome was appropriate bearing in mind the therapy area and available treatment options. How the activity might be perceived to all stakeholders including the public was important in this regard. Documentation with regard to the therapy review service offered and the instructions to the service providers were important as was the training provided in relation to the service and the therapy area. Materials whether they be from the company or third party should not link a therapy review to a particular product. The Panel considered that companies should be confident that those carrying out the service such as the third party service provider pharmacists were appropriately trained.

All discussions with the responsible GPs and other staff including all direct and indirect references to medicines must be non-promotional, fair and accurate and otherwise comply with the Code. This applied irrespective of the fact that the lead GP reviewed and mandated all clinical decisions as such decisions might be indirectly influenced by the preceding discussions eg with the pharmacist/company representative.

The Panel noted that the complaint, which was taken up with a number of companies, was based on an internal email sent by a senior employee of the named third party service provider to the entire clinical team. In the Panel's view, the email in question dated 14 August 2018 might be seen by the third party pharmacists as instructions on how the therapy reviews should be conducted.

The Panel noted that the email described the client plan for the remainder of 2018, specific details for each named pharmaceutical company client were included. The case preparation manager provided each company named in the email with the extract of the email that

specifically applied to it together with the general statements which appeared to apply to all of the named companies. Context was important and the Panel reviewed the email in its entirety. In the Panel's view, the overall impression of the email was such that in the view of the author ie a senior employee of the third party service provider, the therapy services carried out by the third party were inextricably linked to the products of the sponsoring companies. In a few instances the email referred to reviews as being specific company product reviews. For one company the email stated '…you can still recruit any practice where baseline criteria are met and where formulary doesn't preclude [named company, not Ethypharm] products'. It was extremely concerning that in places the email linked the service to particular products or only offered the service in practices where the formulary did not preclude the company's product. This and the reminder regarding developing the business including the phrase 'integrate client product/therapy priorities' could link company products to a therapy review service. Even where a particular product was not mentioned by name it was extremely likely that the company's product would be linked to the relevant therapy review, as understandably many of the recipients might see integrating client product/therapy priorities as increased prescribing of the company's medicines. The reputational gain from supporting implementation of NICE Guidelines and other relevant guidelines and the improvements in patient care might not be seen by recipients of the email as delivering client value or integrating product/therapy priorities. The important consideration for the Panel was the effect and influence of the email in question in relation to all the other arrangements for each therapy review.

The Panel noted that it was an established principle under the Code that pharmaceutical companies were responsible for third parties acting on their behalf even if that third party acted outside the instructions from the pharmaceutical company.

The Panel noted that it appeared from the email that the therapy reviews were not necessarily always driven by pharmaceutical companies, it appeared possible for the third party, a commercial organisation, to propose therapy reviews to a pharmaceutical company in an attempt to gain business.

The linking of product to client companies within the email was particularly concerning when the third party pharmacists could proactively offer a therapy review service to a practice.

The basis for a pharmaceutical company's decision regarding in which areas and in which practices a service would be offered, was important. It might be inappropriate to offer a service only in practices or areas in which a sponsoring company's product was not precluded or was the only or known recommended treatment choice.

The arrangements for delivering the service and its impact on prescribing in the practices targeted was another important consideration for the Panel. This might include how recommendations were made by the pharmacist; by therapy class, specific product, following notes or face-face clinical review.

The Panel noted the complainant's allegation that the third party service provider coached its pharmacists on client value which was a guise for return on investment and that this was historically done verbally. In addition, conversations pharmaceutical company staff and the third party service provider staff had with practices was another important consideration. As was usually the case there was no evidence as to the content of verbal instructions and conversations.

Although companies were not provided with specific outcome data relating to prescribing medicines as the result of the therapy review in a particular practice following the third party pharmacist led clinics, overall data (non-product specific) appeared to be provided by the third party in some cases. The Panel considered that companies would be able to monitor use of their medicines and changes via other means for example sales data.

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The Panel noted Ethypharm's submission that it had had some engagement with the third party service provider, however, such work remained at the design phase and there were no materials, instructions, briefings or training plans that had been approved as part of the medical sign off and as such were not available for circulation.

The Panel did not have before it the clinical commissioning group recommended prescribing guidelines as referred to by Ethypharm so it was unclear how Ethypharm's medicines were included within these guidelines.

The Panel noted it comments above with regard to the impression of the entire email but noted that the email did not refer to a specific Ethypharm medicine nor link the Ethypharm therapy review service to a specific medicine.

