CASE AUTH/3195/4/19 ***NO BREACH OF THE CODE***

ANONYMOUS v CHIESI

Sponsored therapy review services

An anonymous contactable group, which described itself as consisting of GPs, NHS leaders, pharmacists, NHS patients and current staff from a named third party providing therapy review services, complained about a number of therapy review services provided by that third party on behalf of a number of pharmaceutical companies, including Chiesi Limited. The Chiesi service at issue was related to chronic obstructive pulmonary disease (COPD).

Chiesi marketed Atimos Modulite (formoterol), Fostair (formoterol/beclometasone), and Trimbow (beclomethasone/formoterol/glycopyrronium bromide) used in the treatment of certain patients with COPD.

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 Chiesi:

> **'The contract has been signed and materials are already in the approval process with the next meeting scheduled for this week, so we hope to have further news on a "go-live date" very soon.'**

Another extract from the email (final paragraph), provided to Chiesi 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 Chiesi] 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 Chiesi was referred to within the email, a breach of Clause 2 was alleged.

By operating in this way, the 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 Chiesi 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 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 it comments with regard to the impression of the entire email but noted that the email did not refer to a specific Chiesi medicine nor link the Chiesi therapy review service to a specific medicine.

The Panel noted Chiesi's submission that the therapy review service in question had been established to drive quality improvement for patients with COPD through proactive patient identification and pharmacist-led review, to optimise COPD management in line with best practice: the Global Initiative for Chronic Obstructive Lung Disease (GOLD) report; guidelines from the National Institute for Health and Care Excellence (NICE); and practice-defined COPD management framework. One of the objectives stated in the clinical protocol included proactive identification of patients who might benefit from optimisation of current COPD management (pharmacological or non-pharmacological) in line with national and local guidelines and practice-defined COPD management framework.

The lead GP was required to complete the practice-defined COPD management framework in which individual formulations to be considered and which were in line with local formulary. For each therapy class, three formulation options could be entered. The GP specified individual formulations supported by the practice and which COPD guideline/report (GOLD/NICE), local pathway and local formulary (where applicable) to follow. The GP was also required to complete a specification to support non-pharmacological interventions.

The Panel noted the documents provided by Chiesi regarding the arrangements including that the service was provided where a need had been identified for the review of patients with COPD and associated therapeutic management of the disease. The named third party service provider pharmacists could also offer the COPD patient review service to GP practices that expressed an interest in it. If a practice asked about the COPD review service during a promotional call, the representative could give a brief description and provide a service introduction document and might choose to attend the practice the first day of the review to facilitate introduction of the named third party service provider pharmacist.

The Panel further noted that the clinical protocol stated that whilst the service was funded and organised on behalf of Chiesi, any change in COPD management arising from the patient review process remained the choice and sole decision of the lead GP and offering of the service would not be conditional on the prescribing of any Chiesi Ltd product or services. All interventions made by the named third party service provider pharmacist were made according to the lead GP/authorised clinician's direction and authority. The pharmacists involved would have a thorough working knowledge of the

relevant guidelines, reports, and key principles of COPD management and received training.

The clinical protocol stated that upon completion of the project anonymised summary data would be provided to Chiesi in order to monitor the level of benefit to the NHS and its patients. The example report provided by Chiesi included, *inter alia*, a summary of recommendations and interventions following pharmacist led clinics by medicine class. It did not refer to any specific medicine. The Panel noted that Chiesi was not the only company to market a medicine in any of the classes listed in the report.

The Panel noted Chiesi's submission that reference to 'client product/therapy priorities' in the named third party service provider's email was an entirely reasonable part of the business update to indicate where future areas of clinical expertise would need to be developed or enhanced within the teams expected to operate the service. Chiesi firmly rejected the allegation that this was linked to Chiesi's products.

The Panel further noted Chiesi's submission that the named third party service provider sent internal communications to ensure its staff knew about the product ranges marketed by its client companies to meet pharmacovigilance obligations. The Panel noted Chiesi's submission that none of the certified service materials that were used with NHS staff to deliver the services made any link to any individual product or product range.

The Panel noted Chiesi's submission that there was a daily rate for a clinical pharmacist to carry out the therapy review service, there was no additional remuneration or bonus associated with sales of any kind.

Whilst the Panel had concerns including about how the email portrayed the named third party service provider therapy services and its effects on its pharmacists and other staff, it nonetheless noted that the complainant bore the burden of proof. On the balance of probabilities, it was not unreasonable that some, if not all, of the named third party service provider pharmacists would associate the Chiesi therapy review with Chiesi products particularly based on the email at issue. However, taking all the circumstances into account, including its view that Chiesi's written arrangements for the review did not appear to amount to a switch to a Chiesi medicine, the Panel did not consider that the complainant had established, on the balance of probabilities, that the email demonstrated that the arrangements for the COPD therapy review service supported by Chiesi 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, Chiesi had been let down by its third party . 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 Chiesi 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 Chiesi Limited. The Chiesi service at issue was related to chronic obstructive pulmonary disease (COPD).

Chiesi marketed Atimos Modulite (formoterol), Fostair (formoterol/beclometasone), and Trimbow (beclomethasone/formoterol/glycopyrronium bromide) used in the treatment of certain patients with COPD.

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 (copy provided). 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 Chiesi:

> '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
>
> …
>
> **Chiesi**
>
> The contract has been signed and materials are already in the approval process with the next meeting scheduled for this week, so we hope to have further news on a 'go-live date' very soon.'