The Panel did not consider that the complainants had provided evidence that the email demonstrated that the arrangements for the review with regard to opioid usage which was in the development stage and was due to be supported by Ethypharm were such that they failed to meet the requirements of Clause 19.2. Nor had the complainants provided evidence that the therapy review constituted disguised promotion. The Panel therefore ruled no breach of Clauses 19.2 and 12.1 of the 2016 Code.

In the Panel's view Ethypharm had been let down by the third party service provider. The Panel had serious concerns about the impression given by the entire email. However, it did not consider that in the particular circumstances of this case the complainants had provided evidence to show that Ethypharm had failed to maintain high standards and no breach of Clause 9.1 was ruled.

Given its rulings of no breach of the Code the Panel consequently ruled that there was no breach of Clause 2.

APPEAL BY THE COMPLAINANTS

The complainants appealed the Panel's ruling of no breach of Clause 9.1 failing to maintain high standards. The complainants were pleased with the following comments and ruling by the Panel:

> The Panel had serious concerns about the impression given by the entire email.
>
> In the Panel's view, Ethypharm had been let down by the third party .
>
> In the view of a senior employee at the named third party service provider, the therapy services carried out by the third party were inextricably linked to the products of the sponsoring companies.

> The email in question might be seen by the third party service provider pharmacists as instructions on how the therapy reviews should be conducted.
>
> It was extremely concerning that in places the email linked the service to particular products … and the reminder regarding developing the business including the phrase 'integrate client product/therapy priorities' could link company products to a therapy review service. Even where a particular product was not mentioned by name, it was extremely likely that the company's product would be linked to the relevant therapy review, as understandably many of the recipients might see integrating client product/therapy priorities as increased prescribing of the company's medicines.

The complainants requested that the Appeal Board consider the Panel's strongly worded comments above. The complainants alleged that these comments were not conducive to therapy review service which was maintaining high standards of Code compliance.

The complainants noted that it was an established principle under the Code that pharmaceutical companies were responsible for third parties acting on their behalf even if that third party acted outside the instructions from the pharmaceutical company. The complainants alleged that it was clear that there had been a gross failing on the part of the third-party.

The complainants disagreed that it had not provided evidence to show that Ethypharm had failed to maintain high standards. The complainants alleged that the email dated 14 August 2018 was enough evidence. Even though a specific Ethypharm product was not mentioned, the Panel had serious concerns about the impression given by the entire email. The complainants stated that what Ethypharm perhaps did not understand was that within the email, several specific products were named and linked to therapy reviews from other companies. Ethypharm was named within that email and therefore the email as a whole caused serious concern to the complainants and the PMCPA.

The complainants stated that the focus of the complaint related to the phrase 'integrate client product/therapy priorities'. This phrase which referred to ALL of the clients within the email was of major significance and the complainants wanted the Appeal Board to review the wording again. Client product/therapy did not mean therapy area or disease area, it meant product of the client and therefore linked the product of any client referenced within the email to their respective therapy review. As the Panel had said, the phrase 'could link company products to a therapy review service. Even where a particular product was not mentioned by name, it was extremely likely that the company's product would be linked to the relevant therapy review, as understandably many of the recipients might see integrating client product/therapy priorities as increased prescribing of the company's medicines'.

The complainants agreed with this damning summary from the Panel which supported the complainants' complaint that it influenced the pharmacists and set the expectation for client product making a clear and obvious link between the therapy reviews named and product of the clients.

The complainants alleged that Ethypharm had naively partnered with the third party service provider for commercial gain and as the PMCPA had rightly said, they had been let down by them. There must be accountability in this case and under the Code, Ethypharm were

responsible for the actions of the third party service provider and therefore had not maintained high standards.

In relation to the stage of the review service, the complainants noted the following:

> '[the email] Ethypharm – a new review based on Opioid usage which was currently a red-hot topic in primary care that we are launching in the […] region with a view to expansion across the country when training resource allows.'

Ethypharm had stated that the service remained at the design phase and that there were no materials that had been approved. Yet the original complaint email (14 August 2018) clearly showed that the team was being informed of a 'launch'. The complainants alleged that if the service was in the design phase with no approved materials, there was no guarantee that the service would even be developed and it would be unrealistic to email the team referring to a 'launch'.

The complainants alleged that either the author of the email was attempting to paint an optimistic outlook for remaining staff (albeit misleading) on the back of mass resignations, and the service was in fact in the design phase only, or that the service was considerably closer to launch than the Panel were led to believe.

The complainants alleged that either way, live service or not, the complainants urged the Appeal Board to consider how the NHS and patients might view the pharmaceutical Industry on reading the facts within the case report.

It must not be possible for a pharmaceutical company to partner with an 'independent' clinical service provider, even in early stages, and an email of this nature to be written with no accountability or consequences whatsoever. The complainants stated that they appealed that a breach of Clause 9.1, at the very least, was entirely appropriate in this case, which might also serve as a warning to other pharmaceutical companies and clinical service providers wishing to partner in this manner, to show that this kind of behaviour would not be tolerated.

The complainants urged the Appeal Board not to rule that the complainants, on the balance of probabilities, had not discharged their burden of proof that high standards had not been maintained. The complainants were certain that they had discharged the burden of proof, on the balance of probabilities, and the comments made by the Panel around the email in question supported this.

The complainants requested for a fair appeal hearing and for the Appeal Board to consider the points above around the email dated 14 August 2018. Specifically, their responsibility around third parties acting on behalf of the pharmaceutical company and where the accountability lay.

COMMENTS FROM ETHYPHARM

Ethypharm submitted that it saw no new information contained in the complainants' appeal and reiterated its previous response that the possibility of it carrying out a non-promotional therapy review service for patients prescribed strong opioids reached only an initial development stage.

Before proceeding beyond this initial stage, Ethypharm submitted that it would have ensured that any materials, protocols and services provided by the third party service provider for such a

review would be fully compliant with the Code and there was no question of Ethypharm having 'naively partnered with [the third party service provider] for commercial gain' as had been suggested by the complainants. On the contrary, the purposes of proceeding with the review would have been that of enhancing patient care and/or benefitting the NHS and maintaining patient care and it was probable that the successful completion of the review would have actually reduced sales through dosage reduction and the possible elimination of opioid prescribing in some cases. Clinical pharmacists involved in carrying out the review would first agree the clinical protocol with the relevant GP and would then implement the review, under strict instructions that they must not recommend a specific pharmaceutical product there would be no linking of any particular product to any particular therapy review. The findings of the review would have been presented to the authorising GP and any changes in therapy would be made by that GP. Separately, Ethypharm was aware, generally, that GPs very much valued the benefits of sponsored therapy reviews, because they simply did not have sufficient practice time to address this area.

As previously advised, Ethypharm recommended that the PMCPA reviewed its processes, as Ethypharm found it unacceptable that the complainants, purporting to represent patients, healthcare professionals, the industry and tax payers, could make unsubstantiated claims which damaged companies and the industry and potentially disadvantaged patients and the NHS. As the complaints were anonymous, Ethypharm were unable to take legal action against them or understand their real motives.

Also as previously commented, rather than the review activity, Ethypharm were contemplating being seen as 'unacceptable conduct', it believed it should be regarded as responsible activity.

As a company which marketed strong opioids, Ethypharm had taken the decision to review all aspects of how it could reduce any patient risk and also assist appropriate and cost-effective prescribing. In this context, Ethypharm's specific objectives for the project were:

- With the GP practice permission, to review all patients on strong opioids to ensure they were receiving the appropriate dose.
- To review whether these patients should be on opioids at all.
- To identify where the practice is not adhering to the clinical commissioning group recommended prescribing guidelines, designed to ensure the most cost-effective medicine is prescribed.

Ethypharm submitted that it trusted that these objectives would be seen as sensible and appropriate and that this unmerited appeal would be dismissed by the Appeal Board.

FINAL COMMENTS FROM THE COMPLAINANTS

The complainants highlighted the following part of the review reported by Ethypharm:

> 'To identify where the practice is not adhering to the CCG recommended prescribing guidelines, designed to ensure the most cost-effective medicine is prescribed.'

The complainants expressed concern as to Ethypharm funding a therapy review service including a section on ensuring the most cost-effective opioid medicines were prescribed. Ethypharm further claimed that 'It is probable that the successful completion of the review would have actually reduced sales through dosage reduction and the possible elimination of opioid