Another extract from the email (final two paragraphs), provided to Chiesi 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 Chiesi] 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 Chiesi 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 Chiesi, the Authority asked it to consider the requirements of Clauses 2, 9.1, 12.1 and 19.2 of the 2016 Code. Attention was drawn to the supplementary information of Clause 19.1. Relevant extracts of the email were provided to the company and not the complete email.

RESPONSE

Chiesi stated that the named third party service provider had confirmed that the email in question was addressed and intended for its staff; it was not intended for general release to clinicians or the wider NHS. The third party service provider had explained that the email discussed progress made as a company in delivering Code compliant services and it did not comprise any instructions, training information or guidance in relation to any of its services. The third party also confirmed that all briefing documents for therapy reviews were certified by the relevant pharmaceutical company and released in an internal document sharing system.

Chiesi submitted that it had obtained from the named third party service provider the service schedule for the medical educational goods and services (MEGS) therapy review service in question and cross-checked it against all internal documentation on its approval system to ensure that they aligned. The documentation included the clinical protocol, briefings (documents and presentations), training, leavepieces, feedback questionnaires, and all patient-facing material. All documents were certified in accordance with Clauses 19.1, 19.2 and 14.3.

In relation to the briefings and training specifically, Chiesi provided copies of the documents below which related to each aspect of the service:

- Documentation between Chiesi and the named third party service provider in relation to the service
    - Clinical Protocol
    - Master Service Agreement
    - Pharmacovigilance Training
- Training from the third party service provider to the clinical pharmacist team
    - Clinical Protocol
    - Pharmacist Briefing Document
- Training to Chiesi sales force in relation to the service
    - Briefing Document
    - Briefing Presentation
    - Validation
- Materials available for use by clinical pharmacist team
    - Service Introduction Document
    - Patient Summary Sheet
    - Individual Patient Assessment Form
    - Post Service Practice Feedback Questionnaire
    - Patient Feedback Questionnaire
    - Patient letters
- Materials available for use by sales force with health professionals
    - Service Introduction Document – promotional call
    - Service Introduction Document – non-promotional call.

With regard to the therapy service and how its ongoing implementation complied with the Code, Chiesi referred to the guidance provided in the supplementary information in Clauses 19.1 or 19.2.

Chiesi stated that the therapy review service had been established to drive quality improvement for patients with COPD through proactive patient identification and pharmacist-led review, to optimise COPD management in line with best practice:

- the Global Initiative for Chronic Obstructive Lung Disease (GOLD) report;
- guidelines from the National Institute for Health and Care Excellence (NICE) and
- practice-defined COPD management framework.

There was no personal benefit to any individual and there would be a ‘transfer of value’ to the GP practice receiving the service.

All documentation related to the COPD therapy review service was non-promotional; it clearly identified Chiesi as the sponsoring company and did not refer to any specific medicine. The declaration of sponsorship, which accurately reflected Chiesi’s involvement, was sufficiently prominent to ensure that readers were aware of it from the outset. The following declaration was included in all documentation other than patient facing material: ‘This service is funded by and delivered on behalf of Chiesi Ltd, as a service to medicine, by [the named third party service provider]’. The declaration included on patient facing material was ‘This service is delivered by an independent company and is paid for and provided on behalf of Chiesi Ltd. Chiesi Ltd is a pharmaceutical company’.

Chiesi submitted that there was a comprehensive salesforce briefing, training slides and validation which gave guidance to the commercial team as to how to introduce the therapy review service in compliance with the Code. In particular, the commercial team were advised of the following:

'
- The COPD patient review service is a non-promotional therapy review programme and may not be linked in any way to the promotion of products. In order to comply with this requirement, the COPD patient review service must not be signed up during a promotional call.
- You may introduce the COPD patient review service by giving a brief description of the service during a promotional call but cannot instigate a detailed description of the service at the same time as a call when products are being promoted. If, following your brief description of the COPD patient review service, the practice is interested in receiving more information you would proceed to organise a non-promotional call.
- If a practice asks about the COPD patient review service during a promotional call, a brief description can include leaving the service introduction document. No other materials relating to the patient review service can be used during a promotional call. An arrangement must be made to return to the practice on a later date to discuss the service in more detail during a non-promotional call.
- During a non-promotional call, you can use the Service Details document to guide a more detailed discussion about the service. In addition, you can use the service authorisation form to sign up the practice to receive the review service.'

The commercial team was also asked to adhere to the following:

'
- Chiesi Ltd support of this review service must NOT be dependent on the customer prescribing a Chiesi Ltd product. This must be neither the fact in practice nor the impression given either verbally or in any documents connected with the project, internally or externally.
- Detailed discussions about the service must NOT be initiated at the same time as a call at which products are promoted. Detailed description of the service may only take place during a non-promotional call.
- If during a promotional visit by you, a change in medication to one of the company's products is agreed, you may NOT then offer the COPD patient review service to facilitate the change as this would be seen as a way for the company to ensure that the agreed change would in fact be made.'

As the therapy review service involved direct contact with patients, no one from Chiesi was involved with the service beyond describing it and signing a practice up to receive it. After that, a trained clinical pharmacist from the named third party service provider or a health professional from the practice, would undertake any relevant patient contact and/or patient identification.

The Master Service Agreement between Chiesi and the named third party service provider stipulated the daily rate for a clinical pharmacist to carry out the review service; there was no additional remuneration or bonus associated with sales.

The clinical protocol required the named third party service provider to ensure that patient confidentiality was maintained; the clinical pharmacists were contractually required to comply with the relevant data protection legislation and confidentiality agreement.

Chiesi explained that the named third party service provider information governance policies were designed to align with wider NHS policy. The third party service provider was an NHS business partner and as such it met with the terms and conditions of the Department of Health's (DoH's) Information Governance (IG) assurance statement through completion of the NHS IG Toolkit (the Data Security and Protection Toolkit from March 2019) assessment on an annual basis. The Toolkit was a performance tool produced by the DoH and hosted by NHS Digital. The Toolkit drew together the legal rules and central guidance set out above and presented them in one place as a set of information governance requirements. The third party service provider ensured that all working practices complied with the General Data Protection Regulation (EU) 2016/679. The clinical protocol contained further details on confidentiality.

Chiesi explained the comprehensive clinical protocol and clinical pharmacist briefing provided written instructions as to how to carry out the therapy review service. These included the responsibilities of Chiesi, the practice and the named third party service provider, as well as patient confidentiality.

The clinical protocol described the training requirements for all pharmacists involved in the delivery of the service, which included a working knowledge of GOLD/NICE guidelines and appropriate respiratory qualifications from accredited providers.

The clinical protocol also described consideration of the full range of pharmacological and non-pharmacological interventions such as (but not limited to) initiation or cessation of treatments, a change in dose, preparation, treatment or referral for further support recommended to improve outcomes in COPD (eg pulmonary rehabilitation, smoking cessation). A practice-defined COPD management framework was completed at each practice.

The clinical protocol described how proposed interventions were made with a clear rationale and recommended in accordance with the practice-defined COPD management framework which was clearly marked for individual authorisation within the individual patient assessment form. This allowed the patient to receive optimal pharmacological and/or other non-pharmacological intervention as directed by the lead GP or authorised clinician. All interventions made by the named third party service provider pharmacist were made according to the lead GP/authorised clinician's direction and authority as defined within the clinical protocol.

There was no link between Chiesi's products and the provision of the therapy review service as evidenced in the service documentation and the Master Service Agreement between the named third party service provider and Chiesi.

Chiesi also noted that the clinical protocol stated 'Whilst the service is funded and organised on behalf of Chiesi Ltd, any change in COPD management arising from the patient review process remains the choice and sole decision of the lead GP and offering of the service will not be conditional on the prescribing of any Chiesi Ltd products or services'.

Details of the transfers of value were described in the Master Service Agreement. All Chiesi transfer of values were uploaded on the ABPI Disclosure Portal on an annual basis in accordance with Clause 24 of the Code.

Chiesi stated that given the importance of compliance with the Code, it chose to partner with a well-known and well-respected independent service provider, which had good examples of similar services in other therapy areas. A published example was provided.

There were also numerous discussions which took place, both internally as well as with the named third party service provider and there was an assessment of risk about service introduction and how to mitigate any potential risks around the method and materials to be used when introducing the service to ensure that the training covered all of the required elements.

Chiesi submitted that it usually undertook audits of therapy review services to ensure compliance, however the therapy review service in question had only been live for 6 months and no audit of it had been carried out to date. Previous services had been audited, and Chiesi would audit the named third party service provider service before the end of October 2019 (ie when it had been live for 12 months). Chiesi noted that the Master Service Agreement contained details of the reporting provided to Chiesi on the service provision: 'Supplier will provide a monthly report of all clinical activity for the services performed by the pharmacists. The report will include the date of the clinic, the name of the supplier's pharmacist conducting the clinic, the health professional they interacted with, confirmation of asthma or COPD clinic and the number of patients who attended each clinic'.

Chiesi stated that it measured success for the therapy review service based on the benefit derived by GPs in helping to deliver better care for patients. In that regard Chiesi summarised anonymised feedback from the patient and practice questionnaires:

- 98% of patients agreed or strongly agreed that speaking with the pharmacist helped them to better understand how to use their COPD medicines and inhalers
- 95% of patients agreed or strongly agreed that they felt more confident using their medicines and inhalers
- 98% of patients agreed or strongly agreed that they would recommend the service to someone else with COPD
- 100% of practices agreed or strongly agreed that the interventions made by the pharmacist were appropriate
- 96% of practices agreed or strongly agreed that the service was structured in a way that minimised workload for the practice
- 100% of practices confirmed that the service prioritised patient care, encouraged patient self-management and improved practice quality outcome framework (QoF) achievement.

Free text patient comments included 'It really helped to learn how to do my spacer inhaler properly as I wasn't doing it right', 'Very efficient and gave me confidence', 'Pharmacist made me feel very confident and explained all my medications and options' and 'Very informative, very good service received'. This high level of satisfaction demonstrated the direct benefit of the therapy review service to patients and the NHS. Chiesi stated that it viewed such high levels of satisfaction as a success and did not believe they could have been achieved if the service was not a genuine therapy review service which covered all options (pharmacological and non-pharmacological).

Chiesi did not know what proportion of patients were changed to its products as a result of the reviews because it was not appropriate for it to request (or have access to) this metric and would be otherwise non-compliant with the Code.

With regard to coaching with relevance to 'client value', Chiesi confirmed that the named third party service provider pharmacist team was trained on the clinical protocol and clinical pharmacist brief in relation to the provision of the therapy review service.

In addition, the following training was provided to the named third party service provider pharmacists team:

- Therapy review service training via a training cascade led by National Lead Pharmacists (NLPs).
- Levels of competence for delivering a service were assessed during field training days and field visits by NLPs or Regional Lead Pharmacists (RLPs). Correct understanding and application of the protocol, briefing document and clinical competence were assessed and, once a pharmacist was deemed fully competent, a 'sign off' and update to training records was completed before they worked unsupervised.
- Quality assurance visits of field-based trainers worked to ensure on-going quality and standards were maintained.
- Thorough working knowledge of the relevant guidelines and key principles of COPD (as outlined in the briefing document)
- Therapy area training from a named RCGP accredited provider.