prescribing in some cases'. The complainants alleged that it was ludicrous that Ethypharm suggested that a pharmaceutical company would commit financial resource in sponsoring a therapy review service which would reduce sales. Ethypharm did not comment on what impact the cost-effective prescribing part of the review would have on its sales, which was conveniently at the end of its response to the appeal. The complainants alleged, with their multidisciplinary team and vast experience in the medical industry, that it was a strategy for Ethypharm to boost sales by switching brands to the Ethypharm brands of opioids. The complainants had experience of pharmaceutical companies only offering therapy reviews in clinical commissioning groups where they had formulary inclusion. The complainants also alleged that Ethypharm provide/provided financial rebate schemes to clinical commissioning groups for prescribing their brands and examples were provided. The complainants alleged whether there was a similar financial incentive offered to clinical commissioning groups to reduce/deprescribe opioids. The complainants stated they had contacted several clinical commissioning groups with an Ethypharm rebate scheme and there had been no such incentive identified. It was the complainants' opinion that safe prescribing of opioids was a huge area requiring many hours of patient consultations to reduce and stop opioids yet Ethypharm included brand changes to formulary in its top 3 objectives for the third party service provider project. There was no clinical need for this. These changes could be managed by clinical commissioning group medicines optimisation teams, pharmacy technicians, practice-based pharmacists and clinical decision tool software. The clinical need should be to review patients to ensure appropriate dosing, reducing, stopping, addressing dependence, tolerance, misuse and co-prescribing of medication likely to cause harm with opioids to name a few examples.

The complainants noted Ethypharm's comments: 'we would recommend that the PMCPA review their processes, as we find it unacceptable that an "anonymous" organisation, purporting to represent patients, healthcare professionals, the industry and tax payers can make claims which potentially damage companies and the industry. As they are anonymous, we are unable to take legal action against them or to understand their motives for such accusations'. The complainants alleged that Ethypharm had partnered with the third party service provider without being aware of the rules and regulations surrounding industry sponsored therapy review services. In short, Ethypharm had not conducted due diligence and in turn had compromised its integrity.

The complainants stated that to make a recommendation to the PMCPA that it reviews its processes was laughable. Perhaps Ethypharm should have familiarised itself with the PMCPA Constitution and Procedure first. The PMCPA assessed complaints and evidence first to decide if it went before a Panel yet Ethypharm expressed its desire for legal action against the complainants for making 'damaging' claims.

The complainants stated that Ethypharm needed to understand that by venturing into pharmaceutical company sponsored therapy reviews carried risk and that it was an established principle under the Code that pharmaceutical companies were responsible for third parties acting on their behalf even if that third party acted outside the instructions from the pharmaceutical company.

The complainants reminded the Appeal Board of comments from the Panel based on the Ethypharm complaint set out in the appeal above.

With the PMCPA's comments in mind, the complainants alleged that high standards had not been maintained and that a Clause 9.1 ruling, at the very least, was completely justified.

APPEAL BOARD RULING

The Appeal Board noted the Panel's general comments above and considered that they were relevant to all the related therapy review cases and the email in question. Each individual case would be considered on its own merits. In that regard the Appeal Board noted Ethypharm's submission that it had had some engagement with the named third party service provider, however, such work remained at the design phase and there were no materials, instructions, briefings or training plans that had been approved as part of the medical sign off and as such were not available for circulation. The Appeal Board considered that the relationship between Ethypharm and the third party service provider was not fairly reflected in the email.

The Appeal Board noted that it could be argued that the email in question did not refer to a specific Ethypharm medicine or therapy review service. The Appeal Board noted that within the email at issue another pharmaceutical company's medicine had been linked to that company's therapy review service.

The Appeal Board noted that the email at issue was a single internal communication within the third party service provider. The Appeal Board was concerned that the third party had linked another company's product to a therapy review service in the email. Whilst the Appeal Board considered that the wording of the phrase 'integrate client product/therapy priorities' could be improved it did not consider overall that the phrase in itself or in the context of the email related to a particular Ethypharm medicine. Further there was no agreed Ethypharm therapy review service to be offered.

In the Appeal Board's view, Ethypharm had been let down by its potential third-party service provider. The Appeal Board noted the Panel's serious concerns about the impression given by the entire email. However, the Appeal Board did not consider that, in the particular circumstances of this case, the complainants had provided evidence that Ethypharm had failed to maintain high standards and it upheld the Panel's ruling of no breach of Clause 9.1. The appeal was unsuccessful.

This case was one of a number of cases as follows; Case AUTH/3188/4/19 Bayer, Case AUTH/3190/4/19 Takeda, Case AUTH/3191/4/19 Amgen, Case AUTH/3193/4/19 Novartis, Case AUTH/3194/4/19 GlaxoSmithKline and Case AUTH/3195/4/19 Chiesi.

Complaint received **30 April 2019**

Case completed **14 October 2020**