The following general training was also provided to the named third party service provider pharmacists:

- Clinical and information governance (including data protection/general data protection regulations (GDPR))
- Incident and complaint reporting process
- Company continuing professional development policy
- Code training
- Digital communications
- Pharmacovigilance reporting requirements and British Healthcare Business Intelligence Association (BHBIA) online training.

Given the comprehensive training provided to the pharmacist team, in addition to the clear guidance provided in the clinical protocol and pharmacist brief, Chiesi firmly considered that there was no disguised promotion and therefore no breach of the Code.

Chiesi completely refuted the specific allegations that client value was a guise for return on investment and that it was not Code compliant for an independent clinical service provider to email the pharmacists about integrating client product/therapy priorities into their internal resources and schedules. Chiesi considered that it was important that the clinical pharmacists received therapy-specific clinical training in the therapy areas in which they worked in order to deliver review services to the highest possible standard and with up-to-date knowledge of the latest treatment options and therapy guidelines. The named third party service provider sent internal communications to ensure that its staff knew about the product ranges marketed by client companies so that staff could meet their pharmacovigilance obligations in relation to those products. However, none of the certified service materials that were used with NHS staff to deliver the services made any link to any individual product or product range.

Chiesi addressed the allegation that, 'We now have written proof of [the named third party service provider] linking their therapy review services to the products of the sponsoring pharmaceutical company. This is commercial bias.' which was alleged in relation to the following unredacted text specifically pertaining to Chiesi contained in the email at issue. Chiesi submitted that the statement in the email that 'The contract has been signed and materials are already in the approval process with the next meeting scheduled for this week, so we hope to have further news on a "go-live date" very soon' did not link Chiesi's products to provision of the therapy review service, and was therefore not in breach of Clauses 19.1 and 19.2. To provide further evidence that there was no link between Chiesi's products and provision of the service, there was no reference to Chiesi's products in any documentation related to the therapy review service nor in the Master Service Agreement. In addition Chiesi referred to the clinical protocol that 'Whilst the service is funded and organised on behalf of Chiesi Ltd, any change in COPD management arising from the patient review process remains the choice and sole decision of the lead GP and offering of the service will not be conditional on the prescribing of any Chiesi Ltd products or services'.

With regard to the complainants' reference to specific wording in the email related to other companies and alleged that, *inter alia*, '… the other therapy reviews named in this same email have a clear and obvious link to 'client product/therapy priorities' Chiesi pointed out that the text related to other companies was redacted in the copy provided. Whilst, in the absence of context, Chiesi could not evaluate its relevance it assumed it was entirely unrelated to Chiesi products and therefore it strongly refuted the allegation that the email in question linked Chiesi products in a manner that was inconsistent with Clauses 19.1 and 19.2.

Reference to 'client product/therapy priorities' in the named third party service provider email was an entirely reasonable part of the business update to indicate where future areas of clinical expertise would need to be developed or enhanced within the teams expected to operate the service. Chiesi firmly rejected the allegation that this was linked to Chiesi's products in a manner that is in breach of Clause 19.1 or 19.2.

Chiesi was confident that the service complied with each of the requirements of Clause 19.1 and 19.2, including the supplementary information.

In the circumstances set out above, Chiesi did not consider that there was a breach of Clause 2, 9.1, 12.1, 19.1 or 19.2 of the Code.

In response to a request for further information Chiesi submitted that it was aware that the named third party service provider communicated with its staff in relation to product ranges for the purposes of ensuring compliance with their pharmacovigilance obligations. This was evident from the pharmacist briefing document as well as from the copy of the email provided by the Authority with its letter of 9 May. The pharmacist briefing document, which was certified, was provided to all pharmacists who provided the therapy review service on behalf of the third party service provider. Paragraph 22 on page 17 set out the pharmacovigilance procedure to be followed in the case of an adverse event and it referred to 'the Chiesi Ltd portfolio'. Naturally, pharmacists delivering the service would need to be aware of the products in the portfolio in order to discharge their pharmacovigilance obligations within the 24-hour period. Chiesi submitted that it was not in possession or aware of any the third party service provider internal communications which specifically referenced the Chiesi product range in the context of the Chiesi therapy review service.

The clinical protocol stated that anonymised summary data from an individual practice would be forwarded to a member of Chiesi staff. The data Chiesi received was aggregated data across practices, an example was provided.

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 its 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 named 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 Chiesi] 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 service provider, 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 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 it comments above with regard to the impression of the entire email but noted that the email did not refer to a specific Chiesi medicine nor link the Chiesi therapy review service to a specific medicine.

The Panel noted Chiesi's submission that the therapy review service in question had been established to drive quality improvement for patients with COPD through proactive patient identification and pharmacist-led review, to optimise COPD management in line with best practice: the Global Initiative for Chronic Obstructive Lung Disease (GOLD) report; guidelines from the National Institute for Health and Care Excellence (NICE); and practice-defined COPD management framework. One of the objectives stated in the clinical protocol included proactive identification of patients who might benefit from optimisation of current COPD management (pharmacological or non-pharmacological) in line with national and local guidelines and practice-defined COPD management framework.

The lead GP was required to complete the practice-defined COPD management framework in which individual formulations to be considered and which were in line with local formulary. For each therapy class, three formulation options could be entered. The GP specified individual formulations supported by the practice and which COPD guideline/report (GOLD/NICE), local pathway and local formulary (where applicable) to follow. The GP was also required to complete a specification to support non-pharmacological interventions.

The Panel noted that according to the clinical protocol the service was provided where a need had been identified for the review of patients with COPD and associated therapeutic management of the disease. According to their brief, the named third party service provider

pharmacists could also offer the COPD patient review service to GP practices that expressed an interest in it which might be because they required additional resource to effectively review their COPD population, they lacked a respiratory specialist, or they were in an area of high COPD prevalence or where variations in care existed in comparison to other clinical commissioning groups (CCGs)/practices within their own locality. The Panel noted that the salesforce briefing document stated that the service might be introduced by a Chiesi representative giving a brief description during a promotional call. If the practice was interested in receiving more information a non-promotional call would be organised where a detailed description of the service could be given. A detailed description could not be given at the same time as a call when products were being promoted. If a practice asked about the COPD review service during a promotional call, the representative could give a brief description and provide a service introduction document and might choose to attend the practice the first day of the review to facilitate introduction of the named third party service provider pharmacist.

The Panel further noted that the clinical protocol stated that whilst the service was funded and organised on behalf of Chiesi, any change in COPD management arising from the patient review process remained the choice and sole decision of the lead GP and offering of the service would not be conditional on the prescribing of any Chiesi Ltd product or services. All interventions made by the named third party service provider pharmacist were made according to the lead GP/authorised clinician's direction and authority as defined within the clinical protocol. Each face-to-face consultation might result in a proposed pharmacological or non-pharmacological intervention such as (but not limited to) initiation or cessation of treatments, a change in dose, preparation, treatment or referral for further support recommended to improve outcomes in COPD.

According to the clinical protocol all the named third party service provider pharmacists involved would have a thorough working knowledge of the relevant guidelines, reports, and key principles of COPD management including GOLD and NICE and received appropriate training as defined within the third party company guidelines including external respiratory training from an accredited provider, internal training on COPD review service overseen by national and regional lead pharmacists, annual internal Code compliance training in relation to the provision of MEGS, and annual pharmacovigilance (PV) training. It was in the remit of a senior employee of the third party service provider to ensure that pharmacists worked within the clinical protocol at all times; a senior employee and the senior pharmacist management team undertook regular field visits to ensure company procedures and agreed clinical protocols were adhered to and that pharmacists remained up to date in their knowledge of COPD management.

The clinical protocol stated that upon completion of the project anonymised summary data would be provided to Chiesi in order to monitor the level of benefit to the NHS and its patients. The Panel noted that the example report provided by Chiesi included, *inter alia*, a summary of recommendations and interventions following pharmacist led clinics by medicine class. It did not refer to any specific medicine. The Panel noted that Chiesi was not the only company to market a medicine in any of the classes listed in the report.

The Panel noted Chiesi's submission that reference to 'client product/therapy priorities' in the named third party service provider email was an entirely reasonable part of the business update to indicate where future areas of clinical expertise would need to be developed or enhanced within the teams expected to operate the service. Chiesi firmly rejected the allegation that this was linked to Chiesi's products.

The Panel noted that Chiesi refuted the allegation that the named third party service provider pharmacists were coached on client value which was a guise for return on investment. The Panel noted that the email itself did not refer to client value, this was a term used by the complainants. The Panel noted Chiesi's submission that it was important that the third party pharmacists received therapy-specific clinical training in the therapy areas in which they worked in order to deliver review services with up-to-date knowledge of the latest treatment options and therapy guidelines. The Panel further noted Chiesi's submission that the third party service provider sent internal communications to ensure its staff knew about the product ranges marketed by its client companies so staff could meet their pharmacovigilance obligations in relation to those products. The Panel noted Chiesi's submission that none of the certified service materials that were used with NHS staff to deliver the services made any link to any individual product or product range.

The Panel noted Chiesi's submission that Schedule 4 of the Master Service Agreement between Chiesi and the named third party service provider stipulated the daily rate for a clinical pharmacist to carry out the therapy review service, there was no additional remuneration or bonus associated with sales of any kind.

The introduction to the PMCPA Constitution and Procedure stated that a complainant had the burden of proving their complaint on the balance of probabilities.

The Panel noted the complainants' allegation that they now had written proof that the third party service provider linked its therapy review services to the products of the sponsoring pharmaceutical company; historically the third party had done it verbally, being careful not to put anything in writing.

Whilst the Panel had concerns including about how the email portrayed the third party therapy services and its effects on the third party pharmacists and other staff, it nonetheless noted that the complainant bore the burden of proof. On the balance of probabilities, it was not unreasonable that some, if not all, of the pharmacists would associate the Chiesi therapy review with Chiesi products particularly based on the email at issue. However, taking all the circumstances into account, including its view that Chiesi's written arrangements for the review did not appear to amount to a switch to a Chiesi medicine, the Panel did not consider that the complainant had established, on the balance of probabilities, that the email demonstrated that the arrangements for the COPD therapy review service supported by Chiesi 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, Chiesi had been let down by its third party. 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 Chiesi 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 for 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, Chiesi had been let down by its third party.
>
> On the balance of probabilities, it was not unreasonable that some, if not all, of the third party service provider pharmacists would associate the Chiesi therapy review with Chiesi's products.
>
> In the view of a senior employee of 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.
>
> In the Panel's view, 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 linking of product to client companies was particularly concerning when the third party service provider pharmacists could proactively offer a therapy review service to a practice.

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 a therapy review service which was maintaining high standards of Code compliance.

The complainants started by setting context. The complaints alleged that the complaint was specifically based upon the email sent by a senior employee of the named third party service provider dated 14 August 2018. It was widely accepted that the approved protocols and documents for an industry sponsored therapy review were never going to be found to make any link to the increased prescribing of the product of the sponsoring company. They would always be produced to refute any claims of bias and to avoid any reprimand. What the complainants were exposing was what went on behind the official paperwork. As an example, the Panel had rightly said, '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'. The complainants had uncovered an email which exposed the true relationship between an 'independent' clinical service provider and the products of their clients.

The complainants stated the point for this appeal that although Chiesi claimed to have been Code compliant, 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. It was clear that there had been a gross failing on the part of their third-party.

The complainants disagreed that they had not provided evidence to show that Chiesi had failed to maintain high standards. The complainants maintained, as they had done from the beginning, that the email dated 14 August 2018 was enough evidence. Even though a specific Chiesi product was not mentioned, the Panel had serious concerns about the impression given by the entire email and stated that 'on the balance of probabilities, it was not unreasonable that some, if not all, of the [third party service provider] pharmacists would associate the Chiesi therapy review with Chiesi's products'. This conclusion alone was damning enough, on the balance of probabilities, to rule a breach of Clause 9.1 in the complainants' opinion.

The complainants highlighted the following phrase which was the focus of the complaint: 'integrate client product/therapy priorities'. This phrase referred to ALL of the clients within the email. This was of major significance and the complainants would like the Panel 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 complainant's 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 what Chiesi perhaps did not understand was that within the email, several specific products were named and linked to therapy reviews from other companies. Chiesi was named within this email and therefore the email as a whole caused serious concern to the complainants and the PMCPA. However, contrary to the view of the Panel and the complainants, Chiesi was of the opinion that the reference to 'client product/therapy priorities' was an 'entirely reasonable part of the business update' claiming that future areas of clinical expertise would need to be developed or enhanced within the teams expected to operate the service. The complainants stated that there was a difference between a credible communication around developing future areas of clinical expertise and sending a business update implying increased prescribing of the company's medicines. This was a gross error of judgement and Chiesi had been ill advised in their attempt to deflect the statement.

Chiesi also claimed that '[the named third party service provider] sent the internal email to ensure that it's staff knew about the product ranges marketed by client companies so that staff could meet their pharmacovigilance obligations in relation to those products'. The complainants maintained that that Code compliant therapy review services must not be linked to product and that it was ludicrous to attempt to explain that the email in question referred to client company's products for pharmacovigilance purposes. The complainants requested that the PMCPA take a firm stance on such absurd responses to prevent Chiesi bringing the industry into further disrepute. The Panel had already expressed serious concerns about the impression given by the entire email.

Chiesi 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, Chiesi were responsible for the actions of the third party and therefore had not maintained high standards.

The complainants alleged that it must not be possible for a pharmaceutical company to partner with an 'independent' clinical service provider and an email of this nature to be written with no accountability or consequences whatsoever. The complainants 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 noted that Chiesi had carried out no audits of the therapy review service in the first 6 months. It was a serious failing that they had not done this considering Chiesi's public history of breaches of the Code.

The complainants stated that Chiesi had, of course, produced their protocols and briefings to the Panel which showed this to be a Code compliant service, on paper. The complainants urged the Appeal Board not to rule that the complainants, on the balance of probabilities, had not discharged its 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 CHIESI

Chiesi reminded the Appeal Board that both the complaint and the appeal were hinged on a solitary email, dated 14 August 2018 and written by a senior employee of the named third party service provider, to the clinical team. No evidence was provided to the Panel to demonstrate that the therapy review service was being operated *de facto* in a way which either linked products to the therapy review service or breached the Code in any other respect. This was notwithstanding the fact that the complainants were (at the time the complaint was submitted) said to comprise existing third party service provider staff.

Chiesi stated that it was clear that the Panel considered the email in question and the circumstances of the complaint in some detail before arriving at its conclusions. Indeed, the first line of the appeal acknowledged this. It was equally clear that the complainants agreed with many of the comments made by the Panel and the essence of the appeal was the complainants' assertion that the Panel did not correctly apply the Code to the facts as it adjudged them to be.

Chiesi stated that the appeal began by setting out some of the comments made by the Panel with which the complainants 'were pleased'. The wording of some of those comments was significant. For example (emphasis added):

- 'In the Panel's view, the email in question MIGHT BE seen by the [named third party service provider] pharmacists as instructions on how the therapy reviews should be conducted';

- '… 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.'

Chiesi stated that the diction in the ruling appeared to have been carefully chosen by the Panel which was, Chiesi accepted, seriously concerned about the impression given by the email taken as a whole. Nonetheless, as the examples above demonstrated, despite it making additional enquiries of Chiesi in the normal manner, the Panel had no evidence before it to prove that the therapy review service was, in practice, run in such a way as to link it to products. Had there been any such evidence of this, Chiesi felt sure this would have been brought to the Panel's attention given: (i) the fact that existing named third party service provider employees featured among the complainants; and (ii) the malevolent tone of the complaint. The complainants alleged that the Panel's comments 'were not conductive to therapy review service which was maintaining high standards of Code compliance' but there was no *prima facie* case made out that the service, as provided, fell short of such standards, something which was acknowledged by the Panel.

Chiesi stated that the complainants had, of course, been selective in choosing the sections from the Panel's comments in order to present their case in the best possible light. However, the sections they had included in their appeal needed to be read in the context in which they were written.

Chiesi stated that, by way of example, the complainants quoted the Panel as having stated:

> 'On the balance of probabilities, it was not unreasonable that some, if not all, of the [named third party service provider] pharmacists would associate the Chiesi therapy review with Chiesi's products.'

However, the remainder of the paragraph in the Panel's letter was important as it followed on:

> 'However, taking all the circumstances into account, including its view that Chiesi's written arrangements for the review did not appear to amount to a switch to a Chiesi medicine, the Panel did not consider that the complainant had established, on the balance of probabilities, that the email demonstrated that the arrangements for the COPD therapy review service supported by Chiesi 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…..'

A further example was the extract quoted by the complainants which read:

> 'It was extremely concerning that in places the email linked the service to particular products….'

Chiesi stated that the complainants omitted to mention that this did not relate to Chiesi, a fact which was recognised by the Panel in the immediately preceding sentence.

Protocols and documents

Chiesi stated that the complainants made a cynical reference to approved protocols and documents which, in their view, were '… never going to be found to make any link to the increased prescribing of the product of the sponsoring company'. In the case of Chiesi's protocol and documentation this was indeed true. The complainants did, however, suggest that they were exposing 'what goes on behind the official paperwork' and they further suggested that the email in question 'exposes the true relationship between [the named third party service provider] … and the products of their clients'. With respect, one email could not and did not provide such insight, as was readily accepted by the Panel.

The pharmaceutical industry was, by necessity, highly regulated and robust documentation and processes were a cornerstone of self-regulation. Operationally such documentation and procedures were a clear framework required to ensure MEGS benefited patients and supported healthcare organisations at the same time as ensuring there was no link to promotion/inducement to prescribe. To suggest that the protocols and documentation were intentionally used for other subversive purposes was both unfounded and potentially undermined the legitimate purpose of services important to patients and healthcare organisations.

Responsibility for third parties

Chiesi agreed with the established principle that pharmaceutical companies were responsible, under the Code, for the actions or inaction of third parties with whom they engaged. Notwithstanding, pharmaceutical companies could only be held in breach of the Code in circumstances where this action or inaction itself resulted in a breach of the Code. In this particular case, despite the content of the email in question, no action taken by the named third party service provider was proven, or even alleged, to be in breach of the Code and therefore Chiesi could not be liable for a breach of the Code. This explained why, in Chiesi's view, despite the Panel stating that '… on the balance of probabilities, it was not unreasonable that some, if not all, of the third party service provider pharmacists would associate the Chiesi therapy review with Chiesi's products', the Panel did not find that Chiesi was in breach of the Code.

Naming of products

Chiesi stated that the complainants made reference to the fact that '… several, specific products were named and linked to therapy reviews from other companies'. The email did not link Chiesi's products to the provision of the therapy review service and there was no reference to Chiesi's products in any documentation related to the therapy review service, nor in the master service agreement between the named third party service provider and Chiesi. Furthermore, the Clinical Protocol stated:

> 'Whilst the service is funded and organised on behalf of Chiesi Ltd, any change in COPD management arising from the patient review process remains the choice and sole decision of the lead GP and offering of the service will not be conditional on the prescribing of any Chiesi Ltd products or services.'

With regard to the reference to 'client product/therapy priorities' in the final paragraph of the email in question, Chiesi firmly rejected the allegation that this linked to Chiesi's products in a manner which was in breach of Clause 19.1 or 19.2.

The complainants questioned the comments Chiesi made regarding pharmacovigilance in its response to their complaint. Chiesi stated that it stood by those comments. It was important that the clinical pharmacists received therapy-specific clinical training to the therapy areas in which they carried out therapy review work, in order to deliver therapy review services to the highest possible standard and with up-to-date knowledge of the latest treatment options and therapy area guidelines.

A therapeutic review service involved direct contact between a third party (acting on behalf of Chiesi) and the patient by telephone and/or face-to-face interaction. Adverse events, product quality complaints and special situations which were required to be reported to the marketing authorisation holder, eg safety information, might be received by the third party (acting on behalf of Chiesi). Chiesi was obliged to consider internal reporting timelines to ensure compliance with legislative requirements. As such, an update of client product/therapy priorities would serve to build on the core PV training of the named third party service provider representatives.

Chiesi stated that it understood that the third party service provider sent internal communications to ensure that its staff were aware of the product ranges marketed by client companies in order that staff could meet their pharmacovigilance obligations in relation to those products.

Chiesi previously provided details of the comprehensive training with which the named third party service provider pharmacist team was provided. This included training on the Clinical Protocol (CHRES20181220) and Clinical Pharmacist Brief (CHRES20181220a).

The Clinical Protocol made it clear that the therapy review service must not be linked to products:

- Section 1.1 entitled 'Introduction to the service', stated ***'[the named third party service provider] will not recommend a specific pharmaceutical company's products'***;
- the same section further stated: ***Whilst the service is funded and organised on behalf of Chiesi Ltd, any change in COPD management arising from the patient review process remains the choice and sole decision of the lead GP and offering of the service will not be conditional on the prescribing of any Chiesi Ltd products or services'*** and
- Section 8 entitled 'Conduct of the COPD patient review', stated in the very first numbered paragraph: ***'[the named third party service provider] is a service provider to the NHS and has no role in the promotion or sale of pharmaceutical products'.***

Given the comprehensive training provided to the pharmacist team, in addition to the clear guidance provided in the clinical protocol and pharmacist brief, Chiesi firmly believed there was no disguised promotion and there would be no confusion on behalf of the pharmacists that therapy review services must not be linked to products.

Commercial gain

Chiesi stated that the complainants alleged that Chiesi had chosen to partner with the named third party service provider for commercial gain. Once again, there was no foundation whatsoever for this allegation and Chiesi invited the Appeal Board to dismiss it. Chiesi provided funding for the therapy review service, at a significant cost, with the aim of driving quality

improvement for patients with COPD, through proactive patient identification and pharmacist-led review, to optimise COPD management in line with best practice. The benefits of the service were more fully set out in Chiesi's response to the Panel. The service was set up to drive quality improvement for patients with COPD, through proactive patient identification and pharmacist-led review, to optimise COPD management in line with best practice, in particular:

- GOLD report;
- NICE guidelines and
- practice-defined COPD management framework.

Chiesi submitted that there had been a high level of satisfaction achieved by both practices and patients (according to patient feedback) and this demonstrated the direct benefit of the therapy review service to both patients and the NHS. Chiesi viewed such high levels of satisfaction a success and did not believe they could have been achieved if this was not a genuine therapy review service which covered all options (pharmacological and non-pharmacological).

Accountability

Chiesi noted the complainants' view that it must not be possible '… for an email of this nature [to] be written with no accountability or consequences whatsoever'. This was an internal email sent within the named third party service provider and Chiesi did not have sight of it until the complaint was made. Whilst, as Chiesi had acknowledged above, it was responsible for the actions and/or inaction of third parties with whom it engaged where there was a breach of the Code, Chiesi could not be accountable for internal only communications of which it had no knowledge where there was no empirical link to external actions and/or inaction which might be considered to constitute a *de facto* breach. If this was held to be incorrect, the natural consequence would be an expectation that all pharmaceutical companies would approve every internal email communication of all third parties with whom they contract. This was not required under the Code and was neither realistic nor desirable.

Audits

Chiesi stated that the complainants alleged that not undertaking an audit after 6 months of the commencement of the named third party service provider service constituted a serious failing, '… considering Chiesi's public history of ABPI Breaches of the Code'. Chiesi disagreed. Chiesi gave meticulous attention to the setting up of the agreement with the third party service provider and the associated documentation and it was always its intention to audit the service within the first year. Chiesi carried out an audit in October 2019 and there were some minor findings which were all addressed by the third party in a timely manner.

It was correct that Chiesi had previously been found in breach of the Code in respect of a therapy review service. This was on one occasion, in Case AUTH/2352/8/10 (further cases (Cases AUTH/2097/2/08 and AUTH/2103/3/08) concerned a clinical support service but no breaches were ruled). Case AUTH/2352/8/10 was some 10 years ago and the circumstances of that case could be clearly distinguished from those in the present case not least as (i) the clinical support service which was the subject of that complaint was operated by Chiesi itself and not by engaging a third party; and (ii) the complaint in that case was that it was effectively a switch service rather than a genuine therapeutic review service.

Chiesi stated that it had taken very seriously the findings of previous cases and, as well as taking corrective measures, had made great strides in refining its processes and procedures to

make them as robust as possible, optimising training and really giving the compliance culture the highest level of importance and recognition. Chiesi stated that it took its responsibilities under the Code, including in engaging with third parties, very seriously as evidenced by the comprehensive and compliant documentation which was in place with the named third party service provider in respect of the therapy review service in question.

Conclusion

Chiesi stated that in its view, the appeal lacked merit and Chiesi intended to rigorously defend it.

FINAL COMMENTS FROM THE COMPLAINANTS

The complainants alleged that Chiesi's response often detracted from the main complaint. The complainant's stated that their complaint was based upon the email. The complainant's requested the Appeal Board consider the Panel's comments in relation to the Chiesi complaint and make their appropriate judgement.

The complainant's alleged that if serious concerns had been raised by the Panel along with its strong comments then how it could not be ruled as a failure to maintain high standards. The complainant's alleged that this would be appropriate to encourage a change in behaviour between pharmaceutical companies and service providers and would benefit the reputation of the industry.

Although Chiesi submitted that it had not directly breached any clauses in the Code, the complainants alleged that it was its association with the third party service provider which meant that it was in breach. 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.

On a final note, the complainants noted that Chiesi had commented on its history of previous cases. In response to Chiesi's comments the complainants were gravely concerned to learn the details of Case AUTH/2352/8/10 that Chiesi employed its own team of pharmacists known as the CSS (Clinical Support Service) and was found to be operating a switch service. The Panel had ruled a breach of Clause 2 in that case as Chiesi had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The CSS department has since closed. The complainants commended Chiesi for its honesty and openness.

The complainants acknowledged that they were deviating from the original complaint nevertheless thought it was relevant for the Appeal Board to consider the wider picture. The complainants referred to alleged links between the Chiesi CSS team (prior to AUTH/2352//8/10) and the third party service provider. It appeared that Chiesi could not operate its own CSS team so it had recruited the third party service provider to take its place. This was of concern based on the complaint AUTH/2352//8/10 and the email at issue.

The complainant's requested the Appeal Board review the email in question and the Panel's comments relating to it and reconsider a breach of Clause 9.1.

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 that it could be argued that the email in question did not refer to a specific Chiesi medicine nor link the Chiesi therapy review service to a specific medicine. The Appeal Board noted however that the phrase 'integrate client product/therapy priorities' appeared towards the end of the email and appeared to apply to all the therapy reviews.

In the Appeal Board's view, it appeared that Chiesi's documentation was not unreasonable in that it did not appear to link the therapy review service to Chiesi's product. 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 complainants had alleged that the focus of their complaint was in relation the term 'integrate client product/therapy priorities' that appeared in the email. The Appeal Board noted that the email at issue was a single internal communication within the named third party service provider. The Appeal Board was concerned that the third party service provider 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 Chiesi medicine. Nor was evidence provided by the complainants to show that the email in question impacted on the delivery of the Chiesi service.

In the Appeal Board's view, Chiesi had been let down by its 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 Chiesi 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/3197/4/19 Ethypharm.

Complaint received **30 April 2019**

Case completed **14 October 2020**